

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

NORTH AMERICAN MEDICAL
CORPORATION and ADAGEN
MEDICAL INTERNATIONAL,
INC.,

Plaintiffs

v.

AXIOM WORLDWIDE, INC.,
JAMES GIBSON, JR., NICHOLAS
EXARHOS, REN SCOTT,
REHABCO, INC., ALTADONNA
COMMUNICATIONS, INC.,
BENJAMIN A. ALTADONNA, and
SEASIDE DATA SYSTEMS, INC.,

Defendants.

CIVIL CASE NO.
1:06-CV-1678-JTC

ORDER

This matter is currently before the Court on Defendants Axiom Worldwide, Inc. (“Axiom”), Gibson, Exarhos, and Scott’s (“the Axiom Defendants”) motions to dismiss [#31, #112] and Plaintiffs’ motions for preliminary injunction [#6, #93]. Plaintiff North American Medical Corporation (“NAM”) designs and manufactures physiotherapeutic spinal devices, commonly known as traction devices, which are used, for example, to treat lower back pain. Plaintiff Adagen Medical International, Inc. (“Adagen”) is an authorized distributor of NAM’s devices. Defendant Axiom manufactures a physiotherapeutic device known generally as the DRX 9000

and is a competitor of NAM. Plaintiffs brought this action for unfair competition, alleging that Defendants, particularly Axiom and Defendant Altadonna Communications, Inc. (“ACI”), Axiom’s commissioned sales representative, have engaged in a campaign of false advertising and trademark infringement to Plaintiffs’ detriment.

I. Motions to Dismiss [#31, #112]

The Axiom Defendants move to dismiss on multiple grounds, including, inter alia, that: (i) Plaintiffs lack standing to pursue this action; (ii) these proceedings should be dismissed or stayed in favor of a pending opposition action at the Patent and Trademark Office (“PTO”); (iii) the Court lacks personal jurisdiction over individual Defendants Gibson, Exarhos, and Scott; and (iv) Plaintiff Adagen should be dismissed under the “first filed” rule.

Under Rule 12(b), on which most of the Axiom Defendants’ arguments are based, the Court may dismiss a claim “only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.” Jean v. Dorelien, 431 F.3d 776, 778 (11th Cir. 2005) (citation omitted). In considering a motion to dismiss, the Court must accept the Complaint’s allegations as true and construe them in the light most favorable to Plaintiffs. Powell v. United States, 945 F.2d 374, 375 (11th Cir. 1991).

A. Lack of Standing to Pursue Intellectual Property Claims

Plaintiffs bring several claims related to enforcement of NAM's intellectual property, including trademark infringement, trade dress infringement, and copyright infringement. The Axiom Defendants argue that Plaintiffs lack standing to pursue these claims because Plaintiffs' ownership of the intellectual property at issue is being challenged in ongoing bankruptcy proceedings ("the Adversary Proceeding"). (See Defs.' Mot. to Dismiss at 8 ("The claims asserted in this case are all dependent on NAM's right to manufacture, market[,] and sell the Accu-Spina device.")) Therefore, they request the Court dismiss, or in the alternative, stay this action pending the outcome of the Adversary Proceeding.

To establish standing, Plaintiffs must "demonstrate that [they have] suffered 'injury in fact,' that the injury is 'fairly traceable' to the actions of the defendant, and that the injury will likely be redressed by a favorable decision." Nat'l Alliance for the Mentally Ill v. Bd. of County Comm'rs of St. Johns County, 376 F.3d 1292, 1295 (11th Cir. 2004) (quoting Bennett v. Spear, 520 U.S. 154, 162, 117 S. Ct. 1154, 1161 (1997)).

Regardless of the Adversary Proceeding, Plaintiff NAM at present owns the trademarks and copyrights Plaintiffs seek to enforce in this action. Thus, they have standing, at least at this stage, to pursue these claims. Notably,

however, it is questionable whether a favorable result for Defendants in the Adversary Proceeding would have any effect on Plaintiffs' ability to prosecute these claims. While the Adversary Proceeding involves the issue of whether NAM misappropriated a patent from its predecessor company Cluster, and thus the technology which underlies NAM's spinal therapy products, Plaintiffs' claims here do not go to this underlying technology. In other words, Plaintiffs are not attempting to enforce a patent which they may or may not own. Instead, Plaintiffs claims focus primarily on Defendants' misuse of the intellectual property NAM has developed to promote this technology (i.e., the trademarks and trade dress). Consequently, if it is determined that a company other than NAM owns the patent, it will have little effect on NAM's ability to use trademarks and trade dress it has developed to market its spinal therapy products, although it may prevent NAM from marketing the spinal therapy products themselves.

The Court **DENIES** the Axiom Defendants' motion to dismiss or stay these proceedings in favor of the Adversary Proceeding.

B. Lack of Standing to Pursue RICO Claims

In Counts XV and XVI of their Complaint, Plaintiffs charge Defendants with violations of 18 U.S.C. § 1962(c), the federal RICO statute, and with conspiracy to violate this section, respectively. The Axiom Defendants argue

that Plaintiffs lack standing to bring these claims.

The federal RICO statute provides:

It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.

18 U.S.C. § 1962(c). In order to establish a cause of action under RICO, Plaintiffs must show “(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity.” Sedima, S.P.R.L. v. Imrex Co., 473 U.S. 479, 496, 105 S. Ct. 3275, 3285 (1985). To have standing to pursue a RICO claim, Plaintiffs must also show “that [they] [have] been injured in [their] business or property by the conduct constituting the violation.” Id. Importantly, “when the alleged predicate act is mail or wire fraud, the plaintiff must have been a target of the scheme to defraud and must have relied to his detriment on misrepresentations made in furtherance of that scheme.” Pelletier v. Zweifel 921 F.2d 1465, 1499-1500 (11th Cir. 1991).

The only predicate acts alleged in the Complaint are that Defendants have engaged in mail and wire fraud by making misrepresentations to induce consumers to purchase their products. As noted above, however, when mail or wire fraud forms the basis of a RICO claim, the claimant must establish reliance on the alleged misrepresentations. There is no question in this case

that Plaintiffs, as Defendants' competitors, were not the target of, nor did they rely upon, the misrepresentations. Instead, it is the potential customers of Plaintiffs and Defendants who were targeted by the allegedly false claims. Thus, Plaintiffs have failed to establish standing to pursue these claims. The Court **GRANTS** the Axiom Defendants' motion to dismiss Counts XV and XVI.

C. Dismissal or Stay Pending Proceedings at the PTO

Plaintiffs allege in this action that Defendants have infringed NAM's trademarks. Defendants have challenged, via oppositions proceedings at the PTO, NAM's ownership of one of these trademarks – namely, the phrase “We Sell Science.” As a result, Defendants argue that the Court should dismiss or stay these proceedings under the “primary jurisdiction doctrine” pending resolution in the PTO of which party has priority to the mark.

Under the doctrine of primary jurisdiction, the Court “may dismiss or stay an action pending a resolution of some portion of the actions by an administrative agency.” Smith v. GTE Corp., 236 F.3d 1292, 1298 n.3 (11th Cir. 2001) (quoting Wagner & Brown v. ANR Pipeline Co., 837 F.2d 199, 201 (5th Cir. 1988)). The primary jurisdiction doctrine becomes relevant “whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of

an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views.” Id. (quoting United States v. Western Pac. R.R. Co., 352 U.S. 59, 64, 77 S.Ct. 161, 165 (1956)).

Most courts to address the issue have not applied the primary jurisdiction doctrine in trademark infringement actions. See 5 J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition § 32:48 (4th ed. 2007). Likewise, this Court finds that applying the doctrine in this case would be inappropriate. First, the doctrine is applied most often in cases where the administrative agency has unique expertise in an area unfamiliar to courts. E.g., Far East Conference v. United States, 342 U.S. 570, 574, 72 S. Ct. 492, 494 (1952) (antitrust action challenging shipping rates properly within primary jurisdiction of Federal Maritime Board). However, unlike some of these more specialized areas, trademark law is within the traditional competence of federal district courts. Cf. Goya Foods, Inc. v. Tropicana Prods., Inc., 846 F.2d 848 (2d Cir. 1988). Second, certain determinations of the PTO, including resolution of opposition proceedings, may be challenged in a district court action under 15 U.S.C. § 1071(b), and those determinations are given very little deference. Thus, it does not make sense to delay this entire litigation, of which the “We Sell Science” issue is so small a part, in

order to await the PTO's essentially nonbinding resolution of the issue. See PHC, Inc. v. Pioneer Healthcare, Inc., 75 F.3d 75, 80 (1st Cir. 1996) (“[A]waiting the [PTO’s] action is less attractive . . . because . . . its administrative findings can so easily be relitigated in court.”). Thus, given that the result of the PTO proceedings is likely to have little effect here, Plaintiffs’ interest in adjudicating their rights outweighs any potential benefit in awaiting the PTO’s determination.

For these reasons, the Court declines to invoke the primary jurisdiction doctrine and dismiss or stay this action pending the outcome of PTO opposition proceedings. The Axiom Defendants’ motion in this regard is **DENIED**.

D. Lack of Personal Jurisdiction over Individual Defendants Gibson, Exarhos, and Scott

Individual Axiom Defendants Gibson, Exarhos, and Scott move to dismiss under Rule 12(b)(2) for lack of personal jurisdiction. They contend that they do not have the requisite minimum contacts in Georgia for this Court to assert long-arm jurisdiction over them.

In order to determine whether the Court has personal jurisdiction over a particular defendant, it must engage in a two-step inquiry. First, the Court “must determine whether the exercise of jurisdiction is appropriate under the forum state’s long-arm statute.” Mut. Serv. Ins. Co. v. Frit Indus., Inc., 358

F.3d 1312, 1319 (11th Cir. 2004). The relevant portion of Georgia’s long-arm statute provides:

A court of this state may exercise personal jurisdiction over any nonresident . . . , as to a cause of action arising from any of the acts, omissions, ownership, use, or possession enumerated in this Code section, in the same manner as if he were a resident of the state, if in person or through an agent, he:

- (1) Transacts any business within this state;
- (2) Commits a tortious act or omission within this state, except as to a cause of action for defamation of character arising from the act;
- (3) Commits a tortious injury in this state caused by an act or omission outside this state if the tort-feasor regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in this state; . . .

O.C.G.A. § 9-10-91.

Under subsection (1), Georgia courts may “exercise personal jurisdiction over any nonresident who transacts any business in [Georgia] . . . ‘to the maximum extent permitted by procedural due process.’” Innovative Clinical and Consulting Services, LLC. v. First Nat’l Bank, 620 S.E.2d 352, 355 (Ga. 2005) (citation omitted). Likewise, under subsection (2) Georgia courts may exercise personal jurisdiction “over a nonresident who commits a tortious act or omission within [Georgia], insofar as the exercise of that personal jurisdiction comports with constitutional due process” Id. (internal footnote omitted). In contrast with subsections (1) and (2), which are coextensive with constitutional due process, subsection (3) permits the

exercise of personal jurisdiction over a nonresident who commits a tortious injury in Georgia caused by an act or omission outside Georgia only if the tortfeasor “regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in [Georgia].” Id.

The second step of the analysis depends on “whether the exercise of personal jurisdiction over the defendant would violate the Due Process Clause of the Fourteenth Amendment to the United States Constitution, which requires that the defendant have minimum contacts with the forum state and that the exercise of jurisdiction over the defendant does not offend ‘traditional notions of fair play and substantial justice.’” Mut. Serv. Ins. Co., 358 F.3d at 1319 (citing Int’l Shoe Co. v. Washington, 326 U.S. 310, 316, 66 S. Ct. 154, 158 (1945)).

Defendant Axiom regularly does and solicits business in Georgia. The record reveals, in addition to its widespread advertising which reaches Georgia, Axiom has sold at least 14 physiotherapeutic spinal devices in this state for a total of over \$1.3 million. There is no dispute that Defendant Axiom is subject to personal jurisdiction in Georgia. The question is whether Defendants Gibson, Exarhos, and Scott’s activities in their capacity as Axiom officers and employees subject them to personal jurisdiction as well.

“[I]t is . . . well settled that personal participation by a corporate employee, officer, or director in the wrongful activities of a corporation is sufficient to make the individual, as well as the corporation, substantively liable for a tort.” Delong Equip. Co. v. Washington Mills Abrasive, 840 F.2d 843, 851 (11th Cir. 1988); see also Foxworthy v. Custom Tees, Inc., 879 F. Supp. 1200, 1206 (N.D. Ga. 1995) (Freeman, J.). When the individual can be held substantively liable for the corporation’s wrongful activities, it follows that the individual is also subject to the forum’s long arm jurisdiction if such jurisdiction can be asserted over the corporation. A corporation cannot infringe a trademark or falsely advertise on its own. Rather, the corporation’s agents direct its actions. Thus, “[w]here a corporation commits a wrongful act, and the law holds the individual equally and inseparably liable for the corporate act, then the basis for the exercise of jurisdiction is the same.” Foxworthy, 879 F. Supp. at 1206. As the Eleventh Circuit concluded in Delong,

[I]t is reasonable and comports with notions of “fair play” and “substantial justice” to extend a forum’s long-arm statute to a non-resident individual who commits an act in the forum for which he can be held substantively liable, even if his actions in and contacts with the forum were entirely in his capacity as a corporate officer or director. The crucial matter is whether the individual defendant can be held personally liable for acts committed in the forum, not whether his contacts with the forum arose in his personal capacity. If substantive liability can extend to an individual for acts performed on behalf of a corporation,

then the individual is amenable to the forum's long-arm statute, at least in situations where the nonresident individual physically was present in the forum when he participated in the tort.

Delong, 840 F.2d at 851-52 (emphasis added, footnote omitted); see also Foxworthy, 879 F. Supp. at 1206 n.9 (recognizing Delong rationale also applies in situations where nonresident individual was not physically present in forum).

As discussed below, infra Section II, Plaintiffs have established a likelihood of succeeding on the merits of their false advertising claims. It is undisputed that these activities reached Georgia, and therefore subject Defendant Axiom to personal jurisdiction here. Viewing the record in the light most favorable to Plaintiffs, as must be done at this stage, individual Defendants Gibson, Exarhos, and Scott personally participated, and played an integral role, in this advertising campaign, including the false representations made by Axiom to promote the DRX 9000. Accordingly, these Defendants are liable for the torts committed by Defendant Axiom, and like Axiom, they are subject to the personal jurisdiction of this Court.

E. Remaining Grounds for Dismissal

The Court has reviewed the remainder of the Axiom Defendants' grounds for dismissal, including the motion to dismiss Plaintiff Adagen under the "first filed" rule, but finds them to be without merit. Accordingly, the

Court **DENIES** all remaining aspects of the Axiom Defendants' motions to dismiss.

II. Motions for Preliminary Injunction [#6, #93]

Plaintiffs NAM and Adagen request preliminary injunctive relief on their claims for false advertising and trademark infringement. Specifically, they request the Court enjoin Defendants from making certain allegedly false representations about Axiom's DRX 9000.¹ In addition, they request the Court enjoin Defendants from using, and thereby infringing, NAM's trademarks as "meta tags" on Axiom's website.

In order to obtain a preliminary injunction, Plaintiffs must establish that: (1) they are likely to succeed on the merits of their claims; (2) they will suffer irreparable harm unless an injunction issues; (3) the threatened injury outweighs any harm that granting injunctive relief would cause Defendants; and (4) granting injunctive relief would not be adverse to the public interest. McDonald's Corp. v. Robertson, 147 F.3d 1301, 1306 (11th Cir. 1998). The grant or denial of a preliminary injunction is within the sound discretion of the Court. Sierra Club v. Georgia Power Co., 180 F.3d 1309, 1310 (11th Cir. 1999).

¹ For purposes of this Order, reference to the DRX 9000 includes the DRX 9000C, the DRX 3000, and all other similar versions of the device.

A. Likelihood of Success on the Merits

1. Plaintiffs' False Advertising Claims

Section 43(a) of the Lanham Act, codified at 15 U.S.C. § 1125(a), provides:

(1) Any person who, on or in connection with any goods or services, or any container for goods, 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 . . .

(B) 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 in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

In order for Plaintiffs to establish likelihood of success on the merits under this section, they must establish that: (1) the challenged advertisements are false or misleading; (2) the advertisements deceived, or have the capacity to deceive, consumers; (3) the deception has a material effect on purchasing decisions; and (4) Plaintiffs have been injured, or are likely to be injured, by the false advertising.² Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc., 299 F.3d 1242, 1247 (11th Cir. 2002).

Four classes of allegedly false representations are at issue in this case. They relate to Defendants' claims that: (1) the DRX 9000 is patented; (2) the

² Plaintiffs must also establish that the misrepresented product affects interstate commerce, an element the parties do not dispute.

DRX 9000 has been “approved” by the FDA; (3) the DRX 9000 is the only device cleared by the FDA to provide “true spinal decompression”; and (4) the DRX 9000 was designed by NASA, approved or endorsed by NASA, or is somehow based upon NASA research. The Court addresses each of these classes of representations³ below.

a. false or misleading advertisements

i. *patent claims*

One of the allegedly false representations at issue in this case is that the DRX 9000 is in some way patented. This claim has taken many forms, including that the DRX is a “patented” machine, uses “patented” technology, incorporates a “patented” algorithm or process, or includes “components” patented by Axiom.⁴

For example, Defendant Scott, in an Axiom infomercial, discusses the “patented” logarithmic curve:

³ There are hundreds of individual advertisements in the record, each of which may make a claim in a slightly different manner than another. The result is that hundreds of representations are at issue. As will be seen, the Court has, where appropriate, classified these representations into general categories. Further, the Court has focused on those representations that are literally false, because as discussed below, *infra* Section II.A.1.b., Plaintiffs cannot at this time show likelihood of success on the merits on the representations that are not literally false.

⁴ There is little doubt that Defendants may advertise, if true, that the DRX 9000 contains patented components. They may also advertise, if true, that they have patents pending on portions of the DRX 9000. The Court deals here with Defendants’ claims which represent that Axiom own patents which cover the device.

This is the patented logarithmic curve which the DRX 9000 utilizes to create true spinal decompression. Other companies may claim to promote spinal decompression, but only Axiom Worldwide has patented the process.

(Bignault Decl. ¶ 4, Ex. B (emphasis added).) Appearing on the screen in writing during this portion of the video are the phrases “patented” and “Axiom Worldwide Patented Process.” (*Id.*; see also Pls.’ Ex. 171 (“Many companies claim to promote spinal decompression, but only Axiom Worldwide has patented the process.”).) On a promotional video, Dr. Gruber, a DRX 9000 purchaser, describes the patents he “saw” while visiting Axiom’s facility in Tampa, Florida: “But when you come down here and you see the machine and you see what goes into it and you see the technology, the patents, it’s very impressive.” (Pls.’ Ex. 171.)

These patent claims were presented to potential customers who visited Axiom’s facility in Tampa for sales workshops. Axiom made and repeated the claims in PowerPoint presentations used in its Tampa selling sessions, for example, by discussing both “patent pending technology” as well as “What has Axiom Patented.” (Pls.’ Ex. 80.) Interestingly, every PowerPoint, whether acknowledged by Axiom or not, prominently displays on its third page an official-looking but undisputedly fake “patent document” for a “Spinal Decompression Therapy System and Method.” (*Id.* at 3.) The document bears the name and seal of the PTO, but contains a reference to the fictitious “US

Federal Court Docket No. 16386 US 01.” (Id.) These representations regarding the patent status of the DRX 9000 were repeated by Defendants ACI and Altadonna in marketing materials and by Defendant Seaside Data Systems, Inc. (“Seaside”) on customer websites.

It is undisputed that Axiom does not own a patent on the DRX 9000, or on any of the DRX 9000’s components or processes. Although Axiom may have filed a currently pending patent application, that fact does not permit Defendants to claim that Axiom has “patented” anything. Moreover, many of the misrepresentations occurred even before Axiom had applied for patent. Thus, it is clear that these claims, specifically that Axiom’s DRX 9000 is patented, or that Axiom owns one or more patents directed to portions of the DRX 9000, are literally false.

ii. FDA approval

The next misrepresentation at issue concerns Defendants’ claims that the DRX 900 has been “approved” by the FDA. Claims of FDA approval are widespread in Defendants’ marketing materials. The claim repeatedly appears in Axiom promotional videos narrated by Defendant Scott (Bignault Decl. ¶¶ 3-4, Exs. A-B), in Axiom press releases (Bignault Decl. ¶ 15, Ex. N), and in printed promotional materials provided to chiropractors. For example, advertisements claim that “[t]he DRX 9000 is sold worldwide and is CE, FDA,

ISO, and CSA approved.” (Pls.’ Ex. 67 (emphasis added).) The FDA approval claim was also included in many seminar and marketing materials created and distributed by Defendants ACI and Altadonna. Examples of such statements include: “FDA Approved Technology That Allows D.C.’s To Treat Herniated Disc Patients & Collect \$150-\$200 Per Visit Cash!” (Pls.’ Ex. 50 at 1); “FDA Approval – why it’s important but not good enough for Axiom Worldwide” (Pls.’ Ex. 88); and “How You Can Use This FDA Approved, Space-Age Technology to Instantly Collect Up To \$35,000-\$50,000 Every 30 Days!” (Pls.’ Ex. 38 at 3.) Defendant Seaside created hundreds of websites claiming that the DRX 9000 was FDA approved, thus spreading the claim across the Internet. These websites describe the DRX 9000 as “the FDA approved spinal decompression technology” (see, e.g., Stadick Dep. at 47-48, 62; Pls.’ Exs. 198, 199), or the “patented and exclusive FDA approved DRX 9000 technology.” (See, e.g., Bignault Decl., Ex. G.)

These statements that the DRX 9000 is FDA “approved” are literally false. To understand why, it is necessary to look to the statutory framework pertaining to FDA “approval” versus FDA “clearance.” Regulation of medical devices is governed by the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended by the Medical Device Amendments of 1976, 90 Stat. 539, 21 U.S.C. § 301 et seq. Under these regulations, medical devices are divided

into three categories: “Class I devices are those that present no unreasonable risk of illness or injury and therefore require only general manufacturing controls; Class II devices are those possessing a greater potential dangerousness and thus warranting more stringent controls; Class III devices ‘presen[t] a potential unreasonable risk of illness or injury’ and therefore incur the FDA’s strictest regulation.” Buckman Co. v. Plaintiffs’ Legal Committee, 531 U.S. 341, 344, 121 S. Ct. 1012, 1015 (2001) (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)(II)).

The FDA requires Class II devices such as the DRX 9000 to go through either a premarket notification process or a premarket approval process. Under the former process, at issue here, the applicant must submit a premarket notification, commonly known as a 510(k) notice, to the FDA with a description of the device and other information necessary for the FDA to determine whether it is substantially equivalent to a device already cleared for commercial sale by the FDA. If the FDA determines that the device is substantially equivalent to a similar device that is already on the market, and that the intended use is not likely to lead to a harmful use outside the stated intended use, the FDA will essentially “clear” the device for marketing. (See generally Linscott Decl.; cf. Fender v. Medtronic, Inc., 887 F. Supp. 1326, 1329 & n.1 (E.D. Cal. 1995).)

The FDA's regulations make clear that

Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

21 C.F.R. § 807.97 (emphasis added). In other words, there is a difference – both legal and factual – between a device that is FDA “approved” and a device that is merely “cleared” by the FDA for marketing.

Because the claims at issue represent that the DRX 9000 is “FDA approved,” and it is not, the claims are literally false.

iii. FDA cleared to perform “true spinal decompression”

Recently, Axiom began a variant on its FDA claims. It has begun to claim that the DRX 9000 is the only device on the market cleared by the FDA as a “True Spinal Decompression System” or for “true spinal decompression.” (E.g., Pls.’ Exs. 6, 8; see also Pls.’ Ex. 7 (“The DRX 9000™ is the only system to receive FDA 510K clearance for True Spinal Decompression™”).) As discussed above, a party seeking to market a Class II device must submit a “premarket notification” to the FDA. This submission requires the party to

identify the purposes of the device and to demonstrate that it has the same intended use as a device already cleared for commercial sale. (See generally Linscott Decl.) If the FDA determines that the device is substantially equivalent to a similar device that is already on the market, and that the intended use is not likely to lead to a harmful use outside the stated intended use, the FDA will, in essence, “clear” the device for marketing. (Id.) Notably, when it does so, the FDA uses the same description as the applicant.

Here, Defendant Axiom submitted a 510(k) notice to the FDA for the “DRX 9000 True Non-Surgical Spinal Decompression System.” (Pls.’ Ex. 87.) When the FDA determined that the device was substantially equivalent to a legally marketed predicate device, it approved the application for the “DRX 9000 True Non-Surgical Spinal Decompression System.” (Id.) Consequently, Defendants now claim that the DRX 9000 is the only device on the market cleared by the FDA as a “True Spinal Decompression System.” Plaintiffs cry foul, claiming that “Axiom has put words in the mouth of the FDA and, once it received clearance, passed them off as an official approval of a supposedly unique and highly desirable quality of the DRX 9000.”

While these claims should not be looked to as a model of truth in advertising, the representations made are not literally false, though they may be misleading. As discussed below, infra Section II.A.1.b., Plaintiffs have not

offered evidence that this claim deceives, or has the capacity to deceive, consumers. Consequently, they cannot meet their burden at this juncture to show likelihood of success on the merits, and the Court ends analysis of this class of representations here.

iv. NASA affiliation

Finally, Plaintiffs protest Defendants' advertisements that tout an affiliation with NASA. These representations range from claims that the DRX 9000 was developed by, or in conjunction with, NASA; that NASA endorses the DRX 9000; or that NASA engineers developed the device.

For example, in a promotional video,⁵ Defendant Axiom touts a development partnership with NASA: "Developed through the collaboration of engineers at Axiom Worldwide in Tampa, Florida and NASA engineers at the Kennedy Space Center, the DRX 9000 demonstrates . . ." (Pls.' Ex. 176.) The video later states: "Axiom Worldwide and NASA: developing space age technology to provide the best back pain treatment on Earth." (*Id.*) Another advertisement, a commercial for the DRX 9000, states that the DRX 9000 is "based on NASA technology." (Pls.' Ex. 173; *cf.* Pls.' Ex. 174 (suggesting that science of spinal decompression began with the space program).) Another advertisement states: "Discovered by NASA, this FDA approved treatment is

⁵ It is unclear from the record whether this video or portions of this video were disseminated to potential customers.

changing the lives of thousands of people worldwide.” (Pls.’ Ex. 136.) To complement and reinforce the NASA connection, Defendants in their advertising and promotional materials persistently use depictions of the space shuttle, the moon and the earth, rockets blasting off from a launching pad, space-walking astronauts, etc. (See, e.g., Pls.’ Exs. 27, 176.)

The only facts in the record that tie the DRX 9000 to NASA, however, are that: (1) NASA scientists may have discovered that anti-gravity had positive effects on astronaut spinal columns;⁶ (2) a NASA engineer “moonlighted” on the DRX 9000 project – that is, he consulted on the DRX 9000 project on his own time and not in his capacity as a NASA engineer; and (3) one of Axiom’s employees formerly worked for Honeywell, a company that contracted for NASA. In view of these facts and other evidence in the record, Defendants’ claims that the DRX 9000 resulted from a joint collaboration between Axiom and NASA engineers, that NASA engineers developed the DRX 9000, that part of the DRX 9000 was discovered by NASA, and that the DRX 9000 contains or embodies NASA technology, are literally false. On the other hand, Defendants’ claims that the DRX 9000 is based on NASA research or discoveries are, based on the record, more likely literally true, though they may be misleading.

⁶ Defendants have testified this is true, but have yet to produce direct evidence to substantiate the claim.

b. capacity to deceive

The second element Plaintiffs must show is that Defendants' claims deceived, or have the capacity to deceive, consumers. When the claims at issue are literally false, capacity to deceive is presumed. Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc., 299 F.3d 1242, 1247 (11th Cir. 2002) (“[O]nce a court deems an advertisement to be literally false, the movant need not present evidence of consumer deception.”). On the other hand, when the claims are literally true but misleading, the moving party is required to present evidence of deception. Id. This evidence can take the form of consumer surveys, market research, or expert testimony. Id.; see also Hickson Corp. v. Northern Crossarm Co., 357 F.3d 1256, 1261 (11th Cir. 2004) (“Consumer survey research often is a key part of a Lanham Act claim alleging that an advertisement is misleading or deceptive.”). At this stage in the proceedings, Plaintiffs have not offered such evidence of deception. Accordingly, where the Court has found a statement, or class of statements, to be literally false, the Court presumes deception. On the other hand, where the Court has determined that the statement or claim is literally true, but potentially misleading, Plaintiffs have failed to demonstrate that the claims deceived, or have the capacity to deceive, consumers. In other words, Plaintiffs cannot at this juncture establish likelihood of success on the merits

for misrepresentations that are literally true but potentially misleading.

c. materiality

Third, Plaintiffs must show that Defendants' misrepresentations were material or "likely to influence the purchasing decision." Johnson & Johnson, 299 F.3d at 1250 (quoting Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave., 284 F.3d 302, 311 (1st Cir. 2002)). Plaintiffs may also demonstrate materiality by showing that Defendants "misrepresented an inherent quality or characteristic of the product." Id. (quoting Nat'l Basketball Ass'n v. Motorola, Inc., 105 F.3d 841, 855 (2d Cir. 1997)).

There is little question that the classes of representations at issue, taken individually as well as together, are material. As one commentator has observed,

Claims relating to . . . regulatory approval . . . have been presumed to be material under this essential characteristics or qualities rubric. So have claims relating to health, safety and other areas of obvious consumer concern. Some of these types of claims are treated as virtually per se material because of their obvious potential effect on purchasing decisions

Richard J. Leighton, Materiality and Puffing in Lanham Act False

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Rep. 585, 595 (2004) (footnotes omitted). The record reflects that these

representations also affected purchasing decisions. For example, Shelley

West, a chiropractor who purchased a DRX 9000, indicated that she viewed

the DRX 9000 being patented as a “positive.” (West Dep. at 75-76.) She also indicated that she viewed the FDA approval as a “positive.” (Id. at 76; see also Gruber Dep. at 109; Hortman Dep. at 64 (stating that FDA approval had “an effect” on his decision to purchase the DRX 9000).)

Finally, the widespread manner in which Defendants have advertised these claims indicates that Defendants themselves believed the claims to be material in selling the DRX 9000. See Saks Fifth Ave., 284 F.3d at 312 (“It seems reasonable to infer from defendants’ aggressive marketing strategy highlighting the ‘cashmere’ nature of the blazers that defendants themselves believed cashmere to be an inherent and important characteristic of the blazers.”).

d. injury resulting from the false advertising

When a statement is literally false, the Court presumes that it will cause injury to a competitor. Cf. Energy Four, Inc. v. Dornier Medical Sys., Inc., 765 F. Supp. 724, 734 (N.D. Ga. 1991) (“Proof of falsity is sufficient to sustain a finding of irreparable injury for purposes of a preliminary injunction.”). Moreover, the record reveals that actual injury to Plaintiffs has resulted from Defendants’ misrepresentations. For example, evidence suggests a significant drop in Plaintiffs’ sales corresponding to Defendants’ misrepresentations about the DRX 9000. (Rubin Dep. at 66, 132.)

2. *Plaintiffs' Trademark Infringement Claims*

Section 43(a) of the Lanham Act, codified at 15 U.S.C. § 1125(a), provides:

(1) Any person who, on or in connection with any goods or services, or any container for goods, 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 –
(A) 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 . . . , shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

To prevail on a claim of trademark infringement, Plaintiffs must establish that: (1) they possess a valid trademark; and (2) Defendants have adopted an identical or similar mark such that consumers are likely to confuse the two. Int'l Stamp Art, Inc. v. U.S. Postal Serv., 456 F.3d 1270, 1274 (11th Cir. 2006).

Plaintiff NAM is the owner of federal registrations for the trademarks Accu-SPINA® and IDD Therapy®. Plaintiffs accuse Defendant Axiom of using these trademarked terms as “meta tags” on its website. (See Pls.’ Ex. 68.) A meta tag is a word or list of words hidden within the source code of a website used to “identify[] the content of the website for search engines.” 4 J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition § 25:69

(4th ed. 2007). When a website includes the trademarked terms of another entity as meta tags, “[t]he result may be that the trademark is used so as to confuse and divert someone looking for a web site that is sponsored by the owner of that trademark.” Id. Applied to this case, the effect of Axiom’s inclusion of the terms Accu-SPINA® and IDD Therapy® on its website is that persons looking for Plaintiff’s website or products may be diverted to Axiom’s website instead.

Although the Eleventh Circuit has not yet addressed the issue, many courts have determined that use of a competitor’s trademark as a meta tag constitutes actionable trademark infringement. See Promatek Indus., Ltd. v. Equitrac Corp., 300 F.3d 808, 811-814 (7th Cir. 2002) (upholding preliminary injunction); see also generally Brookfield Commnc’s, Inc. v. W. Coast Entm’t, 174 F.3d 1036 (9th Cir. 1999). Given the factors relevant for determining whether there exists a likelihood of confusion, see Alliance Metals, Inc. v. Hinely Indus., Inc., 222 F.3d 895, 907 (11th Cir. 2000), the Court finds that Plaintiffs have a fair chance of succeeding on the merits of their trademark infringement claim.

B. Irreparable Harm

The harm occasioned by trademark infringement and false advertising, where the statements at issue are literally false, is ordinarily presumed to be

irreparable. See Int'l Kennel Club of Chicago, Inc. v. Mighty Star, Inc., 846 F.2d 1079, 1092 (7th Cir. 1988) (“[T]he damages occasioned by trademark infringement are by their very nature irreparable”); Energy Four, Inc. v. Dornier Medical Sys., Inc., 765 F. Supp. 724, 734 (N.D. Ga. 1991) (Forrester, J.) (In false advertising cases, “[p]roof of falsity is sufficient to sustain a finding of irreparable injury for purposes of a preliminary injunction.”). As Professor McCarthy has noted, “It is difficult to imagine an unfair competition case where damages are adequate to remedy the problem of defendant’s continued acts.” 5 J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition § 30:2 (4th ed. 2006). Thus, Plaintiffs have established that they will suffer irreparable harm unless an injunction issues.

C. Balance of Harms

Plaintiffs have established that the balance of harms tips in favor of issuing a preliminary injunction. To allow Defendants to continue to make false statements about the DRX 9000 and to infringe Plaintiff NAM’s federally registered trademarks will cause substantial, irreparable harm to Plaintiffs. On the other hand, enjoining these activities will not cause substantial harm to Defendants, particularly where, as discussed below, the Court will not require Defendants to issue corrective advertising at this time.

D. Public Interest

Preventing the consumer confusion associated with Defendants' use of Plaintiff NAM's trademarks and the consumer deception associated with Defendants' use of false statements to promote the DRX 9000 are in the public interest. Energy Four 765 F. Supp. at 734 ("Consumer deception, by its very nature, is against the public interest."); Davidoff & CIE, S.A. v. PLD Int'l Corp., 263 F.3d 1297, 1304 (11th Cir. 2001) ("[T]he public interest is served by preventing consumer confusion in the marketplace.").

III. Remedy

Based on the foregoing, the Court finds that limited preliminary injunctive relief is appropriate. Accordingly, Defendants, their officers, directors, agents, servants, members, and employees, and all other persons in active concert or participation with them who receive actual notice of this Order, are **ENJOINED** as follows:

(1) Defendants are prohibited from:

(a) Falsely representing that the DRX 9000, or any portion or feature thereof, is patented by Defendant Axiom;

(b) Falsely representing that the DRX 9000 is FDA "approved";

or

(c) Falsely representing that there is any affiliation between

NASA and Axiom or between NASA and the DRX 9000, including, but not limited to, claims that: (i) the DRX 9000 resulted from a joint collaboration between Axiom and NASA engineers; (ii) NASA engineers developed the DRX 9000; (iii) part of the DRX 9000 was discovered by NASA; (iv) the DRX 9000 contains or embodies NASA technology; or (v) NASA endorses the DRX 9000.

(2) Defendant Axiom is prohibited from using the terms “Accu-Spina,” “IDD Therapy,” or any other NAM trademark as meta tags on its website.

(3) Defendants shall file with the Court, and serve upon Plaintiff within thirty (30) days of service of this Order, a report in writing under oath setting forth in detail the manner and form in which they have complied with the injunction pursuant to 15 U.S.C. § 1116(a).

IV. Conclusion

Plaintiffs’ motion for preliminary injunction [#6] is **GRANTED in part** and **DENIED in part**. Plaintiffs’ motion for preliminary injunction [#93] is **DENIED**. The Axiom Defendants’ motion to dismiss [#31] is **GRANTED in part** and **DENIED in part**. Specifically, the motion is **GRANTED** with respect to Counts XV and XVI of the Complaint related to Plaintiffs’ federal RICO claims. The motion is **DENIED** in all other respects. The Axiom Defendants’ motion to dismiss Plaintiff Adagen under the “first filed” rule

[#112] is **DENIED**. The Axiom Defendants' motion for sanctions [#113] is **DENIED**. The Axiom Defendants' motion to amend [#121] is **DENIED as moot**.

SO ORDERED, this 29th day of March, 2007.

A handwritten signature in blue ink, appearing to read "Jack Camp", written over a horizontal line.

JACK T. CAMP
UNITED STATES DISTRICT JUDGE