# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF KENTUCKY CENTRAL DIVISION AT LEXINGTON

REYN PHARMA, LLC	)
P.O. Box 13727	)
Lexington, Kentucky 40583	)
Plaintiff,	) ) Civil Action No
v.	)
	)
INNOVATIVE NUTRITION	) JURY TRIAL DEMANDED
206 Rt. 25A	)
East Setauket, New York 11733	)
	)
-and-	)
	)
STEUBEN PARK RESEARCH CORP.	)
Port Jefferson, New York 11777	)
	)
Defendants.	)
	<i>,</i>

#### **COMPLAINT**

Plaintiff Reyn Pharma, LLC. ("Reyn") brings this Complaint against Defendants Innovative Nutrition ("Innovative") and Steuben Park Research Corporation ("Steuben") for patent infringement and alleges as follows:

# **NATURE OF THE COMPLAINT**

- 1. This is an action for patent infringement arising under the Patent Laws of the United States, including 35 U.S.C. §271 and §§281-285.
- 2. This action for patent infringement specifically relates to Defendants' infringement of United States Patent No. 9,492,381 entitled "METHOD OF ADMINISTERING HYALURONAN FORMULATION FOR PREVENTING AND AMELIORATING OSTEOARTHRITIS."

### **PARTIES**

- 3. Plaintiff Reyn is a limited liability company organized and existing under the laws of the Commonwealth of Kentucky, with a mailing address of P.O. BOX 13727, Lexington, Kentucky 40583 and a principal place of business located in Lexington, Kentucky.
- 4. Reyn and its licensee, Cogent Solutions Group, LLC ("Cogent"), are in the business of researching, developing, manufacturing, marketing, and selling proprietary ingredients and formulations containing hyaluronan for animal and human consumption and use.
- 5. Defendant Innovative is, upon information and belief, a sole proprietorship operating in the State of New York, having a principal place of business located at 206 Rt. 25A, East Setauket, New York.
- 6. Defendant Steuben is a New York corporation having a business address in Port Jefferson, New York. Defendants' product's labels identify Steuben as the distributor.
- 7. Defendants are in the business of manufacturing, marketing and selling dietary supplements for human consumption, including orally administrable supplement formulations containing hyaluronan.
- 8. Defendants are direct competitors of Plaintiff in the field of oral liquid hyaluronan formulations for the purpose of supporting joint health in humans.
- 9. Previously, Defendant Innovative was a licensed reseller of Plaintiff's HA product BAXYL, but then Defendants created their own product to compete with Plaintiff; however, in the process, Defendants unlawfully used Plaintiff's copyrighted written material and trademarks. Now, Defendants are infringing Plaintiff's federally-protected patent rights.

## **JURISDICTION AND VENUE**

10. This action arises under the Patent Laws of the United States, 35 U.S.C. §101 *et seq.*, including 35 U.S.C. §271. This Court has federal-question subject-matter jurisdiction under

28 U.S.C. §§1331 and 1338(a).

- 11. This Court has personal jurisdiction over Defendants for at least the following reasons: Defendants transact business in Kentucky; Defendants contract to supply goods in Kentucky; Defendants supply goods in Kentucky; Defendants' tortious conduct caused injury in Kentucky; and, Defendants' tortious conduct caused injury in Kentucky even when Defendants were located outside of Kentucky.
  - 12. The basis of this Complaint arises from Defendants' conduct.
- 13. Defendants' violative conduct occurred in Kentucky, as its advertising, marketing, and sales of its Joint Relief product was directed to members of the relevant purchasing public located in Kentucky.
- 14. Defendants have actual knowledge of Reyn's federally protected rights, and thus, the injury caused by Defendants occurred in Kentucky.
  - 15. Defendants regularly do and/or solicit substantial business in Kentucky.
  - 16. Defendants have sold and shipped its product to purchasers in Kentucky.
- 17. Defendants use and maintain an internet website that advertises its products, and Defendants' website also allows for the purchase of its products by people throughout the United States, including Kentucky.
- 18. Defendants' website provides, in part, "We deliver Metagenics, . . . supplements to your door at the best possible price." Defendants' website further provides, "[w]e sell the most efficacious, highest quality, completely natural supplements from manufacturers like Metagenics, Pure Encapsulations, Joint Relief, and Emerson Ecologics."
- 19. In fact, Defendants' website refers potential purchasers to their affiliate company's website, Metagenics.com. On this website, Defendants' affiliate's website expressly

provides that, "Serving the following states & regions: Illinois (except Chicago), ... Ohio, Kentucky, and St. Louis, MO". See, http://inutrition.metagenics.com/offices-distributors.

- 20. Defendants maintain a page on Facebook.com that actively advertises its Joint Relief product throughout the United States, including Kentucky.
- 21. Defendants' Facebook page (www.facebook.com/Hyaluronan/) includes: a button to "Shop Now"; a posting from Defendants' principal that "Joint Relief is now available in over 350 stores in the USA.... If your favorite health food store doesn't have it yet tell him to contact us at:"; and, by selecting the "Shop Now" button, potential purchasers can place orders for Defendants' product.
- 22. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

## **FACTS**

- 23. United States Patent No. 9,492,381 ("the '381 Patent") entitled "METHOD OF ADMINISTERING HYALURONAN FORMULATION FOR PREVENTING AND AMELIORATING OSTEOARTHRITIS" was issued by the United States Patent and Trademark Office on November 15, 2016.
- 24. Reyn is the assignee and sole owner of the entire right, title, and interest in and to the '381 Patent by virtue of an assignment from the sole inventor, James D. Smith, Jr. The assignment was recorded in the records of the United States Patent and Trademark Office at Reel/Frame 031806/0764 on December 18, 2013.
- 25. The '381 Patent includes method claims directed to orally administering a liquid hyaluronan composition comprising hyaluronan and a pharmaceutically acceptable carrier of a certain pH range to a vertebrate subject for: i) slowing, attenuating, mitigating, and/or

ameliorating the loss of articular cartilage [claims 1-6]; ii) for slowing, attenuating, mitigating, and/or ameliorating joint discomfort [claims 7-18]; iii) for reducing joint pain [claims 19-24]; and, iv) for supporting joint health [claims 25-30].

- 26. Hyaluronan ("HA") is the accepted scientific nomenclature for hyaluronic acid and physiological salts of hyaluronic acid. HA is a long, unbranched polysaccharide chain comprised of repeating disaccharide units of glucuronic acid and glucosamine.
- 27. Reyn and Cogent have grown to be among the country's leading polysaccharide ingredient based companies specializing in the research, development, manufacture, and sale of proprietary polysaccharide ingredients, including HA compositions, for humans, dogs, cats, and horses. Their innovative and high quality products are widely recognized and appreciated in both the animal and human markets.
- 28. Reyn and Cogent have a history of ground-breaking innovation within the human supplement industry having confirmed that orally administered, exogenous HA is bioavailable, absorbed, and efficacious for the support of joint and bone health in vivo.
- 29. The commitment to innovation is further demonstrated in part by sponsorship of pre-clinical university research and clinical investigations of proprietary HA ingredients.
- 30. The research and development successes include pre-clinical and clinical demonstrations that orally administered exogenous HA is effective for more than just the palliative treatment of joint pain and discomfort, and that orally administered, exogenous HA has disease modifying properties including the amelioration of joint cartilage loss.
- 31. Reyn and Cogent have spent a significant amount of time, effort, resources, and money investigating, researching, and developing its HA-containing compositions and formulations for addressing, maintaining and supporting joint health in humans and animals.

- 32. Because of their attention and commitment to the chemistry of HA, the science of HA's functions and properties in the body, and the development of safe and effective products, Reyn and Cogent have enjoyed significant success throughout the United States.
- 33. Defendants currently market and sell a directly competing HA formulation for humans under the trade designation "Joint Relief".
  - 34. Defendants' Joint Relief product is a liquid HA composition that is sold in bottles.
- 35. Defendants' Joint Relief product is sold for oral consumption by humans to slow, mitigate, attenuate, or ameliorate the loss of articular cartilage, for support of joint health, and/or for relief from joint discomfort and pain.
- 36. The product label affixed to the front of Defendants' liquid-containing bottle prominently displays the product name "Joint Relief" in bold, capital letters, and the tagline "Natural Relief for Joint Pain" is positioned immediately below the product name "Joint Relief." The product name and tagline collectively signal to relevant purchasers that the liquid product is intended to address joint problems and to provide relief from joint pain.
- 37. The word "Hyaluronan" appears immediately below the tagline "Natural Relief for Joint Pain." The inclusion of the word "Hyaluronan" on the product label immediately conveys to the relevant purchasers that the liquid product contains HA.
- 38. The lower portion of the front product label also touts the advantages/functions of Defendants' Joint Relief product, and includes the phrases "Reduces Joint Pain," "Protects Cartilage," "Lubricates Joints" and "Controls Inflammation."
- 39. The back label of Defendants' Joint Relief product states, "Hyaluronic acid (HA), also known as hyaluronan is a mucopolysaccharide occurring naturally in all bones and cartilage structures through the human body. Both of these structures provide a resilient rigidity to the

overall structure of the human body. HA is especially found in various forms of cartilage but none more than the hyaline cartilage. As you've probably guessed it, hyaline is short for hyaluronic acid. Hyaline cartilage covers the ends of the long bones where articulation (bending) occurs and provides a cushioning effect for the bones."

- 40. The word "Hyaluronan" in large, bold font type, and the phrase "Liquid Dietary Supplement," appear on the back panel of the product label immediately above the nutritional facts. The nutritional facts clearly state that each serving of the Joint Relief product is 30mg of hyaluronan (hyaluronic acid).
- 41. Defendants actively market and sell the Joint Relief product on their internet website www.joint-relief.net.
- 42. Defendants' internet website is replete with references to using the "Joint Relief" product for addressing joint pain and health.
- 43. The top banner on each and every page of Defendants' internet website prominently displays the phrase "The Joint Relief Company" in large, bold, red font to signal to the relevant purchasing public that Defendants specialize in the marketing and sale of products for joint health.
- 44. The home page of Defendants' internet website reproduces a photograph of a bottle of the Joint Relief product. The front label of the product prominently displays the name of the product "JOINT RELIEF" in large capital letters set off from the other text on the label.
- 45. To the right of the photograph of the "Joint Relief" bottle, the home page recites the heading "Natural Relief for Joint Discomfort" and lists a number of functions of the "Joint Relief" product that are also found on the product label.

- 46. The home page of Defendants' internet website states, "If you're looking for the highest quality, all natural Hyaluronic Acid (HA) supplement look no further. Joint Relief's new great tasting lemon flavor liquid has the absorption advantage of being a high molecular weight liquid, in an all natural, non-GMO, vegan formula. Joint Relief has no artificial ingredients and is manufactured right here in the U.S.A. So if you're suffering from joint discomfort or the inflammation associated with osteoarthritis give Joint Relief a try!"
- 47. Regarding the intended purchasers and users of the Joint Relief product, the home page of Defendants' internet website states, "So, if you're suffering from joint discomfort or the inflammation associated with osteoarthritis give Joint Relief a try!"
- 48. Defendants' internet website includes numerous claims relating to the intended purpose of its Joint Relief product. Examples of Defendants' product claims include the following: "Joint Relief has proven to be an effective supplement for joint pain . . ."; "Joint Relief alleviates discomfort and offers flexibility, in effect, lubricating the joints"; "This natural joint pain relief supplement . . ."; and "Put an end to joint pain with Joint Relief."
- 49. One of Defendants' website pages (http://www.joint-relief.net/HA-and-your-body-.html) includes a testimonial from a naturopathic doctor who has used Innovative's Joint Relief product, and states "As a naturopathic medical doctor for the past 20 years, I have no shortage of options for treating myself, however, every time I worked out, my knees were still hurting me. Incredibly, after only one week of using Joint Relief as directed my knees were nearly PAIN FREE. I highly recommend both the product and the company behind the product."
- 50. Another one of Defendants' website pages (http://www.joint-relief.net/Why-Joint-Relief-.html) states, "Why Choose Joint Relief? Because Joint Relief was developed for maximum bioavailability and efficacy. It is a safe and effective oral liquid hyaluronan

supplement for the support of joint health and mobility in humans. Don't just reach for any hyaluronan product on the store shelf. You deserve better!" Near the bottom of the same website page, Defendants' claim, "Complete relief from joint pain. Experiencing joint pain? We understand how excruciating it can be. Joint Relief is one of the most reliable sources for joint pain and soreness relief. An oral liquid hyaluronan supplement, Joint Relief improves joint health and mobility in individuals. It's a chemical-free, high quality, all-natural joint pain relief formula."

- 51. Defendants also advertise and market the Joint Relief product on Twitter.com. Innovative tweeted on July 2, 2016 a photograph of its product, marketing materials and informational brochures for the Joint Relief product. These marketing materials are entitled "STOP THAT JOINT PAIN!" The informational brochure is entitled "JOINT RELIEF" and the front cover of the brochure includes the phrase "A Breakthrough for Healthy Joints."
- 52. Defendants' Twitter page includes the tagline, "Joint Relief. Natural Relief for joint pain that won't cost an arm & a leg."
- 53. Defendants tweeted on July 20, 2016, "If you are suffering from joint pain or the inflammation associated with arthritis, please check us out at http://www.joint-relief.net."
- 54. Defendants tweeted on August 16, 2016, "Joint Relief is one of the most effective products for Joint Pain and Arthritis. Please check us out at: http://www.joint-relief.net."
- 55. Defendants tweeted on October 25, 2016, "Joint Relief is one of the most effective products on the market to fight Joint Pain. Visit us at: http://www.joint-relief.net."
  - 56. Defendants also advertise and market the Joint Relief product on Facebook.com.

- 57. Defendants posted on Facebook on November 23, 2016 at 6:37AM, "Joint Relief is still one of the most effective ways of fighting joint pain and the inflammation associated with arthritis. Please visit us at: www.joint-relief.net Happy Thanksgiving everyone."
- 58. Defendants posted on Facebook on July 23, 2016, "Joint Relief is one of the most effective oral supplements to help stop joint pain and combat the inflammation that is associated with arthritis. Please visit us at www.joint-relief.net."
- 59. Defendants posted on Facebook on May 29, 2016, "Reduce your joint pain with Joint Relief, a natural, hyaluronic acid supplement that promotes healthy joints. Offered by The Joint Relief Company, Joint Relief is a must-have supplement: . . ."

### **COUNT I**

#### **INFRINGEMENT OF UNITED STATES PATENT NO. 9,492,381**

- 60. Reyn realleges and incorporates by reference the allegations set forth above as though fully set forth herein.
  - 61. James D. Smith filed the application for the '381 Patent on October 15, 2013.
- 62. The '381 Patent claims the benefit of the filing date of United States Provisional Application For Patent Serial No. 60/735,551 filed on November 10, 2005.
- 63. The '381 Patent was examined by the United States Patent Office and was issued on November 15, 2016.
  - 64. A true and correct copy of the '381 Patent is attached as Exhibit A.
- 65. Independent claim 1 of the '381 Patent is directed to orally administering a liquid composition comprising hyaluronan polymer and a pharmaceutically acceptable carrier and having a pH in the range of about 2.5 to about 4.5 to a vertebrate subject for slowing, attenuating, mitigating, and/or ameliorating the loss of articular cartilage.

- 66. Independent claim 7 of the '381 Patent is directed to orally administering a liquid composition comprising hyaluronan polymer and a pharmaceutically acceptable carrier and having a pH in the range of about 2.5 to about 4.5 to a vertebrate subject for slowing, attenuating, mitigating, and/or ameliorating joint discomfort.
- 67. Independent claim 13 of the '381 Patent is directed to orally administering a liquid dietary supplement comprising hyaluronan and a pharmaceutically acceptable carrier and having a pH in the range of about 2.5 to about 4.5 to a vertebrate subject for slowing, attenuating, mitigating, and/or ameliorating joint discomfort.
- 68. Independent claim 19 of the '381 Patent is directed to orally administering a liquid dietary supplement comprising hyaluronan and a pharmaceutically acceptable carrier and having a pH in the range of about 2.5 to about 4.5 to a vertebrate subject for reducing joint pain.
- 69. Independent claim 25 of the '381 Patent is directed to orally administering a liquid composition comprising hyaluronan and a pharmaceutically acceptable carrier and having a pH in the range of about 2.5 to about 4.5 to a vertebrate subject for supporting joint health.
  - 70. Defendants' Joint Relief product is a liquid composition that is sold in a bottle.
- 71. As evidenced by its product label, written marketing materials, Facebook posts, and Twitter tweets, Defendants' Joint Relief product contains HA as the sole active ingredient.
- 72. According to the Joint Relief product label and internet website, the Joint Relief product contains the pharmaceutically acceptable carrier water.
  - 73. Defendant's Joint Relief product is for oral administration to humans.
- 74. Defendants direct their human customers to orally administer the liquid HA composition, and a human is a vertebrate subject.

- 75. The Joint Relief product label provides a serving size (1/2 teaspoon; 2.5 ml) and directions for administration of the HA composition ("As a dietary supplement take one teaspoon orally twice daily for the first 7 days, followed by a half teaspoon twice daily thereafter."). The product label for directs the purchaser to orally administer a therapeutically effective amount of the liquid HA composition.
- 76. Reyn has had the pH of Defendants' Joint Relief liquid product measured by an independent third-party testing laboratory, which confirmed that the pH of the product falls within the pH range of about 2.5 to about 4.5 recited in the independent claims 1, 7, 13, 19 and 25 of the '381 Patent.
- 77. Defendants' product label affixed to the product packaging directly instructs purchasers of the Joint Relief product to orally administer the supplement for maintaining normal joint and health supporting healthy joint function.
- 78. Defendants are also well aware that orally administering the Joint Relief product results in slowing, attenuating, mitigating, and/or ameliorating the loss of articular cartilage, relieving joint pain and discomfort, joint stress, and promotes joint flexibility.
- 79. Defendants sell the Joint Relief product to those customers who have orally administered the product in accordance with the directions provided by Defendants for the specific purposes set forth in Defendants' product label and marketing materials, namely, supporting and maintaining normal joint health and function.
- 80. Defendants' human customers that orally administer the Joint Relief product as directed by Defendants for the purposes relating to joint health advertised and marketed by Innovative directly infringe at least claims 1, 7, 13, 19, and/or 25 of the '381 Patent.

- 81. Reyn provided notice of the '381 Patent to Defendants on November 17, 2016. Counsel for Defendants confirmed receipt of Reyn's notice letter.
- 82. Despite having actual knowledge of the '381 Patent, Defendants continue to market, offer for sale, and sell their Joint Relief product for the purposes of i) slowing, attenuating, mitigating, and/or ameliorating the loss of articular cartilage in a vertebrate subject; ii) slowing, attenuating, mitigating, and/or ameliorating joint discomfort in a vertebrate subject; iii) reducing joint pain in a vertebrate subject; and, iv) supporting joint health in a vertebrate subject.
- 83. Because of its actual knowledge of the '381 Patent, Defendants have knowledge that the induced acts constitute infringement of the '381 Patent by the purchase and use the Joint Relief product in accordance with the instructions provided by Defendants and for the specific purpose set forth in Defendants' marketing and technical literature for the product.
- 84. Defendants' acts of advertising, marketing, offering for sale, and selling the Joint Relief product constitutes actively aiding and abetting customers that purchase the product to commit acts that constitute direct infringement of the '381 Patent, and, thus, Defendants have the specific intent to encourage the purchasers of its product to directly infringe the '381 Patent.
- 85. Defendants' aforementioned activities related to the offering for sale and sale of its Joint Relief product constitute inducement to infringe at least claims 1, 7, 13, 19, and/or 25 of the '381 Patent under 35 U.S.C. §271(b).
- 86. Plaintiff is entitled to recover from Defendants the damages sustained by Plaintiff as a result of Defendants' wrongful acts in an amount subject to proof at trial, including lost profits and an amount not less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

- 87. The infringement by Defendants of the '381 Patent will continue to cause Plaintiff irreparable injury and damage for which there is no adequate remedy at law unless and until Defendants are permanently enjoined from infringing said patent.
- 88. In light of their actual knowledge and disregard of Reyn's patent rights, and to the extent that Defendants' conduct has continued after such notice, Defendants' conduct constitutes willful infringement of the '381 Patent.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiff Reyn respectfully requests that the Court enter judgment in its favor against Defendants, granting the following relief:

- A. An adjudication that Defendants have infringed at least claims 1, 7, 13, 19, and/or 25 of the '381 Patent literally, and/or under the doctrine of equivalents;
- B. A grant of a permanent injunction pursuant to 35 U.S.C. 283, enjoining Defendants and their agents, servants, officers, directors, members, owners, principals, employees, affiliated entities, related companies, and all persons or other entities in active concert or participation with it from continued infringement of the '381 Patent;
- C. An accounting of all Defendants' profits in connection with their Joint Relief product;
- D. An award to Plaintiff Reyn damages in an amount adequate to compensate Reyn for Defendants' acts of infringement of the '381 Patent;
- E. An award to Plaintiff Reyn in an amount equal to all profits Defendants gained from its infringement of the '381 Patent;
- F. An award of pre-judgment and post-judgment interest on all sums of money awarded to Plaintiff Reyn;

G. A finding that Defendants' acts of infringement of the '381 Patent were willful

and/or in bad faith;

H. A trebling of all damages awarded to Plaintiff Reyn;

I. An award to Plaintiff Reyn of reasonable attorney fees in connection with this

civil action pursuant to 35 USC §285;

J. An award to Plaintiff Reyn of all its costs in connection with this civil action;

and,

K. Any and all such further relief as this Court may deem just and proper, and/or

which this Court finds that Plaintiff Reyn is entitled to under the law, in equity, and/or pursuant

to this Court's inherent powers.

**JURY DEMAND** 

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff respectfully

requests a trial by jury of any and all issues on which a trial by jury is available under applicable

law.

Respectfully submitted,

/s/Andrew R. Smith\_

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