National Advertising Division Says Pre-Launch Investor Presentation Can Be Challenged Under Advertising Law

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It has long been a fundamental tenet of advertising law that comments made to investors, and particularly those made before the commercial launch of a product or service, do not constitute the kind of "advertising" that is regulated by the Federal Trade Commission (the "FTC") or the National Advertising Division (the "NAD") of BBB National Programs, and are outside the reach of the Lanham Act. That is because advertising law regulates communications that propose a commercial transaction; in contrast, the securities laws govern communications to investors that are designed to promote investments. A recent decision from the NAD has put a big crack in that jurisdictional wall, and threatens to breach the dam that has long shielded comments made in investor presentations from potential liability for false advertising.

In *PLx Pharma, Inc. (Vazalore)*, Report #6912, NAD/CARU Case Reports (December 2020), the NAD accepted jurisdiction over a challenge that related to claims made on a website that was directed to investors, not to consumers.[1] Although there are some facts that might help limit the reach of this precedent, the NAD's decision to assert jurisdiction over this investor-focused website opens the door to more challenges to comments companies make about their products in the context of investor presentations. Marketers now need to be more vigilant about the claims they make in investor calls, and potential challengers now have a new forum for objecting to hyperbolic or deceptive claims made in the context of investor presentations.

Who Is the NAD and Why Does It Matter?

The NAD is the advertising industry's forum for self-regulation of advertising disputes.[2] Although the NAD lacks enforcement power, its decisions are highly influential given its expertise in assessing the accuracy of claims made in advertisements, and given the FTC's active endorsement of the NAD process.

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1 *See* https://bbbprograms.org/media-center/newsroom/plxpharma-vazalore-aspirin-claims

2 *See* https://bbbprograms.org/programs/all-programs/national-advertising-division.

An NAD challenge is typically initiated by a letter filed by a competitor who believes an advertiser's claims to be false.[3] The letter must identify the advertising at issue and explain the reason that the challenger believes the claims to be unsubstantiated. The advertiser is then given three weeks to respond; it is the advertiser's burden to present evidence that substantiates the accuracy of its claims. Thereafter, the challenger has two weeks to reply and the advertiser has two weeks for a sur-reply. There is no discovery, and the process moves relatively quickly, which makes the NAD a popular forum for advertising disputes.

Once the briefing is completed, the NAD will meet with each party separately to discuss the case, and will issue its decision. If the NAD finds the advertising was not substantiated, it will recommend modifications to the advertising. Although the decisions do not have the force of law or precedent, the vast majority of advertisers voluntarily comply with the NAD's recommendations. If an advertiser declines to comply with the recommendations, the NAD will refer the matter to the FTC or other regulatory agency for enforcement proceedings.[4]

The Dispute

Bayer HealthCare, the maker of the original aspirin, filed a challenge before the NAD against claims made by PLx Pharma concerning its new form of liquid-filled aspirin capsule named Vazalore. Although Vazalore is not yet available for sale, it has received approval from the Food and Drug Administration (the "FDA"). To promote the company and its pipeline of drugs, PLx Pharma included claims about the efficacy of Vazalore on a website that was targeted to investors. Those claims included statements that:

- Vazalore was "Faster and more predictable . . . than enteric coated aspirin";
- "Vazalore has up to 5X greater absorption than enteric coated aspirin"; and
- "Vazalore delivers 2X better platelet response than enteric coated aspirin."

Notably, the challenged claims were published on a corporate website that was intended to attract investors (rather than on a product website that was intended to promote the drug to doctors or to sell products to the consuming public). Although the website was

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[3] *See* https://bbbnp-bbbp-stf-use1-01.s3.amazonaws.com/docs/default-source/bbb-national-programs/procedures/nad_narbprocedures_12-2-2020.pdf.

[4] https://www.ftc.gov/enforcement/cases-proceedings/closing-letters-and-other-public-statements/resolution-of-referrals-from-nad.

generally available to the public, the claims were not part of an affirmative advertising campaign aimed at getting health care providers or consumers interested in the product.

The NAD Accepts Jurisdiction Because Consumers Could Become Aware of the Claims

Normally, claims made on websites or in presentations targeted to investors are not actionable under the Lanham Act, and are not considered advertising that can be regulated by the FTC or NAD. That is in part because allegations that investors were given false or deceiving material are typically addressed by the Securities and Exchange Commission (the "SEC") under Section 10(b) of the Securities Exchange Act of 1934[5] and Section 17(a) of the Securities Act of 1933.[6] In contrast, Section 5(a) of the FTC Act, 15 U.S.C. § 45(a) and Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), are primarily concerned with consumer confusion in the sale of goods and services.[7]

Despite this jurisdictional hurdle, Bayer – which contended that the claims comparing Vazalore to regular aspirin were false – challenged the PLx Pharma investor website before the NAD. Bayer argued that the website constituted "national advertising" within the jurisdiction of the NAD because the claims were publicly available, could be seen by consumers, and could influence future consumer behavior.

PLx Pharma objected to the NAD's jurisdiction. It noted that, under NAD's own rules, "national advertising" is limited to "any paid commercial message, in any medium (including labeling), if it has the purpose of inducing a sale or other commercial transaction or persuading the audience of the value or usefulness of a company, product or service."[8] PLx Pharma argued that the NAD lacked jurisdiction to hear the case because Vazalore had not been launched and was not on sale, so the claims on the investor website could not induce a sale or commercial transaction of Vazalore. In fact, it argued, it had never advertised Vazalore to consumers; rather, it only discussed

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5 15 U.S.C. § 78j(b) (2004) (prohibiting the "use or employ, in connection with the purchase or sale of any security . . . [of] any manipulative or deceptive device or contrivance [through any means of interstate commerce] in contravention of such rules and regulations as the Commission may prescribe.");

6 15 U.S.C. § 77q(a) (2010) (prohibiting fraud, deceit, or the use of "untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading" in the offer or sale of securities through interstate commerce).

7 *See, e.g.*, *Coastal Abstract Serv. v. First Am. Title Ins. Co.*, 173 F.3d 725 (9th Cir. 1999) (test to determine whether statements can fairly be labeled "advertising or promotion" under the Lanham Act considers, among other things, whether the statements were made for the purpose of influencing consumers to buy defendant's goods or services and were disseminated sufficiently to the relevant purchasing public to constitute "advertising" or "promotion" within that industry).

8 NAD/NARB Procedures Rule 1.1(A).

Vazalore on "a small corporate website, directed at attracting investors, not product sales."[9]

The NAD rejected PLx Pharma's argument. It accepted jurisdiction, even though the intended audience was investors, on the ground that the product claims at issue were designed to persuade the audience of the value of the company and its products, constituting "national advertising" for purposes of NAD jurisdiction.[10] Moreover, the NAD held, even if the website was targeted to investors, it still was publicly available, including to consumers, and could therefore have some impact on ***potential consumers***. Furthermore, although Vazalore is not available for sale, false claims about the product might generate future interest in the product. That is especially the case since some of the claims on the website contained language that would appeal to and be relevant to consumers rather than investors, such as "[i]f recommended by your doctor, Vazalore may provide…" and "[c]onsult your healthcare provider before using this product for your heart."[11]

The NAD concluded that "[t]he clear purpose of the website is to generate interest in the product" not only with investors, but also "with both consumers and health care [sic] professionals until [such] time" that Vazalore is launched.[12] For that reason, the NAD accepted jurisdiction over Bayer's challenge and applied traditional false advertising principles to the claims made on PLx Pharma's investor website (some of which the NAD found were unsupported).

Impact of the Decision

Although public companies have long taken care to ensure that comments they make in investor presentations are accurate, they have not generally been concerned that such comments could subject them to false advertising challenges. They also generally were not concerned that the SEC would take action against exaggerated product claims made in investor meetings (unless the misleading statements were made intentionally or recklessly, and they were material to trading in the securities of the company). This decision is significant because it provides an opening for competitors to challenge false, misleading or deceptive claims about a product made in the context of investor presentations, especially if the investor materials are publicly available.

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9 *PLx Pharma, Inc. (Vazalore)*, Report #6912, NAD/CARU Case Reports (December 2020) at 3–4.

10 *Id.* at 4.

11 *Id.*

12 *Id.*

To minimize the risk of challenge, companies should consider whether product claims made in investor materials should undergo the same rigorous legal review as claims made in traditional advertisements. In addition, they should clearly label investment materials as being intended only for investors. For example, companies might include a disclaimer that the materials are not product advertising but are only to be used in evaluating a potential investment. Finally, in any such investor materials, companies would be well advised to minimize use of statements that look like advertisements directed to consumers. PLx Pharma's use of statements like "[c]onsult your healthcare provider before using this product for your heart" in its investor materials substantially undermined its jurisdictional defense that these statements were only intended for investors in the company and not for consumers.

For competitors, this decision opens a new avenue to challenge product claims made in investor meetings, calls or presentations. That is significant, as it may provide a forum for early challenges, even before a competitive product is launched. Many companies—both in the pharmaceutical space and otherwise—will promote their pipeline of products to investors before the products are in the market, and even before the products are approved, in order to show investors the value of the underlying business. If competitors can challenge exaggerated or false claims at this early stage in the process, they may be successful at stopping those claims from being made by the time the product is ready for launch.

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