UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA, TAMPA DIVISION

Novo Nordisk A/S et al. v. Infinity Medical Institute, LLC

Novo Nordisk · No. 8:24-cv-02123-SDM-CPT · Decided December 23, 2025

OPINION

UMNIIDTEDDL ES TDAISTTERS IDCITS TORFI FCLTO CROIDUART TAMPA DIVISION NOVO NORDISK A/S et al, Plaintiffs, v. CASE NO. 8:24-cv-02123-SDM-CPT INFINITY MEDICAL INSTITUTE, LLC, Defendant. _____/ ORDER Novo Nordisk A/S and Novo Nordisk, Inc., sue (Doc. 1) Infinity Medical In- stitute, LLC, for false and misleading advertising and unfair competition.

The plain- tiffs served Infinity (Doc. 11), but Infinity fails to answer or otherwise appear. The clerk defaulted Infinity (Doc. 21), and the plaintiffs moved (Doc. 14) for default judg- ment. An order (Doc. 17) denied the original motion (Doc. 14) and found that "[b]ecause each of the advertisements is misleading, the plaintiffs must advance proof of actual consumer deception." The plaintiffs move (Doc.

18) again for default judgment. By defaulting, Infinity admits a well-pleaded fact alleged in the complaint. In re Lorenzo, 606 Fed. App'x 548, 553 (11th Cir. 2015). Infinity does not admit a con- clusion of law. Cotton v. Mass. Mut. Life Ins. Co., 402 F.3d 1267, 1278 (11th Cir. 2005). If the complaint establishes a "sufficient basis" for the entry of judgment, the plain- tiffs are entitled to a default judgment.

Lorenzo, 606 Fed. App'x at 553. The com- plaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

The Lanham Act, 15 U.S.C. § 1125(a)(1)(B), creates a private right of action against "[a]ny person who... uses in commerce any... false or misleading repre- sentation of fact, which... in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another per- son's goods, services, or commercial activities." To state a claim for false or mislead- ing advertising under Section 1125(a)(1)(B), the plaintiffs must show: (1) the advertisements of the opposing party were false or misleading; (2) the advertisements deceived, or had the capacity to deceive, con- sumers; (3) the deception had a material effect on purchasing deci- sions; (4) the misrepresented product or service affects interstate com- merce; and (5) the movant has been—or is likely to be—injured as a result of the false advertising.

Hickson Corp. v. N. Crossarm Co., 357 F.3d 1256, 1260 (11th Cir. 2004) (citations omitted). The plaintiffs' state law claims are subject to the same standard. Crystal Entm't & Filmworks, Inc. v. Jurado, 643 F.3d 1313, 1323 (11th Cir.2011) ("[T]he le- gal standards [that] apply to [the FDUTPA] claim are the same as those... ap- plied under section 43(a) of the Lanham Act."); Planetary Motion, Inc. v. Tech- splosion, Inc., 261 F.3d 1188, 1193 n. 4 (11th Cir.

2001) ("Courts may use an anal- ysis of federal infringement claims as a 'measuring stick' in evaluating the merits of state law claims of unfair competition."). A claim for false advertising requires proof that an advertisement is literally false. See Osmose, Inc. v. Viance, LLC, 612 F.3d 1298, 1309 (11th Cir. 2010). A claim for misleading advertisement requires proof that the advertisement, even if literally true, nonetheless actually deceived the public.

See Johnson & Johnson Vision Care, Inc. v. 1-8000 Contracts, Inc., 299 F.3d 1242, 1247 (11th Cir. 2002); BellSouth Advert. & Pub. Corp. v. Lambert Pub., 45 F. Supp. 2d 1316, 1323–24 (S.D. Ala. 1999). A consumer survey is often "key" proof of deception. Hickson, 357 F.3d at 1261. If a "full-blown" consumer survey or market study is unavailable, "the plaintiff still must provide some sort of expert testimony or similar evidence." Johnson & Johnson, 299 F.3d at 1247.

The distinction between a literally false statement and a merely misleading statement is a "fine line" delineated by analyzing the meaning in full context. Johnson & Johnson, 299 F.2d at 1248 (quoting N. Am. Med. Corp. v. Axiom Worldwide, Inc., 522 F.3d 1211, 1216 (11th Cir. 2008). A literally false statement conveys an unambigu- ous meaning. Osmose, 612 F.3d at 1309.

If susceptible to several meanings, a state- ment is more likely misleading. Time Warner Cable, Inc. v. DIRECTV, Inc., 497 F.3d 144, 158 (2d Cir. 2007). The more implicit, attenuated, and suggestive the meaning, the more likely that the statement is merely misleading. United Indus. Corp. v. Clorox Co., 140 F.3d 1175 (8th Cir. 1998).

The plaintiffs identify four of Infinity's statements as false or misleading: Semaglutide is now an FDA approved treatment for chronic weight management! We have seen SO much patient success! Studies have shown that in conjunction with lifestyle intervention, semaglutide effectively helps reduce food cravings and aids in weight loss. Semaglutide, the active ingredient (Wegovy, Ozempic, Rybelsus) is a medicine used for weight loss in specific patients[.]

With prescriptions to [Ozempic® and Wegovy®] getting harder to find, many patients are seeking out alternatives, including generic compounded semaglutide. Each of the four statements is misleading, but none is literally false.

The fourth statement is the closest. The FDA has not approved any generic versions of We- govy®, Ozempic®, and Rybelsus®. Infinity misleadingly suggests the existence of generic, compounded semaglutide. But the statement is not literally false: at least more than one patient is seeking generic, compounded semaglutide.

Because each of the advertisements is misleading, the plaintiffs must advance proof of actual consumer deception. The plaintiffs submit a 2025 National Consumers League survey finding (1) that a majority or near-majority of women mistakenly believe that compounded, non-FDA-approved forms of semaglutide (such as the product advertised by Infinity) are as safe as FDA-approved versions (such as those sold by the plaintiffs), contain the same ingredients, and are themselves FDA-approved and (2) that these miscon- ceptions are attributable to "widespread advertising." (Doc.

18-2 at Ex. H) Also, the plaintiffs submit an FDA warning letter explaining that advertised suggestions of equivalence to FDA-approved drugs, references to brand-name products, or FDA ap- proval are "false or misleading" because compounded drugs are not FDA-approved. (Doc. 18-2 at Ex. G) The complaint establishes materiality. A misrepresentation is material if it concerns an inherent quality or characteristic of the product.

Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc., 299 F.3d 1242, 1250 (11th Cir. 2002). Here, Infinity allegedly represented that its compounded semaglutide is FDA-approved, clinically studied, or equivalent to Ozempic®, Wegovy®, or Rybelsus®. (Doc. 1 at ¶¶ 35–44.) Whether a drug is FDA-approved, has undergone clinical testing, or is equivalent to a branded medication concerns an inherent quality or characteristic of the drug and is therefore material.

Infinity advertised semaglutide on a public website. (Doc. 1 at ¶¶ 32–34) Inter- net advertising satisfies the Lanham Act's "in commerce" requirement. Planetary Mo- tion, Inc. v. Techsplosion, Inc., 261 F.3d 1188, 1195 (11th Cir. 2001).

Finally, Infinity's conduct injured Novo Nordisk by diverting consumers away from Novo Nordisk and harming Novo Nordisk's reputation by confusing consum- ers. Such an injury falls within the zone of interests protected by the Lanham Act. ThermoLife Int'l LLC v. Vital Pharm. Inc., 2019 WL 4954622, at *2 (S.D. Fla. Oct. 8, 2019).

The plaintiffs' motion (Doc. 18) for default judgment on each count is GRANTED. Infinity is ENJOINED from using any Novo Nordisk trademark in any manner likely to cause confusion, mistake, or deception, or otherwise to infringe a Novo Nordisk mark. Also, Infinity is ENJOINED from advertising, stating, or directly or indirectly suggesting that the unapproved compounded semaglutide sold or promoted by Infin- ity: (a) is, or contains, a genuine or authentic Novo Nordisk medicine, including, but not limited to, Ozempic®, Wegovy®, or Rybelsus®; (b) is sponsored by, affiliated with, or associated with Novo Nordisk; (c) is approved by the FDA, has been reviewed by the FDA, or has been demonstrated to the FDA to be safe or effective for its intended use; (d) achieves, or has been shown or proven to achieve, a therapeutic result, effect, or outcome similar or identical to any Novo Nordisk medicine; (e) is associated or connected in any way with Novo Nordisk or any Novo Nordisk medicine; or (f) contains any ingredient supplied by Novo Nordisk, approved by the FDA, or identical to any ingredient in a Novo Nordisk medi- cine.

Finally, Infinity is ENJOINED from engaging in any further unfair or decep- tive act or practice. No later than JANUARY 6, 2026, Infinity must produce to the plaintiffs an accounting of profit derived from any semaglutide-related product or service. No later than FEBRUARY 21, 2026, the plaintiffs must move for damages and any additional monetary relief.

The clerk must enter a judgment consistent with this order for the plaintiffs and against the defendant. ORDERED in Tampa, Florida, on December 23, 2025. AAD WN Arete STEVEN D. MERRYDAY UNITED STATES DISTRICT JUDGE -6-