

NECESSARY IMPLICATIONS AND SCINTILLAS OF SUPPORT:

The Lanham Act Defendant's Burden Post-*Novartis*

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THE THIRD CIRCUIT COURT of Appeals, in *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co.*,¹ recently advanced two doctrines that could shift significantly the burdens of proof in Lanham Act false-advertising litigation. Under the Lanham Act,² liability arises if the commercial message or statement is either (1) literally false or (2) literally true or ambiguous but has the tendency to deceive consumers because of any implied message.³ If a claim is literally or expressly false, courts may enjoin the claim without reference to its impact on the buying public.⁴ Otherwise, the plaintiff bears the burden of proving, usually through the use of a consumer survey, that consumers are actually receiving the challenged implied claim, as well as that the claim is false.⁵ The court in *Novartis* addressed the burden of proof required in the fuzzy middle ground of advertising claims that are not expressly false, but rather are susceptible to only one interpretation that is impliedly false. *Novartis* also addressed whether completely unsubstantiated claims are actionable without affirmative evidence of their falsity. In a significant departure from past decisions, the Third Circuit shifted the burden of proof to the advertiser in both these situations.

Background of the Two Doctrines

In the early 1980s, federal courts began entertaining the idea that advertising messages could, in fact, be considered “expressly false” even though the false message was not spelled out verbatim in the advertisement itself. For example, in *Vidal Sassoon, Inc. v. Bristol-Myers Co.*,⁶ the Second Circuit held that, even though a shampoo commercial in which an adult model claimed that the advertised shampoo was rated

higher in “tests with over nine hundred women like me” did not contain the words “nine hundred *adult* women like me,” the advertisement nonetheless conveyed that message expressly to consumers. The commercial was deemed false because the referenced study included girls as well as women. Similarly, in *Tambrands, Inc. v. Warner-Lambert Co.*,⁷ the court found the claim that a home pregnancy kit produces results “in as fast as ten minutes” was facially false because it stated by necessary implication that the kit was a ten-minute test, when in fact the test required at least thirty minutes to obtain negative results. In *Cuisinarts, Inc. v. Robot-Coupe Int'l Corp.*,⁸ the court found that a food-processor advertisement that contained a scoreboard comparing the adoption of two different food processors in Michelin three-star restaurants in France had falsely stated, by necessary implication, that both suppliers built professional model food processors. In one case, *Warner-Lambert Co. v. BreathAsure, Inc.*,⁹ the Third Circuit held that even the name of a product, standing alone, can necessarily imply a false claim. However, none of the courts applying the doctrine had clearly articulated the important differences of burden of proof between a necessarily implied claim and an implied but possibly ambiguous claim. Courts had also not addressed the important question of what should happen when an advertiser has no substantiation whatsoever for a challenged claim.

Until very recently, with the exception of “establishment claims,” in which the advertiser represents that specific evidence exists in support of the claim being asserted, courts have required that parties challenging an advertisement prove that a claim is false, even if the advertiser had no substantiation for the challenged claim.¹⁰ However, in *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*,¹¹ the Third Circuit suggested a modified approach. While the court did not need to rule on whether the plaintiff could satisfy its burden of proving falsity by simply showing that the defendant’s advertisements about its own drug’s effectiveness were inadequately substantiated, it noted that, where advertising claims are “completely unsubstantiated,” there is “a plausible argument that the claim is literally false because the advertiser has absolutely no grounds for believing that its claim is true.”¹²

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Novartis

These two incipient Lanham Act doctrines came together recently in *Novartis*—an advertising dispute between rival makers of heartburn relief products Mylanta (made by Johnson & Johnson-Merck) (J&J), and Maalox (made by Novartis). Under prior decisions and FDA rules, sellers of antacids are permitted to advertise their products' degree of "strength" based on their FDA acid neutralization ratings, but may not quote the ratings directly or otherwise imply that greater strength means greater efficacy in heartburn relief.

J&J claimed in advertisements that its new Mylanta Night Time Strength was "made just for" or "specially formulated for" night-time heartburn, and was "strong enough to get rid of even your toughest night-time heartburn." Novartis argued that the use of "night time" to designate the "strength" of Mylanta Night Time Strength communicated to consumers that there was a particular time of day during which Mylanta Night Time Strength was formulated to be most effective, and not just a level of medicinal strength. Novartis also asserted that J&J had overstepped the safe harbor of advertising the

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"strength" of antacid heartburn remedies and was improperly linking the strength of Mylanta Night Time Strength to a claim of greater efficacy in relieving heartburn symptoms. The federal district court in New Jersey held that J&J had not literally claimed either that Mylanta Night Time Strength's higher strength was associated with greater efficacy or that the product was especially effective at night, but that "the 'Nighttime Strength' designation necessarily communicates that MNTS is in fact specifically or especially suited for night time use," and was more effective in general at relieving heartburn.¹³ The court enjoined J&J from using the Night Time Strength name.¹⁴

In dicta, the court also addressed the substantiation for J&J's general efficacy claim. Noting that "J&J admits that it is unaware 'of *any* data from controlled clinical studies that proves, one way or the other, whether antacids with higher ANC ratings provide better heartburn relief than antacids with lower ANC ratings,'" ¹⁵ the court rejected J&J's reliance on the general pharmacological principle of "dose response," i.e., that more active ingredient generates more effect. The court wrote that, "[b]ased on the Third Circuit's insight [in *Sandoz*], it would be plausible that here, J&J's claim that MNTS remedies night time heartburn would be

per se false given that the advertiser relies on pure speculative hypothesis and does not appear to have 'at least some semblance of support' for its claim."¹⁶

J&J appealed. The Third Circuit affirmed the district court and also articulated legal standards for the application of both the necessary implication and unsubstantiated claims doctrines.

The court set forth the following standard in determining whether a claim is necessarily implied:

- A claim is said to be necessarily implied when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated; and
- The claim must be unambiguous in that the consumer will unavoidably receive the message; that is, the greater the degree to which a message relies upon the viewer or consumer to integrate its components to reach the claim, the less likely it is that the claim is necessarily implied.¹⁷

In other words, if there is more than one plausible interpretation of the challenged advertisement, a claim cannot be *necessarily* implied. In those instances, the implied claim would still have to be established through extrinsic evidence.

On the question of completely unsubstantiated claims, the court held that, "although the plaintiff normally has the burden to demonstrate that the defendant's advertising claim is false, a court may find that *a completely unsubstantiated advertising claim* by the defendant is *per se false* without additional evidence from the plaintiff to that effect."¹⁸ This part of the decision is especially significant in that it appears to shift part of the Lanham Act burden of proof to the defendant, requiring the defendant to come forward with some semblance of support for its advertising claims. If challenged on substantiation, a Lanham Act defendant (in the Third Circuit, at least) apparently now has to prove that its claims are at least minimally substantiated. If the defendant makes such a showing, the burden shifts back to the plaintiff to prove that the claim is false.

However, the court did not articulate how much substantiation is necessary to satisfy the defendant's initial burden. Instead, the court pointed out that "J&J does not argue or present any evidence" in support of its advertising claims, and "[o]n appeal, J&J has not directed our attention to any evidence in the record that was overlooked by the District Court."¹⁹

Implications of the *Novartis* Decision

The necessary implication doctrine has been a clearly developing theory in Lanham Act jurisprudence, for which *Novartis* has provided the most extensively reasoned argument and legal standard. In cases where a consumer will "unavoidably" receive a false but unstated message from an advertisement, a court may interpret the claim as if it were literally false without introducing a consumer survey or other extrinsic evidence to prove the plaintiff's alleged interpretation. A court may even rule that a claim has a necessary

implication *in spite of* consumer survey evidence suggesting that the claim is ambiguous or has alternative meanings, as was done in *Novartis*.²⁰

In *Pharmacia Corp. v. GlaxoSmithKline Consumer Healthcare, L.P.*,²¹ Pharmacia and GlaxoSmithKline (GSK) sued each other regarding advertising of nicotine “patches” to aid smoking cessation. The court preliminarily enjoined portions of both parties’ advertising, based explicitly on the *Novartis* theory that completely unsubstantiated claims are to be deemed false. The necessary implication doctrine was also crucial to the court’s rulings, demonstrating how these two principles can interact.

Pharmacia challenged a GSK television advertisement comparing the attributes of its NicoDerm CQ patch, which can be worn for 16 or 24 hours at the user’s option, to those of Pharmacia’s Nicotrol patch, which can only be worn for 16 hours. After highlighting this feature, the advertisement stated that “more doctors prefer the patch that gives you the choice.” The court concluded that the claim necessarily implied that “doctors prefer NicoDerm over Nicotrol because NicoDerm offers consumers a 16-or-24-hour choice.”²²

In analyzing whether the claim was false, the court noted that some of the five studies proffered by GSK did in fact demonstrate that doctors preferred NicoDerm CQ over Nicotrol generally, and that one of the other studies demonstrated that more doctors preferred a patch that offered a 16-or-24-hour option.²³ But according to the court, these studies did not substantiate the claim under the *Novartis* standard because, while the tests might substantiate premises on which the claim was based (doctors prefer NicoDerm and doctors prefer a 16-or-24-hour patch), no single test addressed whether doctors preferred NicoDerm over Nicotrol *because* of NicoDerm’s 16-or-24 hour choice. Because it found that GSK did not produce any evidence supporting this implied claim, the court held that the claim was “completely unsubstantiated” and *per se* false without reference to “any additional evidence from the plaintiffs” to that effect.

For its part, GSK challenged Pharmacia’s television commercial for the Nicotrol patch. At the beginning of this commercial, a man was shown tossing restlessly in bed and suddenly awakening, accompanied by the voiceover, “Trying to beat cigarettes? Having trouble sleeping? You’re probably using NicoDerm.” Switching to a shot of the Nicotrol product, the voiceover continued, “The new step-down patch from Nicotrol was designed to let you sleep.” Relying again on the *Novartis* doctrine of necessary implication, the court held that, “[in] context, there is only one message consumers can take away from the statement ‘Nicotrol was designed to let you sleep’”: the unambiguous, necessarily implied claim that Nicotrol helps you sleep better than NicoDerm.”²⁴

The court found the “design” claim to be entirely unsupported and “*per se* false,” noting that “[t]he Lanham Act forbids completely baseless claims as well as demonstrably false ones.”²⁵ The court also found the trouble-sleeping claim to be *per se* false on the same basis, noting that “before a

Lanham Act complainant has a burden to prove a claim is false, the alleged violator must be able to point to some evidence supporting the veracity of the claim.”²⁶

Even more recently, in *Bellsouth Telecommunications, Inc. v. Hawk Communications, LLC*,²⁷ the court endorsed the *Novartis* completely-unsubstantiated theory—becoming the first court in the Eleventh Circuit to do so—in finding to be *per se* false the claim of an accelerated dial-up Internet service provider that its dial-up service was faster or as fast as DSL-based Internet service. The defendant in *Bellsouth*, like GSK in *Pharmacia*, proffered studies in support of its claim. The court discussed and dismissed each of these studies on various relevance and/or methodological grounds before reaching its conclusion that the claim was “completely unsubstantiated.”

After *Novartis*

Pharmacia and *Bellsouth* are the first cases to consider how much substantiation, beyond none at all, the defendant needs in order to shift the burden of proving falsity to the plaintiff. In finding that the defendants offered “not one scintilla of evidence” in support of their claims,²⁸ the courts in these cases seemed to discount indirect evidence that could have given the defendants some bases for their claims. This suggests that courts may not limit the *Novartis* rule to the literal zero-substantiation case, in which an advertiser does not proffer any evidence whatsoever in support of the claim, or candidly admits that it has no such evidence. The *Pharmacia* and *Bellsouth* courts showed a willingness to evaluate the *sufficiency* of proffered substantiation, even though they concluded that the sum of this substantiation did not amount to a “scintilla.”

In the wake of these decisions, advertisers should understand that the *Novartis* standard may require that they produce some *direct*, rather than indirect or inferential supporting evidence, or perhaps a greater quantum of indirect evidence.²⁹

Under prior case law, an advertiser might have felt reasonably secure from a Lanham Act challenge even if it had no substantiation for an advertising claim. The traditional rule had been that the plaintiff has the burden to prove the falsity of advertising claims. An advertiser might, for example, view a claim as needing no substantiation because it is a vague statement of general superiority and therefore not actionable as “puffing.”³⁰ Or an advertiser may have some substantiation for what it believes its claims mean, but not for other possible implied meanings. If a court disagrees with the advertiser’s view of that claim is merely puffing, or disagrees with the meaning of its claim, the advertiser may find itself facing a substantiation challenge that it did not anticipate. In *Pharmacia v. GlaxoSmithKline*, both Pharmacia and GSK were held accountable for failing to substantiate claims that they asserted they were not even making.

Based on the *Pharmacia v. GlaxoSmithKline* and the *BellSouth v. Hawk Communications* decisions, an advertiser

may not only make wholly unsubstantiated literal advertising claims at its own peril, but also risks Lanham Act liability if it has no substantiation—or perhaps *not enough* substantiation—for (1) any literal and unambiguous interpretation of its claims that a court may adopt, or (2) any implied claims that can be inferred from its literal claims, whether established by extrinsic evidence or by the court under the *Novartis* “necessary implication” doctrine. ■

¹ 290 F.3d 578 (3d Cir. 2002).

² 15 U.S.C. § 1125(a).

³ See, e.g., *Johnson & Johnson-Merck Consumer Pharms. Co. v. Rhone-Poulenc Rorer Pharms.*, 19 F.3d 125, 135 (3d Cir. 1994).

⁴ *Coca-Cola Co. v. Tropicana Prods., Inc.*, 690 F.2d 312, 317 (2d Cir. 1982).

⁵ *American Home Prods. Corp. v. Johnson & Johnson*, 577 F.2d 160, 167 (2d Cir. 1978).

⁶ 661 F.2d 272, 273–75 (2d Cir. 1981).

⁷ 673 F. Supp. 1190, 1193–94 (S.D.N.Y. 1987).

⁸ No. 81 Civ. 731-CSH, 1982 WL 121559 (S.D.N.Y. June 9, 1982).

⁹ 204 F.3d 87 (3d Cir. 2000).

¹⁰ See, e.g., *Procter & Gamble Co. v. Chesebrough-Pond's Inc.*, 747 F.2d 114, 119 (2d Cir. 1984).

¹¹ 902 F.2d 222 (3d Cir. 1990).

¹² *Id.* at 228 n.7.

¹³ 129 F. Supp. 2d 351,363 (D.N.J. 2000).

¹⁴ *Id.* at 363–64.

¹⁵ *Id.* at 361.

¹⁶ *Id.* at 362.

¹⁷ *Id.* at 590.

¹⁸ *Novartis*, 290 F.3d at 586–87.

¹⁹ *Id.* at 590.

²⁰ *Id.* at 601 (J. Bright, dissenting).

²¹ 292 F. Supp. 2d 594 (D.N.J. 2003), and 292 F. Supp. 2d 611 (D.N.J. 2003).

²² 292 F. Supp. 2d at 606.

²³ *Id.* at 607.

²⁴ *Id.* at 618.

²⁵ *Id.* at 620.

²⁶ *Id.* at 621.

²⁷ Civ. Action 1:04-CV-280-MHS (N.D. Ga. Apr. 12, 2004) (order granting preliminary injunction).

²⁸ *Pharmacia*, 292 F. Supp. 2d at 607.

²⁹ An alternative interpretation of the *Pharmacia* court's decision is that the court interpreted the claim, “Doctors prefer the patch that offers a choice,” as an establishment claim—that is, an explicit claim that a study of doctors produced the result that the doctors preferred the patch offering a choice. This would not implicate the *Novartis* substantiation doctrine, but only the settled rule concerning establishment claims, discussed above. However, the court did not allude in its decision to the claim being an establishment claim, nor would it have been necessary to dismiss GSK's studies as providing not even a “scintilla” of support for the claim if the court were analyzing the claim as an establishment claim.

³⁰ See *Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 227 F.3d 489, 496 (5th Cir. 2000); *Lipton v. Nature Co.*, 71 F.3d 464, 474 (2d Cir. 1995).

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