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IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

DRAGAN VASIC, On Behalf of Himself and All Others Similarly Situated,

Plaintiff,

vs.

PATENT HEALTH, L.L.C., an Ohio Limited Liability Company, ARTHUR MIDDLETON CAPITAL HOLDINGS, INC., an Ohio Corporation, and DOES 1 through 20,

Defendant.

Case No. 3:13-cv-00849 AJB (MDD)

SECOND AMENDED CLASS ACTION COMPLAINT FOR:

1. VIOLATION OF CONSUMERS LEGAL REMEDIES ACT, CIVIL CODE §§ 1750, *et seq.*; and
2. VIOLATION OF THE UNFAIR COMPETITION LAW, BUSINESS AND PROFESSIONS CODE §§ 17200, *et seq.*

DEMAND FOR JURY TRIAL

Plaintiff DRAGAN VASIC brings this action on behalf of himself and all others similarly situated against Defendant PatentHEALTH, LLC, ("PatentHEALTH"), ARTHUR MIDDLETON CAPITAL HOLDINGS, INC. ("Arthur Middleton"), and DOES 1 through 20 (collectively, "Defendants"[1]) and states:

NATURE OF ACTION

1. Defendants distribute, market, and sell the "Trigosamine" line of glucosamine-based supplements. Defendants represent that the Trigosamine products provide a variety of health benefits centered on lubricating joints, building cartilage, and relieving joint pain in human joints. Defendants represent that the primary active ingredients in their Trigosamine products[2] are "Glucosamine" and "Chondroitin Sulfate." Through an extensive and uniform nationwide advertising campaign, Defendants represent that Trigosamine is "[a] scientifically-advanced [*sic*], once-a-day formulation that helps build and maintain healthy joints and cartilage, while also helping to relieve joint discomfort." *See* Product Label, Trigosamine Max Strength with Vitamin D at ¶ 21. Defendants further warrant that the Product "provides the body with the essential building blocks needed to lubricate, relieve and build healthy joint cartilage while promoting overall joint and bone health." *See id.* The front of the product label emphasizes its purported benefits, that it will simultaneously "Lubricate" joints, "Relieve" pain, and "Build" cartilage. *Id.*

2. The statements represented on the Trigosamine product packaging are "structure-function" claims which must be limited to a description of the role that a dietary ingredient is "intended to affect the structure or function in humans." 21 U.S.C. § 343(r)(6). In order to make a structure-function claim, the dietary supplement

[1] As detailed in the section entitled "PARTIES" below, there is a unity of interest and ownership between Defendant PatentHEALTH and Defendant Arthur Middleton such that their separate personalities do not exist. Therefore, Plaintiff's allegations are intended to be against both PatentHEALTH and Arthur Middleton jointly since Arthur Middleton is the alter ego of PatentHEALTH.

[2] The Trigosamine Products include: (1) Trigosamine Max Strength; and (2) Trigosamine Fast-Acting (together, "Trigosamine products" or "Products").

manufacturer is required to have substantiation that such statements are truthful and not misleading. *Id.*

3. Defendants do not have any competent, reliable, scientific evidence that substantiates their representations about the health benefits of consuming Trigosamine. In fact, all available scientific evidence demonstrates that the Trigosamine products have no efficacy at all, are ineffective in the improvement of joint health, and provide no benefits related to the reduction of pain in human joints or protecting cartilage from breakdown. Numerous scientifically valid studies have been conducted on the ingredients, including the core or primary ingredient in the Trigosamine products, glucosamine, and they have universally demonstrated that glucosamine and glucosamine in combination with other ingredients, such as chondroitin sulfate, have absolutely no scientific value in the treatment of joint pain or discomfort.

4. Further, pursuant to 21 C.F.R. § 101.93(f), Defendants are prohibited from making "disease claims" about their product. Disease claims are generally described as statements which claim to diagnose, mitigate, treat, cure, or prevent disease where the statements claim "explicitly or implicitly, that the product . . . [h]as an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology." 21 C.F.R. § 101.93(g)(2). Defendant makes representations on the product label for the Trigosamine products which directly relate to the treatment of Osteoarthritis. The Mayo Clinic defines symptoms of osteoarthritis as follows:

- ***Pain.*** Your joint may hurt during or after movement.
- ***Tenderness.*** Your joint may feel tender when you apply light pressure to it.
- ***Stiffness.*** Joint stiffness may be most noticeable when you wake up in the morning or after a period of inactivity.
- ***Loss of flexibility.*** You may not be able to move your joint through its full range of motion.
- ***Grating sensation.*** You may hear or feel a grating sensation when you use the joint.

- ***Bone spurs.*** These extra bits of bone, which feel like hard lumps, may form around the affected joint.

See http://www.mayoclinic.com/health/osteoarthritis/DS00019/DSECTION=symptoms (last viewed March 24, 2014).

5. Defendants represent that the active ingredients in the Trigosamine products provide relief for nearly all of these symptoms. The product labeling states that it will "build healthy joint cartilage" and "reduce[] joint discomfort." *See* Product Labels at ¶ 21. These bold claims are in addition to other misrepresentations claiming that it is "clinically tested" and provides "clinically shown results in just 3 days!" *Id.*

6. Defendants did not obtain the requisite New Drug Application ("NDA") prior to marketing and selling their Trigosamine products. As such, making these statements and representations without NDA approval from the FDA constitutes misbranding and false and misleading conduct pursuant to 21 C.F.R. § 101.93.

7. Defendants convey their uniform, deceptive message to consumers through a variety of media including their website and online promotional materials, and, most importantly, at the point of purchase, on the front of the Products' packaging and labeling where it cannot be missed by consumers. The only reason a consumer would purchase Trigosamine is to obtain the advertised joint-health benefits, which the Trigosamine products do not provide.

8. As a result of Defendants' deceptive advertising and false claims regarding the efficacy of the Trigosamine products, Plaintiff and the proposed Class have purchased products which do not perform as represented, and they have been harmed in the amount they paid for the Trigosamine products, which in the case of Plaintiff Vasic is approximately $25.00.

9. Plaintiff brings this action on behalf of himself and other similarly situated consumers who have purchased Defendants' Trigosamine products to halt the dissemination of this false, misleading, and deceptive advertising message, correct the false and misleading perception it has created in the minds of consumers, and obtain

redress for those who have purchased the Products. Based on violations of California's unfair competition laws, Plaintiff seeks injunctive and monetary relief for consumers who purchased the Trigosamine products.

JURISDICTION AND VENUE

10. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum or value of $5,000,000 and is a class action in which there are in excess of 100 class members, and many members of the Class are citizens of a state different from Defendants.

11. This Court has personal jurisdiction over Defendants because Defendants are authorized to and do conduct business in California. Defendants have marketed, promoted, distributed, and sold the Trigosamine products in California, and Defendants have sufficient minimum contacts with this State and/or sufficiently avail themselves of the markets in this State through their promotion, sales, distribution, and marketing within this State to render the exercise of jurisdiction by this Court permissible.

12. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred while he resided in this judicial district.

PARTIES

13. Plaintiff Dragan Vasic resides in San Diego County, California. In or around November 2012, Plaintiff was exposed to and saw Defendants' representations regarding the joint-health benefits of Trigosamine Max Strength by reading the product label in a Walgreen's store near his home in San Diego, California. In reliance on the claims listed on the product label, described herein and above, and specifically those claims listed on the front of the product label, that Trigosamine Max Strength would "lubricate" joints, "relieve" pain, and "build" cartilage, Plaintiff purchased the Trigosamine Max Strength product at Walgreen's. Plaintiff read each of the material representations on the product label. He paid approximately $25.00 for the product. At the time, Plaintiff Vasic was experiencing pain and stiffness in his joints following his regular workouts. He purchased

the product believing it would provide the advertised joint-health benefits and improve his joint soreness and comfort. The Trigosamine product did not provide the stated benefits. As a result, Plaintiff suffered injury in fact and lost money. Had Plaintiff known the truth about Defendants' misrepresentations and omissions, he would not have purchased the Trigosamine product.

14. Defendant PatentHEALTH, LLC is a limited liability company established under the laws of the state of Ohio. Defendant PatentHEALTH's corporate headquarters is located at 8000 Freedom Avenue NW, North Canton, Ohio 44720. PatentHEALTH is a wholly owned subsidiary of Arthur Middleton. Defendant PatentHEALTH manufactures, distributes, markets, and sells the Trigosamine products to tens of thousands of consumers in California.

15. Defendant Arthur Middleton Capital Holdings, Inc. is an Ohio corporation. Defendant Arthur Middleton's corporate headquarters is located at 8000 Freedom Avenue NW, North Canton, Ohio 44720. Arthur Middleton is the sole member of PatentHEALTH. Defendant Arthur Middleton manufactures, distributes, markets, and sells the Trigosamine products to tens of thousands of consumers in California.

16. Plaintiff is informed and believes, and thus alleges, that at all times herein mentioned, each Defendant was the agent, employee, representative, partner, joint venturer, and/or alter ego of the other Defendants, and, in doing the things alleged herein, was acting within the course and scope of such agency, employment, representation, on behalf of such partnership or joint venture, and/or as such alter ego, with the authority, permission, consent, and/or ratification of the other Defendants.

17. Specifically, there exists a unity of interest and ownership between Defendant Arthur Middleton and Defendant PatentHEALTH such that their purported separate personalities do not in reality exist. PatentHEALTH is a wholly owned subsidiary of Arthur Middleton; Arthur Middleton is the sole shareholder and/or member of PatentHEALTH; both Defendants share the same corporate headquarters (located at 8000 Freedom Avenue NW, North Canton, Ohio 44720); both Defendants share the same

president, treasurer, and incorporator; both Defendants share the same agent for service of process; and both Defendants are represented by the same litigation defense counsel in the present matter. California law permits a defendant's corporate form to be disregarded to prevent an inequitable result if there is a unity of interest and ownership between the parent corporation and a subsidiary. *See Slottow v. Am. Cas. Co. of Reading, Pa.*, 10 F.3d 1355, 1360 (9th Cir. 1993) (*citing Mesler v. Bragg Mgmt. Co.*, 39 Cal. 3d 290, 300 (1985)). *See also Del Campo v. Am. Corrective Counseling Servs., Inc.*, No. C 01-21151, 2008 U.S. Dist. LEXIS 93298, at *8 (N.D. Cal. Nov. 10, 2008) (*citing Steven v. Roscoe Turner Aeronautical Corp.*, 324 F.2d 157, 161 (7th Cir. 1963) (when deciding whether to pierce the corporate veil a court considers, *inter alia*, whether the parent and subsidiary corporations have common directors or officers).

18. PatentHEALTH is the alter ego of Defendant Arthur Middleton. Defendant Arthur Middleton's involvement in the management and operation of PatentHEALTH extends beyond its investor status—PatentHEALTH's stakeholders have not adequately capitalized it to cover prospective liabilities. So now, despite tens of millions of dollars in annual sales of the Trigosamine products, the Cuyahoga County Common Pleas Court in Ohio appointed a receiver for the business operations and property of PatentHEALTH. *See Fifth Third Bank v. PatentHEALTH, LLC*, No. CV-13-811271. And public records demonstrate that an outstanding loan in the amount of nearly $3.35 million made from PatentHEALTH to Arthur Middleton remained unpaid by Arthur Middleton at the time the court-appointed receiver filed her inventory of PatentHEALTH's property and assets. *See* Dkt. No. 36, Ex. 1. "[U]nder California law, 'inadequate capitalization of a subsidiary may alone be a basis for holding the parent corporation liable for acts of the subsidiary.'" *Doe v. Unocal Corp.*, 248 F.3d 915, 927 (9th Cir. 2001) (*quoting Slottow*, 10 F.3d at 1360); *accord Advanced Targeting Sys. v. Advanced Pain Remedies, Inc.*, No. 12-cv-02915, 2014 U.S. Dist. LEXIS 11893, at *29 (S.D. Cal. Jan. 30, 2014). *See also Del Campo*, 2008 U.S. Dist. LEXIS 93298, at *8 (factors to consider when deciding whether to pierce the corporate veil are, *inter alia*, whether the subsidiary has grossly

inadequate capital, and the subsidiary has substantially no business except with the parent corporation or no assets except those conveyed to it by the parent corporation).

19. Here, PatentHEALTH was woefully undercapitalized, and the unity of interest and ownership between PatentHEALTH and Arthur Middleton exists. Thus, failure to disregard Defendants' purported separate identities would result in an injustice against Class members.

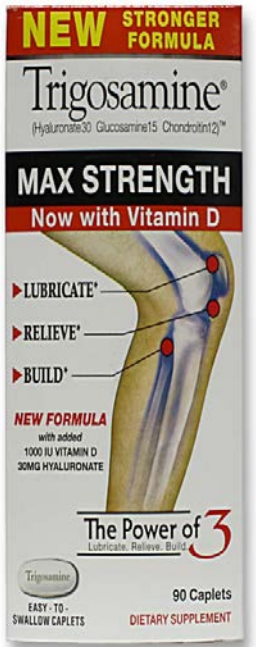
FACTUAL ALLEGATIONS

The Trigosamine Products

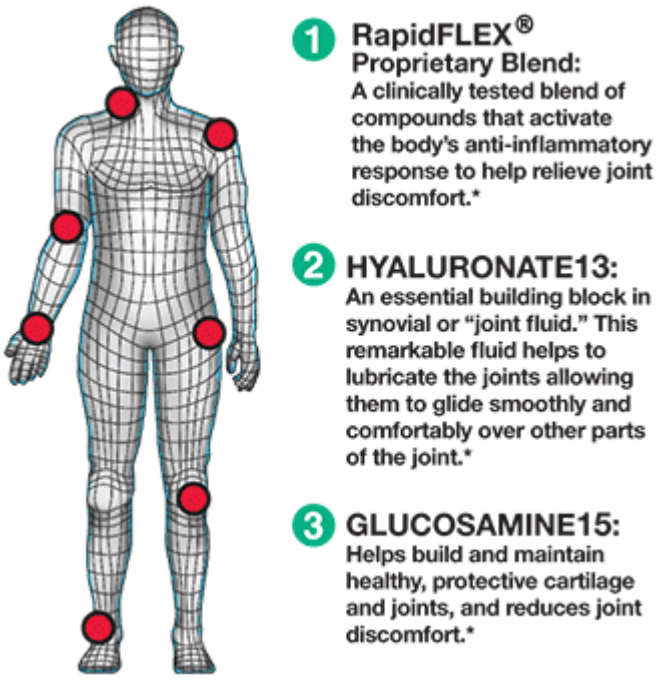
20. Defendants manufacture, distribute, and sell the Trigosamine line of dietary supplements. Those products include: (1) Trigosamine Max Strength; and (2) Trigosamine Fast-Acting.

21. The Trigosamine products are sold at major retail outlets and grocery chains across the country and through online retailers, including at Walgreen's stores, Wal-Mart.com, and Amazon.com. The following are screen shots of the Trigosamine products' labels:

Front:

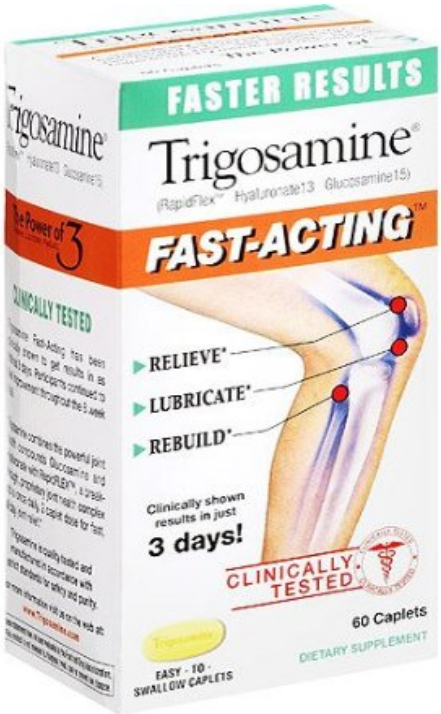


Back:



Side of Trigosamine Max Strength:

Front of Trigosamine Fast-Acting:



22. Since the Products' launch, Defendants have consistently conveyed the message to consumers throughout California that the Trigosamine products will relieve joint pain, lubricate joints, and rebuild joint cartilage. These claims are not substantiated by competent, scientific evidence and are factually baseless.

23. The primary active ingredient in both of the Trigosamine products is glucosamine.[3] The products are virtually identical in that neither is efficacious. The purported differences in the minor ingredients are insignificant and have no bearing on the primary active compound, glucosamine. Glucosamine is an amino sugar that the body produces and distributes in cartilage and other connective tissue. Consumption of glucosamine in the form of a pill has no material effect on the body; it is not absorbed in any meaningful quantity and especially not in the quantity recommended for daily consumption by the product labeling of the Trigosamine products.

24. In addition to glucosamine hydrochloride, Trigosamine Max Strength contains chondroitin sulfate. Chondroitin sulfate is a complex carbohydrate found in the body's connective tissues. Trigosamine Max Strength also contains hyaluronic acid and vitamin D. There is no competent scientific evidence that taking any of these ingredients—let alone through oral administration—results in the body metabolizing them into something that relieves the major symptoms of arthritis, including rebuilding cartilage or providing relief from joint pain.

25. Trigosamine Fast-Acting does not contain chondroitin sulfate. Instead, Trigosamine Fast-Acting contains a trademarked ingredient composition referred to as "RapidFlex," which consists of "Boswellia serrate extract, Curcuma longa extract, [and] Black Pepper extract." There is no competent scientific evidence that taking any of these ingredients—let alone through oral administration—results in the body metabolizing them into something that relieves any of the major symptoms of arthritis, including rebuilding cartilage or providing relief from joint pain. Nor is there any competent, reliable,

[3] Trigosamine Max Strength contains glucosamine hydrochloride (1500 mg), and Trigosamine Fast-Acting contains glucosamine sulfate (1500 mg).

scientific evidence which suggests that the addition of the RapidFlex compound increases or enhances the speed at which the product is metabolized or generates the intended results.

Scientific Evidence on the Primary Ingredients in Trigosamine

26. Contrary to the stated representations on all the Products' labeling and packaging, Defendants do not possess (and have not possessed) competent, scientific evidence that any of these ingredients, taken alone or in combination, are effective in treating the major symptoms of arthritis or any other joint-related ailments.

27. Defendants knew or should have known that glucosamine alone or taken in combination with the other ingredients present in Trigosamine has no actual medicinal value and does not provide any of the warranted benefits as represented by Defendants' Trigosamine products' packaging, labeling, and other advertising. In fact, there is no scientific study demonstrating that any glucosamine product can regenerate cartilage. To the contrary, as numerous studies have confirmed, neither glucosamine, chondroitin, nor any other supplements or ingredients actually regenerate cartilage or provide joint comfort or relief from pain.

28. For example, a 1999 study involving 100 subjects by Houpt et al., entitled, *Effect of glucosamine hydrochloride in the treatment of pain of osteoarthritis of the knee*, 26(11) J. Rheumatol. 2423-30 (1999), found that glucosamine hydrochloride performed no better than placebo at reducing pain at the conclusion of the eight-week trial.

29. In February 2004, a Supplement to the American Journal of Orthopedics contained an article entitled, *Restoring Articular Cartilage in the Knee*. The authors concluded that adult cartilage cannot be regenerated because it is not vascularized, meaning that blood does not flow to damaged cartilage, which prevents any mechanism for regeneration.

30. Likewise, a 2004 study by McAlindon et al., entitled, *Effectiveness of Glucosamine For Symptoms of Knee Osteoarthritis: Results From an Internet-Based Randomized Double-Blind Controlled Trial*, 117(9) Am. J. Med. 649-9 (Nov. 2004),

concluded that "glucosamine was no more effective than placebo in treating symptoms of knee osteoarthritis"—in short, that glucosamine is ineffective. *See also id.* at 646 ("[W]e found no difference between the glucosamine and placebo groups in any of the outcome measures, at any of the assessment time points.").

31. A 2004 study by Cibere et al., entitled, *Randomized, Double-Blind, Placebo-Controlled Glucosamine Discontinuation Trial In Knee Osteoarthritis*, 51(5) Arthritis Care & Research 738-45 (Oct. 15, 2004), studied users of glucosamine who claimed to have experienced at least moderate improvement after starting glucosamine. These patients were divided into two groups: one that continued using glucosamine and one that was given a placebo. For six months, the primary outcome observed was the proportion of disease flares in the glucosamine and placebo groups. A secondary outcome observed was the time to disease flare. The study results reflected that there were no differences in either the primary or secondary outcomes for glucosamine and placebo. The authors concluded that the study provided no evidence of symptomatic benefit from continued use of glucosamine—in other words, any prior perceived benefits were due to the placebo effect and not glucosamine. *See id.* at 743 ("In this study, we found that knee OA disease flare occurred as frequently, as quickly, and as severely in patients who were randomized to continue receiving glucosamine compared with those who received placebo. As a result, the efficacy of glucosamine as a symptom-modifying drug in knee OA is not supported by our study.").

32. A large (1,583 subjects), 24-week, multi-center RCT study sponsored by the National Institute of Health and published in the New England Journal of Medicine (the "2006 GAIT Study") concluded that "[t]he analysis of the primary outcome measure did not show that either [glucosamine or chondroitin], alone or in combination, was efficacious. . . ." Clegg, D. et al., *Glucosamine, Chondroitin Sulfate, and the Two in Combination for Painful Knee Osteoarthritis*, 354 New England J. of Med. 795, 806 (2006).

33. Subsequent GAIT studies in 2008 and 2010 reported that glucosamine and chondroitin did not rebuild cartilage and were otherwise ineffective, even in patients with moderate to severe knee pain for which the 2006 reported results were inconclusive. *See* Sawitzke, A.D. et al., *The Effect of Glucosamine and/or Chondroitin Sulfate on the Progression of Knee Osteoarthritis: A GAIT Report*, 58(10) J. Arthritis Rheum. 3183-91 (Oct. 2008); Sawitzke, A.D., *Clinical Efficacy And Safety Of Glucosamine, Chondroitin Sulphate, Their Combination, Celecoxib Or Placebo Taken To Treat Osteoarthritis Of The Knee: 2 Year Results from GAIT*, 69(8) Ann Rheum. Dis. 1459-64 (Aug. 2010).

34. The GAIT studies are consistent with the reported results of prior and subsequent studies. For example, the National Collaborating Centre for Chronic Conditions ("NCCCC") reported "the evidence to support the efficacy of glucosamine hydrochloride as a symptom modifier is poor," and the "evidence for efficacy of chondroitin was less convincing." NCCCC, *Osteoarthritis National Clinical Guideline for Care and Management of Adults*, Royal College of Physicians, London 2008. Consistent with its lack-of-efficacy findings, the NCCCC Guideline did not recommend the use of glucosamine or chondroitin for treating osteoarthritis. *See id.* at 33.

35. In a 2007 report, Vlad et al. reviewed all studies involving glucosamine hydrochloride and concluded that "[g]lucosamine hydrochloride is not effective." *Glucosamine for Pain in Osteoarthritis: why do trial results differ?*, 56:7 Arthritis Rheum. 2267-77 (July 2007). *See also id.* at 2275 ("[W]e believe that there is sufficient information to conclude that glucosamine hydrochloride lacks efficacy for pain in OA.").

36. In October 2008, the American College of Rheumatology's Journal, Arthritis & Rheumatism, published a report on a double-blind study conducted at multiple centers in the United States examining joint space width loss with radiograph films in patients who were treated with glucosamine hydrochloride. The authors concluded that after two years of treatment with this supplement, the treatment did not demonstrate a clinically important difference in joint space width loss. Sawitzke et al., *The effect of glucosamine and/or chondroitin sulfate on the progression of knee osteoarthritis: A report from the*

glucosamine/chondroitin arthritis intervention trial, 58:10 Arthritis Rheum. 3183-3191 (Oct. 2008).

37. In December 2008, the American Academy of Orthopaedic Surgeons published clinical practice guidelines for the "Treatment of Osteoarthritis of the Knee (Nonarthroplasty)," and recommended that "glucosamine and/or chondroitin sulfate or hydrochloride should not be prescribed for patients with symptomatic OA of the knee." Richmond et al., *Treatment of Osteoarthritis of the Knee (Nonarthroplasty)*, J. Am. Acad. Orthop. Surg. Vol. 17 No. 9 591-600 (2009). This recommendation was based on a 2007 report from the Agency for Healthcare Research and Quality, which states that "the best available evidence found that glucosamine hydrochloride, chondroitin sulfate, or their combination did not have any clinical benefit in patients with primary OA of the knee." Samson et al., *Treatment of Primary and Secondary Osteoarthritis of the Knee*, Agency for Healthcare Research and Quality, 2007 Sep 1. Report No. 157.

38. Studies concerning the type of glucosamine found in the Trigosamine Fast-Acting products (glucosamine sulfate) also demonstrate that it does not provide the joint-health benefits that Defendants represent. For example, a study by Rozendaal et al., entitled, *Effect of Glucosamine Sulfate on Hip Osteoarthritis*, 148 Ann. of Intern. Med. 268-77 (2008), assessing the effectiveness of glucosamine on the symptoms and structural progression of hip osteoarthritis during two years of treatment, concluded that glucosamine was no better than placebo in reducing symptoms and progression of hip osteoarthritis.

39. In March 2009, Harvard Medical School published a study conclusively proving that the ingestion of glucosamine could not affect the growth of cartilage. The study took note of the foregoing 2006 and 2008 studies, which "cast considerable doubt" upon the value of glucosamine. The authors went on to conduct an independent study of subjects ingesting 1500 mg of glucosamine, and proved that ***only trace amounts of glucosamine*** entered the human serum, far below any amount that could possibly affect cartilage. Moreover, even those trace amounts were present only for a few hours after

ingestion. The authors noted that a 1986 study had found no glucosamine in human plasma after ingestion of four times the usual amount of 1500 mg of glucosamine hydrochloride or sulphate. Silbert, *Dietary Glucosamine Under Question*, Glycobiology 19(6):564-567 (2009).

40. In April 2009, the Journal of Orthopedic Surgery published an article entitled, *Review Article: Glucosamine*. The article's authors concluded that, based on their literature review, there was "little or no evidence" to suggest that glucosamine was superior to a placebo even in slowing down cartilage deterioration, much less regenerating it. Kirkham et al., *Review Article: Glucosamine*, Journal of Orthopedic Surgery, 17(1): 72-6 (2009).

41. In 2009, a panel of scientists from the European Food Safety Authority ("EFSA") (a panel established by the European Union to provide independent scientific advice to improve food safety and consumer protection), reviewed nineteen studies submitted by an applicant, and concluded that "a cause and effect relationship has not been established between the consumption of glucosamine hydrochloride and a reduced rate of cartilage degeneration in individuals without osteoarthritis." EFSA Panel on Dietetic Products, Nutrition and Allergies, *Scientific Opinion on the substantiation of a health claim related to glucosamine hydrochloride and reduced rate of cartilage degeneration and reduced risk of osteoarthritis*, EFSA Journal (2009), 7(10):1358.

42. In a separate opinion from 2009, the EFSA panel examined the evidence for glucosamine (either hydrochloride or sulfate) alone or in combination with chondroitin sulfate and maintenance of joints. The claimed effect was "joint[] health," and the proposed claims included "helps to maintain healthy joint[s]," "supports mobility," "helps to keep joints supple and flexible," and "helps rebuild[] cartilage." Based on its review of eleven human intervention studies, three meta-analyses, twenty-one reviews and background papers, two animal studies, one in vitro study, one short report, and one case report, the EFSA panel concluded that "a cause and effect relationship has not been established between the consumption of glucosamine (either as glucosamine

hydrochloride or as glucosamine sulphate), either alone or in combination with chondroitin sulphate, and the maintenance of normal joints." EFSA Panel on Dietetic Products, Nutrition and Allergies, *Scientific Opinion on the substantiation of health claims related to glucosamine alone or in combination with chondroitin sulphate and maintenance of joints and reduction of inflammation*, EFSA Journal (2009), 7(9):1264.

43. A 2010 meta-analysis by Wandel et al., entitled, *Effects of Glucosamine, Chondroitin, Or Placebo In Patients With Osteoarthritis Of Hip Or Knee: Network Meta-Analysis*, BMJ 341:c4675 (2010), examined prior studies involving glucosamine and chondroitin, alone or in combination, and whether they relieved the symptoms or progression of arthritis of the knee or hip. The study's authors reported that glucosamine and chondroitin, alone or in combination, did not reduce joint pain or have an impact on the narrowing of joint space: "Our findings indicate that glucosamine, chondroitin, and their combination do not result in a relevant reduction of joint pain nor affect joint space narrowing compared with placebo." *Id.* at 8. The authors further concluded: "[w]e believe it unlikely that future trials will show a clinically relevant benefit of any of the evaluated preparations." *Id.*

44. On July 7, 2010, Wilkens et al. reported that there was no difference between placebo and glucosamine for the treatment of low back pain and lumbar osteoarthritis and that neither glucosamine nor a placebo were effective in reducing pain-related disability. The researchers also concluded that "[b]ased on our results, it seems unwise to recommend glucosamine to all patients" with low back pain and lumbar osteoarthritis. Wilkens et al., *Effect of Glucosamine on Pain-Related Disability in Patients With Chronic Low Back Pain and Degenerative Lumbar Osteoarthritis*, 304(1) JAMA 45-52 (July 7, 2010).

45. In 2011, Miller and Clegg, after surveying the clinical study history of glucosamine and chondroitin, concluded that "[t]he cost-effectiveness of these dietary supplements alone or in combination in the treatment of OA has not been demonstrated in

North America." Miller, K. and Clegg, D., *Glucosamine and Chondroitin Sulfate*, Rheum. Dis. Clin. N. Am. 37 103-118 (2011).

46. In June 2011, the Journal of Pharmacy & Pharmaceutical Sciences published an article entitled, *The Glucosamine Controversy; A Pharmacokinetic Issue*." The authors concluded that regardless of the formulation used, no or marginal beneficial effects were observed as a result of low glucosamine bioavailability. Aghazadeh-Habashi and Jamali, *The Glucosamine Controversy; A Pharmacokinetic Issue*, Journal of Pharmacy & Pharmaceutical Sciences, 14(2): 264-273 (2011).

47. In 2012, a report by Rovati et al., entitled, *Crystalline glucosamine sulfate in the management of knee osteoarthritis: efficacy, safety, and pharmacokinetic properties*, Ther Adv Muskoloskel Dis 4(3) 167-180, noted that glucosamine hydrochloride "ha[s] never been shown to be effective."

48. In 2012, the EFSA examined the evidence to determine if glucosamine sulfate or glucosamine hydrochloride could substantiate a claimed effect of "contributes to the maintenance of normal joint cartilage." Based on its review of sixty-one references provided by Merck Consumer Healthcare, the EFSA panel concluded that "a cause and effect relationship has not been established between the consumption of glucosamine and maintenance of normal joint cartilage in individuals without osteoarthritis." EFSA Panel on Dietetic Products, Nutrition and Allergies, *Scientific Opinion on the substantiation of a health claim related to glucosamine and maintenance of normal joint cartilage*, EFSA Journal 2012, 10(5): 2691.

49. To date, there are only two studies, both of which are more than a decade old, purporting to claim that the ingestion of glucosamine can affect the growth or deterioration of cartilage, both sponsored by a glucosamine supplement manufacturer: Pavelka et al., *Glucosamine Sulfate Use and Delay of Progression of Knee Osteoarthritis*, Arch. Intern. Med., 162: 2113-2123 (2002); and Reginster et al., *Long-term Effects of Glucosamine Sulphate On Osteoarthritis Progress: A Randomised, Placebo-Controlled Clinical Trial*, Lancet, 357: 251-6 (2001). As noted in the April 2009 Journal of

Orthopedic Surgery article, the methodologies in those studies had "inherently poor reproducibility," and even minor changes in posture by the subjects during scans could cause false apparent changes in cartilage. The authors of the Journal of Orthopedic Surgery article explained the manufacturer-sponsored studies' findings by noting that "industry-sponsored trials report positive effects more often than do non-sponsored trials and more find pro-industry results." No reliable, scientific study has shown that glucosamine and chondroitin, alone or in combination, have a structure-modifying effect that will regenerate cartilage that has broken down or worn away.

50. Despite the lack of competent scientific evidence, Defendants continue to unequivocally claim that Trigosamine provides a variety of health benefits centered on lubricating joints, building cartilage, and relieving joint pain in human joints. Defendants represent that Trigosamine is "[a] scientifically-advanced, once a day formulation that helps build and maintain healthy joints and cartilage, while also helping to relieve joint discomfort." *See* Product Label, Trigosamine Max Strength with Vitamin D at ¶ 21. As the manufacturers and distributors of the Trigosamine products, Defendants possess specialized knowledge regarding the content and effects of the ingredients contained in the Products, and they are in a superior position to learn of the effects—and have learned of the effects—the Products have on consumers.

51. Specifically, Defendants knew or should have known, but failed to disclose, that they have no competent, scientific evidence that the Trigosamine products are effective in treating the major symptoms of arthritis or any other joint-related ailments.

52. Notwithstanding these deceptive representations and material omissions, Defendants conveyed and continue to convey one uniform message: the Trigosamine products, with their exclusive formulas, are effective in reducing joint pain and building joint cartilage.

53. Plaintiff and Class members have been and will continue to be deceived or misled by Defendants' deceptive representations touting the effectiveness of the Trigosamine products. Plaintiff purchased and used the Trigosamine products during the

Class Period, and in doing so, he read, considered, and based his decision to buy the Products on the above-cited label representations. Because the Products' sole purpose is to provide relief from joint discomfort, Defendants' representations and omissions were a material factor in influencing Plaintiff's decision to purchase and use the Trigosamine products. There is no other reason for Plaintiff to have purchased the Trigosamine products, and Plaintiff would not have purchased the Products had he known that the Products were ineffective and that Defendants did not possess competent, scientific evidence to support the claims they made about the Products.

54. As a result, Plaintiff and Class members have been damaged in their purchases of the Products and have been deceived into purchasing products that they believed, based on Defendants' representations, were proven to be effective in treating the major symptoms of arthritis and other joint-related ailments when, in fact, they are not.

55. Defendants, by contrast, reaped enormous profits from their false marketing and sale of the Products.

CLASS DEFINITION AND ALLEGATIONS

56. Plaintiff brings this action on behalf of himself and all other similarly situated California residents pursuant to Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Class:

> All individuals in California who, within the applicable statute of limitations, purchased the Trigosamine products.[4]
>
> Excluded from the Class are Defendants, their parents, subsidiaries, affiliates, officers, and directors; those who purchased the Trigosamine products for the purpose of resale; the Judge to whom this case is assigned and any immediate family members thereof; and those who assert a claim for personal injury arising from the consumption of the Trigosamine products.

[4] As previously stated, the Trigosamine products include: (1) Trigosamine Max Strength; and (2) Trigosamine Fast-Acting.

57. Members of the Class are so numerous and geographically dispersed that joinder of all Class members is impracticable. Plaintiff is informed and believes, and on that basis alleges, that the proposed Class contains many thousands of members. The precise number of Class members is unknown to Plaintiff.

58. Common questions of law and fact exist as to all members of the Class and predominate over questions affecting only individual Class members. The common legal and factual questions include, but are not limited to, the following:

i. Whether Defendants had competent, scientific evidence to support each of the claims that they made about the Products;

ii. Whether the claims discussed herein that Defendants made about the Products were or are misleading or reasonably likely to deceive;

iii. Whether Defendants' alleged conduct violates public policy;

iv. Whether the alleged conduct constitutes violations of the laws asserted herein;

v. Whether Defendants engaged in false and misleading advertising;

vi. Whether Plaintiff and Class members have sustained monetary loss and the proper measure of that loss;

vii. Whether Plaintiff and Class members are entitled to restitution, disgorgement of Defendants' profits, declaratory, and/or injunctive relief; and

viii. Whether Plaintiff and Class members are entitled to an award of compensatory damages.

59. The claims asserted by Plaintiff in this action are typical of the claims of the members of the Class, as the claims arise from the same course of conduct by Defendants, and the relief sought is common. Plaintiff and Class members suffered uniform damages caused by their purchase of the Trigosamine products, which were manufactured, marketed, and sold by Defendants.

60. Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. Plaintiff has retained counsel competent and experienced in both consumer protection and class litigation.

61. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The expense and burden of individual litigation would make it impracticable or impossible for proposed Class members to prosecute their claims individually. It would thus be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs done to them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts, and it would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and it presents no unusual management difficulties under the circumstances here.

62. In the alternative, the Class also may be certified because Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making final declaratory and/or injunctive relief with respect to the members of the Class as a whole appropriate.

COUNT I

Violation of the Consumers Legal Remedies Act – Civil Code §§ 1750, *et seq.*

63. Plaintiff re-alleges and incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.

64. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and prevent Defendants from engaging in the acts described and requiring Defendants to provide full restitution to Plaintiff and Class members.

65. Unless a Class is certified, Defendants will retain monies that were taken from Plaintiff and Class members as a result of Defendants' wrongful conduct. Unless a Class-wide injunction is issued, Defendants will continue to commit the violations alleged, and the members of the Class and the general public will continue to be misled.

66. This cause of action is brought under the Consumers Legal Remedies Act, California Civil Code §§ 1750, *et seq.* (the "Act"). Plaintiff is a consumer as defined by California Civil Code § 1761(d). Defendants' Trigosamine products are goods within the meaning of the Act. *See* Cal. Civ. Code § 1761(a).

67. Defendants violated and continue to violate the Act by engaging in the following practices proscribed by California Civil Code § 1770(a) in transactions with Plaintiff and the Class which were intended to result in, and did result in, the sale of Defendants' Trigosamine products:

> (5) Representing that [the Products] have . . . approval, characteristics, . . . uses, [and] benefits . . . which they do not have . . . .
>
> * * *
>
> (7) Representing that [the Products] are of a particular standard, quality, or grade . . . if they are of another.
>
> * * *
>
> (9) Advertising [the Products] . . . with intent not to sell them as advertised.
>
> * * *
>
> (16) Representing that [the Products have] been supplied in accordance with a previous representation when [they have] not.

68. Defendants violated and continue to violate the Act by representing and failing to disclose material facts on the Trigosamine product labels and packages as described above when Defendants knew or should have known that the representations were unsubstantiated, false, and misleading and that the omissions were of material facts.

69. Pursuant to § 1782(d) of the Act, Plaintiff and the Class seek a court order enjoining the above-described wrongful acts and practices of Defendants and for restitution and disgorgement.

70. Pursuant to § 1782 of the Act, Plaintiff notified all Defendants by certified mail of the particular violations of § 1770 of the Act and demanded that they rectify the problems associated with the actions detailed above and give notice to all affected consumers of Defendants' intent to so act. Copies of the letters were attached to the original complaint as Exhibit A.

71. Pursuant to § 1782 of the Act, Plaintiff notified Defendant PatentHEALTH on or about April 8, 2013, in writing, by certified mail, of the particular violations of § 1770 of the Act and demanded that it rectify the problems associated with the actions detailed above and give notice to all affected consumers of Defendant's intent to so act. Plaintiff similarly notified Defendant Arthur Middleton on or about May 23, 2013. PatentHEALTH and Arthur Middleton failed to appropriately respond to Plaintiff Vasic's letter or agree to rectify the problems associated with the actions detailed above and give notice to all affected consumers within thirty days of the date of written notice pursuant to § 1782 of the Act. Therefore, Plaintiff further seeks claims for actual, punitive, and statutory damages, as appropriate against PatentHEALTH and Arthur Middleton.

72. Defendants' conduct is malicious, fraudulent, and wanton, and they have provided misleading information.

73. Pursuant to § 1780(d) of the Act, attached hereto as Exhibit A is the affidavit showing that this action has been commenced in the proper forum.

COUNT II

Violation of Business & Professions Code §§ 17200, *et seq.*

74. Plaintiff re-alleges and incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.

75. As alleged herein, Plaintiff has suffered injury in fact and lost money or property as a result of Defendants' conduct because he purchased the Products.

76. In the course of conducting business, Defendants committed unlawful business practices by, *inter alia*, making the representations (which also constitute advertising within the meaning of Business & Professions Code §§ 17200 and 17500) and omissions of material facts, as set forth more fully herein, and violating Civil Code §§ 1572, 1573, 1709, 1711, and 1770; Business & Professions Code §§ 17200, *et seq.*, and 17500, *et seq.*; and the common law.

77. Plaintiff and the Class reserve the right to allege other violations of law, which constitute other unlawful business acts or practices. Such conduct is ongoing and continues to this date.

78. Defendants' acts, omissions, misrepresentations, practices, and non-disclosures as alleged herein also constitute "unfair" business acts and practices within the meaning of Business and Professions Code §§ 17200, *et seq.*, in that their conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and unscrupulous because the gravity of the conduct outweighs any alleged benefits attributable to such conduct.

79. As stated in this complaint, Plaintiff alleges violations of consumer protection, unfair competition, and truth in advertising laws resulting in harm to consumers. Plaintiff asserts violations of the public policy of engaging in false and misleading advertising, unfair competition, and deceptive conduct towards consumers. This conduct constitutes violations of the unfair prong of Business & Professions Code §§ 17200, *et seq*.

80. There were reasonably available alternatives to further Defendants' legitimate business interests, other than the conduct described herein.

81. Defendants' claims, nondisclosures, and misleading statements, as more fully set forth above, are also false, misleading, and/or likely to deceive the consuming public within the meaning of Business & Professions Code §§ 17200, *et seq*.

82. Defendants' labeling and packaging as described herein, also constitute unfair, deceptive, untrue, and misleading advertising.

83. Defendants' conduct caused and continues to cause substantial injury to Plaintiff and the other Class members. Plaintiff has suffered injury in fact and has lost money as a result of Defendants' unfair conduct.

84. Plaintiff, on behalf of himself and all other similarly situated California residents, seeks restitution of all money collected from Plaintiff and the members of the Class as a result of unfair competition, an injunction prohibiting Defendants from continuing such practices, corrective advertising, and all other relief this Court deems appropriate, consistent with Business & Professions Code § 17203.

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for a judgment:

A. Certifying the class as requested herein;

B. Awarding Plaintiff and the proposed Class members damages;

C. Awarding restitution and disgorgement of Defendants' revenues to Plaintiff and the proposed Class members;

D. Awarding declaratory and injunctive relief as permitted by law or equity, including enjoining Defendants from continuing the unlawful practices as set forth herein, and directing Defendants to identify, with court supervision, victims of their conduct and pay them restitution and disgorgement of all monies acquired by Defendants by means of any act or practice declared by this Court to be wrongful;

E. Ordering Defendants to engage in a corrective advertising campaign;

F. Awarding attorneys' fees and costs; and

G. Providing such further relief as may be just and proper.

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JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: April 8, 2014

CARPENTER LAW GROUP

By: */s/ Todd D. Carpenter*

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Attorneys for Plaintiff

CERTIFICATE OF SERVICE

The undersigned hereby certify that on April 8, 2014, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system per Civil Local Rule 5.4 which will send notification of such filing to the e-mail addresses denoted on the Electronic Mail notice list, and I hereby certify that I have mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the Manual Notice list. I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

/s/ Todd D. Carpenter
Todd D. Carpenter

EXHIBIT "A"

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Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

DRAGAN VASIC, On Behalf of Himself and All Others Similarly Situated,

Plaintiff,

vs.

PATENTHEALTH, L.L.C., an Ohio Limited Liability Company, ARTHUR MIDDLETON CAPITAL HOLDINGS, INC., an Ohio Corporation, and DOES 1 through 20,

Defendant.

Case No. 3:13-cv-00849 AJB (MDD)

DECLARATION OF TODD D. CARPENTER REGARDING CALIFORNIA CIVIL CODE SECTION 1780(d)

I, Todd D. Carpenter, declare as follows:

1. I am an attorney duly licensed to practice before all of the courts of the State of California. I am the principle and owner of the Carpenter Law Group, and the counsel of record for plaintiff in the above-entitled action

2. Defendant PatentHEALTH, L.L.C., has done and is doing business in the

Southern District of California. Such business includes the marketing, distributing and sale of its Trigosamine joint health supplements. Furthermore, Plaintiff Vasic purchased the Trigosamine Max Strength product in San Diego, California.

3. Defendant Arthur Middleton is the sole member of PatentHEALTH, LLC. Defendant Arthur Middleton manufactures, distributes, markets, and sells the Trigosamine products to tens of thousands of consumers in California.

4. Plaintiff is informed and believes, and thus alleges, that at all times herein mentioned, each Defendant was the agent, employee, representative, partner, joint venturer, and/or alter ego of the other Defendants, and, in doing the things alleged herein, was acting within the course and scope of such agency, employment, representation, on behalf of such partnership or joint venture, and/or as such alter ego, with the authority, permission, consent, and/or ratification of the other Defendants.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 8th Day of April, 2014 in San Diego, California.

/s/ Todd D. Carpenter
Todd D. Carpenter