IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA LP, Plaintiff, v. TAP PHARMACEUTICAL PRODUCTS, INC., Defendant.	)	Civil Action No. 04-1332-KAJ **REDACTED PUBLIC VERSION**

MEMORANDUM OPINION

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Wilmington, Delaware
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JORDAN, District Judge.

I. INTRODUCTION

In this false advertising case, AstraZeneca LP ("AstraZeneca") filed a complaint requesting a declaratory judgment that its "Better is Better" advertising campaign was not false or misleading under § 43(a) of the Lanham Act, 15 U.S.C. §1125(a)(1)(B). (Docket Item ["D.I."] 1 at ¶ 15.) TAP Pharmaceutical Products, Inc. ("TAP") counterclaimed for a judgment that AstraZeneca's campaign was false, and likely to deceive consumers. (D.I. 7 at ¶¶ 34-35.) TAP demanded a jury trial for all issues so triable, and injunctive relief and damages. (*Id.* at 13-14.)

Presently before me are five motions filed by AstraZeneca and TAP. TAP has filed a Motion to Exclude Certain Testimony by Michael Rappeport, one of AstraZeneca's expert witnesses. (D.I. 87.) AstraZeneca has filed four motions, including a Motion for Summary Judgment (D.I. 88), a Motion to Exclude Expert Testimony of Thomas Dupont and Susan S. McDonald (D.I. 91), a Motion to Exclude Expert Testimony of Bert Spilker (D.I. 94), and a Motion to Strike TAP's jury demand (D.I. 97). For the reasons that follow, the Motion to Strike TAP's jury demand (D.I. 97) will be granted, the Motion for Summary Judgment will be granted-in-part and denied-in-part, and the Motion to Exclude Expert Testimony of Thomas Dupont and Susan S. McDonald (D.I. 91) will be granted-in-part and denied-in-part, such that Dr. Dupont's report and all testimony regarding his internet survey and Dr. McDonald's testimony regarding her supplemental expert report will be excluded. All of the other motions will be denied.

II. BACKGROUND

A. Acid Reflux Disease

AstraZeneca and TAP both produce pharmaceuticals that work as proton pump inhibitors ("PPIs") that treat Gastroesophageal Reflux Disease, commonly known as "acid reflux disease." (D.I. 101 at 3.) AstraZeneca's NEXIUM® (esomeprazole magnesium) and TAP's PREVACID® (lansoprazole) compete with each other and other PPIs, as well as other pharmaceuticals and antacids. (*Id.*)

The main symptom of acid reflux disease is heartburn, a condition that causes a burning sensation in the chest when digestive acid backs up into the esophagus. (Declaration of Malcolm Robinson,[1] D.I.110, Ex. D at ¶ 3.) Patients who suffer from acid reflux disease also may suffer from erosive esophagitis ("EE"), a condition that develops from excessive exposure of the esophagus to acid. (Declaration of David A. Johnson,[2] D.I. 90, Ex. K at ¶¶ 14-15.) The only way to determine whether a patient has EE is to perform an upper gastrointestinal endoscopy, but such a procedure is usually only performed when a patient has symptoms such as bleeding, weight loss, chest pain, or difficulty in swallowing. (Robinson Decl., D.I. 110, Ex. D at ¶¶ 4-5.) Thus, a physician is often unaware of whether a patient has EE, and the general focus is on treating the symptoms of acid reflux disease. (*Id.*)

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[1] Dr. Malcolm Robinson is a Professor in the Department of Medicine at the University of Oklahoma, who submitted his declaration in support of TAP's Motion for Preliminary Injunction. (D.I. 110, Ex. D at ¶¶ 1-2.)

[2] David A. Johnson is a Professor of Medicine and Head of Gastroenterology at the Eastern Virgina School of Medicine, who submitted his declaration in opposition to TAP's Motion for Preliminary Injunction. (D.I. 90, Ex. K at ¶ 1.)

There are four grades of EE, generally measured according to two available scales. The Los Angeles scale divides EE sufferers on a scale of grades A-D, while the Hetzel-Dent scale uses grades 1-4. (*Id.* at ¶ 6.) Although comparisons are not precise, Grade 2 of the Hetzel-Dent scale is generally comparable to Grades A and B on the Los Angeles scale, Grade 3 compares with Grade C, and Grade 4 with Grade D. (*Id.* at ¶ 6.) EE which measures as Grades C or D on the Los Angeles scale, or as 3 or 4 on the Hetzel-Dent scale, is considered to be moderate to severe EE. (*Id.* at ¶ 7.)

B. The "Better Is Better" Advertising Campaign

AstraZeneca began a new direct-to-consumer ("DTC") marketing campaign for Nexium in September 2004. (*See* D.I. 1 at ¶ 7; D.I. 7 at ¶ 12.) That campaign, known as the "Better Is Better" campaign, ran until May 2005 and included two television commercials, print advertisements, website materials, and an informational pamphlet. The campaign claimed, among other things, that "recent medical studies ... prove Nexium heals moderate to severe acid related damage in the esophagus better than the other leading prescription medicine." (D.I. 1, Ex. B.) Those recent medical studies, known as the Castell and Fennerty studies (*see infra* section II.C.), show that Nexium healed patients with moderate to severe acid related damage in the esophagus better than Prevacid. (D.I. 1, Ex. C.)

TAP, however, claims that the Better is Better advertising campaign is false. (D.I. 7 at ¶¶ 18-29.) TAP first asserts that the campaign is misleading because it claims that Nexium has been proven superior for the relief of symptoms such as heartburn and acid indigestion, when the Castell and Fennerty studies only show that Nexium was

better at healing EE in patients with moderate to severe damage. (*Id.* at ¶¶ 22-23.) Next, TAP claims that the advertising campaign is literally false because Nexium is only marginally better at healing EE, and that difference is clinically meaningless. (*Id.* at ¶ 24.) TAP finally claims that, because only a small minority of patients who suffer from EE have moderate to severe EE, AstraZeneca's claim that Nexium is better at healing EE is misleading to the majority of people who suffer from EE. (*Id.* at ¶ 25.)

C. Studies on Nexium and Prevacid

1. The Castell Study

The Castell Study, conducted by Dr. Donald O. Castell,[3] compared Prevacid 30 mg with Nexium 40 mg for healing of EE and resolution of heartburn. (Declaration of Donald O. Castell, D.I. 90, Ex. M at ¶ 6.) Prior to testing the study subjects, the investigators identified healing of EE at eight weeks as the primary endpoint for the study. (*Id.* at ¶ 10.) The study found that Nexium, with an overall healing rate of 92.6%, was more effective than Prevacid, with an overall healing rate of 88.8%, for healing EE after eight weeks of treatment, and that the difference was statistically significant. (*Id.* at ¶ 13.) Additional analysis of the results of the study showed that Prevacid was less effective as the severity of EE increased. (*Id.* at ¶ 15.) For Grades A and B, or mild, EE Nexium had a healing rate of 94.6%, while Prevaid had a healing rate of 93.8%. (*Id.*) However, for Grades C and D EE, Nexium had a healing rate of 86.6%, while Prevaid's healing rate was 73.9%. (*Id.*) In fact, the differences in healing

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[3] Dr. Castell is a Professor of Medicine and Director of the Esophageal Disorders Program at the Digestive Disease Center at the Medical University of South Carolina. (Castell Declaration, D.I. 90, Ex. M at ¶ 1.)

were 11.0% for Grade C EE, and 17.0% for Grade D. (Castell Paper, D.I. 90, Ex. V at 581.) Thus, the authors of the study concluded that Nexium was more effective than Prevacid at healing EE, and that "the difference in healing ... was most striking in patients with severe disease." (*Id.*)

2. The Fennerty Study

The Fennerty study was designed to follow up the results of the Castell study, and specifically addressed the healing of moderate to severe EE by Prevacid and Nexium. (Declaration of Dr. M. Brian Fennerty,[4] D.I. 90, Ex. L at ¶ 4.) Like the Castell study, the primary endpoint was the healing of EE at eight weeks. (*Id.* at ¶ 7.) The study found that Nexium was "significantly faster in achieving healing versus [Prevacid], and achieved a 4.9% (statistically significant) better healing rate at eight weeks (82.4% vs. 77.5%).

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[4] Dr. Fennerty is a Professor of Medicine at Oregon Health and Science University, and the Section Chief of Gastroenterology at that institution. (D.I. 90, Ex. L at ¶ 1.)

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D. Survey Evidence

Dr. Thomas Dupont conducted consumer surveys to determine what the Better is Better television advertisement and internet advertisement communicated to consumers. (*See* D.I. 93 at Ex. B, C.) Specifically, Dr. Dupont attempted to determine whether consumers understood that the claim that Nexium was "better" than Prevacid was limited to those suffering from moderate to severe EE. (*Id.*)

1. The Television Survey

The television survey respondents included 479 men and women over the age of twenty-five who either had taken a prescription medicine to treat acid reflux disease or heartburn in the six months prior to the survey, or intended to do so in the six months after the survey. (Expert Report of Thomas Dupont on Television Commercial, D.I. 93, Ex. B at 2.) The surveys were conducted in permanent shopping mall interviewing facilities in twenty cities across the nation. (*Id.* at 20.) 240 people viewed the commercial that AstraZeneca broadcast to advertise Nexium (the "Test Commercial"),

and 239 viewed a "Control Commercial."[7] (*Id.*) Each respondent viewed the commercial twice in succession, and then was asked the following questions:

> 1. Please tell me what that commercial communicated to you about Nexium.
> 2. What else, if anything, did that commercial communicate to you about Nexium? Anything else?
> 3. Do you recall the commercial saying Nexium was better?
> 4. Did the commercial tell you what Nexium was better at doing?
> 5. What did the commercial tell you Nexium was better at doing? Anything else?
> 6. Thinking about what the commercial communicated to you, which one statement on this card best describes what the commercial communicated to you about how Nexium compares with other products?
>
> > 1. It said Nexium heals damage to the esophagus better than other leading prescription medicines, but did not say it was better than the other leading prescription medicines at relieving the symptoms of acid reflux disease, such as heartburn.
> > 2. It said Nexium relieves the symptoms of acid reflux disease, such as heartburn, better than the other leading prescription medicines, but did not say it was better than the other leading prescription medicines at healing damage to the esophagus.
> > 3. It said Nexium is better than the other leading prescription medicines both at healing damage to the esophagus and at relieving the symptoms of acid reflux disease, such as heartburn.[8]
> > 4. None of the above describe what the commercial communicated to me
> > 5. Don't know

(*Id.* at 6,10-11, 16.)

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[7] The Control Commercial was an edited version of the Test Commercial created by Dr. Dupont to account for potential 'noise' in the survey. (Dupont Television Report, D.I. 93, Ex. B at 3.) This commercial eliminated "all references to heartburn and most references to acid reflux disease." (*Id.*)

[8] There were three versions of the questionnaire, in which the first three response choices were rotated. (Dupont Television Report, D.I. 93, Ex. B at 16.) This was done to eliminate bias due to the order of choices. (*Id.*)

In response to the first two questions, 85% of respondents gave non-comparative replies, and 46.3% gave comparative replies.[9] (*Id.* at 6.) Of those that gave comparative replies, 13.8% talked about acid reflux or symptom relief, 7.5% talked about healing damage, and 29.2% said Nexium is better without saying why or how it was better. (*Id.*; *see also id.* at 8-9 for table of specific response results.)

Of all respondents, 85.8% said yes to both questions three and four, and were then asked question five. (*Id.* at 10-11.) In response to question five, 67.9% of respondents said Nexium relieves or treats acid reflux and/or its symptoms better, while 28.8% said it heals damage better. (*Id.* at 11; *see also id.* at 12 for table of specific responses.) Dr. Dupont asserts that, based on the combined results of questions one, two, and five, that 71.1% of respondents took away a message that Nexium provides superior symptom relief, while 32.1% understood that Nexium was better at healing damage. (*Id.* at 13.)

Finally, respondents were asked question six. In response to that question, 20.8% of respondents said Nexium was only better at healing damage to the esophagus, 15.8% said it was better only at treating symptoms of acid reflux disease, and 62.5% said it was better for both. (*Id.* at 17.) Dr. Dupont, however, stated in his report that question six was only included as a precaution, in case the answers to the open-ended questions were ambiguous.[10] (*Id.*) He asserted that question six may have

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[9] A comparative reply is one that compared Nexium to other products, while a non-comparative reply simply stated the benefits of Nexium. (See Dupont Television Report, D.I. 93, Ex. B at 8-9.)

[10] An open-ended question is one that "permit[s] or [is] designed to permit spontaneous and unguided responses." Merriam-Webster's Collegiate Dictionary 812

been either suggestive, overly complex, or both, and that the question was unnecessary because the answers to the open-ended questions were clear. (*Id.*)

2. The Internet Survey

The internet survey was conducted similarly to the television survey: 411 men and women over the age of twenty-five who either had taken a prescription medicine to treat acid reflux disease or heartburn in the six months prior to the survey, or intended to do so in the six months after the survey, answered questions after viewing an advertisement on a computer screen. (Expert Report of Thomas Dupont on Internet Commercial, D.I. 93, Ex. C at 2-3.) 205 respondents viewed the version of the advertisement that was posted on AstraZeneca's website for Nexium (the "Test Ad"), while 206 respondents viewed a "Control Ad."[11] Each respondent was then asked a series of questions, as follows:

> 1. First, please tell me what that ad communicated to you about Nexium.
> 2. What else, if anything, did the ad communicate to you about Nexium? Anything else?
> 3. Do you recall the ad saying that Nexium heals acid-related damage better than the other leading medicine?
> 4. Specifically, what do you recall the ad saying about that? Anything else?
> 5. If you were deciding whether or not you wanted to try Nexium, would the information in the ad you just read make you more likely to try Nexium, less likely to try Nexium, or would it not affect your decision one way or the other?
> 6. Why would it make you more likely to try Nexium?

(10th ed. 2002). A closed-ended question, on the other hand, gives a limited number of responses from which an answer is selected. (Dupont Television Report, D.I. 93, Ex. B at 16.)

[11] Dr. Dupont created the Control Ad by deleting all references to moderate to severe damage from the Test Ad. (Dupont Internet Report, D.I. 93, Ex. C at 3.)

7. Looking at the choices printed on this card, and based on what the ad communicated to you, for what group of people will Nexium heal acid related damage better than the other leading medicine?

1. All people with damage to the esophagus caused by acid reflux disease
2. Only people with moderate to severe damage to the esophagus caused by acid reflux
3. Don't know or no opinion

(*Id.* at 6, 9, 12, 14-15.)

Dr. Dupont compared the results from the respondents who viewed the Test Ad with those who viewed the Control Ad. When looking at the results for the first four open-ended questions, only 11.2% of respondents who viewed the test ad said anything about moderate to severe damage, while no respondents who viewed the control ad made such a statement. (*Id.* at 6-10.) Dr. Dupont stated in his rebuttal expert report that these results "don't help us a lot in understanding whether or not consumers understood the limitation on the claim being made in the ad." (Deposition of Thomas Dupont, D.I. 93, Ex. D at 140:7-10.) He further stated in his deposition that the answers to the open-ended questions alone "means that it is possible that more people understood – more – its possible, but not necessarily true that more people than the 11 percent understood the limitation on the claim." (*Id.* at 140:18-22.)

In response to question seven, the closed-ended question, 38.5% of respondents who viewed the Test Ad said that only people with moderate to severe damage to the esophagus were healed better by Nexium. (Dupont Internet Report, D.I. 93, Ex. C at 13.) However, 38.3% of people who viewed the Control Ad, which did not contain the words moderate to severe, gave the same response. (*Id.*) Dr. Susan Schwarz McDonald, an expert hired by TAP to respond to the criticisms of the studies

put forward by AstraZeneca's expert, Dr. Michael Rappeport, opined that these questions should be excluded from the analysis. (Schwartz Opinion, D.I. 93, Ex. F at 18.) Dr. Schwartz stated:

> It is my hypothesis that in both of these samples, large numbers of respondents were merely guessing. ... [T]here is no doubt that this close-ended survey question cannot be trusted to provide meaningful data. (At best, it offers methodological insight on how survey questions can go astray.) Whenever there is serious doubt about the validity of a close-ended question, as here, it is prudent to default to the most pertinent open-ended question....

(*Id.*)

Questions five and six were designed to address whether the information in the advertisements was material to the consumers in the study. (Dupont Internet Report, D.I. 93, Ex. C at 14-15.) For both the Test Ad and the Control Ad, similar percentages of people said that the advertisement would make them more likely to try Nexium (58.5% for the Test Ad, 54.9% for the Control Ad), less likely to try Nexium (5.9% for the Test Ad, 4.9% for the Control Ad), and that the advertisement would not affect their decision (26.8% for the Test Ad, 30.1% for the Control Ad). (*Id.* at 14.) Of those who said the advertisement would make them more likely to try Nexium, about half (46.7% for the Test Ad and 51.3% for the Control Ad) said they were more likely to try Nexium because it was better or more effective. (*Id.* at 15.) Of those people, only 4.2% of those who saw the Test Ad and 1.8% of those who saw the Control Ad said they were more likely to try Nexium because it heals damage better. (*Id.*)

III. STANDARD OF REVIEW

A. Motion to Exclude Expert Testimony

Motions to exclude evidence are committed to the court's discretion. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir.1994) (on a motion to exclude proffered expert testimony, the trial court's inquiry is a flexible one, and its decision to admit or to exclude expert testimony is reviewed under an "abuse of discretion" standard) (internal citations omitted). "[W]hen the district court's exclusionary evidentiary rulings with respect to scientific opinion testimony will result in a summary or directed judgment," the Court of Appeals will give those rulings "a 'hard look' to determine if a district court has abused its discretion in excluding evidence as unreliable." *Id.* at 750.

B. Summary Judgment

Pursuant to Federal Rule of Civil Procedure 56(c), a party is entitled to summary judgment if a court determines from its examination of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," that there are no genuine issues of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). In determining whether there is a genuine issue of material fact, a court must review the evidence and construe all inferences in the light most favorable to the non-moving party. *Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir. 1976). However, a court should not make credibility determinations or weigh the evidence. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). To defeat a motion for summary judgment, the

non-moving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986) (internal citation omitted). The non-moving party "must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(c). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *Matsushita*, 475 U.S. at 587 (internal citation omitted). Accordingly, a mere scintilla of evidence in support of the non-moving party is insufficient for a court to deny summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).

IV. DISCUSSION

A. Motion to Strike Jury Demand

AstraZeneca has moved to strike TAP's jury demand, arguing that TAP is seeking disgorgement of AstraZeneca's profits, a remedy which is equitable in nature. (D.I. 98 at 4-6.) TAP responds by arguing that it is seeking compensatory damages, and is using AstraZeneca's profits as a measure of those damages. (D.I. 137 at 6-7.)

TAP bases its demand for a jury trial on the Seventh Amendment, which provides that "[i]n Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved." U.S. Const. amend. VII. "[T]he thrust of the Amendment was to preserve the right to jury trial as it existed in 1791." *Curtis v. Loether*, 415 U.S. 189, 193 (1974). In defining the scope of that protection, the Supreme Court has "consistently interpreted the phrase 'Suits at common law' to refer to 'suits in which *legal* rights were to be ascertained and

determined, in contradistinction to those where equitable rights alone were recognized, and equitable remedies were administered.'" *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 41-42 (1989) (emphasis in original) (quoting *Parsons v. Bedford*, 28 U.S. (3 Pet.) 433, 447 (1830)).

In addition to causes of action that were decided in courts of law in 1791, the Seventh Amendment protects the right to a jury trial for causes of action that did not exist at that time but "are analogous to common-law causes of action ordinarily decided in English law courts in the late 18th century, as opposed to those customarily heard by courts of equity or admiralty." *Granfinanciera*, 492 U.S. at 42 (citing *Curtis*, 415 U.S. at 193). To decide whether a jury trial is required for a modern cause of action, courts must balance two factors:

> First, we compare the statutory action to 18th-century actions brought in the courts of England prior to the merger of the courts of law and equity. Second, we examine the remedy sought and determine whether it is legal or equitable in nature. The second stage of this analysis is more important than the first.

Granfinanciera, 492 U.S. at 42 (citing *Tull v. United States*, 481 U.S. 412, 417-18, 421 (1987)) (internal quotations and citations omitted).

Neither party has addressed the first prong of the analysis here, and the Lanham Act is silent on whether a cause of action for false advertising under the Lanham Act § 43(a) requires trial by a jury. *See Daisy Group, Ltd. v. Newport News, Inc.*, 999 F. Supp. 548, 549 -50 (S.D.N.Y. 1998) ("Thus, the initial inquiry on this motion is whether the Lanham Act provides a right of trial by jury. It is undisputed that the statute is silent on the issue of jury trial."); *Sanijet Corp. v. Jacuzzi Inc.*, No. Civ.A. 3:01CV0897-P, 2002

WL 1398546, at *1 (N.D. Tex. Feb. 14, 2002) (same). However, false advertising under the Lanham Act is a statutory tort, most similar to common law causes of action for false advertising and trademark infringement. 4 MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 27:26 (4th ed. 2006) ("§ 43(a) creates a new, statutory federal tort, sui generis, which is limited only by the words of the statute itself").

In Lanham Act cases, courts have generally determined whether or not to grant a jury trial based on the relief sought. *See Ringling Brothers-Barnum & Bailey Combined Shows, Inc. v. Utah Div. of Travel Dev.*, 955 F.Supp. 598, 602-03 (E.D.Va. 1997) (finding, in a trademark dilution case, that "a claim brought under the Act's anti-dilution provision has both legal and equitable characteristics thereby leaving this part of the Seventh Amendment inquiry in equipoise") (citations omitted); *Sanijet Corp.*, 2002 WL 1398546, at *2 (finding, in a false advertising case, that the "[p]laintiff seeking only injunctive relief ... has no right to a jury trial here").

Although AstraZeneca and TAP base their arguments about the jury demand on how TAP is measuring its damages, these arguments are no longer relevant to the case, as I have stricken the opinion of TAP's damages expert, Mr. Creighton Hoffman. (D.I. 154 at 9-15.) Furthermore, for the reasons stated in my May 18, 2006 Memorandum Opinion, TAP will not be allowed to supplement Hoffman's report, or to present an alternative damages theory. (*Id.*) Therefore, TAP has no damages case, and can only request injunctive relief, an equitable remedy. As a result, TAP has no right to a jury trial. *See Sanijet Corp.*, 2002 WL 1398546, at *2. The Motion to Strike TAP's jury demand (D.I. 97) will therefore be granted.

B. Motions to Strike Expert Testimony

AstraZeneca has moved under Rule 702 of the Federal Rules of Evidence to strike the expert testimony of Dr. Bert Spilker, Dr. Thomas McDonald, and the testimony of Dr. Susan S. Schwartz based on her supplemental expert report. TAP has likewise moved to strike the expert testimony of Michael Rappeport.

Rule 702 provides that "if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise[.]" Rule 702 obligates judges to ensure that any scientific or technical testimony admitted is relevant and reliable. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-49 (1999); *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). The party offering the expert testimony has the burden of proving admissibility. *See Daubert*, 509 U.S. at 592 n.10 (citation omitted). The expert must explain how and why he or she has reached the conclusion being proffered and must have as a basis more than a subjective belief or speculation. *See Joiner v. Gen. Elec. Co.*, 522 U.S. 136, 144 (1997) (noting failure of plaintiffs to explain "how and why [they] ... could have extrapolated their opinions"); *Kumho Tire*, 526 U.S. at 152 (an expert must employ "in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"); *Daubert*, 509 U.S. at 590 (expert's testimony "must be supported by appropriate validation"). Further, Rule 702 requires that expert testimony assist the trier of fact. In other words, it must "fit" the issues in the case by having a valid connection to the pertinent inquiry. *Daubert*, 509

U.S. at 591-92. The court "must examine the expert's conclusions in order to determine whether they could reliably follow from the facts known to the expert and the methodology used." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 153 (3d Cir. 1999).

1. Motion to Strike Expert Testimony of Bert Spilker

AstraZeneca has moved to strike the expert testimony of Dr. Bert Spilker, arguing that Dr. Spilker's testimony does not meet the standards set out in Federal Rule of Evidence 702 and *Daubert*. Dr. Spilker opined in two declarations that the differences between Nexium and Prevacid shown in the Castell and Fennerty studies, as well as other studies, while statistically significant, are not clinically significant. (D.I. 96, Ex. H at ¶¶ 11-30.) Dr. Spilker opined that, because of biological and clinical variability, it would be "difficult to imagine that a difference of much less than 20% is enough for the two drugs to be clinically significant." (D.I. 96, Ex. H at ¶ 8.) AstraZeneca claims that Dr. Spilker's opinion should be excluded because he is not a gastroenterologist, has not treated patients for more than ten years, has no experience with PPIs, has done nothing to compensate for his lack of experience, has offered no support for his opinion, and his approach has been rejected by the gastroenterology community. (D.I. 95 at 5-12.) TAP responds by asserting that Dr. Spilker is an expert in clinical trials, that his opinions are based on this expertise, and that they are adequately supported. (D.I. 109 at 2-11.)

AstraZeneca's criticisms of Dr. Spilker's testimony go to the weight, rather than the admissibility of that testimony. Dr. Spilker's lack of expertise in gastroenterology and the fact that he has not treated patients recently, while potentially relevant to the weight his testimony should be given, do not disqualify him from testifying as an expert

in clinical trials. Indeed, AstraZeneca does not appear to dispute Dr. Spilker's qualifications as an expert in clinical trials. (*See* D.I. 136 at 1-2.) Therefore, each of the criticisms that AstraZeneca has raised can sufficiently be addressed on cross-examination, and AstraZeneca's Motion to Strike the Expert Testimony of Dr. Spilker will be denied.

2. Motion to Strike Expert Testimony of Michael Rappeport

TAP has moved to strike the expert testimony of Dr. Michael Rappeport, claiming that Dr. Rappeport's testimony in sections II and III of his report is unsupported, and based on his own perceptions rather than research, and that those sections of the report are contrary to law and based on false medical assumptions. (D.I. 87 at 2-6.) AstraZeneca responds by arguing that Dr. Rappeport will not testify about his own perceptions of the consumer surveys conducted by Dr. Dupont, but will instead critique Dr. Dupont's survey's for failing to ask relevant questions. (D.I. 105 at 6-7.) Further, AstraZeneca argues that Dr. Rappeport's opinions are consistent with the law and are not based on false assumptions. (*Id.* at 7-9.)

TAP's arguments here, like AstraZeneca's arguments in the motion to exclude Dr. Spilker's testimony, go to the weight, not the admissibility of Dr. Rappeport's opinion. TAP's third argument, that sections II and III of Dr. Rappeport's opinion are based on false medical assumptions, carries no weight, as the false medical assumption that TAP identifies does not appear in Dr. Rappeport's report. (D.I. 87, Ex. A at 7-8.) Additionally, AstraZeneca has represented that Dr. Rappeport will not testify as to those assumptions. (D.I. 105 at 9.) Similarly, AstraZeneca has represented that Dr. Rappeport will not testify about his opinions which TAP regards as unsubstantiated,

but instead will critique Dr. Dupont's report. (D.I. 105 at 5-7.) Thus, Dr. Rappeport will be limited in his testimony based on the representations that AstraZeneca has made in its response to TAP's motion, but his testimony will not be excluded.

Finally, TAP argues that Dr. Rappeport's opinion is contrary to law. TAP claims that Dr. Rappeport cannot claim that a consumer can properly perceive that Nexium is superior overall because it is superior in healing moderate to severe EE because there is an "established rule that a pharmaceutical advertising claim that is true with respect to a subset of patients becomes false when presented as an unqualified claim." (D.I. 87 at 5.) However, the cases that TAP relies on do not establish such a rule. In *Am. Home Prods. Corp. v. Johnson & Johnson*, 654 F. Supp. 568 (S.D.N.Y. 1987), the makers of Extra-Strength Tylenol claimed that "You [couldn't] buy a more potent pain reliever without a prescription." *Id.* at 585. However, data showed that while for mild to moderate pain, Advil and Extra-Strength Tylenol were equivalent, for severe pain, Advil was superior. *Id.* Thus, the court found that "[Tylenol's] claim that 'You can't buy a more potent pain reliever without a prescription' is simply not true[.]" *Id.* The ruling was not, as TAP claims, that the claim was true with respect to a subset of patients but false when presented as an unqualified claim. *Id.*; *see also Am. Home Prods. Corp. v. Johnson and Johnson*, 577 F.2d 160, 169 (2d Cir. 1978) (affirming district court finding that two pain relievers were equally effective at relieving pain, when only "two of many studies" indicated any difference at all in efficacy, and those two studies were both flawed and thus discounted by the district court).

Additionally, Dr. Rappeport's testimony is not contrary to the rules that are set out in the cases cited by TAP. Dr. Rappeport argues in his opinion that, even if consumers accurately understood that Nexium is better only for EE, they may still have thought that, because Nexium treats EE better, and all other things being equal, it is better at treating acid reflux disease. (D.I. 87, Ex. A at 5-6.) This is not contrary to the rules set out above. Thus, the testimony of Dr. Rappeport will not be excluded, and the Motion to Strike will be denied.

3. Motion to Strike Expert Testimony of Thomas Dupont

AstraZeneca has moved to exclude the expert testimony and survey evidence of Dr. Thomas Dupont. As to the television survey, AstraZeneca argues that it is inadmissible because Dr. Dupont failed to ask participants whether the commercial addressed symptoms that they routinely experienced, failed to ask participants who said that the commercial communicated a message of superiority the reason for their belief, and ignored data that contradicted his conclusions. (D.I. 92 at 10-16.) As to the internet survey, AstraZeneca argues that the reliable data from that survey does not support the conclusion drawn by Dr. Dupont. (*Id.* at 16-17.) Finally, AstraZeneca argues that the probative value of each of the surveys is outweighed by its prejudicial effect, and that thus the surveys should be excluded under Federal Rule of Evidence 403. (*Id.* at 17-18.) TAP responds by claiming that AstraZeneca's criticisms should be addressed on cross-examination, and asserts that the surveys were properly conducted, asked appropriate questions, and were properly analyzed. (D.I. 108 at 10-

20.) TAP also argues that the survey evidence should not be excluded under Rule 403. (*Id.* at 21-22.)

a. The Television Survey

With respect to the admissibility of the television survey, AstraZeneca first argues that the survey is inadmissible because it failed to address relevant questions. (D.I. 92 at 10-12.) Specifically, AstraZeneca asserts Dr. Susan McDonald, one of TAP's survey experts, opined that the survey was required to address the experiences of the "typical consumer," and that it should address whether the commercial was relevant to the "routine experiences" of the survey respondents. (*Id.*) AstraZeneca claims that the survey failed to address either of these issues. (*Id.*) AstraZeneca's argument, however, can effectively be dealt with on cross-examination, and thus goes to the weight, not the admissibility of the survey. Indeed, as TAP points out, it appears that Dr. McDonald was indicating that the survey needed to address what she referred to as a 'typical' consumer, e.g., one who suffers from acid reflux but not EE. (D.I. 108 at 11.) In fact, Dr. McDonald stated that Dr. Dupont's survey had been designed to answer those very questions. (*See* McDonald Report, D.I. 93, Ex. F at 5-6.) Therefore, this issue can effectively be probed on cross-examination and in questioning of AstraZeneca's own expert, so the survey will not be excluded on this ground.

AstraZeneca also argues that Dr. Dupont failed to probe the respondents to the television survey as to why they responded the way they did in response to the open-ended survey questions. (*Id.* at 13-15.) This arg.ument, again, goes to the weight, not the admissibility, of the survey evidence. In particular, although "[t]he '[w]hat makes

you say that?' question is a typical question designed to isolate, and therefore explain, the real thought processes of the respondent" and "[w]ell-designed studies typically employ the '[w]hat makes you say that?'" kind of question, *ConAgra, Inc. v. Geo. A. Hormel & Co.*, 784 F. Supp. 700, 725-26 (D. Neb. 1992), Dr. Dupont's failure to include such a question here does not require that the survey be excluded. AstraZeneca can effectively deal with the issue on cross-examination and in questioning its own expert. Thus, the television survey will not be excluded on this ground.

Finally, AstraZeneca argues that because Dr. Dupont ignored the responses to the closed-ended questions, even when those responses contradicted the responses to the open-ended questions, the television survey should be excluded. (D.I. 92 at 15-16.) AstraZeneca also asserts that Dr. Dupont failed to analyze the reason for the results obtained from the control group in Kansas City, which were different from the results obtained from control groups in other locations. (*Id.* at 16.) However, these critiques of Dr. Dupont's analysis of the survey do not render the survey itself inadmissible. Additionally, any faults AstraZeneca perceives in Dr. Dupont's analysis of the survey evidence can be inquired into on cross-examination. Accordingly, the television survey is admissible, as is testimony about it.

b. The Internet Survey

AstraZeneca has also moved to exclude Dr. Dupont's internet survey and any testimony about it, arguing that the survey does not support Dr. Dupont's conclusions. (D.I. 92 at 16-17.) AstraZeneca asserts that Dr. Dupont testified during his deposition that he needed the result of both the open-ended and closed-ended questions to come

to his conclusion. (*Id.*, citing D.I. 93, Ex. D at 146:16-147:3.) Indeed, Dr. Dupont testified as follows:

> Q: [Referencing page 14 of Dr. Dupont's rebuttal report] you state ... "So, the open ended questions don't help us a lot in understanding whether or not consumers understood the limitation on the claim being made in the ad." ... Do you stand by that statement?
>
> A. Well... I think what that means is that it is possible that more people understood – more – its possible, but not necessarily true that more people than the 11 percent understood the limitation on the claim.
>
> Q: And to –
>
> A: And that you'd have to turn to the close-ended question to see – you know, to see whether, indeed, it's more than 11 percent.
>
> Q: And that's what you did?
>
> A: Yes.
>
> Q: So you would agree that you can conclude from the responses to the open-ended questions that only 11 percent of the people who saw the test ad understood the limitation being made in the ad.
>
> A: I think you conclude that 11 percent did. ... And I think you have to leave open the possibility that more than 11 percent did, and that you can look at the close-ended question to see how high up it could be.
>
> Q: And if, in fact, the close-ended questions have no value, as Susan McDonald states, then you can't look at anything to get that information; isn't that correct?
>
> A: If you accept her position – if, you know, you're going to accept her position about that I think you have to accept, you know, her analysis as well.
>
> ...
>
> Q: Just to clarify, all you know from the open-ended results is that there is a lower bound estimate of 11 percent of people who saw the test ad who understood the limitation?
>
> A: Right.
>
> Q: And if you want further information, in your view, you have to go to the close-ended questions?
>
> A: Right.

(D.I. 93, Ex. D at 140:1-142:15.)

Thus, Dr. Dupont acknowledged that, based on the results of the open-ended questions alone, the only conclusion that could be drawn was that at least eleven percent of the people surveyed understood the message of the advertisement, and that

there was no way to tell how many more people understood the message. Dr. Schwartz stated in her report that the "data generated by the [closed-ended] question suggest that respondents were tending to guess when they chose an answer" (Schwartz Expert Report, D.I. 93, Ex. F at 17), and she thus testified in her deposition that, in her own analysis, she "place[d] no weight on [the responses to the closed-ended question] at all." (Schwartz Deposition, D.I. 93, Ex. E at 144:12.) In fact, Dr. Schwartz stated in her expert report that "there [was] no doubt that this close-ended survey question cannot be trusted to provide meaningful data." (Schwartz Expert Report, D.I. 93, Ex. F at 18.)

Thus, by the statements of TAP's own experts, including Dr. Dupont, the closed-ended question responses are so lacking in reliability as to be effectively meaningless. Dr. Dupont may therefore not testify about the responses to the closed-ended questions. He could at most testify that, based on the responses to the open-ended questions, at least eleven percent of people who saw the advertisement understood that it communicated only that Nexium was better at healing those with moderate to severe damage. Such testimony would provide, as Dr. Dupont himself testified, only a lower bound of the number of people who understood the advertisement. There is no evidence on which the jury could draw an inference about whether the other eighty-nine percent of survey participants were misled by the advertisement. Thus, the internet survey will not be helpful to the jury, as is required of expert testimony by Federal Rule of Evidence 702, because the jury will be unable to determine what, if any, percentage of the survey participants between zero and eighty-nine percent were misled by the Better is Better advertising campaign. The Motion to Strike will therefore be granted to

the extent that the internet survey conducted by Dr. Dupont, and all testimony regarding this survey, will be excluded.

c. Federal Rule of Evidence 403

Finally, AstraZenenca argues that both the Television and Internet Surveys should be excluded under Federal Rule of Evidence 403 because the probative value of each is substantially outweighed by the danger of unfair prejudice and potential to mislead the jury that each presents. (D.I. 92 at 17-18.) However, AstraZeneca's argument simply repeats the arguments it has already made for exclusion under Rule 702. Therefore, for the reasons stated above, the Motion to Strike the Television Survey will be denied, the Motion to Strike the Internet Survey will be granted, and no testimony as to the results of the internet survey will be permitted.

4. Motion to Strike Expert Testimony of Susan McDonald

AstraZeneca has moved to exclude the expert testimony of Dr. Susan S. McDonald based on her supplemental expert report. AstraZeneca contends that the opinions contained in Dr. McDonald's supplemental report invade the province of the fact-finder because they constitute Dr. McDonald's belief as to the weight of the testimony, go to the ultimate issue, and inappropriately address AstraZeneca's intent. (D.I. 92 at 19.) AstraZeneca also asserts that the opinions in Dr. McDonald's supplemental report are not grounded in the methods and procedures of science. (*Id.* at 20.) TAP responds by arguing that the testimony is not mere personal belief, is not on the ultimate issue, is based on market research, and is necessary to rebut testimony from AstraZeneca's witnesses. (D.I. 108 at 23-24.)

Expert witnesses are not "permitted to testify ... regarding [the defendant's] intent, motive, or state of mind, or evidence by which such state of mind may be inferred." *Oxford Gene Tech. Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 443 (D. Del. 2004); *see also id.* at 443, n.9 ("There are several instances in her report which could be interpreted as referring to or inferring [the defendant's] state of mind, including: referring to [the defendant] "recognizing" that its business activities might infringe the '270 patent, that [the defendant] may "feel" that a license is necessary , that [the defendant] may have been "concerned", and that [the defendant] had "concluded" whether it infringed or not.") (internal citations omitted). Here, Dr. McDonald's supplemental report is only one page, and includes her statements that, based on her review of various documents, "[AstraZeneca] was, in fact, seeking to utilize..." data on healing of EE and "[AstraZeneca] aimed" to elevate the importance of such data. (D.I. 93, Ex. G at 2.) This is the same kind of testimony on the intent of a party that was excluded in *Oxford Gene Tech.*, and it will not be permitted here.

TAP claims that it needs Dr. McDonald's testimony to rebut the testimony of AstraZeneca employees who will claim that they didn't intend to convey a false message. (D.I. 108 at 23-24.) However, TAP can rebut this testimony by introducing the market research questionnaires, qualitative studies, and memos that Dr. McDonald relied on in coming to the conclusions in her supplemental report. Accordingly, Dr. McDonald's testimony is excluded to the extent that she intends to testify regarding AstraZeneca's intent, and the Motion to Strike her supplemental expert report is granted to that extent.

E. Motion for Summary Judgment

AstraZeneca has moved for summary judgment, arguing that the Better is Better advertising campaign was not literally false, that the advertisements do not communicate any implied false messages, and that TAP has no evidence that any implied false messages are communicated. (D.I. 89 at 16-28.) TAP responds by arguing that the claims are literally false because, even if there is a statistically significant difference in healing rates for Nexium and Prevacid, that difference is not clinically significant. (D.I. 107 at 32-38.) Further, TAP asserts that its consumer surveys support a finding that consumers were led to believe two false claims: that Nexium is superior to Prevacid for symptom relief, and that Nexium is superior to Prevacid for healing all grades of EE. (*Id.* at 19-31.) I address each of the arguments below.

1. Literal Falsity

Section 43(a) of the Lanham Act, 15 U.S.C. § 1125 (a), states, in relevant part, that

> Any person who, on or in connection with any goods or services ... uses in commerce any ... 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.

When advertising relies on testing, a plaintiff must prove its case by "showing that the tests referred to ... were not sufficiently reliable to permit one to conclude with

reasonable certainty that they established the proposition for which they were cited." *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 62 -63 (2d Cir. 1992).

TAP does not dispute that the Castell and Fennerty studies show that Nexium is better than Prevacid by a statistically significant margin at healing moderate to severe acid related damage in the esophagus. (*See* D.I. 89 at 18; D.I. 107 at 32.) However, TAP claims that even if the studies show that Nexium is better than Prevacid by a statistically significant margin, the difference between the two medications has no clinical or therapeutic significance, and thus, that the Better is Better campaign is literally false. (D.I. 107 at 32-38.)

The cases that TAP cites for the proposition that clinical or therapeutic significance is required, however, are inapposite. Although the cases cited by TAP do require a clinically significant difference between two products, each of those cases is distinguishable from the situation here. In two of the cases cited by TAP, the courts found that there was a likelihood of success on the merits of the false advertising claim where tests that showed superiority had no relevance to a consumer's use of the product.

For example, in *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharma Co.*, 129 F. Supp. 2d 351 (D.N.J. 2000), the Court found a likelihood of success on the merits where advertisements for a product called "Mylanta Night Time Strength" "necessarily impl[ied] a claim of superior relief" by claiming that the product had a greater acid neutralization capacity based on tests performed in a beaker. *Id.* at 360. Experts had stated that the difference was "clinically proven 'to be irrelevant to

efficacy in the body,'" and "that slight differences in [acid neutralizing capacity] do not have clinical significance." *Id.*

Similarly, the Court in *Castrol, Inc. v. Quaker State Corp.*, No. 91 Civ. 8517 (CSH), 1992 WL 47981 (S.D.N.Y. Mar. 2, 1992), stated that although "the 1991 tests demonstrated a statistically significant difference in oiling time[, and] [t]he Quaker State Oil reached the designated areas of the engines more quickly than did the other oils," *id.* at *4, "to the extent tests were performed to demonstrate better wear protection (as opposed to faster flowing), the tests contradict, rather than support the claim." *Id.* at *8. Thus, there was a likelihood of success on the merits of the claim that commercials were literally false in stating that "Quaker State oil 'protects better' than any other leading oil". *Id.*

In the case at bar, by contrast, the Castell and Fennerty studies are relevant to a consumer's use of Nexium. Those studies show that, for patients with moderate to severe acid related esophageal damage, Nexium is at least statistically significantly better at healing that damage. Unlike the studies in Novartis and Castrol, which were totally irrelevant to a consumer's use of the products tested in those studies, the information from the Castell and Fennerty studies is relevant to consumers using Nexium.

Other cases cited by TAP deal not with literal truth or falsity of a claim, but with the implied truth or falsity of a claim. *See Abbott Laboratories v. Mead Johnson & Co.*, 971 F.2d 6, 15-16 (7th Cir. 1992) (affirming district court finding that "Mead's statement that Ricelyte has a lower osmolality than Pedialyte, while literally true, is misleading

because the difference in osmolality has no therapeutic significance"). Thus, TAP's claim that clinical significance is required goes to its implied falsity claims, not its claim that the Better is Better claim is literally false.

TAP also argues that, because FDA regulations on prescription drug advertising, 21 C.F.R. § 202.1(e)(7)(ii), state that an advertisement may be false if it "[u]ses the concept of 'statistical significance' to support a claim that has not been demonstrated to have clinical significance or validity[,]" clinical significance is required in order for the Better is Better campaign to be literally true. (D.I. 107 at 35-36.) However, refusing to ignore the "separate jurisprudence that has evolved" under the Lanham Act and under the FDA, the United States Court of Appeals for the Third Circuit has held "that it is not sufficient for a Lanham Act plaintiff to show only that the defendant's advertising claims of its own drug's effectiveness are inadequately substantiated under FDA guidelines; the plaintiff must also show that the claims are literally false or misleading to the public." *Sandoz Pharma Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229 (3d Cir. 1990). Thus, citation to the FDA guidelines, in the absence of proof of literal falsity or misleading of the public, is insufficient to show that the claims in the Better is Better campaign are false. Because there are no genuine issues of material fact, and TAP cannot meet its burden on literal falsity, summary judgment will be granted to AstraZeneca on this issue.

2. Implied Falsity

Where a plaintiff cannot show that a claim is literally false under the Lanham Act, it must show that the advertisement conveyed an impliedly false message that was misleading to consumers. *Johnson & Johnson-Merck Consumer Pharma Co. v.*

Rhone-Poulenc Rorer Pharma, Inc., 19 F.3d 125, 129 (3d Cir. 1994). However, "where the advertisements are not literally false, plaintiff bears the burden of proving actual deception by a preponderance of the evidence. Hence, it cannot obtain relief by arguing how consumers could react; it must show how consumers actually do react." *Sandoz Pharma Corp.*, 902 F.2d at 228-29. "Public reaction is the measure of a commercial's impact ... [and] the success of the claim usually turns on the persuasiveness of a consumer survey." *Johnson & Johnson-Merck*, 19 F.3d at 129-30 (internal citations omitted). Thus, to prevail on its implied false advertising claims, TAP must show, through its consumer surveys, that consumers were actually misled by AstraZeneca's advertising.

TAP claims that the Better is Better campaign makes two impliedly false claims: that Nexium is better for healing of all grades of EE, not just moderate to severe EE, and that Nexium is better for overall relief of acid reflux disease. (D.I. 107 at 19-31.) TAP relies on the two surveys conducted by Dr. Dupont to show that consumers were misled by the Better is Better campaign. (D.I. 107 at 19-22, 26-31.) Dr. Dupont's Television Survey measured whether consumers were led to believe that Nexium is better for overall relief of acid reflux disease, and his Internet Survey measured whether consumers were led to believe that Nexium is better at treating all grades of EE. This survey evidence is necessary to substantiate TAP's claims of implied falsity. (Preliminary Injunction Transcript, D.I. 90, Ex. A at 37:25-38:10.)

For the reasons already stated (*supra* section IV.B.3.b.), however, the Internet Survey conducted by Dr. Dupont will be excluded from this case, and TAP may not rely upon it. Thus, TAP has no evidence to substantiate a claim that consumers were

misled by the internet advertising in the Better is Better campaign. The survey that Dr. Dupont conducted on the television advertisement, on the other hand, is admissible and TAP may continue to argue that the television advertisement was misleading to consumers. However, TAP can only use the evidence actually presented in the television survey: namely, that consumers were led by the television advertisement to believe that Nexium was better than Prevacid at treating all of the symptoms of acid reflux disease, not just better at relieving EE. TAP may not argue, because it has no evidence to substantiate such a claim, that any of the other aspects of the Better is Better campaign were misleading to consumers. Therefore, to the extent that TAP argues that aspects of the Better is Better campaign other than the television advertisements were misleading to consumers, summary judgment will be granted to AstraZeneca.[12]

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[12] TAP is incorrect to the extent it asserts that it can use the television survey to show that consumers were misled by other media employed in the Better is Better campaign. *See Am. Home Prods. Corp. v. Procter & Gamble Co.*, 871 F.Supp. 739, 762 (D.N.J. 1994) ("The Court rejects AHP's contention that the FSI and television survey, even if probative, can be employed to assess whether other ALEVE print advertising (i.e., the New York Times advertisement) was false or misleading to the public."); *Am. Exp. Travel Related Services Co., Inc. v. MasterCard Int'l Inc.*, 776 F.Supp. 787, 790 (S.D.N.Y. 1991) ("The consumer reaction survey used by plaintiff to attempt to prove that "Directions" conveys a false and misleading message to consumers has no bearing on the new commercial, "Directions 2." The survey does not prove that the new commercial implicitly misleads consumers nor does it raise serious questions going to the merits to make them a fair ground for litigation."). Thus, TAP may not use the television survey to claim that the print advertisements, website materials, or informational pamphlet were false or misleading.

3. False by Necessary Implication

Finally, TAP argues that AstraZeneca's motion for summary judgment should be denied because the claims in the Better is Better advertising campaign are false by necessary implication. (D.I. 107 at 22-25.) For a claim to be false by necessary implication, "the consumer [must] unavoidably receive a false message" from the advertising. *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharma Co.*, 290 F.3d 578, 587 (3d Cir. 2002) (discussing "the common theme" in false by necessary implication cases). TAP failed to make that showing at the preliminary injunction stage of the case, and it has done nothing more here to establish the linkage between the words of the Better is Better advertisements and the false claim that TAP alleges. TAP actually mischaracterizes the words of the television advertisement in its brief, when attempting to draw such a connection. (*See* D.I. 107 at 25 ("The commercial states that 'if you suffer from frequent heartburn' and 'if I told you' that NEXIUM was better for acid reflux disease, you'd want proof."); *compare* Television commercial, D.I. 90, Ex. C ("So if you suffer from acid reflux disease, frequent heartburn, and I told you prescription Nexium heals acid related damage in the esophagus better, you'd want proof.").) Thus, because TAP has failed to adduce evidence to properly support its assertion that the Better is Better campaign presents a claim that is false by necessary implication, AstraZeneca's motion for summary judgment will be granted as to that claim.

In summary, AstraZeneca's Motion for Summary Judgment will be denied as to allegations of impliedly false claims in the television commercial, because genuine

issues of material fact remain as to that claim, and will be granted in all other respects.[13]

V. CONCLUSION

Accordingly, the Motion for Summary Judgment (D.I. 88) will be granted as to TAP's claims that the Better is Better campaign was literally false, that the campaign was literally false by necessary implication, and that it was impliedly false as to all media other than the television commercial. The motion will be denied as to TAP's claims that the television commercial was impliedly false. The Motion to Exclude Expert Testimony of Thomas Dupont and Susan S. McDonald (D.I. 91) will be granted to the extent that Dr. Dupont's report and all testimony regarding his internet survey will be excluded and Dr. McDonald's testimony regarding her supplemental report will be excluded. The motion will be denied in all other respects. The Motion to Strike TAP's jury demand will GRANTED. All of the other motions (D.I. 87, 94) will be denied. An appropriate order will follow.

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[13] The decisions set forth in this Memorandum Opinion, and in the previous opinion and order excluding the expert testimony of Creighton G. Hoffman (D.I. 154, 155) leave this case with what appears to be no other issue to be tried than whether AstraZeneca should be permanently enjoined from pursuing an advertising campaign it has already abandoned. The parties are therefore directed to contact the court forthwith to arrange a teleconference to discuss further proceedings in this matter.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA LP,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 04-1332-KAJ
	)	
TAP PHARMACEUTICAL PRODUCTS, INC.,	)	
	)	
	)	
Defendant.	)	

ORDER

For the reasons set forth in the Memorandum Opinion issued in this matter today,

IT IS HEREBY ORDERED that the Motion for Summary Judgment (D.I. 88) is GRANTED as to TAP's claims that the Better is Better campaign was literally false, that the campaign was literally false by necessary implication, and that it was impliedly false as to all media other than the television commercial, and is DENIED as to TAP's claims that the television commercial was impliedly false.

IT IS FURTHER ORDERED that the Motion to Exclude Expert Testimony of Thomas Dupont and Susan S. McDonald (D.I. 91) is GRANTED to the extent that Dr. Dupont's report and all testimony regarding his internet survey is excluded and Dr. McDonald's testimony regarding her supplemental report is excluded, and is DENIED in all other respects.

IT IS FURTHER ORDERED THAT the Motion to Strike TAP's jury demand is GRANTED.

IT IS FURTHER ORDERED THAT all other motions (D.I. 87, 94) are DENIED.

UNITED STATES DISTRICT JUDGE

Wilmington, Delaware
June 23, 2006