**UNITED STATES COURT OF APPEALS**
**FOR THE SECOND CIRCUIT**

August Term, 2015

(Argued: March 11, 2016 Decided: September 9, 2016)

Docket No. 15-2411

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CHURCH & DWIGHT CO., INC.,

*Plaintiff-Appellee*,

v.

SPD SWISS PRECISION DIAGNOSTICS, GMBH,

*Defendant-Appellant*.

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Before:

LEVAL and WESLEY, *Circuit Judges*, and SANNES, *District Judge*.[1]

Defendant, a marketer of over-the-counter, home pregnancy tests, appeals from the judgment of the United States District Court for the Southern District of New York (Nathan, *J.*), which, following a bench trial, found Defendant liable for false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and issued a permanent injunction prohibiting Defendant from using certain advertising and packaging and requiring it to issue corrective notices and advertising. The false advertising at issue involves the "Weeks Estimator" feature of Defendant's product, which informs the user the number of the weeks elapsed since ovulation. The medical profession traditionally measures the advancement of a pregnancy not from the date of ovulation or fertilization, but rather from the date of last menstrual period, which generally occurs approximately two weeks prior to ovulation. Plaintiff alleged, and the district court agreed, that packaging and advertising messages used by Defendant were false because they implied

[1] The Honorable Brenda K. Sannes, of the United States District Court for the Northern District of New York, sitting by designation.

that Defendant's product measures weeks of pregnancy in a manner consistent with the metric used by doctors.

The Court of Appeals concludes that 1) Plaintiff's Lanham Act claim is not precluded by the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*.; 2) the district court did not err in finding falsity in Defendant's original packaging; 3) the district court did not err in finding the revised packaging impliedly false by reason of consumer confusion; 4) the district court made no error in ruling that Defendant's false messages were material and likely to harm Plaintiff; and 5) the district court was within its discretion in imposing an injunction requiring changes to Defendant's packaging and requiring Defendant to issue corrective notices and corrective advertising.

AFFIRMED.

PAUL D. CLEMENT, Bancroft PLLC, Washington, DC (Jeffrey M. Harris, Amy O. Nyberg, Bancroft PLLC, Washington, DC and Richard M. Goldstein, Lawrence T. Weinstein, Michael T. Mervis, Baldassare Vinti, Jeffrey H. Warshafsky, Q. Jennifer Yang, Proskauer Rose LLP, New York, NY, *on the brief*), *for Plaintiff-Appellee*.

SETH P. WAXMAN, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, DC (Thomas G. Saunders, Ari J. Savitzky, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, DC; Hanna A. Baek, Wilmer Cutler Pickering Hale and Dorr LLP, New York, NY; and Jeffrey G. Knowles, Julia D. Greer, David Mehretu, Alice H. Wang, Coblentz Patch Duffy & Bass LLP, San Francisco, CA, *on the brief*), *for Defendant-Appellant*.

LEVAL, *Circuit Judge*:

In an exceptionally well argued case, Defendant SPD Swiss Precision Diagnostics GmbH, a marketer of over-the-counter pregnancy test kits, appeals from the judgment of the United States District Court for the Southern District of New York (Nathan, *J.*), in favor of Plaintiff Church & Dwight Co. Inc., a leading competing marketer of over-the-counter pregnancy test kits. After a bench trial, the district court found Defendant liable for false advertising, in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). The pregnancy tests of both Plaintiff and Defendant detect pregnancy by the presence in the woman's urine of the hormone human chorionic gonadotropin ("hCG"), which is produced upon the implantation of a fertilized egg in a woman's uterus. In August 2013, following a Food and Drug Administration ("FDA") approval process, Defendant released its new product, the Clearblue Advanced Pregnancy Test with Weeks Estimator (the "Product"). Defendant's Product, in addition to telling the woman whether she is pregnant, is the first such product to also furnish information as to how long (how many weeks) she has been pregnant, which it does by measuring the *amount* of hCG in her urine.

Plaintiff's claims focus on how Defendant's Product packaging characterized the advancement of pregnancy. The information communicated by Defendant's Product was the number of weeks passed *since the woman's*

*ovulation*. (An egg is ripe and capable of fertilization only for twenty-four hours following ovulation.[2] Implantation of the fertilized egg in the uterine lining, which causes the release of hCG, occurs between six and nine days after ovulation.)

For a number of reasons—partially historical, partially because of the desirability of conformity—the metric commonly used by the medical profession to describe how long a woman has been pregnant (notwithstanding its obvious literal inaccuracy) speaks in terms of the number of weeks elapsed not since ovulation, fertilization, or implantation of the egg, but since the woman's last menstrual period (the "LMP") . A pregnant woman's LMP normally occurs approximately *two weeks prior to her ovulation*. Thus, the medical profession's conventional formula to describe how many weeks a woman has been pregnant yields a number two weeks higher than the number furnished by the Product, which measures weeks since ovulation. It is an uncontested given in this litigation that, when the Defendant's Product and the woman's doctor are in complete agreement in estimating how long the woman has been pregnant, the Product would announce a number of weeks that is about two weeks lower than what the doctor would say.[3]

[2] Except when certain in vitro fertilization methods are used.
[3] For example, if a doctor would tell a woman she is three weeks pregnant, then the Product would indicate that the same woman is one week pregnant.

The gist of Plaintiff's claim is that, in informing the user as to how long her pregnancy had been in effect, Defendant's Product communicated the false impression that it uses the same metric and gives the same number of weeks of pregnancy as a medical professional would do.

The district court ruled in favor of Plaintiff. It found, among other things, that Defendant had advertised falsely in its packaging at the time of the Product launch (the "Launch Package") and launch advertising, and also in the revised packaging that Defendant substituted after the FDA had expressed concerns about the Launch Package (the "Revised Package"). The court relied on different theories as between the messages associated with Launch Package and those accompanying the Revised Package. For the Launch Package and its accompanying advertising, the court found, among other things, that these materials unambiguously implied a false message that the Product gives the duration of a pregnancy in terms that are consistent with the metric used by doctors to estimate weeks-pregnant. For the Revised Package, the court relied on survey evidence to support a finding that Defendant communicated a misleading message.

The district court imposed an injunction on Defendant. The court's order, among other things, prohibited Defendant from distributing the misleading materials and from using specified phrases. The order also required Defendant to

issue various corrective notices and advertising acknowledging that it had been found to have engaged in false advertising.

We affirm the district court's judgment. We agree with the district court that Plaintiff's Lanham Act claim is not precluded by the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"). We find no error in the court's finding of falsity in Defendant's Launch Package and advertising messages associated with it by reason of their unambiguous implication that Defendant's Product measures weeks-pregnant in a manner that is consistent with the measurement used by doctors. Nor do we find fault in the district court's finding, based on survey evidence, that the message communicated by the Revised Package was impliedly false. We also find no error in the district court's findings that the falsity was material and injurious to Plaintiff. Finally, we hold that the court did not abuse its discretion in issuing the injunction.

## BACKGROUND

### I. Parties

Plaintiff and Defendant are leading manufacturers of home, over-the-counter pregnancy tests and direct competitors in the U.S. market. Plaintiff uses the brand name "First Response," while Defendant uses the "Clearblue" brand. Plaintiff's First Response products have generally led the home pregnancy test market, and Defendant's Clearblue products have been Plaintiff's closest competitor.

## II. Background Biology and Medical Conventions

The issues raised in this case involve the biology of the reproductive cycle and, relatedly, the medical conventions used by doctors to measure and describe the duration of pregnancy. The district court described these issues with a clarity on which we cannot improve. We set forth the district court's explanation here:

> **The Reproductive Cycle**
>
> . . . .
>
> The typical menstrual cycle lasts 28 days and is marked by two key events: the menstrual period and ovulation. The latter is the release of a ripe egg (or ovum) from the ovary. The time from [LMP] to ovulation, known as the follicular phase of the menstrual cycle, is generally two weeks, but variance in the length of the follicular phase can be "significant." The time from ovulation to the next menstrual period, known as the luteal phase of the menstrual cycle, is two weeks and is subject to much less variance than the follicular phase.
>
> For a successful pregnancy to proceed, the following steps must take place. First, either through sexual intercourse or assisted reproductive technology, sperm must fertilize an egg within 24 hours of ovulation because a ripe egg can survive outside the ovary for only about 12 to 24 hours.[4] In the case of sexual intercourse, fertilization may occur several days after intercourse, but it will not occur more than one day after ovulation. Second, the fertilized egg, now referred to as a blastocyst, must travel down the fallopian tube to the uterus. Third, the blastocyst must adhere to the endometrium (part of the lining of the uterus), a process called implantation, which occurs approximately six to nine days after ovulation. Once implantation occurs, the blastocyst begins secreting [hCG], a hormone that, among

[4] In this passage, the district court was not describing certain in vitro fertilization technologies that permit preservation of an egg for fertilization at a later date.

other things, signals to a woman's body that she is pregnant and prevents menses.

Home pregnancy tests, including [Defendant's] Clearblue brand and [Plaintiff's] First Response brand, determine whether a woman is pregnant by detecting the presence (or absence) of hCG—the hormone released following implantation—in urine.

**The Multiple Methods Used to Determine Pregnancy Duration**

Prior to advances in modern medicine, doctors had only one way to determine a woman's estimated date of delivery: the date of her LMP, which occurs, on average, 40 weeks prior to delivery. Before the development of more advanced medical technology, such as ultrasound, a woman's LMP provided the most readily available and reliable estimate of pregnancy duration, which is also known as gestational age. One of the disadvantages of using LMP for determining pregnancy duration is that it assumes a standard 28-day menstrual cycle and that ovulation occurs on day 14; [however], the follicular phase of the menstrual cycle is prone to vary. In addition, women often have a poor recollection of their LMP. These two shortcomings mean that an estimate based on LMP may provide an inaccurate prediction of the date of delivery.

Ultrasound technology provides doctors with a more sophisticated way to determine pregnancy duration, and it is now "standard practice to take an ultrasound scan of the developing fetus about 8 to 12 weeks after the reported LMP." An ultrasound scan is used to measure a fetus's crown-rump length, which, using a formula, can be converted into an estimate of "embryonic age" (the number of weeks that have passed since fertilization). Because fertilization occurs, on average, two weeks after a woman's LMP, a woman's estimated date of delivery is generally 38 weeks after fertilization. Although ultrasound results are more accurate, "the date of the LMP. . . remains the most commonly used method for estimating gestational age and assigning a due date."

. . . .[5]

**The Standard Convention for Expressing Pregnancy Duration**

Although there are multiple ways to determine a woman's estimated date of delivery, and thus the duration of her pregnancy, there is a separate issue of how to express it—i.e., what words to use to describe "how far along" the pregnancy is. And on this point, which is the point that truly matters for resolution of this case, there is little genuine dispute. Doctors and others use a standard convention to express pregnancy duration. It is stated in terms of the number of weeks since a woman's LMP. As [Defendant]'s medical expert, Dr. Kurt Barnhart, testified: "While doctors have long known that women are not, and cannot be, pregnant at their LMP because ovulation does not occur, on average, for another two weeks, LMP has continued to be a reference point because, until relatively recently, it was either impossible or impractical to estimate when ovulation occurred." He further noted that "even after the advent of ultrasound scanning technology, the methods for estimating when ovulation (and hence fertilization) occurred were generally intrusive, expensive, and/or impractical, and obviously could not be self-administered by a woman at home prior to becoming pregnant." Thus, for both historical and practical reasons, *dating a woman's pregnancy from her LMP has been and remains a widely used method for determining pregnancy duration. But more importantly, it has continued to be the standard—indeed, universal—convention for expressing pregnancy duration*.

In fact, even when pregnancy duration is determined using other methods, such as ultrasound scans, most medical professionals still convert to the LMP convention when communicating pregnancy duration to patients and other medical providers. Ultrasound machines are even programmed to automatically convert an estimate of embryonic age based on crown-rump length into an estimate of pregnancy duration based on weeks since LMP. . . .

[5] We have not included a passage describing in vitro fertilization that is not pertinent to the issues before us.

> "[D]octors typically will date the pregnancy according to the ultrasound results, but they will (by convention) express the duration of pregnancy in terms of the time since LMP would have been expected to occur in a normal menstrual cycle." . . . In short, while doctors may have multiple ways to arrive at the convention—e.g., LMP, ultrasound, date of embryo transfer—they use a standard and uniform convention for expressing pregnancy duration: weeks since LMP.

S.P.A. 5-9 (footnotes, citations, and original brackets omitted) (original emphases omitted and emphasis added).

## III. Defendant's Product

### a. The Weeks Estimator

Before Defendant's Product was released, most pregnancy tests were binary, expressing only whether or not a woman is pregnant, which was detected by the presence of hCG in her urine. Defendant's Product, by measurement of the *amount* of hCG rather than only its presence, additionally estimates time elapsed since implantation. The number of weeks stated by Defendant's Product as having passed is the number of weeks since ovulation. Depending on the Product's hCG measurement, its message to the user reads either "Not Pregnant" or "Pregnant" and "1-2 [weeks]"; "2-3 [weeks]"; or "3+ [weeks]." If the result reads Pregnant, 1-2 weeks, 2-3 weeks, or 3+ weeks, that means that the user is pregnant and that her hCG levels indicate that the stated number of weeks have passed *since ovulation*.

**b. The FDA Clearance Process**

Home pregnancy tests are Class II medical devices and, as such, they are subject to FDA regulation. Specifically, they are subject to the requirements of § 510(k) of the FDCA, 21 U.S.C. § 360(k), known as the "§ 510(k) process." *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-79 (1996). Under the § 510(k) process, a party seeking to market a Class II device must submit a "premarket notification" to the FDA, which must include a description of the device, a statement of intended use, the proposed labeling, and any other information necessary for the FDA to determine if the device is "substantially equivalent" to an existing authorized device. A determination that the new device is substantially equivalent to a preexisting device is essentially a finding that the new device is as safe and effective as the preexisting device, meaning the new device may be marketed without further analysis. *Id.* Under § 513(i)(1)(E) of the FDCA, the FDA may, notwithstanding a substantial equivalence determination, require changes to the product's labeling or promotional materials designed to discourage potential off-label use of the product that might cause harm to consumers. 21 U.S.C. § 360c(i)(1)(E).

Defendant began the § 510(k) process for the Product in 2008. The FDA issued a "hold letter" in August 2012, expressing a concern that the "weeks indicator feature may provide misleading information to lay population of users."

J.A. 7581. The letter noted that "[f]or example, the output of this test is not aligned with gestational aging done by healthcare professionals (*i.e.* it will under-estimate gestational age by an average of 2 weeks)." *Id.* The letter also expressed concern that "users [may] misinterpret the weeks results to be a substitution for gestational age determination or may misinterpret weeks results to mean they are pregnant and their pregnancy is progressing in a healthy manner." *Id.* Among other things, the hold letter required that Defendant remove the phrase "Also Tells you How Far Along you Are" from the Product's box. J.A. 7581-83.

After additional communication between Defendant and the FDA, the FDA issued a final "clearance letter" on December 10, 2012. The clearance letter stated that Defendant could begin marketing the device but also invoked the FDA's § 513(i)(1)(E) authority to impose limitations on the Product's advertising and labeling. The clearance letter required, among other things, that Defendant include a specific "conversion chart" explaining how a doctor would date the pregnancy compared to the Product's results, using language provided by the FDA. It also specified that the Product's results not be expressed as "weeks pregnant," but only as the number of weeks since ovulation. J.A. 3368-69.

Additionally, the clearance letter required that the Product include the following Indications for Use Statement:

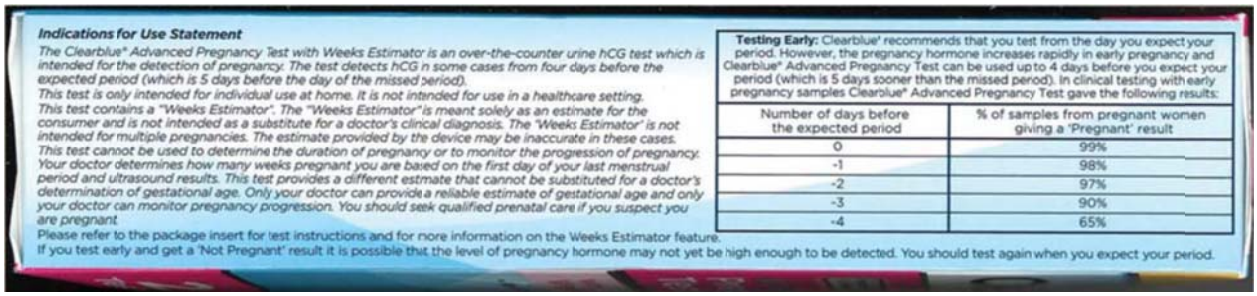
> The Clearblue Advanced Pregnancy Test with Weeks Estimator is an over-the-counter urine hCG test which is intended for the detection of pregnancy. The test detects hCG in some cases from four days before the expected period (which is 5 days before the day of the missed period).
>
> This test is only intended for individual use at home. It is not intended for use in a healthcare setting.
>
> This test contains a "Weeks Estimator." The "Weeks Estimator" is meant solely as an estimate for the consumer and is not intended as a substitute for a doctor's clinical diagnosis. The "Weeks Estimator" is not intended for multiple pregnancies. The estimate provided by the device may be inaccurate in these cases.
>
> This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy. Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that cannot be substituted for a doctor's determination of gestational age. Only your doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression. You should seek qualified prenatal care if you suspect you are pregnant.

J.A. 3370.

The clearance letter stated that the "FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the [FDCA] or any Federal statutes and regulations administered by other Federal agencies." *Id.* Additionally, the letter reminded Defendant that it must obtain FDA approval before modifying or removing any of the required labeling.

**c. The Launch Package and Advertising Campaign**

Defendant launched the Product in August 2013. The Launch Package contained the Product's name—Clearblue Advanced Pregnancy Test with Weeks Estimator—in large font, along with a picture of the Product. The Launch Package also exhibited four windows, designed to appear similar to the window that appears on the Product itself. One window showed the word "Pregnant" on the first line and "1-2 weeks" on the second; the second showed the word "Pregnant" on the first line and "2-3 weeks" on the second; the third showed the word "Pregnant" on the first line and "3+ weeks" on the second; and the fourth read "Not Pregnant." (See image below.) The word "ovulation" did not appear on the front or back of the Launch Package to describe the Product. One side panel of the Launch Package contained the full FDA-required Indications for Use Statement in small font. (See image below.)



**Indications for Use Statement**

The Clearblue® Advanced Pregnancy Test with Weeks Estimator is an over-the-counter urine hCG test which is intended for the detection of pregnancy. The test detects hCG in some cases from four days before the expected period (which is 5 days before the day of the missed period).
This test is only intended for individual use at home. It is not intended for use in a healthcare setting.
This test contains a "Weeks Estimator". The "Weeks Estimator" is meant solely as an estimate for the consumer and is not intended as a substitute for a doctor's clinical diagnosis. The 'Weeks Estimator' is not intended for multiple pregnancies. The estimate provided by the device may be inaccurate in these cases.
This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy. Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estmate that cannot be substituted for a doctor's determination of gestational age. Only your doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression. You should seek qualified prenatal care if you suspect you are pregnant
Please refer to the package insert for test instructions and for more information on the Weeks Estimator feature.
If you test early and get a 'Not Pregnant' result it is possible that the level of pregnancy hormone may not yet be high enough to be detected. You should test again when you expect your period.

**Testing Early:** Clearblue® recommends that you test from the day you expect your period. However, the pregnancy hormone increases rapidly in early pregnancy and Clearblue® Advanced Pregnancy Test can be used up to 4 days before you expect your period (which is 5 days sooner than the missed period). In clinical testing with early pregnancy samples Clearblue® Advanced Pregnancy Test gave the following results:

| Number of days before the expected period | % of samples from pregnant women giving a 'Pregnant' result |
|---|---|
| 0 | 99% |
| -1 | 98% |
| -2 | 97% |
| -3 | 90% |
| -4 | 65% |

The Product launch was accompanied by a marketing campaign. One feature of the campaign was a fifteen-second television commercial that ran from August 28, 2013 to December 2, 2013 (the "TV Commercial"). The commercial showed two women sitting at a kitchen table, engaging in the following dialogue:

> Woman 1: I'm pregnant.
>
> Woman 2: Really?
>
> Woman 1: Two weeks.
>
> Woman 2: You already went to the doctor?
>
> Woman 1: Not yet, but I took this new Clearblue test. It's like two tests in one.
>
> Woman 2: Oh my God, I think I'm going to cry!

J.A. 3384-85. During and after this dialogue, the screen shifted to examples of the various results that can appear on the device, such as "Pregnant / 1-2 Weeks." For two seconds of the commercial, the words "ESTIMATED WEEKS SINCE OVULATION" appeared on the screen, and for nine seconds the following appeared at the bottom of the screen:

> Word "weeks" on display is for illustration only. For home use only.

> Always consult a doctor if you suspect you are pregnant and to confirm, date and monitor pregnancy. Not for multiple pregnancies. Estimates weeks since ovulation up to 3+ weeks. Do not use to monitor pregnancy progress or duration.

The commercial closed with a voiceover: "The new Clearblue pregnancy test also estimates how many weeks. Weeks Estimator. Only from Clearblue." *Id*.

Defendant maintained a webpage dedicated to promoting the Product. A banner at the top of the page stated: "The ONLY Pregnancy Test that Estimates Weeks." A large photo of the Product appeared with the window reading "Pregnant / 1-2 weeks." The webpage stated that the Product "is the FIRST and ONLY pregnancy test that not only tests you if you are pregnant but also estimates the number of weeks. It's like 2 tests in 1!" J.A. 3415.

Defendant also promoted the Product through product placement in the television program "The Doctors." Additionally, Defendant marketed the Product in retailer presentations, web banners, retailer circulars and websites, and in-store advertising. For example, one advertisement that appeared in Walgreens stated "How Far Along Am I? Clearblue Advanced Pregnancy Test with Weeks Estimator tells you in words if you are pregnant, and estimates how many weeks by measuring the pregnancy hormone level." J.A. 3418-19.

**d. The FDA's Response**

After receiving complaints from Plaintiff, the FDA emailed Defendant in

November 2013 stating, "[i]t has come to our attention that [Defendant] is marketing the 'Clearblue Advanced Pregnancy Test with Weeks Estimator' device in violation of the limitations in FDA's clearance letter." J.A. 2152. During a November 18, 2013 conference call with Defendant, the FDA related its concerns. Among other things, the FDA complained that the Launch Package included display windows with the word "weeks." It instructed Defendant to remove the word "weeks" from the windows and replace it with "weeks along" outside the windows.

After some back and forth with the FDA, Defendant submitted a "mitigation proposal" to address the FDA's concerns, which ultimately resulted in the Revised Package and advertising.

**e. The Revised Package and Advertising Campaign**

The Revised Package, which was launched in February 2014, differed from the Launch Package in several ways. The Revised Package included a gray strip in the top right corner with the phrase "Only Test That Estimates Weeks Since Ovulation*". The asterisk linked to the Indications for Use Statement on the side panel. The four screens on the front of the package no longer contained the word "weeks"; instead, "weeks along" was printed below the screens, as specified by the FDA. (See image below.)


Defendant stopped airing the TV Commercial and replaced it with an Internet-Only Commercial. The Internet-Only Commercial was similar to the TV Commercial, but the dialogue was changed to remove the discussion of a doctor and Woman 1's declaration of how far along she was. Defendant also launched a new webpage which essentially made the same changes as those made in the Revised Package. The first paragraph on the webpage was also modified to read: "Clearblue Advanced Pregnancy Test with Weeks Estimator is the FIRST and ONLY pregnancy test that not only tells you if you are pregnant but also estimates the number of weeks since ovulation. It's like 2 tests in 1!" J.A. 3165.

## IV. Proceedings Below

### a. Preclusion Arguments

Plaintiff initiated this action by a complaint filed on January 29, 2014 and moved for a preliminary injunction. Defendant moved to dismiss the complaint.

Defendant's main argument on its motion to dismiss was that the FDCA precluded Plaintiff's Lanham Act claim. On June 3, 2014, the district court denied Defendant's motion to dismiss, finding, among other things, that Plaintiff's Lanham Act claim would not usurp the FDA's role in enforcement of the FDCA and its associated regulations. The district court also directed that the preliminary injunction hearing would be consolidated with the bench trial on liability. *See* Fed. R. Civ. Proc. 65(a)(2).

Before trial, Defendant submitted a motion *in limine* renewing its preclusion argument in light of the Supreme Court's recent decision in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014). The district court adhered to its position that there was no preclusion, finding that *POM Wonderful* reinforced, rather than undermined, the district court's original decision.

**b. Bench Trial on Liability**

At the parties' request, the district court bifurcated trial, as between liability and damages. It then conducted a two-week bench trial on liability in April 2015. The court issued an opinion on July 1, 2015 finding Defendant liable for falsely advertising in the Launch Package and its associated advertising, as well as in the Revised Package. The court also determined that, at least around the time the Launch Package was created, Defendant had deliberately set out to deceive

consumers into believing that the Product could provide a measure of weeks-pregnant consistent with what doctors provide.

**c. Injunction**

The district court concluded that Plaintiff was entitled to an injunction because, among other things, it had demonstrated irreparable harm—the parties were clearly competitors and there was a logical causal connection between Defendant's false advertising and Plaintiff's sales.

On August 26, 2015, the district court entered a permanent injunction. The court's order: (a) enjoined Defendant from communicating in any advertising that the Product provides an estimate of weeks pregnant that is the same as a doctor's estimate; (b) enjoined Defendant from distributing or communicating any of the Launch or Revised Packaging or advertising and required Defendant to remove all current products from points of sale within forty-five days; (c) required Defendant to include with the Product a specified forty-one-word statement clarifying the difference in the estimates, in a particular position and font size; (d) prohibited Defendant from using several phrases in its advertising, such as "weeks pregnant," "weeks along," or "Weeks Estimator"; (e) required Defendant to deliver within seven days to all retailers and distributors a specified written notice ("Corrective Notice") with a copy of the injunction; (f) required Defendant, for one year, to make available copies of the Corrective Notice with copies of the injunction in

prominent locations at all U.S. trade shows and professional meetings attended by Defendant or any of its representatives; (g) required Defendant within seven days to set up and maintain for a year a stand-alone page on its website with a specified messaging about the lawsuit and what the court found to be Defendant's history of providing misleading information about the Product; (h) required Defendant to publish a statement in retailer circulars to the same effect; (i) required Defendant to publish Internet-banner advertising prominently displaying its logo and stating that a federal court has determined that Defendant "engaged in false advertising"; (j) required Defendant to publish in three parenting magazines full-page advertisements including a statement similar to the one on the standalone webpage; and (k) required Defendant to produce a video explaining the difference between the Product's and medical profession's pregnancy length estimates and stating that "a federal court found the manufacturer . . . to have engaged in false advertising," and to make it prominently available on Defendant's webpages, YouTube channels, and Facebook page. S.P.A. 55-60.

## DISCUSSION

On appeal, Defendant raises several challenges to the district court's conclusions. First, Defendant renews its argument that the Plaintiff's Lanham Act claim is precluded by the FDCA. Second, Defendant challenges the district court's finding of Lanham Act liability by arguing that the district court misapplied the

literal falsity and implied falsity analyses to the Launch Package, TV Commercial, and other advertising, that the district court erred in relying on flawed survey evidence to find implied falsity with respect to the Revised Package, and that the district court erred in finding injury and materiality. Finally, Defendant contends that the injunction is inappropriately broad in scope and overly punitive.

Defendant's preclusion argument presents a question of law, which we review *de novo*. *Cf. Goodspeed Airport LLC v. E. Haddam Inland Wetlands & Watercourses Comm'n*, 634 F.3d 206, 209 n.3 (2d Cir. 2011) ("We review *de novo* a district court's application of preemption principles."). When reviewing a district court's judgment following a bench trial, we review the court's findings of fact for clear error and its conclusions of law *de novo*. *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 255, 261-62 (2d Cir. 2014); *see also Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007). We review the scope of a permanent injunction for abuse of discretion. *Merck Eprova*, 760 F.3d at 265.

## I. Preclusion

Defendant contends that Plaintiff's Lanham Act claim is precluded by Congress's provision for intensive regulation of Defendant's Product by the FDA. Defendant argues that it cannot be held liable for its labeling and promotional materials because those materials were under FDA "control," having been

reviewed and approved by the FDA through the FDCA § 510(k) process. Appellant's Br. 23.

We hold that Plaintiff's Lanham Act claim is not precluded. Notwithstanding certain differences, the Supreme Court case of *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014) presents similar facts, and the Court's ruling is instructive. *POM Wonderful* concerned a Lanham Act challenge between two marketers of fruit juice. The plaintiff alleged that the defendant's practice of calling its juice blend "pomegranate blueberry," when it only contained 0.3% pomegranate juice and 0.2% blueberry juice, was deceptive. The defendant argued that a Lanham Act suit regarding the labeling of its product was precluded by the FDCA, which regulates the labeling of food products to protect the public against false labeling. 21 U.S.C. §§ 331, 343.

The Supreme Court addressed the interaction between the Lanham Act's unfair competition provisions and the FDCA. The Court concluded that the Lanham Act claim was not precluded. *POM* Wonderful, 134 S. Ct. at 2238-39. Applying principles of statutory interpretation, the Court found, among other things, that the Lanham Act and the FDCA complement one another because "each [statute] has its own scope and purpose." *Id.* at 2238. The Lanham Act "protects commercial interests against unfair competition, while the FDCA protects public health and safety." *Id*. The Court noted that Congress's intent in maintaining the

distinction between these goals can be further seen in the fact that the FDCA's enforcement is by the FDA, which does not have a mission to protect the concerns of a competitor harmed by the regulated entity's misleading advertising or labeling. *Id*.

The Court also rejected an alternative position, proposed by the government as *amicus curiae*, that Lanham Act claims are not precluded by the mere fact that the FDCA covers a product generally, but are precluded in situations when the FDCA or the FDA, through its regulations, have "specifically require[d] or authorize[d]" a challenged aspect of a label. *Id*. at 2240. The Court rejected the proposition that the FDCA's or FDA's regulation of a label creates a "ceiling" that precludes any further challenges to that label under other statutes. *Id*. The Court concluded that even the government's limited preclusion theory would distort Congress's intent to allow the Lanham Act and the FDCA to exist in tandem to serve the distinct interests each statute protects. *Id*. at 2240-41.

We agree with the district court that *POM Wonderful* is controlling here. We see no reason why the subjugation of Defendant's Product labeling to FDA regulation through the § 510(k) process should categorically immunize it from Lanham Act claims by competitors regarding the regulated labeling. As the *POM Wonderful* opinion noted, regardless of the fact that the FDCA and Lanham Act sometimes overlap in scope and effect, each statute nonetheless has a distinct

purpose, and in carrying out its FDCA duties, the FDA is not charged with protecting the interests of its subject's competitors. *Id.* at 2238-39.

The fact that the FDA has satisfied itself that a product's labeling is sufficiently accurate to secure FDA approval gives no assurance that the intervention of a competitor would not reveal problematic misleading messaging that is harmful to the competitor's interests, which the federal agency either overlooked or failed to appreciate as important. *POM Wonderful* is clear: FDA approval is no substitute for the intervention of a competitor, which by dint of its "market expertise" is uniquely qualified to "provide incentives for manufacturers to behave well." *Id.* FDA approval of the accuracy of a subject's representations does not create a ceiling that bars still better protections against the capacity of the representations to mislead. Indeed, the FDA explicitly warned Defendant in its clearance letter that its approval "does not mean that FDA has made a determination that your device complies with other requirements of the [FDCA] or any Federal statutes and regulations administered by other Federal agencies." J.A. 3370.

Notwithstanding that the FDA's regulation of Defendant's labeling addressed the same issue as raised by Plaintiff in its Lanham Act suit—the risk that consumers will misunderstand Defendant's messages as implying that the Product utilizes the same metric for pregnancy duration as used by medical professionals—

there is no reason to assume that Congress would see the FDCA's precautions as undermined by a court's decision, upon a competitor's suit, that protection of the competitor against unfair competition through false advertising requires still greater protection against consumer miscomprehension than was mandated by the FDA.

We see no merit in Defendant's efforts to distinguish *POM Wonderful*. Although the FDA did not preapprove the juice labels at issue in *POM Wonderful*, as it did here pursuant to its more proactive, extensive, and focused role in drug regulation, the Supreme Court explicitly rejected the government's argument that a Lanham Act claim is precluded to the extent that the FDCA or FDA regulations "specifically require or authorize" aspects of a label that are then challenged under the Lanham Act, noting that the FDA's requirements are a floor, not a ceiling. 134 S. Ct. at 2235.

Defendant's reliance on *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) is also misplaced. At first glance, *PLIVA* appears to share much in common with this case. *PLIVA* involved consumer lawsuits against generic drug manufacturers under state tort laws requiring drug manufacturers to label their drugs so as to reveal to consumers the dangers posed by the drugs. *Id.* at 608-09. The defendant generic drug manufacturers asserted that the state law tort claims were preempted by FDA regulations, which require generic drug labels to be the same as their brand-name

equivalents. *Id.* at 613. The Supreme Court agreed, reasoning that it would be "impossibl[e]" for the defendants to comply with the FDA's rules and also provide the more robust warning that state law required. *Id.* at 618. The Court found impossibility even though the defendants could have requested permission from the FDA to change their labels so as to comply with the state laws. The Court held that when a party must affirmatively seek permission from the federal agency in order to comply with a state law requirement, the state law is preempted. *Id*. at 620-24.

It is true that Defendant here, like the defendants in *PLIVA*, could have marketed the Product under a label that differed from the label approved by the FDA only by obtaining permission of the FDA. This was required by the FDA's clearance letter and the § 510(k) process generally. Nonetheless, we conclude that *PLIVA* is not controlling here because this dispute does not involve the question whether a state law is preempted by a federal agency's regulation; rather, this dispute involves the question whether the application of a federal agency's regulation, promulgated under one federal statute, precludes a private action under another federal statute. While federal law-state law preemption principles can be "instructive" in the federal law-federal law preclusion context, "the Court's [preemption] precedent does not govern preclusion analysis." *POM Wonderful*, 134 S. Ct. at 2236. In a preemption case, concerns about the primacy of federal law

and the "state-federal balance . . . frame the inquiry," but that is not so in a preclusion case. *Id*. The uniformity concerns that drive preemption doctrine are not necessarily applicable when two federal statutes overlap. Our analysis must be governed by *POM Wonderful*, which establishes that a Lanham Act claim is not precluded by FDA regulation under the FDCA because the two statutes serve distinct and complementary purposes.[6]

## II. Lanham Act Liability

### a. Falsity

Defendant contends that the district court erred in finding falsity in its packaging and advertising. To prevail on a Lanham Act false advertising claim, a plaintiff must establish that the challenged message is (1) either literally or impliedly false, (2) material, (3) placed in interstate commerce, and (4) the cause of actual or likely injury to the plaintiff. *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 255-56 (2d Cir. 2014).[7]

A plaintiff may establish falsity in two different ways. To establish literal falsity, a plaintiff must show that the advertisement either makes an express

[6] Defendant further argues that, at minimum, the district court's injunction is precluded because Defendant cannot comply with it without violating the FDA's instructions. Defendant notes that, for example, the district court enjoined Defendant from using the words "Weeks Estimator" in the Product's name unless it is modified to refer to ovulation, even though Defendant cannot change the Product's name without the FDA's approval. This argument fails as a preclusion argument for the reasons explained above.

[7] As the parties do not dispute that Defendant has placed the Product in interstate commerce, we do not address that issue.

statement that is false or a statement that is "false by necessary implication," meaning that the advertisement's "words or images, considered in context, necessarily and unambiguously imply a false message." *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007). A message can only be literally false if it is unambiguous. *Id.* If an advertising message is literally false, the "court may enjoin the use of the message without reference to the advertisement's impact on the buying public." *Tiffany (NJ) Inc. v. eBay Inc.*, 600 F.3d 93, 112 (2d Cir. 2010) (quoting *McNeil–P.C.C., Inc. v. Bristol–Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991)).

If a message is not literally false, a plaintiff may nonetheless demonstrate that it is impliedly false if the message leaves "an impression on the listener or viewer that conflicts with reality." *Time Warner Cable*, 497 F.3d at 153 (quoting *Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 229 (2d Cir. 1999), *as amended on reh'g* (Sept. 29, 1999) (brackets omitted)). Courts have, at times, required a claim of implied falsity to be supported by extrinsic evidence of consumer confusion. *Id*. Alternatively, courts have allowed implied falsity to be supported by evidence that the defendant intended to deceive the public through "deliberate conduct" of an "egregious nature," in which case a rebuttable presumption of consumer confusion arises. *Merck Eprova*, 760 F.3d at 255-56.

The district court engaged in separate falsity analyses as between the Launch Package, together with its associated TV Commercial and additional advertising, and the Revised Package. As the district court relied on the same theories with respect to the Launch Package, TV Commercial, and additional advertising, we address those together before turning to the Revised Package.

### i. The Launch Package, Television Commercial, and Other Advertising

The district court found that the Launch Package, TV Commercial, and other associated advertising were literally false by necessary implication, as well as impliedly false. The court found that although none of these materials expressly stated that the Product estimates weeks-pregnant using a metric consistent with the metric doctors would use, these materials included statements and images, which, when considered in context, unambiguously implied that false message.

Defendant primarily argues that the district court erred in finding literal falsity because these materials were "susceptible to more than one reasonable interpretation" and thus not unambiguous. Appellant's Br. at 45 (quoting *Time Warner Cable*, 497 F.3d at 158). Defendant argues that a reasonable ordinary person in the market for a home pregnancy test could understand Defendant's advertising regarding the Product's ability to measure "weeks" as weeks-since-ovulation/fertilization without forming a belief about whether that measure is the

same or different from the convention used by doctors.

This argument is not persuasive. The issue is not whether Defendant's measure of weeks could have been understood to measure from LMP versus from ovulation/fertilization. The issue is whether Defendant's measurement of weeks would be understood by reasonable consumers to measure by a different metric than used by the medical profession. If an advertising message means something different from what reasonable consumers would understand it to mean, that message can be considered false. *Time Warner Cable*, 497 F.3d at 158 (citing *Novartis Consumer Health, Inc. v. Johnson & Johnson–Merck Pharm. Co.*, 290 F.3d 578, 586-87 (3d Cir. 2002) ("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.' ")). The district court found that the medical profession has a "standard—indeed universal—convention for expressing pregnancy duration." S.P.A. 8. It was undisputed that Defendant's Product does not utilize the medical profession's standard, universal convention. The crucial point is that a reasonable consumer would have assumed from the text of the Launch Package, TV Commercial, and other associated advertising that the Product was not giving a different number than a medical professional would give. The district court concluded that message was false. We can see no error in the court's reasoning.

The Launch Package did not indicate in any visible or clear way that the Product provides a different measurement from a doctor's. The packaging referred to the Product as a "Weeks Estimator" and included sample windows listing possible results such as "Pregnant / 2-3 Weeks." No reference to ovulation was included on the front of the packaging. The only mention of ovulation and of the difference in dating conventions was contained in the small Indications for Use Statement on the side of the box, which, the district court found, was too wordy and "minuscule" to render ambiguous the Launch Package's message that the Product provides an estimate of weeks-pregnant that is consistent with the measurement provided by doctors. S.P.A. 31.

Similarly, the TV Commercial unambiguously implied the false message that the Product provides a measurement of weeks-pregnant that is consistent with the metric used by medical professionals. Like the Launch Package, the commercial discussed the Product's ability to estimate "weeks" without clarifying that it measures weeks since ovulation—and, more importantly, without clarifying that it measures weeks differently from how a doctor would measure. A voiceover in the commercial states, "The new Clearblue pregnancy test also estimates how many weeks." J.A. 3384-85. The commercial also includes shots of the misleading digital screens from the Launch Package. Its references to ovulation in the disclaimers were too fleeting and small to affect a consumer's understanding, and,

furthermore, made no reference to the fact that the Product uses a different metric from the medical profession's universal standard.

Finally, the additional associated advertising—including, among other things, the website, web banners, and in-store advertising—utilized the same misleading "weeks" language as the Launch Package and TV Commercial without revealing in any meaningful way that the number of weeks differs from the number a doctor would provide.

As the Launch Package, TV Commercial, and other advertising all unambiguously implied the false message that the Product provides a measurement of weeks-pregnant that is consistent with the measurement a doctor would provide, we find no error in the district court's findings of literal falsity.

It makes no difference, however, whether the Defendant's messages were literally false, because the district court also correctly found the messages to be impliedly false.[8] The court's finding of implied falsity was supported by actual evidence of consumer confusion (to the effect that consumers understood from the

[8] Implied falsity should not be confused with literal falsity by necessary implication. A court may find a statement literally false by necessary implication, without considering extrinsic evidence, when the advertisement's "words or images, considered in context, necessarily and unambiguously imply a false message." *Time Warner Cable*, 497 F.3d at 158. A message—even a message that is ambiguous—is impliedly false if it leaves "an impression on the listener or viewer that conflicts with reality." *Id.* at 153. Implied falsity is often demonstrated through extrinsic evidence of consumer confusion, *id.*, or though evidence of the defendant's deliberate deception, which creates a rebuttable presumption of consumer confusion. *Merck Eprova*, 760 F.3d at 255-56.

Defendant's messaging that the Product gives the same number of weeks as a doctor would give), and by evidence of Defendant's intent to deceive, which the court found sufficient to give rise to a presumption of consumer confusion. The court found that Defendant engaged in intentional deception because Defendant's "staff recognized and understood that the Weeks Estimator's result did not align with how doctors express pregnancy duration and that this misalignment could confuse consumers." S.P.A. 19. The court cited to extensive evidence in the record supporting this conclusion. We briefly highlight some of the more significant evidence credited by the district court.

Some of this evidence showed that Defendant was clearly aware that LMP is the metric used by doctors. Dr. Sarah Johnson, Defendant's Head of Clinical and Medical Affairs, stated in a peer-reviewed article that pregnancy was historically dated in reference to LMP. Several studies and documents that Defendant submitted to the FDA stated that this was the traditional or conventional practice. Defendant's witnesses at trial, including Dr. Joanna Pike, Defendant's Senior Global Pregnancy Product Manager, and Mark Gittens, Defendant's Chief Compliance Officer, acknowledged the LMP convention. Some evidence also indicated that Defendant was aware that consumers would likely become confused if the distinction between the Product's ovulation metric and the conventional LMP metric was not made explicit. For example, Dr. Pike stated in an email: "I think

FDA would NOT approve if we used 'Weeks Pregnant' in any materials and we are very likely to also confuse consumers and might end up with challenge/complaint." J.A. 4384. Similarly, one of Defendant's board members raised concerns at a board meeting about the digital display, and expressed that the Defendant "[n]eed[ed] to be clearer what this means i.e. from time of conception NOT LMP, we are Not saying what we are doing." J.A. 6215.

The district court also found that statements by Kristen Suarez, Clearblue's Brand Manager, "suggest a deliberate attempt both to evade FDA limitations and convey a false message about the [P]roduct." S.P.A. 24. For example, when discussing promotional materials for CVS, Suarez stated that "we can't actually link together the weeks and pregnant in the way it was on the last couple. What you can say is the only test that estimates weeks, or the only test that also estimates weeks, then the consumer will see Pregnant 1-2 Weeks in the windows and put it together." J.A. 8554. In another email, in response to a suggestion that an advertisement say "Find out how far along you are," Suarez stated, "This is a tricky one, but the FDA doesn't actually want us to say that. I think it can be phrased as a question . . . , or we need to use the 'estimate weeks' language." J.A. 8989-90.

This evidence, together with other evidence noted by the district court, S.P.A. 19-27, supports the district court's finding that the Defendant, at least at the

time the Launch Package, TV Commercial, and additional associated advertising were under development, intended to deceive the public into believing that the Product provides a measurement of weeks-pregnant consistent with the metric used by doctors. This evidence was sufficient to support a presumption of consumer confusion supporting a finding of implied falsity.

**ii. The Revised Package**

Defendant also challenges the district court's finding that the Revised Package was impliedly false. In the Revised Package, Defendant set forth more clearly that the Product measures weeks since ovulation. Among other things, the Revised Package added the phrase "Only Test That Estimates Weeks Since Ovulation*" (with the asterisk directing to the Indications for Use Statement on the side) at the corner.[9] The package also replaced the windows that said "Pregnant" and "1-2 weeks," "2-3 weeks," or "3+ weeks" with windows that said "Pregnant" and "1-2," "2-3," or "3+," with the phrase "Weeks Along" placed below the windows.

To support its finding of implied falsity, the district court relied, in part, on the consumer surveys of Plaintiff's expert witness, Hal Poret. With respect to the Revised Package, "Poret concluded that 16.0% or 17.3% of participants. . .

[9] The Indications for Use Statement on the side of the Revised Package (as well as the Launch Package) included an acknowledgement that doctors measure pregnancy from LMP, but did so in an inconspicuous manner, making it "unlikely to be noticed by consumers." S.P.A. 31-32.

answered both that the [P]roduct estimates the number of weeks a woman is pregnant and that the [P]roduct's estimate of weeks is the same as a doctor's estimate of weeks-pregnant." S.P.A. 36-37. The district court found this to be sufficient evidence of consumer confusion to support finding the Revised Package impliedly false.

Defendant's most forceful argument is that the Poret survey was flawed because the main survey questions at issue failed to test whether survey respondents were confused into thinking that the Product's measurements were the same as a doctor's because of the Product's packaging or because of the survey respondents' preexisting erroneous beliefs about the way pregnancy is measured.

We agree that the consumer confusion revealed by the survey could have been attributable to preexisting consumer ignorance about the conventional medical practice of dating the beginning of pregnancy from LMP. Poret derived his 16.0% or 17.3% deception rate by looking at the number of survey respondents who expressed the belief that the Product measures the number of weeks a woman is pregnant and also answered that "the [P]roduct's estimate of weeks is telling you . . . [t]he same thing as when a doctor gives you an estimate of weeks." J.A. 6680 (emphases omitted); *see also* J.A. 1576. A survey respondent might have given this answer not because the Revised Package confused her into believing that the Product provides the same measurement as provided by a doctor, but because she

was already under the preexisting mistaken belief that a doctor measures pregnancy from the date of ovulation, rather than LMP, and, therefore, any product that purports to "Estimate[] Weeks Since Ovulation" would provide the same estimate as a doctor.

However, in light of the ample evidence that Defendant was aware of this widespread consumer ignorance and took no effective steps to guard against misunderstanding of Defendant's messages attributable to that ignorance, we find no error in the court's use of the Poret survey. Considering the counterintuitive nature of the LMP pregnancy measurement used by doctors (which includes about two weeks prior to ovulation, during which it is biologically impossible for a woman to be pregnant), it must have been obvious to Defendant, a seasoned manufacturer of home pregnancy tests, that many women are not aware that the medical profession measures pregnancy as starting approximately two weeks prior to ovulation and fertilization. The record demonstrates furthermore that Defendant was in fact aware that most consumers do not understand the nature of ovulation and its relation to pregnancy duration. For example, in an email exchange, Brand Manager Suarez stated that "American women just aren't that in tune" with the concept of ovulation, that the concept "doesn't really make sense to them," and that American women "don't have a knowledge of the right days, poor understanding of the details, etc. and it's not common vernacular of how we would

talk [*sic*] anything." J.A. 4709-10. Similarly, a document summarizing a meeting involving Dr. Johnson, notes as an "[a]dditional discussion point[]" that the "[o]verall lack of consumers' understanding of ovulation may cause confusion" and points to the "[n]eed to address the reason why [doctor]s use [a] different method." J.A. 4506.

Defendant misses the point in its argument that the court should not have relied on Poret's survey because the survey failed to test for whether consumer confusion resulted from preexisting ignorance, rather than Defendant's message. Widespread consumer ignorance as to how the medical profession measures the advancement of a pregnancy was the fact—a fact that was known by the Defendant. In the face of consumer ignorance as to how the medical profession measures the advancement of a pregnancy, Defendant's message that the Product estimates weeks since ovulation did nothing to tell ignorant consumers that weeks since ovulation is a different measurement from that used by doctors. It makes no difference whether the widespread consumer ignorance predated the Defendant's Revised Package or was caused by it. The message of the Revised Package—that the Product tells you the degree of advancement of your pregnancy in terms of "weeks since ovulation"—implies a message that this is how the advancement of a pregnancy is measured by medical professionals. The Revised Package did not adequately communicate that its measurement was not consistent with the metric

used by doctors. We therefore conclude that the evidence, including the Poret Survey, amply supported the district court's finding of falsity.

**b. Materiality and Injury**

Defendant contends the district court failed to make findings necessary to support the court's conclusion that Defendant's misrepresentations were material to Plaintiff's claim. Defendant also contends that the district court failed to find a logical causal connection between any falsity in Defendant's messages and injury to Plaintiff.

Plaintiff and Defendant disagree about what exactly is required to satisfy the materiality requirement for a Lanham Act false advertising claim. They agree that for a false message to be material, the defendant must have at least "misrepresented an inherent quality or characteristic of the product." *Merck Eprova*, 760 F.3d at 255. Defendant argues, however, that, according to our precedents, there is an additional requirement that the deception be "likely to influence [consumer] purchasing decisions," citing *NBA v. Motorola, Inc.*, 105 F.3d 841, 855 (2d Cir. 1997). Appellant's Br. 52-53. The district court expressly found that "[t]he Weeks Estimator's ability to estimate weeks is, as the [P]roduct's name conveys, an inherent quality or characteristic of the [P]roduct as it is the key feature that differentiates it from the many other home pregnancy tests on the market." S.P.A. 40. Defendant points out, however, that, in its discussion of the

*materiality* element, the court made no express finding that Defendant's misrepresentation was likely to influence purchasing decisions.

Although the essential elements of the materiality standard indeed appear to be somewhat unsettled in our circuit,[10] we need not resolve the issue now. We assume for purposes of this ruling that a defendant's false advertising is not material to a plaintiff's Lanham Act claim unless that falsity had the capacity to adversely affect the plaintiff's business by influencing consumer purchasing decisions. While the materiality of the falsity and the likelihood of injury to the plaintiff resulting from the defendant's falsity are separate essential elements, in many cases the evidence and the findings by the court that a plaintiff has been injured or is likely to suffer injury will satisfy the materiality standard—especially where the defendant and plaintiff are competitors in the same market and the falsity of the defendant's advertising is likely to lead consumers to prefer the defendant's product over the plaintiff's. *See Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d Cir. 1980) (In Lanham Act claims, the injury "standard is whether it is likely that [defendant]'s advertising has caused or will

[10] In *NBA*, we defined "material" as "an inherent quality or characteristic of the product." 105 F.3d at 855 (internal quotation marks omitted). In so doing, we cited three other circuits and a treatise, and included parentheticals for each citation that defined "material" as "likely to influence purchasing decisions." *Id.* However, our post-*NBA* cases do not mention this "likely to influence purchasing decision" feature of the standard; they focus instead on the "inherent quality or characteristic" descriptor. *See, e.g.*, *Merck Eprova*, 760 F.3d at 255; *Time Warner Cable.*, 497 F.3d at 153 n.3; *S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 238 (2d Cir. 2001).

cause a loss of [plaintiff's] sales," which can be established when defendant and plaintiff "are competitors in a relevant market" and plaintiff demonstrates a "logical causal connection between the alleged false advertising and its own sales position."). In discussing the essential element of likelihood of harm to Plaintiff's business resulting from Defendant's false advertising, the district court expressly found that Plaintiff "lost sales on account of [Defendant's] false advertising." S.P.A. 45. The court concluded its discussion of likelihood of injury stating, "[Plaintiff] established a logical causal connection between [Defendant]'s false advertising and its market harm that is sufficient to establish [Defendant]'s liability for false advertising under the Lanham Act." *Id.*

In our view, the district court's conclusion, although uttered in connection with the element of likely injury, also constituted a finding that Defendant's misrepresentations were likely to influence purchasing decisions and were therefore material to Plaintiff's claim. If consumers, faced with the choice to purchase either the plaintiff's product or the defendant's, are likely to prefer the defendant's product by reason of the defendant's false advertising, the falsity of the defendant's advertising is material to the plaintiff's Lanham Act claim.

The evidence furthermore amply supported the conclusion that the falsity of Defendant's advertising was both material and likely to cause injury to Plaintiff. It is entirely reasonable to expect that, for a significant number of women interested

in learning whether they are pregnant—especially those who have not previously been pregnant or are otherwise ignorant of the details of the reproductive cycle—the information that Defendant's Product will tell them something different from what a doctor would provide would make them less likely to trust Defendant's Product, and more likely to purchase from Plaintiff, Defendant's closest competitor. The district court's finding is further supported by the evidence that this was precisely the risk that motivated Defendant to avoid making clear to consumers that its Weeks Estimator gave information different from what a doctor would give.

We conclude that both the evidence and the district court's findings, to the effect that Plaintiff likely suffered a loss of sales by reason of Defendant's false advertising, adequately supported both the materiality element and the likely injury element. With respect to the injury element, Defendant argues that the district court's reasoning was fallacious because the court relied in part on statistics showing that Plaintiff's share of the market decreased, while the Defendant's share increased upon Defendant's introduction of the Product. Defendant argues that this redistribution of consumer preference was attributable to the important new feature Defendant was offering, and that there is no reason to attribute any diminution in Plaintiff's market share to the falsity of Defendant's advertising. Even assuming, however, that Defendant is correct in discrediting an aspect of the district court's

reasoning, the district court's finding that Plaintiff likely lost market share to Defendant attributable to the falsity of Defendant's concealment was amply supported by the evidence, as explained above.[11] Furthermore, as the trial was bifurcated, the district court went only so far as to find liability. The trial conducted did not encompass the issue of damages awardable to Plaintiff. At the liability stage, the Lanham Act "demands only proof providing a *reasonable basis* for the belief that the plaintiff *is likely to be damaged* as a result of the false advertising." *Johnson & Johnson*, 631 F.2d at 190 (emphases added). We find no fault in the district court's conclusion that Plaintiff suffered a likelihood of loss of sales of its product, attributable to Defendant's false concealment that its Product gave information about the advancement of a pregnancy that was inconsistent with the information that the medical profession would give.

Accordingly, we reject Defendant's contention that the district court erred in finding either the materiality of Defendant's false advertising or the likelihood of injury to Plaintiff's sales resulting from Defendant's false advertising.

[11] Furthermore, "where . . . a plaintiff has met its burden of proving deliberate deception in the context of a two-player market, it is appropriate to utilize a presumption of injury." *Merck Eprova*, 760 F.3d at 259. Defendant and Plaintiff are direct competitors in a sparsely populated market. Plaintiff has been the market leader, followed closely by Defendant. Other home pregnancy test brands (which are manufactured by a co-owner of Defendant) represent only a small portion of the market.

## III. The Injunction

Finally, Defendant contends the district court abused its discretion in fashioning an injunction that is excessively broad and unreasonably punitive.

"It is axiomatic that the contours of an injunction are shaped by the sound discretion of the trial judge and, barring an abuse of that discretion, they will not be altered on appeal." *Merck Eprova*, 760 F.3d at 265. At the same time, injunctive relief should be "no broader than necessary to cure the effects of the harm caused by the violation," *Forschner Group, Inc. v. Arrow Trading Co*., 124 F.3d 402, 406 (2d Cir. 1997), and "should not impose unnecessary burdens on lawful activity," *Patsy's Brand, Inc. v. I.O.B. Realty, Inc*., 317 F.3d 209, 220 (2d Cir. 2003).

Defendant argues first that the injunction's prohibition of further use of the advertising Defendant devised for the Revised Package was abusive because the court's findings never explicitly focused on the contents of this advertising, finding it to be false. We reject the contention. Even if the district court did not explicitly focus on the wording of this advertising in its express findings of falsity, the advertising had the same capacity to mislead as the Revised Package materials that the district court extensively discussed. There is no doubt the district court intended its discussion of the misleading aspects of the Revised Package to refer to the associated advertising as well.

Defendant contends further that the injunction terms were excessively harsh in that they require Defendant to distribute corrective notices that expressly acknowledge that the court found Defendant to have engaged in false and misleading advertising. We disagree. Especially in view of the district court's findings that Defendant was intentionally deceptive in its advertising, we cannot say that the relief ordered by the district court went beyond curing the effects of the harm caused by Defendant's falsity.

Finally, Defendant contends that the court abused its discretion in the sweeping scope of the relief it ordered, especially in view of such factors as the relatively brief time the public was exposed to the deceptive materials and the time passed since their withdrawal. Although Defendant's argument is not unreasonable, and less intrusive requirements might well have sufficed, we cannot say the court's orders constituted an abuse of the court's wide discretion to fashion the terms of injunctive relief.

We have considered Defendant's other arguments, and find them to be without merit.

## CONCLUSION

The judgment of the district court is hereby AFFIRMED.