STATE OF CALIFORNIA ARNOLD SCHWARZENEGGER, Governor

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NOTICE OF PUBLIC MEETING

Notice is hereby given that a meeting of the **Enforcement Committee** of the **Board of Chiropractic Examiners** will be held as follows:

Thursday, April 24, 2008
(Upon Conclusion of the Licensing Committee Meeting)
2525 Natomas Park Drive, Suite 120
Sacramento, CA 95833

AGENDA

Call To Order

Approval of Minutes
- March 27, 2008

PUBLIC COMMENT

Discussion and Possible Action
- California Code of Regulations 306.1 Chiropractic Quality Review Panel (CQRP)

Discussion and Possible Action
- DRX 9000
- Laser Treatments

FUTURE AGENDA ITEMS

PUBLIC COMMENT

ADJOURNMENT

ENFORCEMENT COMMITTEE
Hugh Lubkin, D.C., Chair
Judge James Duvaras, Retired

A quorum of the Board may be present at the Committee meeting. However, Board members who are not on the committee may observe, but may not participate or vote. Public comments will be taken on agenda items at the time the specific item is raised. The Committee may take action on any item listed on the agenda, unless listed as informational only. All times are approximate and subject to change. Agenda items may be taken out of order to accommodate speakers and to maintain a quorum. The meeting may be cancelled without notice. For verification of the meeting, call (916) 263-5355 or access the Board's Web Site at **www.chiro.ca.gov.**

The meeting is accessible to the physically disabled. If a person needs disability-related accommodations or modifications in order to participate in the meeting, please make a request no later than five working days before the meeting to the Board by contacting Marlene Valencia at (916) 263-5355 ext. 5363 or sending a written request to that person at the Board of Chiropractic Examiners, 2525 Natomas Park Drive, Suite 260, Sacramento, CA 95833. Requests for further information should be directed to Ms. Valencia at the same address and telephone number.

California Code of Regulations

§306.1. Chiropractic Quality Review Panel (CQRP).

The board shall establish a Chiropractic Quality Review Panel (CQRP) by county throughout California to hear cases referred by the board's Executive Officer.

(a) The authority and duties of CQRP's are:

(1) To review chiropractic care provided by California licensees.

(2) To act on all matters assigned to it by the board's Executive Officer.

(3) To inspect all chiropractic records where reasonable cause exists to initiate a quality review.

(b) The composition and purpose of CQRP's are as follows:

(1) Each panel shall be composed of three licensees appointed by the board.

(2) Each panel member shall have at least 5 years experience practicing chiropractic in California.

(3) Each panel member shall have no disciplinary action against their license.

(4) The purpose of the CQRP is to review specific complaints and where appropriate to provide recommendations of continuing education and to strengthen aspects of the licensee's chiropractic practice.

(A) The "continuing education" recommendations are limited to specific continuing education seminars required by licensees.

(B) "Recommendations to strengthen aspects of a licensee's practice" will be a panel recommendation consistent with chiropractic standards of care in California.

(c) CQRP Hearing Procedures are as follows:

(1) A closed panel hearing shall be conducted with a court reporter.

(2) Any licensee required to appear before a panel will be notified by certified mail with a summary of the specific complaint together with supporting documents at least 30 days prior to the scheduled panel hearing.

(3) When requested by the panel, licensees shall present to the panel all patient treatment records relevant to the specific complaint as required by California Code of Regulations, Title 16, Section 318.

(4) The failure to present all requested patient records authorizes the panel to presume that the information in the records is adverse to the licensee.

(5) The licensee may bring in any witnesses and documents to assist in responding to the complaint.

(6) The licensee may have counsel present during the panel hearing.

(7) The licensee will be given an adequate opportunity to respond to any questions by the panel.

(8) A postponement of the scheduled panel hearing may be granted by the board's Executive Officer upon a showing of good cause made at least 10 days prior to the scheduled hearing.

(9) The failure of a licensee to appear, without good cause, constitutes grounds for a recommendation to the Executive Officer for filing of a disciplinary action, or further investigation.

(d) CQRP report procedures:

(1) At the conclusion of the CQRP hearing the panel shall prepare a written report based on the evidence presented at the panel hearing with specific recommendations regarding the licensee and/or the licensee's practice.

Panel recommendations are the following:

(A) Continuing education seminars in related field;

(B) Recommendations that would strengthen aspects of licensee's chiropractic practice;

(C) Further investigation;

(D) Refer case to Office of Attorney General for preparation of formal disciplinary action;

(E) Close case with warning;

(F) Close case without warning;

(G) Dismiss complaint.

(2) The report and recommendations shall go directly to the board's Executive Officer.

(3) Any departure from accepted chiropractic procedures or practices shall be outlined in this written panel report with the recommendations from subsection (d)(1)(A)-(G) deemed necessary by a vote of a majority of the three member panel.

(4) All panel recommendations are subject to approval by the board's Executive Officer without further input from the licensee. The executive director shall prepare a final report, which shall include all approved recommendations, and send a copy of the final report to the licensee and panel members.

(5) The evidence presented at the panel hearing shall be submitted to the board office. All evidence used by the panel is admissible in any subsequent disciplinary proceeding against a licensee.

(e) The procedures for appealing the final CQRP report are as follows:

(1) The panel report is reviewed by the board's Executive Officer. After the review, the final report is sent to the licensee. The licensee has 30 days from receipt of the report to file a written appeal with the board.

(2) The appeal shall be considered by a committee of the board consisting of no more than three members.

(3) If the committee grants the appeal a final decision shall be prepared and returned to the Executive Officer for distribution to the licensee and panel members.

(4) If the board's committee denies the appeal, the final report becomes a final decision after 30 days.

(5) The licensee may appeal the final decision by filing a writ of mandate pursuant to California Code of Civil Procedure, Section 1094.5. The writ of mandate shall be filed in a Superior Court in Los Angeles, San Francisco, or Sacramento counties.

NOTE: Authority cited: Sections 1000-4(b), 1000-4(c), 1000-4(d), 1000-4(e), and 1000-10(a), Business and Professions Code (Chiropractic Imitative Act). Reference: Sections 1000-4(h), 1000-6(a), Business and Professions Code.

the licensee deviated from the standard of care. If the osteopathic board determines that there are grounds for discipline, it will refer the case to the attorney general.

Similarly, the speech-language board said it assigns priority to malpractice settlement notices based on the nature of the settlement claim and the degree of patient harm or risk to the public. Because complaints stemming from settlement claims require additional fact finding and investigation, the speech-language board forwards those cases to its investigators to obtain the pertinent facts. After the speech-language board's internal review of the facts or the conclusive opinion of an expert, if it appears that the licensee was negligent or deviated from an acceptable standard of care, the speech-language board refers the case to the attorney general for administrative disciplinary action. The physical therapy board processes malpractice settlement notifications to obtain and review the facts to determine whether there is evidence of a violation that meets the evidentiary standards for citation or other discipline.

In contrast, when processing a malpractice settlement notification, the chiropractic board does not obtain and review documentation or conduct investigations to determine if a violation occurred or refer the matter to an expert to determine if the licensee deviated from an acceptable standard of care. When the chiropractic board does not give priority to processing complaints requiring priority attention or process other complaints more diligently, it may be unnecessarily putting the public at risk.

For Years the Chiropractic Board Has Not Adhered to Its Own Regulation to Establish Chiropractic Quality Review Panels

Since June 1993 the chiropractic board's regulations have required it to establish chiropractic quality review panels (review panels) throughout California. According to the historical documentation, the board's original intent was to reduce the amount of time between complaint intake and resolution. The chiropractic board planned to refer certain complaints—those alleging minor violations of the initiative act that do not meet the criteria for referral to the attorney general for formal discipline—to a program in which a less formal review and early corrective action could possibly prevent the cases from moving down the path of formal discipline. The relevant board regulation states that the purpose of the review panels is to review specific complaints referred by the chiropractic board's executive officer and, when appropriate, provide recommendations of continuing education or other

The intended purpose of the review panels is to review specific complaints referred by the chiropractic board's executive officer and, when appropriate, provide recommendations of continuing education or other corrective actions to strengthen aspects of the licensees' chiropractic practice.

corrective actions to strengthen aspects of licensees' chiropractic practice. Nearly 15 years after adopting the regulation, the chiropractic board still has not established review panels.

The board's rule-making file shows that over the years, when changes in executive officers and board members occurred, so did priorities and efforts to establish the review panels. For example, the chiropractic board's then-executive officer had the chiropractic consultant who was hired in June 1995 develop the groundwork to implement the review panels. By March 1996 the chiropractic consultant had developed a list of qualified chiropractors to serve on the review panels to present to the board members for approval.

However, in April 1996, the chiropractic board hired a new executive officer and asked her to review the plans for establishing the review panels and to gather information from other boards that had established similar panels. In a report dated May 1996 the then-executive officer stated that the Medical Board of California (medical board) had encountered many problems with its review panels, including inconsistent complaint resolutions, lack of control by the medical board, and an increasingly costly review and appeal process that ultimately caused the medical board to eliminate its review panels. The then-executive officer's report also noted that, although the review panel program established by the California State Board of Pharmacy was more effective than that of the medical board, it was also very expensive. In addition, the then-executive officer stated in her report that some deputy attorneys general who had handled cases for the chiropractic board as well as other regulatory boards recommended that the chiropractic board use warning letters, cease-and-desist letters, and citations as a less costly and more efficient approach to informal discipline than the use of review panels. The then-executive officer recommended that the chiropractic board table implementation of the review panels, which the board did in June 1996.

In subsequent years board members and staff have attempted to change the regulation. Specifically, in October 2004, board members tried to amend the wording of the regulation from *shall* to *may*, which would have made the establishment of review panels discretionary. However, because of public opposition, board members tabled the discussion of the regulation change pending further review by the regulation committee. Shortly thereafter, the International Chiropractors Association of California (international association) submitted to the chiropractic board a detailed proposal for the establishment of the review panels. The proposal claimed the review panels could enhance public safety by providing faster complaint resolution and could reduce costs by eliminating the costs for investigators and experts. In March 2005 the chiropractic board ended its attempt to revise the regulation by submitting

a notice to not proceed to the Office of Administrative Law. According to the previous executive officer, the board member who had been working extensively with the proposed regulation at that time was absent from the April 2005 board meeting, and his term expired soon thereafter; as a result, the review panel discussion was never resolved.

The issue of the review panels arose again in December 2006 as a discussion item in a board meeting. The topic has been active since then, with the international association submitting proposals in February 2007 and June 2007 to modify the regulations and the governor appointing a representative from the international association as a member of the chiropractic board in February 2007. Moreover, it is clear from the international association's proposals that it seeks to remove control over the complaint review and discipline processes from the chiropractic board as a state agency and place that control with the individual board members and other licensees. Specifically, the latter proposal includes the formation of a six-member chiropractic review committee, whose members would be appointed by the Legislature. The chiropractic review committee would oversee the review panels and assign them complaints filed against chiropractors. After conducting a hearing, the review panels would submit their recommendations to the chiropractic review committee for review rather than to the chiropractic board's executive officer as the regulations currently state. Under the international association's proposal, the board's executive officer would merely perform administrative duties for the chiropractic review committee.

The chiropractic board's current executive officer does not believe the review panels are the right solution for the board. In September 2007 he prepared a memo to the chair of the board's enforcement committee responding to the question of whether the chiropractic board should move forward with implementing the review panels. In the memo he recommends that the board repeal the regulation related to the review panels. He supports this recommendation by citing concerns with the cost-effectiveness of review panels, the potential for the review panels to make rulings that are inconsistent with the board's enforcement policies, and the potential for the review panels to be viewed as a peer-review system. Moreover, at the November 2007 board meeting, the executive officer noted that the board has considered only the options of using the chiropractic consultant or the review panels for the processing of complaints and that other options need to be considered.

At the November 2007 board meeting the executive officer noted that the board has considered only the options of using the chiropractic consultant or the review panels for the processing of complaints and that other options need to be considered.

As part of our survey of three other regulatory boards with similar enforcement programs, we specifically asked whether they require the establishment of review panels. None of the boards we surveyed

are currently using review panels. The osteopathic board and the speech-language board told us that they do not use review panels or other similar review processes. Specifically, the osteopathic board stated that it relies instead on the case reviews by its expert consultants. The physical therapy board stated that it is currently in the process of preparing to implement a quality control program and that its planned process will include board members reviewing closed cases to ensure timely resolutions and consistency in the process.

We recognize that the issues surrounding the review panels are not simple, but it is clear that the chiropractic board must take some action to remedy its noncompliance with its regulation. In determining what that action might be, we believe the board must consider its complaint review process more broadly. As we noted in previous sections of this chapter, the chiropractic board has not developed standard procedures or required management oversight of its complaint process. Therefore, by instituting a stronger system for reviewing and taking action on complaints, the board will be better able to determine what other processes it should add to complement its ability to promptly and appropriately respond to complaints about chiropractors.

Although we recognize that the issues surrounding the review panels are not simple, it is clear that the board must take some action to remedy its noncompliance with its regulation.

The Chiropractic Board's Recently Vacant Chiropractic Consultant Position Leaves a Gap in Its Available Technical Expertise

As noted in the Introduction, the chiropractic consultant position, under the supervision of the executive officer, provided chiropractic expertise to help staff review complaints against and evaluate the professional conduct of licensees who may have violated chiropractic laws and regulations. During our review, we found that the chiropractic board's enforcement process and its staff relied heavily on the chiropractic consultant to complete its reviews and make decisions on complaints and punishment when violations occurred. Because the chiropractic consultant position has been vacant since August 10, 2007, we asked the executive officer to provide his perspective on the impact to operations, especially to enforcement, licensing, and continuing education, of not having technical expertise on staff. The executive officer explained that because of the current budget situation, the chiropractic board is not planning to fill the vacant chiropractic consultant position. He also said that based on the chiropractic board's initial assessment of the enforcement program and the chiropractic consultant position in particular, it had concerns about the duties and use of the position and did not plan to fill the vacancy until a job analysis was conducted. At the same time, board members expressed concerns about filling the position before instituting a significant change in duties.

International Chiropractors Association of California
ICA of California
9700 Business Park Drive #305
Sacramento, CA 95827
800-275-3515

April 2008

§306.1 Chiropractic Review Committee
The board shall establish a Chiropractic Review Committee to assist the board's executive director. The peer review committee shall evaluate complaints against chiropractic doctors that are referred to it by the board. The Chiropractic Review Committee shall assist the Executive Officer on matters assigned to them.

The Board, through their executive officer and investigative staff, identifies and takes appropriate action against chiropractors who commit unprofessional conduct. This includes acts or omissions evidencing, negligence or incompetence, practicing under the influence of drugs or alcohol, practicing while mentally or physically impaired affecting competence, fraudulently billing patients or health insurance companies, excessively treating patients, altering or creating false records, sexual misconduct, criminal acts and committing ethical violations. The discipline for practitioners committing such act or omissions serves to protect the public from unsafe and, unethical practitioners.

The Committee will be comprised of a chairman and a minimum of three (3) members, all of whom will be appointed by the members of the Board, and all of whom will serve at the pleasure of the Board. They may be removed from the Committee by vote of the Board, at any time, without cause.

The Chiropractic Review Committee may recommend to the Executive Officer:

1. Continuing education recommendations for specific education seminars to improve the licensees' performance.
2. Recommendations to strengthen aspects of a licensee's practice consistent with chiropractic standards of care in California.
3. Letter of Admonishment
4. Citation & Fines
5. Citation / Order of Abatement
6. Further investigation
    a) Use of investigators
    b) Use of expert reviewers
7. Formal Disciplinary Process

The Executive Office may also have a Chiropractic Review Committee Member serve as an expert in an Administrative Law Hearing.

Limitations of Peer Review Committee Members. While serving on the Peer Review Committee, a member shall not:

a. Solicit to do independent medical examinations and/or reviews for insurance companies, attorneys or other third parties.

Compensation and expenses shall be paid as an "Expert Reviewer."

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

FILED
U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
APRIL 7, 2008
THOMAS K. KAHN
CLERK

No. 07-11574

D. C. Docket No. 06-01678 CV-JTC-1

NORTH AMERICAN MEDICAL CORPORATION,
ADAGEN MEDICAL INTERNATIONAL, INC.,
Georgia corporations,

Plaintiffs-Appellees,

versus

AXIOM WORLDWIDE, INC.,
a Florida corporation,
JAMES GIBSON, JR.,
NICHOLAS EXARHOS,
residents of Florida,

Defendants-Appellants.

Appeal from the United States District Court
for the Northern District of Georgia

(April 7, 2008)

Before ANDERSON, BLACK and HILL, Circuit Judges.

ANDERSON, Circuit Judge:

Defendants-Appellants Axiom Worldwide, Inc. ("Axiom"), James Gibson, Jr., and Nicholas Exarhos appeal the district court's grant of a preliminary injunction in favor of the Plaintiffs-Appellees, North American Medical Corporation ("NAM") and Adagen Medical International, Inc. ("Adagen").[1] The district court enjoined the Defendants-Appellants from engaging in certain alleged acts of trademark infringement and false advertising. We now affirm the district court's order in part and vacate and remand it in part.

I. STANDARD OF REVIEW

We will reverse a grant of a preliminary injunction only if the district court abused its discretion. Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc., 299 F.3d 1242, 1246 (11th Cir. 2002). We review the district court's findings of fact under a clearly erroneous standard, noting that a finding of fact is clearly erroneous only when "although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." Id. (quoting Univ. of Ga. Athletic Ass'n v.

[1] Defendant-Appellant Ren Scott originally participated in this appeal as well, but we previously granted a joint motion to voluntarily dismiss him from the case after he reached a settlement agreement with the Plaintiffs-Appellees. Accordingly, we need not address Scott's argument that the district court lacked personal jurisdiction over him.

Laite, 756 F.2d 1535, 1543 (11th Cir.1985)). We review the district court's conclusions of law de novo, "understanding that '[a]pplication of an improper legal standard . . . is never within a district court's discretion.' " Id. (quoting Am. Bd. of Psychiatry & Neurology, Inc. v. Johnson-Powell, 129 F.3d 1, 2-3 (1st Cir. 1997)).

II. BACKGROUND

NAM designs and manufacturers physiotherapeutic spinal devices, commonly known as traction devices, which are used, for example, to treat lower back pain. Adagen is an authorized distributor of NAM's devices. Axiom, a competitor of NAM's, manufacturers a physiotherapeutic device known generally as the DRX 9000. Gibson and Exharhos are, respectively, the president and vice president of Axiom. In the present lawsuit, NAM and Adagen allege that Axiom engaged in unfair competition by infringing NAM's trademarks and by issuing false advertising regarding the DRX 9000.

The trademark infringement claims stem from Axiom's use of two of NAM's registered trademarks: the terms "Accu-Spina" and "IDD Therapy."

Axiom included these terms on its website within meta tags.[2] Although Axiom's website never displayed NAM's trademarked terms to visitors and never mentioned NAM or NAM's products, Axiom nonetheless included the terms within its meta tags to influence Internet search engines. For instance, evidence in this case indicated that, before Axiom removed these meta tags from its website, if a computer user entered the trademarked terms into Google's Internet search engine, Google listed Axiom's website as the second most relevant search result. In addition, Google provided the searcher with a brief description of Axiom's website, and the description included these terms and highlighted them.[3]

The false advertising claims stem from certain statements that Axiom made about its product, the DRX 9000. In particular, two representations by Axiom are

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[2] Meta tags consist of words and phrases that are intended to describe the contents of a website. These descriptions are embedded within the website's computer code. Although websites do not display their meta tags to visitors, Internet search engines utilize meta tags in various ways. First, when a computer user enters particular terms into an Internet search engine, the engine may rank a webpage that contains the search terms within its meta tags higher in the list of relevant results. Second, when a particular webpage is listed as a relevant search result, the search engine may use the meta tags to provide the searcher a brief description of the webpage. See Brookfield Commc'ns, Inc. v. W. Coast Entm't Corp., 174 F.3d 1036, 1045 (9th Cir. 1999).

[3] Incidentally, Axiom makes a brief, conclusory argument that no evidence exists to establish that the meta tags affected the search results. We disagree. The evidence indicates that nowhere in Axiom's website do NAM's two trademarked terms appear (e.g., in comparative adverstising). Rather, the terms appear only in Axiom's meta tags. We cannot conclude that the district court's implied finding of a causal relationship is clearly erroneous.

relevant to this appeal.[4] First, Axiom represented in various ways that an affiliation exists between NASA and Axiom or between NASA and the DRX 9000. Second, Axiom asserted in advertisements that the DRX 9000 is FDA "approved."

The district court issued a preliminary injunction in favor of NAM and Adagen, prohibiting Axiom from using NAM's trademarks within meta tags and prohibiting Axiom from making the challenged statements about the DRX 9000. Among other things, the district court specifically found that Axiom's use of NAM's trademarks created a likelihood of confusion, and the court also found that Axiom's advertising statements are literally false and material to consumers' purchasing decisions.

III. DISCUSSION

At the outset, we note that a district court may grant a preliminary injunction only if the movant establishes the following: "(1) a substantial likelihood of success on the merits of the underlying case, (2) the movant will

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[4] A third representation by Axiom, that Axiom patented the DRX 9000 or any portion or feature thereof, was also deemed literally false by the district court. Because Axiom's brief on appeal fails to challenge this aspect of the district court's ruling, however, Axiom has waived the issue. This circuit has consistently held that issues not raised on appeal are abandoned. See, e.g., Greenbriar, Ltd. v. City of Alabaster, 881 F.2d 1570, 1573 n.6 (11th Cir. 1989).

suffer irreparable harm in the absence of an injunction, (3) the harm suffered by the movant in the absence of an injunction would exceed the harm suffered by the opposing party if the injunction issued, and (4) an injunction would not disserve the public interest." Johnson & Johnson, 299 F.3d at 1246-47. Axiom challenges the district court's order on multiple grounds. First, Axiom argues that NAM and Adagen failed to establish a substantial likelihood of success on the merits of their trademark infringement claims. Specifically, Axiom urges that its use of NAM's trademarks in invisible meta tags is not a "use in commerce" and does not create a likelihood of confusion. Second, Axiom argues that NAM and Adagen also failed to establish a substantial likelihood of success on the merits of their false advertising claims. Specifically, Axiom asserts that its advertising statements are not literally false and are not material to consumers' purchasing decisions. Third and finally, Axiom argues that, even assuming NAM and Adagen are likely to succeed on the merits of these unfair competition claims, the district court erred by categorically presuming that any plaintiff with a viable unfair competition claim will always suffer irreparable harm in the absence of a preliminary injunction. We address each point in turn.

A. Likelihood of Success on the Merits of the Trademark Infringement Claims

Because Axiom's use of NAM's trademarks constitutes a "use in commerce" in connection with the advertisement of goods, and because the district court did not clearly err in its factual finding that a likelihood of confusion exists, NAM and Adagen demonstrated a likelihood of success on the merits of their trademark infringement claims. Regarding trademark infringement, the Lanham Act provides, in relevant part, as follows:

> (1) Any person who shall, without the consent of the registrant –
>
> > (a) use in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive . . .
>
> shall be liable in a civil action by the registrant for the remedies hereinafter provided.

15 U.S.C. § 1114(1)(a) (2006). To prevail on a claim of trademark infringement in this case, plaintiffs must establish: (1) that they possess a valid mark, (2) that the defendants used the mark, (3) that the defendants' use of the mark occurred "in commerce," (4) that the defendants used the mark "in connection with the sale . . . or advertising of any goods," and (5) that the defendants used the mark in a manner likely to confuse consumers. See 1-800 Contacts, Inc. v. WhenU.com, Inc., 414 F.3d 400, 406-07 (2d Cir. 2005); People for Ethical Treatment of

Animals v. Doughney, 263 F.3d 359, 364 (4th Cir. 2001).

Axiom does not challenge the validity of NAM's marks, nor does Axiom dispute that its use of NAM's trademarks affects interstate commerce.[5] Thus, although Axiom purports to challenge whether its placing of NAM's trademarks in its meta tags is a "use in commerce" and whether such use is likely to confuse consumers, Axiom's arguments actually focus only on the second, fourth, and fifth elements. Moreover, because Axiom separates its "use" challenge from its "likelihood of confusion" challenge, we first address the second and fourth elements together (i.e., whether there was a "use . . . in connection with the sale . . . or advertising of any goods"), and we then address the fifth element (i.e., whether such use was in a manner "likely to confuse consumers").

1. Use in Commerce in Connection with the Sale or Advertising of Any Goods

Axiom briefly argues that placing a competitor's trademarks within meta tags, which consumers never view, does not constitute a "use" as required to find trademark infringement under the Lanham Act. However, we readily conclude that the facts of the instant case do involve a "use" as contemplated in the Lanham

[5] The Lanham Act defines "commerce" broadly for jurisdictional purposes as "all commerce which may lawfully be regulated by Congress." 15 U.S.C. § 1127 (2006); see also Bosely Med. Inst., Inc. v. Kremer, 403 F.3d 672, 677 (9th Cir. 2005)(describing "use in commerce" as a "jurisdictional predicate"); Planetary Motion, Inc. v. Techsplosion, Inc., 261 F.3d 1188, 1194-95 (11th Cir. 2001) (same).

Act – that is, a use in connection with the sale or advertisement of goods. In deciding whether Axiom has made an infringing "use," we focus on the plain language of § 1114(1)(a), which, as noted above, requires a "use in commerce . . . of a registered mark in connection with the sale . . . or advertising of any goods." 15 U.S.C. § 1114(1)(a). The facts of the instant case are absolutely clear that Axiom used NAM's two trademarks as meta tags as part of its effort to promote and advertise its products on the Internet. Under the plain meaning of the language of the statute, such use constitutes a use in commerce in connection with the advertising of any goods. Accordingly, we readily conclude that plaintiffs in this case have satisfied that (1) they possessed a valid mark, (2) that the defendant used the mark, (3) that the defendant's use of the mark occurred "in commerce," and (4) that the defendant used the mark "in connection with the sale . . . or advertising of any goods."

In an effort to avoid the foregoing plain meaning of the statutory language, Axiom places its sole reliance on the Second Circuit's 1-800 Contacts case. In that case, whenever a consumer who had installed the defendant's computer program clicked on or searched for the plaintiff's website address, the program generated on the consumer's screen not only the website sought (e.g., plaintiff's), but also a second window displaying pop-up ads for the defendant's alternative,

competing products. 414 F.3d at 404-05. The Second Circuit ultimately held, as a matter of law, that such use of the web address is not a "use in commerce." Id. at 403.

In so holding, the Second Circuit emphasized that the defendant did not use plaintiff's trademark, but rather used its website address, which differed slightly from the mark. Id. at 408-09. Indeed, the court explicitly declined to express an opinion on the appropriate result if defendant had in fact used plaintiff's trademark. Id. at 409 n.11. Even more crucial to the Second Circuit's holding, the court emphasized repeatedly the fact that the defendant never caused plaintiff's trademarks to be displayed to a consumer. Id. at 408-410. The court explained that the defendant used plaintiff's web address merely in the internal directory of its proprietary software, which was "inaccessible to both the C-user and the general public." Id. at 409. Explaining the significance of the fact that the defendant never caused plaintiff's trademark to be displayed to the consumer, the court stated that defendant's use of plaintiff's "website address in the directory does not create a possibility of visual confusion with 1-800's mark." Id.

In rejecting Axiom's invitation to rely on 1-800 Contacts, we initially note that the above two key facts are not present in the case before us. First, unlike the defendant in 1-800 Contacts, Axiom in the instant case did use NAM's two

trademarks in its meta tags; it did not merely use NAM's unprotected website address. Second, and again unlike in 1-800 Contacts, the defendant-Axiom in this case did cause plaintiff's trademark to be displayed to the consumer in the search results' description of defendant's site.[6] Thus, the facts of the instant case stand in stark contrast to those in 1-800 Contacts, and Axiom's reliance on the Second Circuit's opinion is therefore misplaced.

Furthermore, to the extent the 1-800 Contacts court based its "use" analysis on the fact that the defendant did not *display* the plaintiff's trademark, we think the Second Circuit's analysis is questionable. Although we believe that the absence of such a display is relevant in deciding whether there is a likelihood of confusion, we believe that, when the analysis separates the element of likelihood of confusion from the other elements, this fact is not relevant in deciding whether there is a use in commerce in connection with the sale or advertising of any goods. Because the Second Circuit did separate its analysis in this manner, and did purport not to address the likelihood of confusion issue, see id. at 406, its reliance on the fact that there was no display of the plaintiff's trademark (and thus no

[6] As described more fully below, when a consumer in this case entered NAM's trademarks into a search engine, the search results displayed Axiom's website along with a description thereof, which description included NAM's trademarks in a manner likely to confuse consumers and suggest some relationship between Axiom and NAM.

possibility of confusion) undermines the persuasiveness of its analysis of the separate elements of use in commerce in connection with the sale or advertising of any goods.

In sum, we conclude that Axiom's reliance on the Second Circuit decision in 1-800 Contacts is misplaced.[7] We conclude that the plain meaning of the statutory language clearly indicates that Axiom's use of NAM's trademarks as meta tags constitutes a "use in commerce . . . in connection with the sale . . . or advertising of any goods" under the facts of this case. Thus, we turn to the fifth, and final, element that plaintiffs' must establish – that such use was "likely to cause confusion."

2. Likelihood of Confusion

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[7] We also note that several cases, including 1-800 Contacts, refer to 15 U.S.C. § 1127 with respect to the definition of "use in commerce" in the infringement context. See, e.g., 1-800 Contacts, 414 F.3d at 407, 409. However, a leading treatise on trademarks notes that § 1127 "defines the kind of 'use' needed to acquire registerable trademark rights – not to infringe them." J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition § 23:11.50 (4th ed. 2003). McCarthy explains that § 1127 harked back to the common law "affixation" requirement, a formalistic prerequisite to achieving technical trademark status. Id. By contrast, McCarthy observes that § 1114(1) merely requires that a plaintiff's proof of infringement establish a use in commerce "in connection with the sale . . . or advertising of any goods." Id. In any event, McCarthy notes that the cases that inappropriately cite § 1127 in the context of an infringing "use" analysis do not apply that section's affixation limitations. Id. Finally, McCarthy cites Ninth Circuit opinions as correctly construing § 1127. Id. (citing, for example, Bosely Med. Inst., Inc. v. Kremer, 403 F.3d 672 (9th Cir. 2005)). In Kremer, the Ninth Circuit noted that § 1127 is expressly prefaced with the caveat: "unless the contrary is plainly apparent from the context." 403 F.3d at 677. Thus, the Kremer court held that the appropriate issue was whether the use was "in connection with the sale of goods or services." Id.; see also Playboy Enters., Inc. v. Netscape Commc'ns Corp., 354 F.3d 1020, 1024 n.11 (9th Cir. 2004).

The district court's finding that a likelihood of confusion exists is not clearly erroneous. Seven factors are relevant when determining whether a likelihood of confusion exists:

> (1) the strength of the plaintiff's mark; (2) the similarity between the plaintiff's mark and the allegedly infringing mark; (3) the similarity between the products and services offered by the plaintiff and defendant; (4) the similarity of the sales methods; (5) the similarity of advertising methods; (6) the defendant's intent, e.g., does the defendant hope to gain competitive advantage by associating his product with the plaintiff's established mark; and (7) actual confusion.

Alliance Metals, Inc., of Atlanta v. Hinely Indus., Inc., 222 F.3d 895, 907 (11th Cir. 2000). "The findings as to each factor, and as to the ultimate conclusion regarding whether or not a likelihood of confusion existed, are subject to the clearly erroneous standard of review." Frehling Enters., Inc. v. Int'l Select Group, Inc., 192 F.3d 1330, 1335 (11th Cir. 1999).

The district court expressly acknowledged the foregoing factors, but it made an explicit finding only with respect to the ultimate conclusion that there was a likelihood of confusion. Regarding that issue, Axiom's brief on appeal did not challenge the district court's implied findings with respect to any of the subsidiary factors (i.e., the foregoing seven factors). Rather, Axiom challenged only: (1) the district court's implied finding that Axiom's use of NAM's two trademarks as

meta tags caused the Internet search results at issue,[8] and (2) the district court's reliance on Brookfield Communications, Inc. v. West Coast Entertainment Corp., 174 F.3d 1036 (9th Cir. 1999), and Promatek Industries, Ltd. v. Equitrac Corp., 300 F.3d 808 (7th Cir. 2002), with respect to the nature of meta tags and search engines. Axiom argues that those opinions erroneously misled the district court to find a likelihood of confusion; Axiom contends that its use of the meta tags was instead analogous to a store placing its own generic brand next to a brand name product on the store's shelf. Because Axiom has not challenged the district court's implied findings with respect to the subsidiary factors, any such challenge is deemed abandoned. Indeed, it is apparent that the marks are not only similar, but identical; Axiom's meta tags precisely mimic NAM's "IDD Therapy" and "Accu-Spina" trademarks. Axiom concedes that it is a direct competitor of NAM. It is also apparent that Axiom intended to gain a competitive advantage by associating its product with NAM's trademark. Finally, the litigation on appeal has proceeded on the assumption that there would be a likelihood of confusion, unless Axiom's arguments about the nature of meta tags and search engines (i.e.,

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[8] As noted above, we summarily reject this argument. See supra note 3. NAM's trademarks appeared in the Google search result as part of the description of Axiom's website. Because on this record the only possible cause for this is Axiom's use of the trademarks as meta tags, we readily conclude that the district court was not clearly erroneous in its implicit finding that the meta tags caused the search result and thus the likelihood of confusion.

Axiom's challenge to Brookfield and Promatek) prevailed.

Therefore, we address Axiom's challenge to Brookfield and Promatek. In the leading case on this issue, the Ninth Circuit concluded that the Lanham Act bars a defendant from including in its meta tags a competitor's trademark or confusingly similar terms. Brookfield, 174 F.3d at 1065. Accordingly, the Brookfield court enjoined one online video store, West Coast, from using in its meta tags the trademark (and similarly confusing terms) of a competing online video store, Movie Buff. Id. at 1066-67. Despite its ultimate conclusion, the Brookfield court conceded that even when a consumer who enters a company's trademark into a search engine sees a list displaying a competitor's website in addition to the trademark holder's website, the consumer will often be able to find the particular website he is seeking by simply scanning the list of results. Id. at 1062. The court also acknowledged that even if the web user chooses the competitor's website from the list, assuming the allegedly infringed trademark is not actually displayed by the competitor, "it is difficult to say that a consumer is likely to be confused about whose site he has reached or to think that [the plaintiff] somehow sponsors [the competitor's] web site." Id. Nevertheless, the Brookfield court concluded that the competitor's use of the trademark "in metatags will still result in what is known as initial interest confusion." Id. That is, "[a]lthough

there is no source confusion in the sense that consumers know they are patronizing [the competitor] rather than [the plaintiff], there is nevertheless initial interest confusion in the sense that, by using [the trademark] to divert people looking for [the plaintiff's] web site, [the competitor] improperly benefits from the good will that [the plaintiff] has developed in its mark." Id.

In the other case relied upon by the district court, the Seventh Circuit faced facts similar to those in Brookfield and agreed with the Brookfield court's analysis. Promatek, 300 F.3d at 810-13. Other courts, however, have criticized various aspects of the Brookfield opinion. See, e.g., 1-800 Contacts, 414 F.3d at 410-11; Playboy Enters., Inc. v. Netscape Commc'ns Corp., 354 F.3d 1020, 1034-36 (9th Cir. 2004) (Berzon, J., concurring); J.G. Wentworth, S.S.C. Ltd. P'ship v. Settlement Funding LLC, No. 06-0597, 2007 WL 30115, at *6-*7 (E.D. Pa. Jan. 4, 2007); see also J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition § 25:69 (4th ed. 2003) (discussing meta tags, initial interest confusion, and criticisms of the Brookfield court's approach).

Like the Brookfield and Promatek courts, we ultimately conclude that a company's use in meta tags of its competitor's trademarks may result in a likelihood of confusion. However, because NAM and Adagen have demonstrated

a likelihood of actual *source* confusion,[9] we need not decide, as those courts did, whether initial interest confusion alone may provide a viable method of establishing a likelihood of confusion. Unlike those courts, we are not faced with a situation where the trademarks are used without being displayed to consumers.

In Brookfield and Promatek, consumers who entered the plaintiff's trademarks into a search engine saw a list displaying the competitor's website in addition to the trademark holder's website *without* any other indication from the search results that the competitor's website is sponsored by the plaintiff or related to the plaintiff's trademarks. In contrast, in the instant case, when consumers entered NAM's trademarks into a search engine, the search results not only displayed Axiom's competing website, but they also included a brief description of Axiom's website, which description included and highlighted NAM's trademarked terms. That is, the evidence in the instant case specifically shows that if consumers searched with Google for the terms "IDD Therapy" and "Accu-Spina," the first listed result was a legitimate website sponsored by NAM, the

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[9] "Source confusion" exists because consumers are likely to be confused as to whether Axiom's products have the same source or sponsor as NAM's or whether there is some other affiliation or relationship between the two. As has been noted by the Eighth Circuit, "[i]f the products are closely related, and it is reasonable for consumers to believe the products come from the same source, confusion is more likely. Davis v. Walt Disney Co., 430 F.3d 901, 904 (8th Cir. 2005).

owner of these trademarks, and the second entry in the search results was Axiom's competing website. Furthermore, and in contrast to Brookfield and Promatek, as noted above, the search results not only listed the competitor's (i.e., Axiom's) web address, but they also included a brief description of the Axiom's site, and this description included and highlighted both of NAM's trademarked terms, "IDD Therapy" and "Accu-Spina," in addition to Axiom's competing products. Consumers viewing these search results would be led to believe that Axiom's products have the same source as the products of the owner of the "IDD Therapy" and "Accu-Spina" trademarks, or at least that Axiom distributed or sold all of the products to which the brief description referred, or that Axiom was otherwise related to NAM. This, of course, is misleading to the consumer because Axiom is not related in any way to NAM, nor does Axiom distribute or sell the products of NAM. Moreover, there was nothing in Axiom's website itself to disabuse consumers of the notion (suggested by the Google search) that there is some relationship between Axiom and NAM. In other words, if consumers accessed Axiom's website after viewing the Google search results, they would be told all about Axiom's products but would be met with utter silence with respect to NAM's products. For example, there was no comparative advertising in Axiom's website which would have made clear to consumers that NAM's and Axiom's

products are competing items. Thus, the factual situation in the instant case is that Axiom's use of the meta tags caused a likelihood of actual consumer confusion as to source.

The instant case is more like Playboy Enterprises, Inc. v. Netscape Communications Corp., 354 F.3d 1020 (9th Cir. 2004), than Brookfield or Promatek. In Playboy, the defendant, Netscape, sold advertisements to competitors of Playboy and then caused its search engine to pop up banner ads of its advertisers. Playboy, 354 F.3d 1023. The ads appeared when the consumer-searcher typed in the search terms "Playboy" and/or "Playmate," which are trademark terms owned by Playboy. Id. The search engine operated in this manner by using "keying" words in its software. Id. at 1022-23. A competitor's ad could be keyed to pop up in a banner ad along the margin of the search result when the searcher entered "Playboy" and/or "Playmate." Id. at 1023. Thus, the keying words operated in hidden fashion, much like the meta tags in this case. Because the banner ads appeared immediately after the searcher typed in the Playboy trademarks, and invited the user to "click here," id. at 1023, and especially because the banner ads did not clearly identify a source (i.e., the sponsor of the ad), id. at 1025 n.16, 1030, the user was likely to be confused regarding the sponsorship of the unlabeled advertisements. Thus, the Playboy

case involved some actual confusion as to source, unlike the situation in Brookfield where there was never any confusion as to source or affiliation. The instant case is more like Playboy than Brookfield. We note, however, that the source confusion in the instant case is considerably more pronounced than in Playboy. In Playboy, there was no explicit representation of a relationship between the source of the ad and Playboy, while there is an explicit representation in this case of some relationship between Axiom and NAM.

Judge Berzon wrote a concurring opinion in Playboy in which he highlighted this distinction from Brookfield. Id. at 1035-36 (Berzon, J., concurring). Judge Berzon criticized Brookfield, arguing that it involved merely a distraction of a potential customer with another choice in a situation in which the customer was never confused as to source. Id. Rather, the potential customer merely was provided an opportunity for another choice, which clearly was not the sponsor of the original search. Id. Such distraction, Judge Berzon pointed out, was very much like the product placement in a department store. Id. at 1035. When a customer walks in, asks for the Calvin Klein section, and is directed to the second floor, no one thinks that there is a trademark infringement because the store has placed its own (or another competitor's) clothing line in a more prominent place as a distraction. Id.

Because Axiom's use of NAM's trademarks as meta tags caused the Google search to suggest that Axiom's products and NAM's products had the same source, or that Axiom sold both lines, or that there was some other relationship between Axiom and NAM, Axiom's use of the meta tags caused a likelihood of actual source confusion. Thus, the instant case is very different from the product placement in a department store. This case is also very different from Brookfield where there was never source confusion. Finally, the instant case is not subject to the criticism leveled by Judge Berzon.

For the foregoing reasons, and under the particular factual circumstances of this case, we cannot conclude that the district court's finding of a likelihood of confusion is clearly erroneous.[10] Because the district court in this case was not clearly erroneous in finding (1) that plaintiffs possessed valid trademarks; (2) that defendants used those marks, (3) in commerce, (4) in connection with the

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[10] We note that our holding is narrow, and emphasize what kind of case and what kind of facts are *not* before us. This is not a case like Brookfield or Promatek where a defendant's use of the plaintiff's trademark as a meta tag causes in the search result merely a listing of the defendant's website along with other legitimate websites, without any misleading descriptions. This is also not a case where the defendant's website includes an explicit comparative advertisement (e.g., our product uses a technology similar to that of a trademarked product of our competitor, accomplishes similar results, but costs approximately half as much as the competitor's product). Although we express no opinion thereon, such a defendant may have a legitimate reason to use the competitor's trademark as a meta tag and, in any event, when the defendant's website is actually accessed, it will be clear to the consumer that there is no relationship between the defendant and the competitor beyond the competitive relationship. Resolution of the foregoing, as well as other factual situations not before us, appropriately await the day that such factual situations are presented concretely.

advertisement of defendant's goods; and (5) that such use caused a likelihood of confusion to consumers, we conclude that the district court did not err in concluding that plaintiffs demonstrated a likelihood of success with respect to the trademark infringement claim.

B. Likelihood of Success on the Merits of the False Advertising Claims

The district court did not clearly err in its factual findings that Axiom's representations are literally false and material to consumers' purchasing decisions, and thus NAM and Adagen demonstrated a likelihood on success on the merits of their false advertising claims. Regarding false advertising, section 43(a) of the Lanham Act provides, in relevant part, as follows:

> (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.

15 U.S.C. § 1125(a) (2006). To establish a likelihood of success on the merits of a false advertising claim under this section, the movant must demonstrate the

following: "(1) the ads of the opposing party were false or misleading, (2) the ads deceived, or had the capacity to deceive, consumers, (3) the deception had a material effect on purchasing decisions, (4) the misrepresented product or service affects interstate commerce, and (5) the movant has been – or is likely to be – injured as a result of the false advertising." Johnson & Johnson, 299 F.3d at 1247. Axiom only challenges the district court's conclusions regarding the first and third elements – that is, whether Axiom's statements are literally false[11] and whether the statements have a material effect on purchasing decisions.

1. Literal Falsity

The district court did not clearly err when it concluded that Axiom made literally false statements in its advertising.[12] First, the district court did not clearly

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[11] In the present case, we may only sustain the preliminary injunction as it pertains to literally false statements, as opposed to those that are merely misleading. As we have explained before, "once a court deems an advertisement to be literally false, the movant need not present evidence of consumer deception," but in contrast, "[i]f the court deems an ad to be true but misleading, the movant – even at the preliminary injunction stage – must present evidence of deception." Johnson & Johnson, 299 F.3d at 1247. Here, the district court ruled that NAM and Adagen have not offered evidence of deception at this stage of the proceedings, and therefore the district court acknowledged that it could only enjoin those advertising statements that are literally false, not those that are merely misleading. Even if the statements are misleading (but not false), which would satisfy the first element, the second element would remain unsatisfied at this stage, and a preliminary injunction would be inappropriate. Accordingly, if we rule that any of Axiom's representations are not literally false, we would have to reverse that aspect of the preliminary injunction.

[12] Whether a statement is literally false is a finding of fact, which is reviewed only for clear error. Scotts Co. v. United Indus. Corp., 315 F.3d 264, 274 (4th Cir. 2002) (noting that literal falsity of an advertisement is a factual question subject to the clearly erroneous standard);

err when it ruled that Axiom's claims about an affiliation with NASA are literally false. Although one engineer with NASA training or experience participated in Axiom's development of the DRX 9000, this does not constitute a joint collaboration between NASA and Axiom, nor does it support the claim that NASA engineers developed the DRX 9000 or discovered part of the DRX 9000. Similarly, although the DRX 9000 used some components that NASA also uses, that does not mean the DRX 9000 contains or embodies NASA technology. Perhaps these statements could properly be characterized as misleading rather than literally false, but it is a fine line, and we will only reverse the district court if its findings are clearly erroneous. Based on the entire evidence, we are not left with the definite and firm conviction that the district court clearly erred.[13]

Second, the district court likewise did not clearly err when it ruled that Axiom's claims about the DRX 9000 being FDA "approved" are literally false. The DRX 9000 is a Class II medical device, which is only eligible for FDA

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see also Time Warner Cable, Inc. v. DIRECTV, Inc., 497 F.3d 144, 158 (2d Cir. 2007); Hickson Corp. v. N. Crossarm Co., Inc., 357 F.3d 1256, 1261 (11th Cir. 2004) ("The first element of the Lanham Act test requires that the plaintiff show that the statements at issue were either '(1) commercial claims that are literally false as a factual matter . . . .' " (quoting United Indus. Corp. v. Clorox, 140 F.3d 1175, 1180 (8th Cir. 1998))).

[13] Furthermore although Axiom objects that several of its statements regarding NASA only appeared in a video that was never released to any potential consumers, the record contains ample evidence of additional statements, beyond those in the video, that support the district court's ruling of literal falsity.

"clearance" rather than FDA "approval;" FDA approval is a separate process that applies only to Class III devices.[14] See 21 U.S.C. §§ 360c, 360e (2006). Compare 21 C.F.R. § 807.81(a)(1) (2006), with 21 C.F.R. § 814.1(c) (2006). As such, Axiom's statements that the DRX 9000 is FDA "approved" are literally false. In fact, FDA regulations state that it "is misleading and constitutes misbranding" to claim FDA approval when a device is merely FDA cleared. See 21 C.F.R. § 807.97 (2006). Although these regulations use the term "misleading," they also describe such a misrepresentation as "misbranding," and again, it is often a matter of degree whether a statement is literally false or merely misleading. Based on the entire evidence, we are convinced that the district court did not clearly err in judging Axiom's statements literally false.[15]

2. Materiality to Consumers' Purchasing Decisions

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[14] 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. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 345, 121 S. Ct. 1012, 1015 (2001). 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." Id. (quoting § 360c(a)(1)(C)(ii)(II) (1994 & Supp. V)).

[15] Furthermore, despite Axiom's arguments to the contrary, the district court did not step into the FDA's shoes when it ruled that the DRX 9000 was not approved. The district court was not making a determination whether the device should be approved, it merely noted what the FDA had already determined.

The evidence amply supports the district court's conclusion that Axiom's statements are material to consumers' purchasing decisions. Even when a court finds that a defendant's ads are literally false, the plaintiff, to succeed on a claim of false advertising, must still "establish that 'the defendant's deception is 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)). "The materiality requirement is based on the premise that not all deceptions affect consumer decisions." Id.

The types of false claims that the district court enjoined – regarding NASA affiliation and FDA approval – logically would influence a doctor's decision to purchase the DRX 9000 over a competing machine without those qualities. These statements not only represent the quality of the device, but they provide marketing opportunities to the purchasing doctor when he or she in turn is advertising to prospective patients. In fact, after the onset of litigation against Axiom, several doctors who had purchased DRX 9000s sent letters to Axiom expressing their dissatisfaction with the possibility that they might not be able to use Axiom's claims, if the claims proved untrue, to attract patients. These letters provide clear evidence that Axiom's representations would affect doctors' decisions whether to purchase a DRX 9000. Based on this and all other evidence currently in the

record, the district court did not err in its conclusion that these false statements are material to consumers' purchasing decisions.

C. Presumptions of Irreparable Harm

Even though we hold that NAM and Adagen have established a substantial likelihood of success on the merits of their trademark infringement and false advertising claims, we must still evaluate whether NAM and Adagen have demonstrated, with respect to each claim, that they will suffer irreparable harm in the absence of an injunction. In reaching its conclusion that NAM and Adagen satisfied this element of the preliminary injunction test, the district court relied on two presumptions, one regarding the infringement claims and one regarding the false advertising claims. For the reasons that follow, we vacate the preliminary injunction with respect to both the trademark claims and the false advertising claims.

1. Irreparable Harm in False Advertising Cases

The district court erred when it presumed that NAM and Adagen would suffer irreparable harm in the absence of a preliminary injunction merely because Axiom's advertisements are literally false. The district court cited a case out of the Northern District of Georgia, Energy Four, Inc. v. Dornier Medical Systems, Inc., 765 F. Supp. 724, 734 (N.D. Ga. 1991), for the following proposition: "In

false advertising cases, '[p]roof of falsity is sufficient to sustain a finding of irreparable injury for purposes of a preliminary injunction.' " This quote, however, is an incomplete statement of the law. Proof of falsity is generally only sufficient to sustain a finding of irreparable injury when the false statement is made in the context of comparative advertising between the plaintiff's and defendant's products. See McCarthy, supra, § 27:37 ("Where the challenged advertising makes a misleading comparison to a competitor's product, irreparable harm is presumed. But if the false advertising is non-comparative and makes no direct reference to a competitor's product, irreparable harm is not presumed." (internal footnotes omitted)). Although some cases, such as the one cited by the district court, employ language that may suggest a more expansive presumption, such quotes take the original principle out of context without explanation.

Once this presumption is properly stated, it becomes evident that NAM and Adagen are not entitled to the presumption's benefits because Axiom's statements, although false, do not mention NAM's products by name or in any way compare Axiom's products with NAM's products.[16] This is not to say that NAM and Adagen could not demonstrate, absent the presumption, that they will suffer

[16] In reaching this conclusion, we need not address whether this conclusion is also indicated by eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 126 S. Ct. 1837 (2006).

irreparable harm from Axiom's false advertising, but the district court abused its discretion by relying solely on the presumption to find irreparable harm. Accordingly, we vacate the preliminary injunction to the extent it proscribes Axiom's false advertising, and we remand to the district court to determine whether NAM and Adagen will suffer irreparable harm in the absence of a preliminary injunction.

2. Irreparable Harm in Trademark Infringement Cases

Regardless of whether NAM deserves a presumption of irreparable harm on its false advertising claims, our prior cases do extend a presumption of irreparable harm once a plaintiff establishes a likelihood of success on the merits of a trademark infringement claim. Our circuit has acknowledged as much on several occasions. See, e.g., Tally-Ho, Inc. v. Coast Cmty. Coll. Dist., 889 F.2d 1018, 1029 (11th Cir. 1989) (" 'It is generally recognized in trademark infringement cases that (1) there is not [an] adequate remedy at law to redress infringement and (2) infringement by its nature causes irreparable harm.' " (quoting Processed Plastic Co. v. Warner Commc'ns, 675 F.2d 852, 858 (7th Cir. 1982))); McDonald's Corp. v. Robertson, 147 F.3d 1301, 1310 (11th Cir. 1998).

Nonetheless, although established law entitles NAM and Adagen to this presumption in the trademark infringement context, a recent U.S. Supreme Court

case calls into question whether courts may presume irreparable harm merely because a plaintiff in an intellectual property case has demonstrated a likelihood of success on the merits. See generally eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 126 S. Ct. 1837 (2006). In eBay, after a jury had found patent infringement by the defendant, the district court denied the plaintiff's motion for permanent injunctive relief. Id. at 390-91, 126 S. Ct. at 1839. In so doing, the district court "appeared to adopt certain expansive principles suggesting that injunctive relief could not issue in a broad swath of cases." Id. at 393, 126 S. Ct. at 1840. On appeal, the Federal Circuit reversed the denial of injunctive relief, articulating a categorical rule that permanent injunctions shall issue once infringement is established. Id. at 393-94, 126 S. Ct. at 1841. The Supreme Court reversed the Federal Circuit and admonished both the district and appellate courts for applying categorical rules to the grant or denial of injunctive relief. Id. at 394, 126 S. Ct. at 1841. The Court stressed that the Patent Act indicates "that injunctive relief 'may' issue only 'in accordance with the principles of equity.' " Id. at 393, 126 S. Ct. at 1839. Because the Court concluded "that neither court below correctly applied the traditional four-factor framework that governs the award of injunctive relief, [it] vacated the judgment of the Court of Appeals, so that the District Court may apply that framework in the first instance." Id. at 394, 126 S. Ct. at 1841. The Supreme

Court held that while "the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, . . . such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." Id.

Although eBay dealt with the Patent Act and with permanent injunctive relief, a strong case can be made that eBay's holding necessarily extends to the grant of preliminary injunctions under the Lanham Act. Similar to the Patent Act, the Lanham Act grants federal courts the "power to grant injunctions, according to the principles of equity and upon such terms as the court may deem reasonable." 15 U.S.C. § 1116(a) (2006). Furthermore, no obvious distinction exists between permanent and preliminary injunctive relief to suggest that eBay should not apply to the latter. Because the language of the Lanham Act – granting federal courts the power to grant injunctions "according to the principles of equity and upon such terms as the court may deem reasonable" – is so similar to the language of the Patent Act, we conclude that the Supreme Court's eBay case is applicable to the instant case.

However, we decline to express any further opinion with respect to the effect of eBay on this case. For example, we decline to decide whether the district court was correct in its holding that the nature of the trademark infringement gives

rise to a presumption of irreparable injury. In other words, we decline to address whether such a presumption is the equivalent of the categorical rules rejected by the Court in eBay. We decline to address such issues for several reasons. First, the briefing on appeal has been entirely inadequate in this regard. Second, the district court has not addressed the effect of eBay. Finally, the district court may well conclude on remand that it can readily reach an appropriate decision by fully applying eBay without the benefit of a presumption of irreparable injury, or it may well decide that the particular circumstances of the instant case bear substantial parallels to previous cases such that a presumption of irreparable injury is an appropriate exercise of its discretion in light of the historical traditions. See eBay, 547 U.S. at 394-97, 126 S. Ct. at 1841-43 (concurring opinions of Chief Justice Roberts and Justice Kennedy, representing the views of seven Justices). Accordingly, we also vacate the preliminary injunction as it applies to the trademark infringement claim, and remand to the district court for further proceedings not inconsistent with this opinion, and with eBay.

IV. CONCLUSION[17]

[17] We also reject Axiom's argument that the district court failed to exercise its discretion with respect to the bond issue. The district court did exercise its discretion not to require a bond.

In sum, we affirm the district court's findings with respect to the likelihood of success on the merits of the trademark claims and the false advertising claims. However, we vacate the preliminary injunction with respect to both, and we remand to the district court for further proceedings not inconsistent with this opinion.

AFFIRMED IN PART, VACATED AND REMANDED IN PART.

OFFICE OF THE ATTORNEY GENERAL

HARDY MYERS

FOR IMMEDIATE RELEASE
June 28, 2007

AG STOPS OUT-OF-STATE COMPANIES FROM USING 'JUNK SCIENCE' TO PROMOTE CHIROPRACTIC DEVICES

Oregon Chiropractors Disseminated Deceptive Advertisements

Attorney General Hardy Myers today filed settlement agreements with a Florida manufacturer of "spinal decompression devices" and a California chiropractor, who markets promotional services to chiropractors. The agreements resolve allegations that the companies disseminated deceptive advertisements in Oregon that were used by Oregon chiropractors.

Named in Assurances of Voluntary Compliances (AVC) filed in Marion County Circuit Court are Axiom Worldwide, Inc. of Tampa, Florida and Altadonna Communications, Inc. and its owner Benjamin A. Altadonna of Danville, California. Neither AVC admits law violation.

"Oregon chiropractors must do their own homework before purchasing and promoting medical devices," Myers said. "Medical professionals cannot simply rely on the sellers' claims without investigating for themselves."

"Consumers also must be wary of unrealistic health claims that lack adequate substantiation; even those being made by Oregon medical professionals," Myers added.

Oregon Department of Justice (DOJ) lawyers, initially using information from the Oregon Board of Chiropractors, found that Axiom manufactures a "spinal decompression device" called the DRX 9000 used by medical professionals to treat back pain. The devices, costing approximately $100,000 each, were sold throughout the country including nine in Oregon. Along with the device, Axiom provided a marketing

package that included deceptive sample advertisements. Assisting with Axiom's promotion of the DRX 9000 was California chiropractor Benjamin Altadonna and his company Altadonna Communications.

DOJ lawyers found deceptive claims throughout the advertising package including statements that the DRX 9000 had an 86 percent success rate for the treatment of degenerative disc disease, disc herniations, sciatica and post-surgical pain; in fact, the companies did not possess competent and reliable evidence to substantiate the claim.

The companies stated that the Food and Drug Administration (FDA) approved the devices and substantiated their claims of effectiveness. DOJ found the device had merely been cleared as similar to preexisting devices. They also misrepresented the DRX 9000 by claiming it was a scientific and medical breakthrough that resulted from NASA discoveries when, in fact, NASA discoveries had no relationship with the device.

Under the agreements, both companies must change how they market their products. All promotional claims must be substantiated with "competent and reliable scientific evidence," which means tests, analysis, research, studies, or other evidence based on the expertise of professionals in the relevant area.

The agreement also prohibits the companies from misrepresenting scientific studies and patient testimonials.

Axiom must pay DOJ's Consumer Protection and Education Fund a total of $100,000. If Axiom complies with the AVC, $25,000 will be suspended.

Benjamin Altadonna and Altadonna Communications Inc. must pay the state's Consumer Protection and Education Fund a total of $25,000.

Consumers wanting more information about consumer protection in Oregon may call the Attorney General's consumer hotline at (503) 378-4320 (Salem area only), (503) 229-5576 (Portland area only) or toll-free at 1-877-877-9392. The Department of Justice is online at www.doj.state.or.us.

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CONTACT: Jan Margosian, (503) 947-4333 (media line only)
Email: jan.margosian@doj.state.or.us

ENTERED
JUN 28 2007
17

STATE OF OREGON
MARION COUNTY COURTS
JUN 28 2007
FILED

CIRCUIT COURT OF OREGON

MARION COUNTY

IN THE MATTER OF:	Case No. 07C16284
ALTADONNA COMMUNICATIONS., INC AND BENJAMIN A. ALTADONNA.	ASSURANCE OF VOLUNTARY COMPLIANCE

1.

Altadonna Communications, Inc. and Benjamin A. Altadonna have promoted spinal decompression devices to doctors in Oregon and are the Respondents herein. This agreement is between Respondents and the Oregon Department of Justice ("DOJ") acting pursuant to ORS 646.632.

PROCEDURE

2.

This Assurance of Voluntary Compliance ("AVC") is a settlement of a disputed matter. It shall not be considered an admission of a violation of any law, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Respondents expressly denies. This AVC does not constitute an admission by Respondents for any purpose, of any fact or of a violation of any state law, rule, or regulation, nor does this AVC constitute evidence of any liability, fault, or wrongdoing. Respondents enters into this AVC for the purpose of resolving the concerns of DOJ. Respondents do not admit any violation of the State Consumer Protection Laws, and do not admit any wrongdoing that could have been alleged by DOJ. Respondents and DOJ agree that no provision of the AVC operates as a penalty, forfeiture, or punishment under the

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Constitution of the United States, under the Constitution of the State of Oregon, or under any other provision of law.

3.

Respondents acknowledge they received a notice from the State of Oregon pursuant to ORS 646.632(2) of the alleged unlawful trade practice and the relief to be sought. In that regard, DOJ has investigated the advertising practices of Respondents and persons utilizing products manufactured and/or sold and/or promoted by Respondents in the State of Oregon for purposes of determining whether such advertising practices have violated the Oregon Unlawful Trade Practices Act, ORS 646.605 through ORS 646.656 or any other legal requirements. This investigation included, but was not limited to, the matters which are specified in the Notice of Unlawful Trade Practices and Proposed Resolution attached hereto as **Exhibit A**. For purposes of this AVC, the DOJ investigation of Respondents' business practices as described in this paragraph shall be referred to as the "**Matters Investigated**."

4.

Respondents deny that they have engaged in unlawful Trade Practices or violated the Oregon Unlawful Trade Practices Act, ORS 646.605 through ORS 646.656 or any other legal requirements Respondents further state that all marketing materials relating to the DRX9000 was derived from information and representations received from the manufacturer, Axiom Worldwide ("Axiom") and. Axiom had full knowledge of the contents of Respondents marketing materials. Respondents further state that they reasonably relied upon the information and claims received from Axiom relating to Axiom's products

5.

Respondents understand and agree that this AVC applies to Respondents, Respondents' principals, officers, directors, agents, employees, representatives, successors and assigns, jointly

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and severally, while acting personally, or through any corporate or other business entities, whose acts, practices or policies are directed, formulated or controlled by Respondents. Respondents shall be responsible for making the substantive terms and conditions of this AVC known to its officers, directors, managers, and employees who are responsible for implementing the obligations set forth in this AVC.

6.

Respondents understand and agree that if this AVC is accepted by DOJ, it will be submitted to the Circuit Court of the State of Oregon for Marion County for approval, and, if approved, will be filed with the court pursuant to ORS 646.632(2).

7.

Respondents agree to accept service of a conformed or court certified copy by prepaid first class mail sent to the address following Respondent's signature and to Respondent's attorney.

8.

If monies which are ordered to be paid in this AVC are not paid timely, DOJ may convert the AVC to a money judgment under ORS 646.632(2); provided, however, DOJ shall provide Respondents and Respondents' attorney with written notice of any default in payment and Respondent shall have fifteen (15) business days from the date of such notice to cure the default. In the event that such default is not cured, DOJ may convert the AVC to a money judgment as provided herein. Respondents agree that a copy of the money judgment may be sent to Respondents, via first class mail to the address following Respondents' signatures and to Respondents' attorney.

9.

Respondents understands that, in addition to any other sanctions which may be imposed under this AVC or under the law, violation of any of the terms of this AVC may result in contempt of court proceedings, civil penalties of up to $25,000 for each violation, and such

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further relief as the court may deem appropriate. ORS 646.632(4), ORS 646.642(1) and ORS 646.642(2). If DOJ determines that Respondents have failed to comply with any of the terms of this AVC, and if in DOJ's sole discretion, failure to comply does not threaten the health or safety of the citizens of the State of Oregon, DOJ shall notify Respondent in writing at the following facsimile number: (925) 314-9442 and overnight mail addressed to Benjamin Altadonna, 169 E. Prospect Avenue, Suite B Danville, CA 94526 with a copy to Respondents' attorneys, Robert S. Thompson at 4000 SunTrust Plaza, 303 Peachtree Street NE, Atlanta, GA 30308-3243 and Michael Hassen at Jeffers, Mangels, Butler & Marmaro LLP, Two Embarcadero Center, Fifth Floor, San Francisco, CA 94111, or any person subsequently designated by Respondents to receive such notice of failure to comply. The notice shall advise Respondents of the manner in which it is believed that this AVC has been violated. Respondents shall then have fifteen (15) days from the receipt of such written notice to provide a good faith written response to DOJ's determination (the **"Cure Period"**). The response shall include an affidavit containing, at a minimum, either:

(A) a statement explaining why Respondents believe they are in compliance with the AVC; or

(B) an explanation of how the alleged violation occurred and

(1) a statement that the alleged breach has been cured and how; or

(2) a statement that the alleged breach cannot be reasonably cured within fifteen (15) days from receipt of the notice, but:

(a) Respondents have begun to take corrective action to cure the alleged breach;

(b) Respondents are pursuing such corrective action with reasonableness and due diligence; and

(c) Respondents have provided DOJ with a reasonable timetable for curing the alleged breach.

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10.

Nothing herein shall prevent DOJ from agreeing in writing to provide Respondents with additional time beyond the fifteen (15) day period to respond to the notice of failure to comply.

11.

Nothing herein shall be construed to exonerate any contempt or failure to comply with any provision of this AVC after the Effective Date; to compromise the authority of DOJ to initiate a proceeding for any contempt or sanctions for failure to comply; or to compromise the authority of the court to punish as contempt any violation of this AVC. Furthermore, nothing in this subsection shall be construed to limit the authority of DOJ to protect the interest of the State of Oregon. Notwithstanding the foregoing, DOJ agrees that it will not institute an enforcement proceeding relating to the practices at issue in the notice provided under Section 8 against Respondent during the Cure Period.

12.

The parties acknowledge that no other promises, representations or agreements of any nature have been made or entered into by the parties. The parties further acknowledge that this AVC constitutes a single and entire agreement that is not severable or divisible, except that if any provision herein is found to be legally insufficient or unenforceable, the remaining provisions shall continue in full force and effect.

REMEDIES

13.

Respondents shall comply with Oregon's Unlawful Trade Practices Act, ORS 646.605 to ORS 646.656.

14.

Respondents shall not represent or imply that DOJ acquiesces or approves of Respondents' past business practices, current practices, efforts to reform its practices, or any future practices that Respondents may adopt or consider adopting. DOJ's decision to settle this

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matter or to otherwise unilaterally limit current or future enforcement action does not constitute approval or imply authorization for any past, present, or future business practice.

15.

Respondents shall pay the sum of Twenty-five Thousand Dollars ($25,000) to DOJ for deposit to the Consumer Protection and Education Revolving Account established pursuant to ORS 180.095. Said sum shall be used by DOJ as provided by law. The monies due under this paragraph shall be paid to DOJ within thirty (30) days following approval of this AVC by the Court.

16.

Effective immediately upon execution by Respondents of this AVC, Respondents agree to adhere to each of the following requirements, which Respondents contend they already comply with::

A. When promoting products in Oregon, Respondents shall not make any express or implied statements that have the capacity, tendency or effect of deceiving or misleading or that fail to state any material fact, the omission of which deceives or tends to deceive.

B. Respondents, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of products in Oregon, shall not make any representation, expressly or by implication, concerning such products' efficacy, performance, safety or benefits, unless, at the time the representation is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

C. For purposes of this Assurance, *"competent and reliable scientific evidence"* shall mean tests, analysis, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

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D. Respondents shall not disseminate any patient testimonial in Oregon that does not clearly and conspicuously disclose what the generally expected performance would be in the depicted circumstances or clearly and conspicuously disclose the limited applicability of the experience described by the patient testimonial to what consumers may generally expect to achieve.

E. When Respondents present information in detailing pieces, brochures, booklets, mailing pieces, published journals, magazines, other periodicals and newspapers, and broadcast through media such as radio, television, the Internet, and telephone communications systems, that references a clinical study, Respondents shall (1) accurately reflect the methodology used to conduct the clinical study; (2) shall not present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; (3) shall not use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations; (4) shall not present information from a study in a way that implies that the study represents larger or more general experience with the product than it actually does; (5) shall not use statistics on numbers of patients, or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case.

F. Respondents shall not use of the term "FDA approved" in reference to the FDA 510 (k) clearance process.

G. Nothing in this AVC shall require Respondents to: (1) take an action that is prohibited by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301, *et seq.*, or any regulation promulgated thereunder, or by the FDA; or (2) fail to take action as required by the

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Federal Food, Drug and Cosmetic Act or any regulation promulgated thereunder, or by the FDA.

RELEASE

17.

Based on inquiry into Respondents' promotional practices, the Attorney General has concluded that this AVC is the appropriate resolution of any alleged violation of the Oregon's Consumer Protection Laws. The Attorney General acknowledges by his execution hereof that this AVC terminates his inquiry under the State Consumer Protection Law of Respondents.

18.

In consideration of the Remedies, payments, undertakings, and acknowledgments provided for in this AVC, and conditioned on Respondents making full payment of the amount specified in Paragraph 14, the State releases and forever discharges, to the fullest extent permitted by law, Respondents and their past and present officers, directors, shareholders, employees, representatives, agents, affiliates, parents, subsidiaries, predecessors, attorneys, assigns, and successors (collectively, the "Releasees"), of and from any and all civil causes of action, claims, damages, costs, attorney's fees, or penalties that the Attorney General could have asserted against the Releasees under the State Consumer Protection Law by reason of any conduct that has occurred at any time up to and including the Effective Date of this Judgment relating to or based upon the Matters Investigation of this AVC ("Released Claims").

19.

The Released Claims set forth in Paragraph 17 specifically do not include the following claims:

(a) private rights of action by consumers, provided, however, that this Judgment does not create or give rise to any such private right of action of any kind;

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(b) Medicaid fraud or abuse;

(c) claims of antitrust, environmental or tax liability;

(d) claims for property damage; and

(e) claims to enforce the terms and conditions of this AVC.

GENERAL PROVISIONS

20.

A. Nothing in this AVC shall be construed to authorize or require any action by Respondent in violation of applicable federal, state or other laws.

B. This AVC shall be effective ("**Effective Date**") on the date that it is approved by the Marion County Circuit Court and Respondent has been notified via facsimile and regular U.S. mail that all the parties hereto have fully executed this AVC.

C. If Respondents believe that modification of the terms of this AVC become warranted due to (1) changes in the marketplace or applicable law, including, but not limited to, administrative rules or (2) an erosion in Respondents' competitive position as a result of the terms of this AVC, Respondent may submit the proposed modification in writing to DOJ. DOJ will respond within a reasonable period of time after the receipt of the request.

D. In the event any law or regulation is enacted or adopted by the federal government or by the State of Oregon which creates an impossible conflict with the terms of this AVC such that Respondents cannot comply with both the statute or regulation and the terms of this AVC, the requirements of such law or regulation, to the extent of the impossible conflict, and after written notice by Respondents, shall replace any provisions contained herein so the compliance with such law or regulation shall then be in compliance with this AVC.

E. At any time during the term of this AVC, Respondents shall have the right to request that DOJ, based on Respondents' act or performance of the terms of this AVC, modify or terminate this AVC. DOJ shall make a good faith evaluation of Respondents' request and make a prompt decision (in no event more than forty-five (45) days from Respondents' request)

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as to whether to grant Respondents' request. The decision whether to grant Respondents' request to modify or terminate this AVC shall rest solely within the discretion of DOJ.

F. All notices and other communications relating to this AVC between DOJ and Respondents shall be in writing and shall be deemed to have been given when delivered in person to the parties' designated representatives at their addresses set forth below, or when received or refused, if sent to parties' designated representatives at their addresses given below by registered or certified mail with return receipt requested, or to such other representatives or addresses as the parties shall designate by a notice sent in like manner.

G. Any notices required to be sent to DOJ or Respondents by this AVC shall be sent by United States mail, certified mail, return receipt requested, or other nationally recognized courier service that provides for tracking services and identification of the person signing for the document. Any such notice shall be sent to the following address:

For Respondents, see paragraph 9.

For the Attorney General: David A. Hart, Assistant Attorney General, Department of Justice, 1162 Court Street, N.E., Salem, Oregon 97301-4096

H. This AVC may be executed and delivered in counterparts, each of which shall be an original, but such counterparts together shall constitute but one and the same AVC.

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1162 Court Street NE
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PHONE: (503) 947-4333

APPROVAL BY COURT

APPROVED FOR FILING and SO ORDERED this 26 day of June, 2007.

Circuit Court Judge

REVIEW BY RESPONDENT'S ATTORNEY

Approved as to form.

Robert S. Thompson
Attorney for Respondent

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PHONE: (503) 947-4333

RESPONDENTS' SIGNATURE AND ACKNOWLEDGMENT

Respondents have read and understands this agreement and each of its terms. Respondents agree to each and every term.

Corporate Respondent

I, Ben Altadonna, being first duly sworn on oath depose and say that I am the President of Altadonna Communications Ltd and am fully authorized and empowered to sign this Assurance of Voluntary Compliance on behalf of Altadonna Communications Ltd and bind the same to the terms hereof.

Ben Altadonna
Print Name

President
Title

Address 169 E. Prospect Ave Suite B
Danville CA 94526

SUBSCRIBED AND SWORN to before me this 25th day of June, 2007. by Benjamin Anthony-Altadonna

Sarita Bhateja
Notary Public

INDIVIDUAL RESPONDENT

Benjamin S. Altadonna
A.

Address 169 E. Prospect Suite B
Danville CA 94526

SUBSCRIBED AND SWORN to before me this 25th day of June, 2007.

Sarita Bhateja
Notary Public

SARITA BHATEJA
Commission # 1578009
Notary Public - California
Contra Costa County
My Comm. Expires Jun 7, 2009

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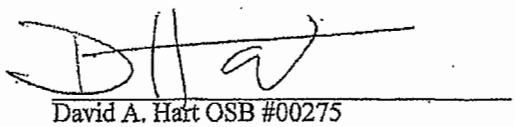
ACCEPTANCE OF DOJ

Accepted this 28th day of June, 2007.

HARDY MYERS
Attorney General



David A. Hart OSB #00275
Assistant Attorney General
Department of Justice
Of Attorneys for Plaintiff
Financial Fraud/Consumer Protection Section
1162 Court Street NE
Salem, OR 97301-4096
Phone: (503) 947-4333
Fax: (503) 378-5017
Email: david.hart@doj.state.or.us

DEPARTMENT OF JUSTICE

STATE OF OREGON

IN THE MATTER OF ALTADONNA COMMUNICATIONS, INC. AND BENJAMIN A LTADONNA Respondent.	NOTICE OF UNLAWFUL TRADE PRACTICES AND PROPOSED RESOLUTION

TO: BENJAMIN A. ALTADONNA
c/o Robert, S. Thompson, Esq.
Hawkins & Parnell LLP
4000 Suntrust Plaza
303 Peachtree Street NE
Atlanta, GA.3038-3243

This notice is to inform you the Oregon Attorney General is authorized to file a lawsuit against you 10 days after you receive this notice. The Attorney General is required by statute to give you this notice. See Oregon Revised Statute 646.632.

You may avoid the filing of a lawsuit by delivering an Assurance of Voluntary Compliance [AVC] to the Financial Fraud Section of the Oregon Department of Justice within 10 days after you receive this notice.

An AVC must be in writing and state what actions you intend to take to resolve the violations described below. The AVC is not an admission of violation of law and is submitted to a Circuit Court for the State of Oregon for approval and filing.

Before submitting the AVC to the Circuit Court, it must be approved and accepted by the Attorney General. Once filed with the court, any willful violation of the terms of an AVC is a contempt of court which may result in punitive or remedial sanctions including confinement and civil penalties of up to $25,000 per violation.

Exhibit A
Page 1 of 3

DEPARTMENT OF JUSTICE
1162 Court Street NE
Salem, OR 97301-4096
PHONE: (503) 947-4333

This notice becomes a public record after 10 days have passed following your receipt of this notice.

The Attorney General sent you this notice because there are concerns you violated the Oregon Unlawful Trade Practices Act, ORS 646.605 through ORS 646.656, including but not limited to the following alleged conduct.

A) Misrepresenting the efficacy of the DRX 9000 and 9000C "axial decompression" devices by claiming an 86% success rate for the treatment of degenerative disc disease, disc herniations, sciatica, and post surgical pain, when in fact, you do not possess competent and reliable evidence to substantiate this claim.

B) Misrepresenting that the FDA approved the devices and substantiated your efficacy claims when in fact, this is not the case.

C) Misrepresenting that the DRX 9000 and 9000C was a scientific and medical breakthrough that resulted from NASA discoveries when in fact, this is not the case.

D) Misrepresenting that patient testimonials relating to the DRX 9000 and DRX 9000C are typical treatment outcomes when in fact, you do not possess competent and reliable evidence to substantiate this claim.

E) Misrepresenting the nature of DRX 9000 and DRX 9000C treatment by encouraging those seeking coverage by insurance companies for DRX 9000 and DRX 9000C treatments to submit treatment codes other than the one customarily used for unattended mechanical traction.

If we file the lawsuit, we will ask the court to order you to pay:

1) Civil penalties of up to $25,000 for each violation;

2) Restitution to anyone harmed by your acts; and

3) Our reasonable attorney's fees, costs and disbursements.

In addition, we may ask the court to order that you be permanently enjoined from conducting any aspect of any trade or commerce in the State of Oregon.

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PHONE: (503) 947-4333

Exhibit A
Page 2 of 3

Dated this 15th day of June, 2007.

David A. Hart OSB #00275
Assistant Attorney General
Department of Justice
Financial Fraud/Consumer Protection Section
1162 Court Street NE
Salem, OR 97301-4096
Phone: (503) 947-4333
Fax: (503) 378-5017
Email: david.hart@doj.state.or.us

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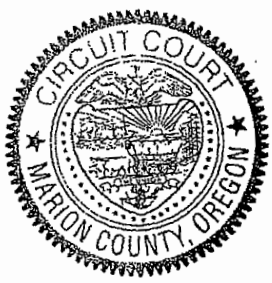
Exhibit A
Page 3 of 3



STATE OF OREGON } ss
County of Marion

The foregoing copy has been compared and is certified by me as a full true and correct copy of the original on file in my office and in my custody.

In Testimony Whereof, I have hereunto set my hand and affixed the seal of the Court on: 10/28/07

TRIAL COURT ADMINISTRATOR

By