PRECEDENTIAL

Filed May 14, 2002

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 01-1154

NOVARTIS CONSUMER HEALTH, INC.

v.

JOHNSON & JOHNSON-MERCK CONSUMER
PHARMACEUTICALS CO.,
Appellant

Appeal from the United States District Court
for the District of New Jersey
D.C. No. 00-cv-05361
District Judge: Honorable William G. Bassler

Argued: March 14, 2001

Before: RENDELL, AMBRO, and BRIGHT,*
Circuit Judges

(Opinion filed: May 14, 2002)

Steven A. Zalesin (Argued)
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Counsel for Appellant

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* The Honorable Myron H. Bright, Senior Circuit Judge, United States Court of Appeals for the Eighth Circuit, sitting by designation.

Bruce P. Keller (Argued)
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OPINION OF THE COURT

AMBRO, Circuit Judge:

This is an appeal from a preliminary injunction entered by the United States District Court for the District of New Jersey against the Appellant, Johnson & Johnson-Merck Consumer Pharmaceuticals Co. ("J&J"). The Appellee, Novartis Consumer Health, Inc. ("Novartis"), moved the District Court for a preliminary injunction pending a trial

on the merits of its claim that J&J engaged in false advertising in violation of section 43(a) of the Lanham Act, 15 U.S.C. S 1125(a). The District Court granted the motion and enjoined J&J from using "Mylanta Night Time Strength" as the designation for its over-the-counter liquid heartburn medicine that competes directly with the Maalox line of liquid antacid products marketed by Novartis. The District Court had jurisdiction to enter the injunction pursuant to 28 U.S.C. S 1331. We have appellate jurisdiction pursuant to 28 U.S.C. S 1292(a)(1). For the reasons noted below, we affirm the District Court's decision to enter the preliminary injunction.

I. Background Facts & Procedural History

The parties produce over-the-counter drugs that treat heartburn. Heartburn is caused by stomach acid that backs up ("refluxes") into the esophagus. This acid reflux is likely to occur shortly after a meal, when the stomach produces high volumes of acid to begin the digestion process. Heartburn also occurs more frequently at night because acid more easily refluxes into the esophagus when a person is lying down and because, during sleep, the body naturally secretes acid that raises the stomach pH levels. According to a Gallup Organization Study for the American

Gastroenterological Association entitled "Understanding Heartburn In America," of the 60 million Americans who experience heartburn, almost 80% experience symptoms at night. With this market, producers of heartburn remedies vigorously compete to capture sales among nighttime heartburn sufferers.

There are three types of heartburn remedies currently on the over-the-counter market. Stomach acid "blockers" such as Pepcid AC and Zantac 75 treat heartburn by reducing the production of stomach acid for approximately eight to twelve hours. "Rafting agents" such as Gaviscon form a foam layer on top of the stomach contents so that, when reflux occurs, the foam backs up into the esophagus rather than the acidic gastric contents. The foam barrier lasts for about three to four hours. Finally, there are "antacids" that work by neutralizing excess acid already present in the stomach. Antacids provide fast relief, but the effects wear off within thirty to sixty minutes because antacids have no effect on the production of new stomach acid. Novartis produces and markets the Maalox brand of antacids while J&J produces and markets the Mylanta brand.

The strength of an antacid is measured by the product's ability to neutralize acid in a beaker (i.e.,"in vitro") over a fifteen minute period. This acid neutralization capacity ("ANC") does not, however, represent an antacid's effectiveness in the human body (i.e., "in vivo"), or its ability to relieve the symptoms of acid reflux, because other factors -- such as rate of gastric emptying, rate of secretion of acid, and degree of mixing between the antacid and

gastric contents -- all bear on the antacid's efficacy. See Johnson & Johnson-Merck Consumer Pharm. Co. v. Rhone-Poulenc Rorer Pharm., Inc., 19 F.3d 125, 127 (3d Cir. 1994) (hereinafter "Rorer"). Although ANC ratings may be provided to physicians, the FDA prohibits manufacturers of antacid products from listing ANC scores on their product labels because it believes that consumers might mistake the ANC rating as a measure of effectiveness in vivo. See 38 Fed. Reg. 31264 (Nov. 12, 1973). However, under Rorer manufacturers are permitted to categorize and label antacids by comparative strengths. Rorer, 19 F.3d at 136.

J&J announced the introduction of "Mylanta Night Time Strength" ("MNTS") in March 2000 and began shipping in June. After its introduction, the two brands of antacids were available in the following strengths:

MAALOX:	MYLANTA:
Regular Strength	Regular Strength
Extra Strength	Extra Strength
Maximum Strength	Night Time Strength

MNTS has more active ingredients per teaspoon than other antacids. It has 500 milligrams of each of aluminum hydroxide and magnesium hydroxide while Maximum Strength Maalox has 500 milligrams of aluminum hydroxide and 450 milligrams of magnesium hydroxide. MNTS's ANC rating is also higher than all other antacid products. Its ANC rating is roughly 7% higher than Maximum Strength Maalox and 25% higher than Extra Strength Mylanta.1

In August 2000, J&J launched a national advertising campaign in support of MNTS. In nationally disseminated television commercials, J&J claimed that MNTS was"made just for" nighttime heartburn, that it was "the strongest antacid you can get," and that it was "something strong enough to get rid of even your toughest nighttime heartburn." The announcer then stated, "Go ahead, enjoy your night," while the words "New Mylanta Nighttime" appeared on the screen. The disclaimer "does not contain sleep aid" also briefly appeared on the screen, allegedly in letters that were minuscule relative to the size of the phrase "The Strongest Antacid."

J&J disseminated other promotional materials as well. In August 2000, J&J published a "free standing insert" print advertisement in Sunday newspapers nationwide that advertised MNTS as the "solution for heartburn at its worst," and as having been "specially formulated for Night Time heartburn." In small letters, the lower left-corner of

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1. MNTS's price is commensurately higher than that of Extra Strength Mylanta (as indeed is Maalox Maximum Strength compared to its Extra Strength antacid) though, as noted above, the duration of effective relief in each product is essentially the same.

the advertisement stated "does not contain a sleep aid." J&J's website purportedly boasted that MNTS "is the first and only antacid formulated specifically to relieve your toughest nighttime heartburn," and promised that the product would deliver a restful night's sleep because "you may know you have to be up early the next day, but your stomach doesn't."

Shortly after the national advertising campaign began, Novartis expressed its objections to J&J over the MNTS name and the advertising claims made in the campaign. In response, J&J decided to revise its television commercial and website to eliminate many of the disputed claims. The revised television commercial for MNTS pictured a woman sitting down on a couch after dinner. The announcer stated: "What a time for really tough heartburn. Good thing there's something just as tough." MNTS was then described as "the strongest antacid you can get" that is"made strong to work on even tough nighttime heartburn . . . fast." As the commercial closed, the woman had her eyes closed and her head tilted back on the sofa.

The revised website stated, "Do you experience your heartburn at night? 76% of heartburn sufferers say they do. If you do, here is great news for you! Introducing MYLANTA Nighttime Strength. MYLANTA Nighttime Strength begins neutralizing acid on contact. In fact, no other antacid is faster or stronger. And MYLANTA does not contain a sleep aid so you can sleep naturally at night. MYLANTA Nighttime Strength works on even your tough nighttime heartburn."

On October 31, 2000, Novartis filed a complaint pursuant to section 43(a) of the Lanham Act, 15 U.S.C. S 1125(a), and the New Jersey Consumer Fraud Act, N.J.S.A.S 56:8-1, et seq., alleging that J&J's advertisements regarding MNTS and the name and packaging of the product itself are false and misleading. On December 8, 2000, Novartis filed a motion for a preliminary injunction pending the outcome of its Lanham Act claims.2 In both its complaint and its

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2. Novartis did not argue for a preliminary injunction pending the outcome of its claims under the New Jersey Consumer Fraud Act. See Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co., 129 F. Supp. 2d 351, 355 n.2 (D.N.J. 2000).

motion for preliminary injunction, Novartis alleged that the MNTS name and associated packaging and advertisements were false because, inter alia, they communicated, either explicitly or implicitly, the following false or misleading claims:

(1) MNTS is "specially formulated," and therefore better than other antacids, at relieving night time heartburn; and

(2) MNTS provides heartburn relief throughout the night.

Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co., 129 F. Supp. 2d 351, 358 (D.N.J. 2000).

Neither party requested discovery. The District Court held oral argument on December 18 and 19, 2000. The Court then issued an opinion and order on December 22, 2000, granting Novartis' motion and enjoining J&J from:"(1) marketing and disseminating Mylanta Night Time Strength under that name; (2) using the designation 'Night Time' or 'Night Time Strength' on any antacid product;[and] (3) otherwise claiming, either explicitly or implicitly, in any packaging, advertising, or other promotional materials, that Mylanta Night Time Strength is specially formulated for night time heartburn, provides all night relief, and/or possesses a strength that correlates with its efficacy." 129 F. Supp. 2d at 369. The District Court further ordered that Novartis post a security bond in the amount of $1,000,000 by December 29, 2000.3 Id. J&J filed a timely notice of appeal.4

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3. The bond amount was later increased to $9,180,000 by order of the District Court entered on February 22, 2001.

4. Novartis urges us to conclude that the appeal is moot because, when applying to this Court for an emergency stay of the preliminary injunction, J&J unequivocally swore that it would have to abandon the MNTS product line if the injunction remained in place for as much as six weeks, a period that expired on February 2, 2001. By order entered on January 22, 2001, a panel of this Court denied the stay because, inter alia, it did not credit J&J's assertion that it would suffer irreparable harm before it could complete the appeal process. It would be

II. Discussion

We review the District Court's ultimate decision to grant a preliminary injunction for abuse of discretion. See, e.g., Sandoz Pharm. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 226 (3d Cir. 1990). However, an injunction is"an extraordinary remedy, which should be granted only in limited circumstances." Instant Air Freight Co. v. C.F. Air Freight, Inc., 882 F.2d 797, 800 (3d Cir. 1989). In exercising its discretion, the District Court must be convinced that the following factors favor granting preliminary relief: (1) the likelihood that the moving party will succeed on the merits; (2) the extent to which the moving party will suffer irreparable harm without injunctive relief; (3) the extent to which the nonmoving party will suffer irreparable harm if the injunction is issued; and (4) the public interest. Clean

Ocean Action v. York, 57 F.3d 328, 331 (3d Cir. 1995). The District Court's predicate findings of fact are reviewed for clear error, and its conclusions of law receive plenary review. Sandoz, 902 F.2d at 226.

On appeal, the parties have made arguments pertaining to the District Court's findings on all four factors above. Additionally, J&J has argued that the injunction issued by the District Court violates the First Amendment because it is overbroad. We address first whether the District Court properly found that Novartis would be likely to succeed on the merits. We then turn to the Court's findings regarding irreparable harm, balancing of harms, and the public interest. Finally, we focus on whether the injunction issued is overbroad.

A. Likelihood of Success on the Merits

Novartis brought its underlying claim against J&J pursuant to S 43(a) of the Lanham Act, which prohibits

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inequitable now to find the appeal moot based on that estimation of irreparable harm that had previously been rejected. We therefore decline to apply a doctrine of judicial estoppel to find this appeal moot. See SunAmerica Corp. v. Sun Life Assur. Co. of Canada , 77 F.3d 1325, 1332 (11th Cir. 1996) (declining to apply doctrine of judicial estoppel because "the District Court was not fooled" by defendant's representations in its application for a stay of preliminary injunction).

false advertising in interstate commerce. Section 43(a) provides in pertinent part:

> (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. S 1125(a). 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. Castrol Inc. v. Pennzoil Co., 987 F.2d 939, 943 (3d Cir. 1993) ("a plaintiff must prove either literal falsity or consumer confusion, but not both") (emphasis in original). We will address Novartis' allegations under each theory.

1. Did J&J Disseminate Literally False Claims Re "Mylanta Night Time Strength"?

If a plaintiff proves that the challenged commercial claims are "literally false," a court may grant relief without considering whether the buying public was actually misled. Rorer, 19 F.3d at 129. In analyzing whether an advertisement or product name is literally false, a court must determine, first, the unambiguous claims made by the advertisement or product name, and second, whether those claims are false. Clorox Co. v. Proctor & Gamble Commercial Co., 228 F.3d 24, 34 (1st Cir. 2000). A "literally false" message may be either explicit or "conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated." Id. at 35. Regardless, only an unambiguous message can be literally false. "The greater the degree to which a message relies upon the viewer or consumer to integrate its components and draw the apparent conclusion, however, the less likely

it is that a finding of literal falsity will be supported." United Indus. Corp. v. Clorox Co., 140 F.3d 1175, 1181 (8th Cir. 1998); see Warner-Lambert Co. v. BreathAsure, Inc., 204 F.3d 87, 96 (3d Cir. 2000); Castrol, 987 F.2d at 946; see also Cuisinarts, Inc. v. Robot-Coupe Int’l Corp., 1982 WL 121559, at *2 (S.D.N.Y. June 9, 1982).

The District Court found that the MNTS product name and/or advertising conveyed two messages that are literally false by necessary implication: (1) that the MNTS product is superior to other products in providing nighttime relief, 129 F. Supp. 2d at 360-61; and (2) that the product is specially formulated for nighttime relief, id. at 364. We will discuss each of these messages in turn after briefly reviewing the cases where courts have found a false message necessarily implied from a product’s name or advertisement.

The common theme in these cases is a finding, based on a facial analysis of the product name or advertising, that the consumer will unavoidably receive a false message from the product’s name or advertising. When consumer deception can be determined by examining the challenged name or advertising on its face, the plaintiff is excused from the burden of demonstrating actual deception through the use of a consumer survey.

For example, in BreathAsure, the defendant claimed that its capsules would freshen breath when swallowed, and that they were more effective at freshening breath than other products like gum, mints, and mouthwash because the capsule would "[f]ight the problem at its source." BreathAsure, 204 F.3d at 89. During the course of litigation it became clear that the capsules had no effect on bad breath because in fact bad breath originates in the mouth, not in the stomach. See id. at 90. The District Court found that the BreathAsure product claim was therefore misleading because it "implie[d] assurance where there [was] no basis for it," and we concurred. Id. at 96. In addition, because "[t]he name [BreathAsure] falsely tells the

consumer that he or she has assurance of fresher breath . . .," id. at 97, we enjoined use of that name.

In Castrol, the defendant's advertisements claimed that motor oil viscosity breakdown leads to engine failure. The

advertising also claimed that the defendant's brand of motor oil outperformed any leading motor oil against viscosity breakdown. We affirmed the District Court's conclusion that these two claims taken together necessarily implied that "Pennzoil outperforms the other leading brands with respect to protecting against engine failure, because it outperforms them in protecting against viscosity breakdown, the cause of engine failure." Castrol, 987 F.2d at 947. Because this implied message of superior protection against engine failure was false, the defendant, Pennzoil, was permanently enjoined from using these challenged advertisements. See id. at 948.

In Cuisinart, the defendant's advertisement stated: "Robot-Coupe: 21, Cuisinart: 0. WHEN ALL 21 OF THE THREE-STAR RESTAURANTS IN FRANCE'S MICHELIN GUIDE CHOOSE THE SAME PROFESSIONAL MODEL FOOD PROCESSOR, SOMEBODY KNOWS THE SCORE-SHOULDN'T YOU?" Cuisinart, 1982 WL 121559, at *2. The District Court for the Southern District of New York found that the advertisement necessarily implied a message that both Robot-Coupe and Cuisinart built professional model food processors and that restauranteurs presented with two existing alternatives had chosen the Robot-Coupe model. This implied message was false because Cuisinart did not in fact make a professional model food processor. The Court therefore issued a preliminary injunction prohibiting the use of this advertisement. See id. at *2-3.

As noted already, the District Court here found that the MNTS name and advertising necessarily imply a claim that MNTS provides superior relief for nighttime heartburn. 129 F. Supp. 2d at 359-60. It provided the following reasons for this determination:

> While night time sufferers may indeed be likely to opt for a higher strength antacid, the "Night Time Strength" designation does more than simply promise a "higher" strength; it claims that its strength corresponds to effectiveness such that it can even remedy night time heartburn, the symptoms of which tend to be "severe" or "moderate."
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> Consistent with the label, the television commercial promises that MNTS is "made strong to work on even

> tough nighttime heartburn." J&J's website also provides that MNTS "works on even your tough

> nighttime heartburn." Despite the FDA conclusion that the ANC rating might confuse the public, the MNTS product name and advertising play upon and reinforce the perception that greater strength provides relief for more severe heartburn, which often can occur at night. In other words, MNTS is named and advertised to suggest that its strength gives it the ability to fight greater heartburn. Therefore, J&J's advertisements necessarily imply a claim of superior relief.

Id. at 360.

In short, the District Court found that the MNTS name and advertising would "play upon" and "reinforce" consumer perceptions and "suggest" that its strength correlates to greater efficacy. The very use of these verbs is instructive. When a Court considers whether a product's name and advertising are misleading, it may examine consumer survey evidence demonstrating that they"play upon" or "reinforce" consumer perceptions, or otherwise "suggest" false messages. By contrast, when a Court considers whether a message is necessarily implied from the product's name and advertising, it must determine whether the false message will necessarily and unavoidably be received by the consumer.

In this case, consumers will only receive a message of superior relief from the MNTS name and advertising if they assume that a product that provides "Night Time" relief is more effective than a product that provides "Extra Strength" or "Maximum" relief. The MNTS name and advertising alone do not require that this inference will be made. The District Court therefore clearly erred in finding that a message of superior efficacy is necessarily implied from the MNTS name and advertising. Instead, Novartis should have been required to prove through a consumer survey that the name and advertising actually misled or had a tendency to mislead consumers into believing that the product provided nighttime heartburn relief superior to any other product in the market.5

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5. Because we hold that a message of superior relief is not necessarily implied from the MNTS name and advertising, we need not address

Although the District Court erred in finding that a message of superior efficacy is necessarily implied from the MNTS name and advertising, it did not err when it found that the MNTS name is literally false by necessary implication because it conveys the unambiguous message that the product is specially formulated to relieve nighttime heartburn. The Court found that "the product name Mylanta 'Night Time Strength' necessarily implies a false message . . . that it possesses a quality that is particularly efficacious for those suffering from heartburn at night." 129 F. Supp. 2d at 364. It reasoned as follows:

> Here, by naming its product "Night Time Strength," J&J maintains that its goal was to emphasize the strength of the product, rather than its duration. Clearly, the designations such as "regular,""extra," or "maximum" would have sufficiently described the level of strength of MNTS. The use of "nighttime," however, is as Novartis points out, a temporal designation communicating that the product is effective in remedying "nighttime" heartburn. Cf. Bristol-Myers Squibb Co. v. McNeil-P.P.C., Inc., 973 F.2d 1033, 1040-41 (2d Cir. 1992) ("PM" designation immediately conveys night time use). Indeed J&J admits that MNTS is "targeted exclusively to the needs of nighttime sufferers." Miller Decl., at P 17.

Id. We agree with the District Court that the term "nighttime" conveys a different meaning than the terms "regular," "extra," and "maximum." The latter terms describe different degrees of strength and are descriptions that are arguably supported by evidence of different ANC ratings.6 By contrast, the "nighttime" designation describes

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whether that message is a false one. Were we to have reached this issue, however, we would have agreed with the District Court that a message of superior relief is false. Declarations from experts in both Rorer and the current litigation explain that a slightly higher ANC rating cannot support a message of superior efficacy. See Castell Decl. PP 6-11; Albrecht Decl. PP 10-11.

6. As we noted supra n.5, we do not mean to say that differences in ANC rating can support claims of greater efficacy. From our holding in Rorer, however, it appears that sufficient differences in ANC rating may support a claim of greater strength, i.e., regular, extra, and maximum strengths. Rorer, 19 F.3d at 136-37.

not a degree of strength, but rather a time when the product will be effective. The phrase "nighttime strength" therefore necessarily conveys a message that the MNTS product is specially made to work at night. We cannot say that the District Court's finding to that effect is clearly erroneous.

We also cannot say that the District Court clearly erred in finding that this message is false. J&J argues that the Court improperly shifted the burden of proof from Novartis to J&J when considering this question. It points out that the plaintiff, Novartis, "bears the burden of showing that a challenged advertisement is false or misleading, not merely that it is unsubstantiated by acceptable tests or other proof." Sandoz, 902 F.2d at 228. While this is generally the case, in Sandoz we specifically declined to answer "whether completely unsubstantiated advertising claims violate the Lanham Act absent proof that consumers are actually misled by this lack of substantiation." Id. at 228 n.7 (emphasis in original). We explained that

> [i]n such a case, 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. A Lanham Act plaintiff may be permitted to presume that consumers expect advertisers to have at least some semblance of support for their publicly-disseminated claims. However, since that is not the question before us, we do not decide whether a completely unsubstantiated claim is per se false or whether a Lanham Act plaintiff can presume that a defendant must have some substantiation for its advertising claims.

Id.

Today we decide what we left open in Sandoz. We hold 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.

Here, the District Court observed that "J&J does not argue or present any evidence to show that MNTS was

specifically formulated for night time heartburn or that its product actually remedies heartburn at night more effectively than heartburn during the daytime." 129 F. Supp. 2d at 363. On appeal, J&J has not directed our attention to any evidence in the record that was overlooked by the District Court. We therefore conclude that the message of special formulation for nighttime relief that is necessarily implied from the MNTS name is a completely unsubstantiated advertising claim, and that the District Court did not clearly err by concluding that this claim is per se false.

2. Did J&J Disseminate Misleading Claims Re"Mylanta Night Time Strength"?

Absent a finding that an advertising claim is literally false, a plaintiff may still allege a successful Lanham Act cause of action by proving the following five elements by a preponderance of evidence:

> (1) that the defendant has made false or misleading statements as to his own product [or another's]; (2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; (3) that the deception is material in that it is likely to influence purchasing decisions; (4) that the advertised goods traveled in interstate commerce; and (5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc.

Rorer, 19 F.3d at 129 (alteration in original). The burden, as we pointed out already, rests with the plaintiff. Sandoz,

902 F.2d at 228.

As noted above, we believe the District Court properly concluded that Novartis is likely to succeed on the merits of its Lanham Act claim because the MNTS name necessarily implies the literally false message that the product is specially formulated for nighttime use. Alternatively, we would still affirm the determination that Novartis is likely to succeed on the merits because we agree that Novartis will likely be able to prove, through the use of a consumer survey, that the MNTS name and label mislead consumers into believing that the product provides all-night relief. See Rorer, 19 F.3d at 129-30; Sandoz, 902 F.2d at 228-29.

The District Court gave significant weight to the results of a consumer survey designed by Dr. Gerald L. Ford. See 129 F. Supp. 2d at 364-67. The Ford survey was conducted in what is called a "double blind" fashion during which both the respondents and the interviewers are unaware of the purpose of the survey or its sponsor. According to Dr. Ford, 432 respondents were split into two groups known as "cells." The first cell was asked to focus on the MNTS product line as it would likely appear in retail stores. The second cell served as a control group that was asked to focus on the Mylanta Extra Strength product. In the MNTS cell, approximately 30% of the respondents expressed their belief that MNTS provided relief that lasted the whole night. By contrast, less than 5% of the respondents in the control cell believed that Mylanta Extra Strength provides relief that lasts all night. After netting out this "noise,"7 the survey results indicated that a total of 25% of respondents received a message that the MNTS product provides all-night relief.

The District Court accepted this 25% figure as sufficient proof that the MNTS product name "deceive[s] a substantial portion of the intended audience." 129 F. Supp. 2d at 367. Indeed, this figure is higher than others that have been found sufficient to support a Lanham Act violation. See Rorer, 19 F.3d at 129, 134 n.14 (assuming without deciding that "[w]ith regard to what constitutes a substantial or significant number of consumers who are misled[,] . . . 20% would be sufficient"); see also Church & Dwight Co. v. S.C. Johnson & Son, 873 F. Supp. 893, 911 (D.N.J. 1994) (acknowledging that 21% to 34% would be sufficient); McNeilab, Inc. v. Am. Home Prods. Corp., 501 F. Supp. 517, 525, 527 (S.D.N.Y. 1980) (holding that 23% was sufficient).

J&J argues that the survey results were not credible because the survey contained leading or suggestive questions.8 The evidentiary value of a survey depends on its

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7. The responses of the control cell are called"noise." They represent the percentage of people that would have found a message of "all-night relief " irrespective of the labeling claim.

8. The Ford survey contained, in part, the following questions:

underlying objectivity as determined through many factors, such as "whether [the survey] is properly'filtered' to screen out those who got no message from the advertisement, whether the questions are directed to the real issues, and whether the questions are leading or suggestive." Johnson & Johnson-Merck Consumer Pharm. Co. v. SmithKline Beecham Corp., 960 F.2d 294, 300 (2d Cir. 1992). A survey is "not credible if it relies on leading questions which are 'inherently suggestive and invite guessing by those who did not get any clear message at all.' " Rorer , 19 F.3d at 134.

Dr. Ford's declaration states that the survey is objective because a full filter question was used (Q7.0) that asked: "[B]ased just upon your review, does the labeling on this product communicate anything . . . about how long this product will provide relief?" He declares that"[o]nly

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Q6.0: Based just upon your view, what is the main message communicated by the labeling on this product?

Q6.1: (asked only if "yes" to question Q6.0): What other messages, if any, are communicated by the labeling on this product?

Q6.2: What other messages, if any, are communicated by the labeling on this product? (same as question Q6.1)

Q7.0: Again, based just upon your review, does the labeling on this product communicate anything to you about how long this product will provide relief?

Q7.1 (asked only if "yes" to question Q7.0): What does the labeling communicate to you with regard to how long this product will provide relief?

Q7.2: Why do you say that?

Q7.3: Again, based just on your review, does the labeling on this product communicate anything to you about how long, in hours, this product will provide relief?

Q7.4 (asked only if "yes" to question Q7.3): What does the labeling communicate to you with regard to how long, in hours, this product will provide relief? Why do you say that?

Q7.5: Why do you say that?

129 F. Supp. 2d at 365.

respondents who received such a message were asked follow-up questions to determine precisely what message about duration they received." The follow-up questions were

therefore, in his view, not misleading.

However, J&J argues that the Ford survey is improper because the filter question itself was suggestive and misleading. It maintains that the survey presented respondents with a leading question about the product's duration of relief when the subject's responses to the first three questions (Q6.0, Q6.1, Q6.2) demonstrated that they had been left with no impression about how long the product would work. In short, J&J is arguing that the filtering was applied too late, and should have occurred after Q6.2, not after Q7.0.

In Rorer, we affirmed the District Court's decision to ignore survey results that "suffered from repetitive and leading questions and no filter mechanism." 19 F.3d at 135 (internal quotations omitted). The questions asked in that survey were as follows:

> 2a. What ideas did the advertiser try to get across about Maalox tablets in the commercial?
>
> 2b. What other ideas did they try to get across?
>
> 2c. What did they show in this commercial about Maalox tablets? What else? Anything else?
>
> 3a. In the commercial you just saw, they said Maalox tablets are the strongest. What does that mean to you?
>
> 3b. What is the commercial saying that Maalox tablets are strongest at doing?
>
> 5a. The commercial you just saw contained the statement, "Your doctor will tell you they're the strongest," referring to Maalox tablets. What does that statement mean to you?

Id. at 133 n.12. The District Court rejected results from questions 3a, 3b and 5a for the following reasons:

> The first "communication" questions [2a, 2b and 2c] were most probative. For the second series of

> questions, the survey failed to filter out those respondents who recorded a message of superiority on first viewing. By flagging Rorer's "strongest claim" ("in the commercial you just saw, they said Maalox is the strongest antacid there is. What does that mean to you?"), the "comprehension" question colored the answers. The next questions9 . . . were even more suggestive. By asking what ESMP [Extra Strength Maalox Plus] was strongest at doing, they called for the answer "relief." The technique of punctuating open-ended questions with repeated probes is questionable but did not discredit the responses to questions (2a),

(2b), and (2c).

Id. at 135. Thus, the District Court found that 2a, 2b, and 2c were not leading questions, but 3a, 3b and 5a were leading because a proper filter had not been applied to "screen out those respondents who recorded a message of superiority on first viewing." The comprehension question that should have served as a filter (question 3a) was itself a leading question.

We believe the filter in this case is qualitatively different from the one in Rorer. In Rorer, the comprehension question asked: "In the commercial you just saw, they said Maalox tablets are the strongest. What does that mean to you?" It was clearly flagging for the attention of the survey respondent the specific message in the commercial that the plaintiff alleged to be misleading (namely, that Maalox tablets are the strongest) and leading the respondent to answer that strength means something other than what it says. Respondents then answered that the strongest tablets would provide good relief or better relief, which is not true because strength does not correlate to efficacy. The respondents were led to convey that they had received this message of efficacy because, had they responded that "strongest means strongest" (the only answer that would

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9. Although the District Court referred to these"next questions" as "(3a) in the ‘Minty Tablets’ survey and (4) in the‘Firefighter’ survey," we believe that it meant to say (3b), not (3a), in the Minty Tablets survey. The Court was referring to the question that asked what Extra Strength Maalox Plus was strongest at doing, which was question (3b).

have been true), they would have believed that they were being unresponsive to the question.

By contrast, the comprehension question in the Ford survey (Q7.0) asked generally whether the product label communicated anything about how long the product would provide relief. It did not ask respondents to focus on the MNTS name before answering this question. Moreover, it did not lead them to respond that the product provides all-night relief. Although the question prompted respondents to comment on duration of relief, the respondents were free to say that the label communicated that the product provides fast-acting, short-term relief. To do so would not have been unresponsive to the question. The District Court therefore did not abuse its discretion by concluding that the Ford survey met a proper filter question threshold and could be accorded significant weight. Rorer, 19 F.3d at 134 ("the probative value of a consumer survey is a highly fact-specific determination and a court may place such weight on survey evidence as it deems appropriate"); see also Havana Club Holding, S.A. v. Galleon S.A., 203 F.3d 116, 131 (2d Cir. 2000) ("A district court has broad discretion concerning the weight of particular evidence, including consumer surveys such as those proffered here . . . ."), cert.

denied, 531 U.S. 918 (2000).10

In addition to challenging the objectivity of the Ford survey, J&J disputes the District Court's use of its results. J&J argues that the District Court's finding can only be supported by respondents who answered that the product name implied that there was all-night relief. However, only questions Q8.0, Q8.1, and Q8.211 ask the respondent to

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10. After rejecting J&J's argument that the survey was improper because it lacked proper filtering questions, the District Court stated that, in any event, any "bias that may have resulted from any leading questions was eliminated by the use of the control group." 129 F. Supp. 2d at 365 (citing Volkswagen Aktiengesellschaft v. Uptown Motors, No. 91 Civ. 3447 (DLC), 1995 WL 605605, at *4 (S.D.N.Y. May 11, 1995)). We refrain from adopting this position because we are uncertain whether the effects of asking leading questions without proper filtering may be greater on the MNTS test cell than the control cell.

11. Questions Q8.0, Q8.1, and Q8.2 of the Ford Survey read as follows:

evaluate the product name, whereas questions Q6.0 through Q7.5 ask the respondent to evaluate the product's label. Taking only the answers to questions Q8.0 through Q8.2 into account, less than 5% of respondents indicated that the product name communicates a message of all-night relief.

Nevertheless, we agree with Novartis that excluding all answers to questions Q6.0 through Q7.5 is too restrictive. Counting responses to all survey questions, 60% of the persons finding an 'all night' message referred to the name. It has already been established that 25% of respondents reported that they had received a message of all-night relief. If 60% of those respondents referenced the product name in their answers, it is fair to conclude that at least 15% of the total number of respondents (60% of 25% = 15%) derived a message of all-night relief from the product name, not the entire product label.

Assuming arguendo that only 15% of respondents received a message of all-night relief from the MNTS name, we need not vacate the injunction. Relying upon Coca-Cola Co. v. Tropicana Prods., Inc., 690 F.2d 312, 317 (2d Cir. 1982), the District Court observed that even a 15.5% figure would be sufficient to demonstrate a likelihood of substantial consumer confusion.12 129 F. Supp. 2d at 367. In Coca-Cola the consumer survey evidence demonstrated only 7.5% consumer deception. Coca-Cola Co. v. Tropicana Prods., Inc., 538 F. Supp. 1091, 1096 (S.D.N.Y.), rev'd, 690 F.2d 312 (2d Cir. 1982). There, the District Court denied

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> Q8.0: Again, based upon your review, does the name on this product communicate anything to you about the product?

Q8.1: (asked only if "yes" to question Q8.0): What does the name on this product communicate to you about the product?

Q8.2: Why do you say that?

12. Although the 15.5% figure that the District Court considered was proferred by J&J under a different rationale than the one used on appeal, the District Court did find that 15.5% would be sufficient to support a finding of substantial consumer confusion. 129 F. Supp. 2d at 367.

the injunction sought by the plaintiff because, inter alia, "a level of consumer confusion significantly below 15% does not indicate plaintiff ’s probable success on the merits." Id. On appeal, the Second Circuit reversed, finding that"a significant number of consumers would be likely to be misled." Coca-Cola, 690 F.2d at 317. 13

In an analogous context involving trademark cases under the Lanham Act, courts have held that survey evidence of 15% confusion is sufficient to demonstrate actual confusion. See Sara Lee Corp. v. Kayser-Roth Corp., 81 F.3d 455, 466-67 & n.15 (4th Cir. 1996) (15-20% confusion was sufficient to establish "actual confusion . . . to a significant degree"); Goya Foods, Inc. v. Condal Distribs., Inc., 732 F. Supp. 453, 457 n.7 (S.D.N.Y. 1990) (9-10% confusion was sufficient to demonstrate "meaningful evidence of actual confusion"). Likewise we believe that survey evidence demonstrating that 15% of the respondents were misled by the MNTS name is sufficient to establish the "actual deception or at least a tendency to deceive a substantial portion of the intended audience," Rorer, 19 F.3d at 129, necessary to establish a Lanham Act claim for false or misleading advertising under section 43(a). The District Court therefore did not clearly err when it found that Novartis would likely be able to establish this element of its Lanham Act claim.

To summarize, we affirm the District Court’s conclusion that Novartis would likely be able to succeed on the merits. Novartis will likely be able to prove that the MNTS name necessarily implies a false message that the product is specially formulated for nighttime relief, or alternatively that the MNTS name and label mislead a substantial portion of consumers to believe that the product provides all-night relief.

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13. Although the Second Circuit’s holding was made before Federal Rule of Civil Procedure 52(a) was amended to provide that a district court’s findings of fact cannot be set aside unless clearly erroneous, its holding nevertheless supports the view that a 7.5% figure could sustain a finding of substantial consumer confusion.

B. Irreparable Harm, Balance of Harms, and the Public Interest

Before granting a preliminary injunction, a district court must consider the extent to which the moving party will suffer irreparable harm without injunctive relief. Clean Ocean, 57 F.3d at 331. Here, the District Court found that Novartis would likely suffer irreparable harm if a preliminary injunction did not issue. See 129 F. Supp. 2d at 367-68. The Court further concluded that the balance of harms and the public interest weighed in favor of issuing the injunction. See id. at 368-69. J&J objects to each of these findings. All are reviewed for clear error, and the ultimate decision to grant the injunction is reviewed for abuse of discretion. See Sandoz, 902 F.2d at 226.

J&J argues that the District Court applied the wrong standard when evaluating whether Novartis had demonstrated irreparable injury. The District Court stated that "although the plaintiff need not come forward with specific evidence that the challenged claims actually resulted in some definite loss of sales, the plaintiff must establish that it has a reasonable basis for believing that it is likely to suffer injury as a result of the false advertising." 129 F. Supp. 2d at 367 (citing Johnson & Johnson v. Carter-Wallace, Inc., 631 F.2d 186, 190 (2d Cir. 1980), and BreathAsure, 204 F.3d at 95-96). J&J argues that whether the plaintiff has a "reasonable basis for believing that it is likely to suffer injury" is the standard for determining whether the plaintiff has standing to bring a false advertising claim seeking, as an ultimate remedy, that a permanent injunction be imposed against the defendant. It maintains that to satisfy the irreparable injury requirement for obtaining a preliminary injunction, Novartis was required to satisfy the additional burden of demonstrating "potential harm which cannot be redressed by a legal or an equitable remedy following a trial." Instant Air Freight, 882 F.2d at 801.

We agree that the cases relied upon by the District Court, Carter-Wallace and BreathAsure, discussed the standing requirement for a Lanham Act claim rather than the irreparable injury requirement for obtaining a preliminary injunction. Carter-Wallace, 631 F.2d at 190; BreathAsure,

204 F.3d at 95-96. In those cases, we reviewed district court decisions denying and granting, respectively, permanent injunctions after bench trials on the merits. See Carter-Wallace, 631 F.2d at 187-88; BreathAsure, 204 F.3d at 90-91. In both, we concluded that, as a matter of standing and as a substantive element of a Lanham Act violation, the plaintiff must demonstrate "a reasonable basis for the belief that the plaintiff is likely to be damaged as a result of the false advertising." Carter-Wallace, 631 F.2d at 189-90; accord BreathAsure, 204 F.3d at 93. Carter-Wallace and BreathAsure did not discuss, however, the standard for evaluating whether a plaintiff seeking a

preliminary injunction will suffer irreparable harm if the injunction is not issued. We agree that this standard -- i.e., potential harm that cannot be redressed following trial -- differs from the standing requirement and injury element for a Lanham Act claim -- i.e., a reasonable basis for believing that a plaintiff is likely to suffer injury.

Nonetheless, we conclude that the District Court's error in citing the wrong standard was harmless because there is sufficient evidence in the record to support a finding of irreparable harm necessary to issue a preliminary injunction. The District Court observed that the promotion and sale of MNTS had already had a measurable effect on Maalox's market share as reflected by a decrease in sales of Maalox that corresponds to the increased sales for MNTS. 129 F. Supp. 2d at 369. We are satisfied that this loss of market share constitutes irreparable harm. See Moltan Co. v. Eagle-Picher Indus., Inc., 55 F.3d 1171, 1175 (6th Cir. 1995) (affirming decision to grant preliminary injunction where manufacturer's false claims were causing irreparable injury to a competitor in the form of lost sales and market share); Cordis Corp. v. Medtronic, Inc., 835 F.2d 859, 864 (Fed. Cir. 1987) ("a loss in market share caused by an injunction could result in irreparable harm"); see also Pappan Enters., Inc. v. Hardee's Food Sys., Inc., 143 F. 3d 800, 805 (3d Cir. 1998) ("Grounds for irreparable injury include loss of control of reputation, loss of trade, and loss of goodwill."); Opticians Ass'n v. Indep. Opticians, 920 F.2d 187, 195 (3d Cir. 1990) (same). In a competitive industry where consumers are brand-loyal, we believe that loss of market share is a "potential harm which cannot be

redressed by a legal or an equitable remedy following a trial." Instant Air Freight, 882 F.2d at 801.

Before granting an injunction, a district court must balance the relative harm to the parties, i.e. , the potential injury to the plaintiff if an injunction does not issue versus the potential injury to the defendant if the injunction is issued. Sandoz, 902 F.2d at 226. In this case, the Court concluded that the balance of harms favored issuing the injunction. 129 F. Supp. 2d at 368-69. We agree.

J&J argued before the District Court that it would suffer substantial injury if a preliminary injunction were to issue because, after a certain period of time, it would be unable to relaunch the MNTS product. It maintains that if that were to occur it would lose the value of its substantial investment and goodwill in the MNTS product name.

The District Court discounted J&J's claims of potential injury, in part because "any financial loss that will be suffered by J&J as a result of its decision to name its product 'Night Time Strength' is self-imposed." 129 F. Supp. 2d at 369. We reject J&J's assertion that it was error for the Court to have done so. As we have previously ruled, the injury a defendant might suffer if an injunction were

imposed may be discounted by the fact that the defendant brought that injury upon itself. See Pappan, 143 F.3d at 806 ("The self-inflicted nature of any harm suffered by [the party opposing the injunction] also weighs in favor of granting preliminary injunctive relief."); Opticians Ass'n, 920 F.2d at 197 ("By virtue of this recalcitrant behavior, the [party opposing the injunction] can hardly claim to be harmed, since it brought any and all difficulties occasioned by the issuance of an injunction upon itself.").

Moreover, we disagree with J&J's assertion that the potential harm to it from losing the MNTS product line if the injunction were issued outweighs the potential harm to Novartis from losing market share if the injunction were not issued. A case relied upon by J&J, Genovese Drug Stores, Inc. v. TGC Stores, Inc., 939 F. Supp. 340, 350-51 (D.N.J. 1996), does not persuade us otherwise. There, the District Court was persuaded that an injunction would have put the defendant out of business by forcing it to change the

name of its two, new health care stores. It noted that "if defendant were forced to preliminarily change its name and then succeed in this lawsuit, it would be economically unsound and, most likely, financially unfeasible for defendant to return to its original name." Id. at 350-51. The Court found that "[s]uch harm is irreparable, and more devastating than the possibility of harm to plaintiff 's reputation and good will [if the injunction did not issue]." Id. Because of this, and because the plaintiff had failed to demonstrate a likelihood of success on the merits, the Court denied injunctive relief.

By contrast, the preliminary injunction issued against J&J does not require that it abandon its entire brand name.14 The preliminary injunction also does not require J&J to abandon its product name forever; it only requires that the company cease shipping the MNTS product under that name until the end of litigation on the merits. If the District Court rules for J&J on the merits, shipping the MNTS product currently in inventory may continue. Like the District Court, we are not persuaded by J&J's assertion that it would be unable to relaunch the product under the MNTS name after a short period of time. See discussion supra n.4. Moreover, the injunction does not prohibit J&J from shipping the product currently in inventory under a different name, label, and advertising that is not literally false and/or misleading, such as "Maximum Strength Mylanta." Finally, we observe that, unlike the plaintiff in Genovese, Novartis has demonstrated a likelihood of success on the merits. As other circuit courts have observed, "[t]he more likely the plaintiff is to win, the less heavily need the balance of harms weigh in his favor." NLRB v. Electro-Voice, Inc., 83 F.3d 1559, 1568 (7th Cir. 1996); accord Abbott Labs. v. Mead Johnson & Co. , 971 F.2d 6, 12 (7th Cir. 1992). We therefore agree that the

14. We think it fair to say that, even if J&J were to lose its entire investment in the MNTS product line to date (estimated at approximately $9 million based on the bond amount imposed by the District Court, discussed supra n.3), it would not, as one of the largest companies in America, go out of business. See "Fortune 500 list" (Apr. 15, 2002), available at http://www.fortune.com/lists/F500/index.html (listing J&J 47th on the Fortune 500 list).

balance of harms weighs in favor of granting the preliminary injunction.

Finally, we find no error in the District Court's finding that the public interest favors issuing the injunction. 129 F. Supp. 2d at 369. We agree with those district courts that have found that "[t]here is a strong public interest in the prevention of misleading advertisements, and this interest is particularly strong where over-the-counter drugs are concerned." American Home Prods. Corp. v. Johnson & Johnson, 654 F. Supp. 568, 590 (S.D.N.Y. 1987) (citing Upjohn Co. v. American Home Prods. Corp., 598 F. Supp. 550, 557 (S.D.N.Y. 1984)); accord Church & Dwight, 873 F. Supp. at 912; W.L. Gore & Assoc., Inc. v. Totes, Inc., 788 F. Supp. 800, 814 (D. Del. 1992). Moreover, we believe that where the plaintiff has demonstrated a likelihood of success on the merits, the public interest leans even more toward granting the injunction.

All told, the District Court did not clearly err when it found that Novartis would suffer irreparable harm if the injunction were not issued, and the equities, including the balance of harms and the public interest, weigh in favor of granting the preliminary injunction. Because we are also affirming the District Court's finding that Novartis will likely be able to succeed on the merits of its Lanham Act claim, we find no abuse of discretion in the Court's decision to grant a preliminary injunction pending the outcome of a trial on the merits.

C. Is The Injunction Overbroad?

J&J argues that the preliminary injunction imposed by the District Court violates the First Amendment because it enjoins all use of the MNTS name instead of ordering as a narrower remedy that a disclaimer be added to the label explaining that the product provides only short-term relief.15

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15. Novartis argues that the issue of overbreadth is waived because plaintiff failed to raise it before the District Court. We disagree. The cases relied upon by Novartis held that a plaintiff 's claim that the defendant had violated his First Amendment rights was waived on appeal when it was not presented properly to the District Court in the first instance. See Hopkins v. Saunders, 199 F.3d 968, 974 (8th Cir.

It is true that injunctive relief should be "no more burdensome to the defendant than necessary to provide complete relief to plaintiffs." Califano v. Yamasaki, 442 U.S. 682, 702 (1979); accord Ameron, Inc. v. U.S. Army Corps of Eng'rs, 787 F.2d 875, 887-88 (3d Cir. 1986), adopted in part on reh'g by 809 F.2d 979, 981 (1987). Moreover, because commercial speech is entitled to appropriate protection under the First Amendment, an injunction restraining allegedly false or misleading speech must be narrowly tailored to "cover only the speech most likely to deceive consumers and harm [the plaintiff]." ALPO PetFoods, Inc. v. Ralston Purina Co., 913 F.2d 958, 972 (D.C. Cir. 1990); see also Mobius Mgmt. Sys., Inc. v. Fourth Dimension Software, Inc., 880 F. Supp. 1005, 1024-25 (S.D.N.Y. 1994).

The preliminary injunction in this case prohibits J&J from: "(1) marketing and disseminating Mylanta Night Time Strength under that name; (2) using the designation'Night Time' or 'Night Time Strength' on any antacid product; [and] (3) otherwise claiming, either explicitly or implicitly, in any packaging, advertising, or other promotional materials, that Mylanta Night Time Strength is specifically formulated for night time heartburn, provides all-night relief, and/or possesses a strength that correlates with its efficacy." 129 F. Supp. 2d at 369. We think this injunction is not overbroad, for it only reaches claims that are false. See Castrol, 987 F.2d at 949 (injunction was "not overbroad because it only reache[d] the specific claims that the district court found to be literally false").

The District Court concluded, and we agree, that Novartis will likely prove that the MNTS name, inter alia , necessarily implies a false message that the product is specially

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1999), cert. denied, 531 U.S. 873 (2000); Ferrill v. Parker Group, Inc., 168 F.3d 468, 475 (11th Cir. 1999); Moulton v. Vigo County, 150 F.3d 801, 803 (7th Cir. 1998). This situation is distinguished from the current case where the defendant is arguing that an injunction issued by the District Court violates the First Amendment because it is overbroad. J&J correctly points out that the first real opportunity to comment on the overbreadth of an injunction issued by the District Court is on direct appeal to this Court.

formulated for nighttime relief. We do not believe that a disclaimer can rectify a product name that necessarily conveys a false message to the consumer. The Court therefore did not violate the First Amendment by prohibiting J&J from using the MNTS designation.

However, the injunction does more than prohibit the use of the MNTS name. It also prohibits J&J from "otherwise claiming" in its packaging, advertising, or promotional materials that MNTS is specially formulated for nighttime heartburn, provides all-night relief, or possesses a strength that correlates with greater efficacy. We conclude that the

injunction does not violate the First Amendment in doing so because each of these messages is false. As discussed above, the message that MNTS is specially formulated for nighttime heartburn is false. Moreover, J&J does not dispute that a message of all-night relief would be false. It merely argues that this message is not received from the product's name. Finally, it is well settled that a product's strength, as demonstrated in vitro, does not correlate to greater efficacy at relieving symptoms in the body. See Rorer, 19 F.3d at 128. Because each of these messages is false, the injunction may outright prohibit J&J from making them, either explicitly or implicitly, in its packaging, advertising, or promotional materials.

We note that had we limited our holding to affirm only the District Court's finding that the MNTS product name is misleading (and not literally false or necessarily implying any false message), the issue of whether the injunction could prohibit all use of that product name, as opposed to requiring a disclaimer, would have been a closer question. At one time the Second Circuit held that "[d]isclaimers are a favored way of alleviating consumer confusion." Consumers Union of United States, Inc. v. Gen. Signal Corp., 724 F.2d 1044, 1053 (2d Cir. 1983). It did so because it observed that "[a]bsolute prohibitions of speech as provided for in the instant preliminary injunction are improper where there is any possibility that an explanation or disclaimer will suffice." Id. The Second Circuit has since retreated from the position taken in Consumers Union and shifted the burden to the defendant to demonstrate that a disclaimer would suffice to protect consumers. See Home

Box Office, Inc. v. Showtime/The Movie Channel Inc. , 832 F.2d 1311, 1316 (2d Cir. 1987); Charles of the Ritz Group Ltd. v. Quality King Distrib., Inc., 832 F.2d 1317, 1324 (2d Cir. 1987) ("In [Home Box Office], this court considered and rejected appellants' claim that disclaimers are a favored way of alleviating substantial consumer confusion."). Even so, the District Court's "determination of whether to grant relief in the form of an absolute injunction or through the use of a disclaimer will not be disturbed on appeal . . . unless there has been an abuse of discretion." Soltex Polymer Corp. v. Fortex Indus., Inc., 832 F.2d 1325, 1329-1330 (2d Cir. 1987).

Likewise, we believe that district courts should consider ordering the narrowest remedy possible to protect the public from misleading product names or advertising. This may include using disclaimers rather than absolute prohibitions on speech. Although we are skeptical whether disclaimers can cure false advertising claims (made literally or by necessary implication), they may be able to dispel misleading messages implied by a product's name. If a district court is not persuaded that the defendant's proposed disclaimer would protect consumers fully, it may take the more significant measure of entering a complete prohibition on false speech.

III. Conclusion

To summarize our holding, we conclude that the District Court did not abuse its discretion by preliminarily enjoining J&J, pending the outcome of a trial on the merits, from marketing and distributing the MNTS product under that name and from otherwise claiming that the product is specifically formulated to relieve nighttime heartburn, provides all-night relief, or possesses a strength that correlates with greater efficacy. We affirm the Court's finding that Novartis will likely succeed on the merits of its Lanham Act claims. Although we do not agree that the MNTS name and advertising necessarily imply a message of superior efficacy, we affirm the Court's rulings that (1) the MNTS name necessarily implies a false message of special formulation for nighttime relief and that (2) the MNTS name and label mislead a substantial portion of consumers to

believe that the product provides all-night relief. We also affirm the Court's findings that Novartis is likely to suffer irreparable harm, and that the balancing of harms and the public interest favor issuing the preliminary injunction. Finally, we conclude that the injunction is not overbroad because it merely prohibits J&J from disseminating false speech. We therefore affirm the judgment of the District Court.

BRIGHT, Circuit Judge, dissenting:

In its decision today, the majority creates a new rule that allows a district court to conclude that a completely unsubstantiated advertising claim can be per se false, despite the fact that, under FDA regulations, no antacid manufacturer can substantiate its efficacy claims in any meaningful way. I believe that the majority goes too far when it states that, as a matter of law, "Night Time Strength" necessarily conveys a claim of special formulation for nighttime relief that implies falsity. I reject the claim of false advertising against Johnson & Johnson-Merck. I therefore dissent.

The Food and Drug Administration's regulations recognize that greater strength does not mean greater effectiveness. FDA rules prohibit any antacid manufacturer from claiming that its product is more effective than another antacid at relieving the symptoms of heartburn. However, under FDA regulations and Johnson & Johnson-Merck Consumer Pharms. Co. v. Rhone-Poulenc Rorer Pharms., 19 F.3d 125, 127-28 (3rd Cir. 1994), antacid manufacturers can rely on differences in ANC ratings to support claims of greater strength. As a result, the antacid industry has the "unfortunately common" advertising practice of touting ANC ratings, promising symptom relief,

and inviting consumers to correlate strength with effective relief. Rorer, 19 F.3d at 132. This may fool the consumer, but it is permissible advertising.

The makers of Mylanta Night Time Strength targeted consumers' concerns about relief of nighttime heartburn. Mylanta gave its product a clever name and stated that the product works at night. This is not false. MNTS does work at night and provides relief. Indeed, all the antacid products of both companies work in the morning, at noon, and at night.

The majority's factual and legal examination of the name[1] Mylanta Night Time Strength tracks the following logic: (1)

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1. It is important to note that the majority's holding focuses solely on the name of the product, not the advertising. The falsity is, therefore, derived entirely from the name, Mylanta Night Time Strength.

because the "nighttime" designation describes a time[2] when the product will be effective, the phrase "nighttime strength" necessarily conveys a message that MNTS is specially formulated to work at night; (2) it is completely unsubstantiated that MNTS is specially formulated to work at night; (3) therefore, the message conveyed by the"Night Time" designation is per se false.

The majority's first premise is flawed. The majority claims that the phrase "Night Time Strength" necessarily and unavoidably conveys the message that the product is specially formulated to work at night. Despite the majority's best efforts to the contrary, this message is not unambiguously conveyed. MNTS's name may suggest that the product is specially formulated for nighttime heartburn, but the words "Night Time" no more necessarily imply special formulation for nighttime relief than the words "Extra Strength" necessarily imply special formulation for greater effectiveness. Both phrases are suggestive and neither are literally false, see United Indus. Corp. v. The Clorox Co., 140 F.3d 1175, 1181 (8th Cir. 1998) (a merely suggestive conclusion "relies upon the viewer or consumer to integrate its components"), but the majority characterizes the former implication as necessary, but the latter merely suggestive.

The majority recognized this difficulty when it rejected the district court's finding that the name MNTS necessarily implies a message of superior efficacy:

> In this case, consumers will only receive a message of superior relief from the MNTS name and advertising if they assume that a product that provides "Night Time" relief is more effective than a product that provides "Extra Strength" or "Maximum" relief. The MNTS name and advertising alone do not require that this inference will be made.

Maj. Op. at 11. The same logic applies to the message of special formulation; consumers will only receive a message that MNTS is specially made for heartburn if they assume

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2. The district court refers to the adjective"nighttime" as conveying "a temporal designation."

that the name "Night Time" indicates how the product is chemically composed.

Furthermore, in its oral argument to the district court, Novartis recognized there were "four possible communications" that the name Mylanta Night Time Strength could convey.3 If the plaintiff can identify four distinct messages in the name, how can the majority conclude there is only one inescapable message? J&J also points out that none of the respondents in Novartis's consumer survey identified the "unambiguous" message that MNTS was specially formulated to work at night. Only the district court was able to discern this message. As the Second Circuit has noted, "It is not for the judge to determine, based solely upon his or her own intuitive reaction, whether the advertisement is deceptive. Rather, as we have reiterated in the past, '[t]he question in such cases is - what does the person to whom the advertisement is addressed find to be the message?'" Johnson & Johnson-Merck Consumer Pharms. Co. v. SmithKline Beecham Corp., 960 F.2d 294, 297-98 (2d Cir. 1992) (emphasis in original) (citations omitted).

As an alternative holding, the majority contends that Novartis is likely to succeed on the merits because it will be able to prove, through use of a consumer survey, that the MNTS name and advertising mislead consumers into believing that the product provides all-night relief. I disagree.

An injunction is an "extraordinary remedy" and the hotly contested results of the consumer survey do not provide the requisite likelihood that Novartis will succeed on the merits. The Ford Survey contained only three truly open-ended questions, which resulted in about seven percent of respondents stating that the MNTS label conveys anything about all-night relief. The next series of questions relied on a leading question: "how long" the product would provide relief. Such questions are "inherently suggestive and invite

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3. The four communications the name could convey are: (1) that it lasts all night; (2) that it is specially formulated; (3) that it is the most effective; or (4) that it is a sleep aid. Novartis refers to these options as "the universe of necessary implications." App. at A66-68.

guessing by those who did not get any clear message at all" and surveys that rely on them are not credible. Rorer, 19 F.3d at 134.

J&J argues that the suggestiveness of the questions is borne out by the fact that when the survey questions directed the consumer's attention to the name, Mylanta Night Time Strength, and asked if the name communicated anything, less than five percent responded that the name communicated that the product lasts all night or "overnight."

The consumer survey results indicate, at most, borderline levels of consumer confusion. They do not support the district court's decision to implement a sweeping injunction against MNTS.

Finally, I believe that the public interest concerns expressed by the majority and the district court are entirely misplaced. Essentially, both parties use marketing techniques to increase their market share of different strengths of antacid even though there is no provable difference in terms of effectiveness. Mylanta, knowing that people are most concerned with nighttime heartburn, focused its advertising on that concern. The majority appears to hold that, as a matter of law, antacid manufacturers can only label their products with terms that describe different degrees of strength such as regular, extra, and maximum. All other words, such as nighttime, necessarily convey a false message. If we were truly concerned about the public interest, both companies would be forced to label their products with the following: GREATER STRENGTH AND GREATER PRICE DO NOT EQUAL GREATER RELIEF.

Because a preliminary injunction should not have been granted in this case, I dissent.

A True Copy:
Teste:

Clerk of the United States Court of Appeals
for the Third Circuit