UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Church & Dwight Co., Inc., Plaintiff, –v– SPD Swiss Precision Diagnostics, GmbH, Defendant.	14-CV-585 (AJN) OPINION & ORDER

ALISON J. NATHAN, District Judge:

Plaintiff Church & Dwight Co, Inc. ("C&D") and Defendant SPD Swiss Precision Diagnostics, GmbH ("SPD") are leading manufacturers of home pregnancy tests, and they fiercely compete for market share in this product category. The present dispute between the parties concerns SPD's recently launched "Clearblue Advanced Pregnancy Test with Weeks Estimator" ("Weeks Estimator"), which the Food and Drug Administration ("FDA") cleared for the intended use of telling a woman (1) whether she is pregnant and, if she is pregnant, (2) how many weeks have passed since she ovulated. C&D contends that the product's name and advertising convey the false message that the product tells a woman how many weeks pregnant she is consistent with how a doctor would estimate weeks pregnant. This is false, C&D contends, because doctors estimate pregnancy duration based on how many weeks have passed since a woman's last menstrual period—not weeks since ovulation.

In April 2015, the Court presided over a two-week bench trial. Following this trial and with the benefit of post-trial briefing, the Court makes the following findings of fact and conclusions of law, which are expanded upon below: (1) SPD engaged in false advertising in violation of the Lanham Act; (2) SPD engaged in intentional deception of an egregious nature; (3) C&D is entitled to a permanent injunction; (4) SPD engaged in false advertising in violation

of New York State law; and (5) C&D failed to prove that SPD breached the parties' prior settlement agreement.

I. PROCEDURAL HISTORY

Shortly after this action commenced in early 2014, C&D moved for a preliminary injunction and SPD moved to dismiss C&D's complaint. SPD's primary argument in opposition to a preliminary injunction and in favor of dismissal was that the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, precludes C&D's Lanham Act claim. In an Opinion and Order Dated June 3, 2014, the Court denied SPD's motion to dismiss and consolidated the preliminary injunction with a bench trial on liability pursuant to Federal Rule of Civil Procedure 65(a)(2). *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-CV-585 (AJN), 2014 U.S. Dist. LEXIS 76752 (S.D.N.Y. June 3, 2014) ("*Church & Dwight I*"). At the parties' request, the Court also bifurcated liability and damages. Dkt. No. 42.

In advance of trial, SPD submitted two motions *in limine*. First, SPD moved to limit the scope of the case to the ten pieces of advertising attached to C&D's Complaint, generally referred to as the "launch" advertising for the Weeks Estimator. On October 28, 2014, the Court denied that motion, finding that a prior arbitration between the parties cleared the way for C&D's lawsuit and that C&D framed its Complaint in terms of false messages, not specific pieces of advertising. *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-CV-585 (AJN), 2014 U.S. Dist. LEXIS 158551 (S.D.N.Y. Oct. 28, 2014) ("*Church & Dwight II*").

Next, SPD renewed its previously rejected preclusion argument, contending that the Supreme Court's decision in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), and additional documentary evidence provided support for this preclusion defense. The Court, however, held that *POM Wonderful*'s analysis bolstered its prior conclusion that the FDCA did not preclude the Lanham Act claim here. *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-CV-585 (AJN), 2015 U.S. Dist. LEXIS 67187, at *22-23 (S.D.N.Y. Mar 24, 2015) ("*Church & Dwight III*"). *POM Wonderful* observed that the FDCA and Lanham

Act complement each other in major respects and that the remedies of the two acts promote a "fundamental" harmony; among other things, "'[t]he FDA . . . does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess.'" *Id.* at *21 (quoting *POM Wonderful*, 134 S. Ct. at 2238-39). Drawing on this analysis, the Court concluded that "the FDA's perspective and expertise as compared to the knowledge of day-to-day competitors is at least as limited with respect to medical devices as it [was] for food and beverage labeling" in *POM Wonderful*. *Id.* at *23. In short, the Court held that it would "not 'elevate the FDCA and the FDA's regulations over the private cause of action authorized by the Lanham Act' because 'the FDCA and the Lanham Act complement each other in the federal regulation of misleading labels.'" *Id.* at *29 (quoting *POM Wonderful*, 134 S. Ct. at 2241).

Also in advance of the bench trial, SPD submitted five motions and C&D submitted one motion to exclude expert witness testimony pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). *See* Dkt. Nos. 254, 265, 267, 269, 271, 273. The Court reserved decision on the *Daubert* motions prior to and during trial, but denied all of them following the close of trial. Tr. 1406:5-8. Bearing in mind that the *Daubert* gatekeeping standard is of less relevance, and thus applied more flexibly, when, as here, the judge is the factfinder, the Court concluded the testimony was admissible because it was based on sufficient facts or data, the product of reliable principles and methods, and reliably applied to the facts of this case. *See generally Louis Vuitton Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 579, 629, 645-46 (S.D.N.Y. 2007).

The Court conducted the eight-day bench trial in accordance with its Individual Practices in Civil Cases for non-jury proceedings. Prior to trial, the parties submitted declarations of direct and rebuttal testimony as well as copies of anticipated exhibits and deposition designations that they intended to use at trial. The parties also submitted proposed findings of fact and conclusions of law. At trial, the parties called only those witnesses whom they intended to cross-examine and played video depositions of witnesses who were unavailable. In all, the Court received direct testimony declarations from 17 witnesses, 15 of whom also provided live

testimony, as well as several hundred exhibits from both parties.[1] Following trial, the parties filed post-trial briefing and updated proposed findings of fact[2] that were fully submitted on May 20, 2015.

II. FINDINGS OF FACT[3]

Semantic disputes complicated much of this case. Stripped to the essential facts, which are described in greater detail below, the case is quite simple. Doctors have a number of ways to determine pregnancy duration, also known as gestational age, but they have a standard convention for expressing it. This standard convention expresses pregnancy duration in terms of the number of weeks that have passed since a woman's last menstrual period ("LMP"); that is, a woman's expected date of delivery is 40 weeks after her LMP, so if a woman is pregnant and 4 weeks have passed since her LMP she is said to be 4 weeks pregnant. SPD's Weeks Estimator tells a woman if she is pregnant and provides an estimate of the number of weeks that have passed since a woman last ovulated, which is, on average, two weeks after a woman's LMP. Thus, the Weeks Estimator provides an estimate of "weeks" that is expressed differently from the standard convention for expressing pregnancy duration. Despite this inconsistency, SPD's advertising for the Weeks Estimator conveys the message that the product provides an estimate of weeks pregnant that is consistent with a doctor's estimate of weeks pregnant. Therein lies the problem for SPD.

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[1] Direct and rebuttal testimony declarations are cited using the last name of the witness followed by DT or RT and refer to the final declarations as modified at trial. *See* Dkt. No. 363. The trial transcript is cited using Tr. followed by the page and line number for the citation. *See* Dkt. Nos. 373-388. C&D's admitted exhibits are cited as PTX; SPD's admitted exhibits are cited as DTX. *See* Dkt. No. 363. The Court addresses certain objections to exhibits herein; to the extent not expressly addressed at trial or in this Opinion, the Court hereby overrules the objection or concludes it was waived or abandoned. Due to the multiple briefs and other filings submitted over the course of this case, unless otherwise noted, the Court refers to the parties' filings using the Court's Electronic Case Filing ("ECF") docket numbers, abbreviated as Dkt. No. __.

[2] Both parties submitted post-trial proposed findings of fact and were provided an opportunity to respond to each other's proposed findings of fact with opposing record citations. *See* Dkt. Nos. 369, 370, 372, 392. The abbreviation "PPF" represents Dkt. No. 372, which incorporates C&D's proposed findings of fact and SPD's responses. The abbreviation "SPD PPF" represents Dkt. No. 392, which incorporates SPD's proposed findings of fact and C&D's responses. If a party did not oppose a proposed finding of fact with an appropriate record citation, and if that unopposed proposed finding of fact was supported by an appropriate record citation, the Court deemed that fact admitted and incorporates such unopposed facts as factual findings of the Court.

[3] To the extent that any finding of fact reflects a legal conclusion, it shall to that extent be deemed a conclusion of law, and vice versa.

A. The Parties

C&D and SPD are direct competitors in the U.S. market for home pregnancy tests. PPF ¶ 1. C&D's leading home pregnancy test brand, First Response, has been the market leader for many years, and SPD's leading brand, Clearblue, has been First Response's primary competitor. PPF ¶ 1.

B. The Reproductive Cycle

To understand this case requires a basic understanding of the reproductive cycle. The typical menstrual cycle lasts 28 days and is marked by two key events: the menstrual period and ovulation. Patrizio DT ¶ 6; Barnhart DT ¶ 9. The latter is the release of a ripe egg (or ovum) from the ovary. Patrizio DT ¶ 6; Barnhart DT ¶ 9. The time from the last menstrual period ("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." Barnhart DT ¶ 9; Patrizio DT ¶ 6. 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. Barnhart DT ¶ 9; Patrizio DT ¶ 10.

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. Patrizio DT ¶ 7; Barnhart ¶ 8. In the case of sexual intercourse, fertilization may occur several days after intercourse, but it will not occur more than one day after ovulation. Tr. 396:13-16; *see also* Tr. 218:10-14; Patrizio DT ¶ 7; Barnhart DT ¶ 8. Second, the fertilized egg, now referred to as a blastocyst, must travel down the fallopian tube to the uterus. Patrizio DT ¶ 7. 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. Patrizio DT ¶ 8. Once implantation occurs, the blastocyst begins secreting human chorionic

gonadotropin ("hCG"), a hormone that, among other things, signals to a woman's body that she is pregnant and prevents menses. Patrizio DT ¶ 8; Barnhart DT ¶ 34.[4]

Home pregnancy tests, including SPD's Clearblue brand and C&D'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. PPF ¶ 2; Barnhart DT ¶ 4.

C. 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. PPF ¶ 6; Barnhart DT ¶ 10; PTX 50 at 2; PTX 51 at 1; PTX 121; DTX 121 at 1. 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. Barnhart ¶¶ 10-11; PTX 50 at 2; PTX 51 at 1. 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; as noted, the follicular phase of the menstrual cycle is prone to vary. PTX 50 at 2; PTX 51 at 1; Barnhart DT ¶ 13. In addition, women often have a poor recollection of their LMP. PTX 50 at 2; PTX 51 at 1, 3. These two shortcomings mean that an estimate based on LMP may provide an inaccurate prediction of the date of delivery. *See, e.g.,* Barnhart DT ¶ 13; PTX 50 at 2; DTX 113 at 2; DTX 114 at 1.

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." Barnhart DT ¶ 14; Tr. 132:24-133:1; PTX 51 at 3. 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). Tr. 444:4-12, 133:2-9, 918:18-919:2; PTX 51 at 3; DTX 121 at 4-5. Because fertilization occurs, on average, two weeks after a woman's LMP, a woman's estimated

[4] If the blastocyst does not travel down to the uterus it may adhere to the lining of the fallopian tube, which will cause an ectopic pregnancy; such blastocysts will secrete hCG even though a successful pregnancy will not result. Tr. 1251:16-1252:1; Patrizio DT ¶ 57.

date of delivery is generally 38 weeks after fertilization. Patrizio DT ¶ 24; Tr. 830:9-11, 832:2-9, 918:20-919:2; DTX 121 at 1; PTX 50 at 2. Although ultrasound results are more accurate, "the date of the LMP is usually the only piece of data available in very early pregnancy to determine gestational age; therefore, it remains the most commonly used method for estimating [gestational age] and assigning a due date." PTX 51 at 1; Barnhart DT ¶¶ 10-11.

Finally, in the context of in vitro fertilization, doctors have an additional method to determine pregnancy duration: the date of embryo transfer. PTX 50 at 2-3; DTX 121 at 9. In such contexts, doctors retrieve an egg from a woman, fertilize it, and then wait either three or five days to replace the embryo in the woman's uterus. Tr. 179:22-180:11; Patrizio RT ¶ 12-13; PTX 50 at 2-3. Thus, "for a day-5 embryo, the [estimated date of delivery] would be 261 days from the embryo replacement date. Likewise the [estimated date of delivery] for a day-3 embryo would be 263 days from the embryo replacement date." PTX 50 at 3; Tr. 439:1-440:24.

D. 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. Patrizio DT ¶¶ 11-13, 22; Barnhart DT ¶¶ 10-11, 24; Patrizio RT ¶¶ 2-3; Tr. 182:7-10, 197:4-23, 238:1-11, 265:1-4, 266:11-267:4, 277:17-21, 830:1-831:4, 833:11-834:22, 837:4-9, 1271:7-9, 1261:5-1261:12; PTX 1 at 3; PTX 2; PTX 50 at 1; PTX 51 at 1; PTX 52 at 1; PTX 53 at 10; PTX 54 at 11; PTX 55 at 5; PTX 121 at 1; PTX 149 at 3-4. As SPD'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." Barnhart DT ¶ 11. He further noted that "[e]ven 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." Barnhart DT ¶ 11. 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. Barnhart DT ¶ 11; PTX 50 at 2; PTX 51 at 1; PTX 55 at 5; PTX 121.

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. Tr. 175:1-176:6, 238:24-239:9, 837:4-9; Patrizio DT ¶¶ 11-14; Patrizio RT ¶ 15. 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. Tr. 175:7-11; PTX 55 at 5. As noted, in some cases, a woman may not recall the date of her LMP or her recollection may be inconsistent with an estimate based on an ultrasound scan. Even in these cases, "doctors 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." Patrizio DT ¶ 12; Patrizio RT ¶ 9; Tr. 175:1-176:6. Similarly, in the context of in vitro fertilization, the embryonic age based on the date of embryo transfer is converted into an estimate of pregnancy duration in terms of weeks since LMP. Patrizio DT ¶ 13-14; Tr. 168:3-10, 179:22-182:10. 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.

That there is a single convention is unsurprising as it allows patients, doctors, and other healthcare providers to use the same metric for scheduling testing and other appointments during the course of pregnancy. PPF ¶ 6; Patrizio DT ¶ 11; Tr. 240:19-241:2, 830:12-18, 831:15-22, 835:15-836:13. Dr. Kurt Barnhart, SPD's expert witness, explained, "as we're moving forward

in a pregnancy, we want to make sure we're using the same standard so when we set a due date we're not – we're all working on the same convention and the same scale." Tr. 831:15-22.

Moreover, pregnant women have traditionally relied on their doctors for an estimate of pregnancy duration. Feldman RT ¶ 4; *see also* Tr. 479:23-25, 1184:5-10; PTX 100 at 5; PTX 121 at 1; PTX 149 at 4; DTX 37 at 1. SPD's suggestion that women could figure this out on their own based on their "own awareness of when they ovulated, had intercourse, and other relevant facts" combined with knowledge drawn from "myriad sources of information in books and on the internet regarding pregnancy dating," Dkt. No. 372 ¶ 6 (citing Daly ¶¶ 15-16, 42 & n.7-10), is unpersuasive and does not change the fact that historically doctors have been the authoritative source of information for women to find out how many weeks pregnant they are. Indeed, as described below, the FDA required SPD to include the following statement on all product advertising: "Only your doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression." PTX 3 at 4; PTX 1 at 3.

E. The Clearblue Advanced Pregnancy Test with Weeks Estimator

Unlike other pregnancy tests, which merely tell a woman whether she is pregnant, SPD's Weeks Estimator also provides an estimate of the number of weeks that have passed since fertilization. PPF ¶ 5. To explain, the blastocyst begins producing hCG after fertilization, but hCG levels are not detectable in a woman's urine until there is contact between the blastocyst and the woman's body (usually at implantation in the uterus but sometimes as a result of an ectopic pregnancy). PPF ¶ 2; Patrizio DT ¶ 57; Tr. 1251:16-1252:1. These hCG levels rise rapidly and predictably during early pregnancy and can be used to estimate the number of weeks that have passed since fertilization. PPF ¶ 5. And because fertilization occurs within 24 hours of ovulation, the date of fertilization provides a proxy for the date of ovulation (and vice versa). Barnhart DT ¶ 8; Patrizio DT ¶ 7; Tr. 915:15-18.

Like other home pregnancy tests, then, the Weeks Estimator uses the presence or absence of hCG in the urine to tell a woman if she is pregnant. But if she is pregnant, the Weeks Estimator also uses the level of hCG in the urine to provide an estimate of how many weeks have

passed since ovulation. When a woman uses the product, a digital screen on the device will tell her if she is "Pregnant" (or "Not Pregnant"), and, depending on her hCG level, the screen will provide a result showing "1-2," "2-3," or "3+"—meaning, she is pregnant and it has been 1-2, 2-3, or 3+ weeks since ovulation. PPF ¶ 5.

F. The FDA Clearance Process

Home pregnancy tests are subject to FDA regulation as Class II medical devices. *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *8-11; *Church & Dwight III*, 2015 U.S. Dist. LEXIS 67187, at *6-8. Under 21 U.S.C. § 360(k), more commonly known as the "510(k) process," a party seeking to market a Class II medical device must submit to the FDA "a description of the device and a statement of the intended use of the device, the proposed labeling to be included on the device, and the information necessary for the FDA to determine if the device is 'substantially equivalent' to a pre-existing device.'" *Church & Dwight III*, 2015 U.S. Dist. LEXIS 67187, at *6-7 (quoting *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *10). "A finding of substantial equivalence means the device 'has the same technological characteristics as the predicate device' or 'has different technological characteristics and . . . is as safe and effective as a legally marketed device, and . . . does not raise different questions of safety and effectiveness than the predicate device.'" *Id.* at *14 (quoting 21 U.S.C. § 360c(i)(1)(E)(ii)(III)). If the FDA identifies "a use of the device not identified in the proposed labeling," however, it can still approve the device but with limitations on the device's labeling; "[t]he resulting clearance from the FDA is known as SE [substantial equivalence] with limitations." *Id.* at *14 (citations and internal quotation marks omitted).

In August 2012, the FDA issued a "Hold Letter," PTX 149 at 3-11, for SPD's 510(k) application because it had identified a potential concern with the Weeks Estimator's product labeling, i.e., its packaging. *Id.* at *11-12. Specifically, the FDA noted that the "weeks indicator feature may provide misleading information to lay population of users" largely because "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.* (quoting PTX 149 at 3-4);

PPF ¶ 23. In light of this concern, the FDA required SPD to modify the "Indications for Use" statement on product packaging to include the following additional language:

> 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 can not be substituted for a doctor's determination of gestational age.

Id. at *12-13 (quoting PTX 149 at 4). The Hold Letter also requested changing the product's name from "Conception Indicator," which led SPD to propose, and the FDA to accept, "Weeks Estimator." *Id.* at *13. The Hold Letter made a number of other requests, including, among other things, removing the statement "*Also Tells You How Far Along You Are*" from every area of the box. *Id.* at *13-14 (citing PTX 149 at 5). Following additional back-and-forth communications between SPD and the FDA, the FDA issued a "Clearance Letter" for the Weeks Estimator, which allowed SPD to begin marketing the product consistent with the FDA's directives as described in the Clearance Letter. *Id.* at *14-15. Among other things, the FDA instructed SPD (1) not to express the product's results as "weeks pregnant" and (2) to express the results only as "the number of weeks that may have passed since ovulation." PPF ¶ 14.

G. The Launch Advertising

In August 2013, SPD commenced an ambitious marketing campaign for the Weeks Estimator that was touted as the largest advertising expenditure in this product category. Tr. 1073:19-1074:10; PTX 100 at 7. Despite FDA's warnings, internal SPD marketing documents described the "communication idea" for this campaign as: "Clearblue Advanced Digital Pregnancy Test with Weeks Estimator gives women the reassurance of knowing much more of their pregnancy because it is the only test that can also tell you how far along you are." PTX 209 at 9. In line with this strategy, and as described below, the Weeks Estimator's launch advertising consistently communicated the message that the product estimates "weeks pregnant," "weeks along," and similar ideas, while downplaying (or omitting) the message that the product provides an estimate of weeks since ovulation or that the product's estimate of "weeks" does not align with how a doctor would express an estimate of weeks pregnant.

1. The Launch Package

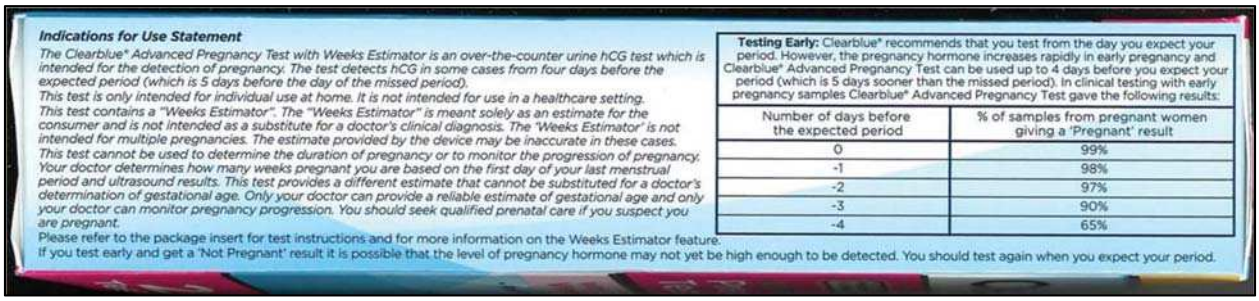
The launch package for the Weeks Estimator was on store shelves from August 2013 to February 2014. Daly DT ¶ 65. At the top left-hand corner of the box, "Clearblue" appears in large blue font, and on the top right-hand corner the word "NEW" appears against a yellow strip. PTX 3 at 2. In the middle left-hand side of the box the following words appear on four separate lines: "ADVANCED // Pregnancy Test // with Weeks Estimator // Results 5 DAYS Sooner." PTX 3 at 2. To the right of this language are four gray squares resembling digital screens with the following words inside them: "Pregnant // 1-2 Weeks"; "Pregnant // 2-3 Weeks"; "Pregnant // 3+ Weeks"; "Not Pregnant." PTX 3 at 2. To the right of the four gray squares there is an image of the actual product. PTX 3 at 2. In the lower left-hand corner of the box there is small white font stating: "See side of pack for details." PTX 3 at 2. The lower right-hand side of the package also contains an image of a white caduceus. PTX 3 at 2. The back panel is identical to the front panel; the only difference is that the back panel is arranged vertically while the front panel is arranged horizontally. PTX 3 at 1-2. The word "ovulation" does not appear anywhere on the front or back of the box. PTX 3 at 1-2. (An image of the front of the Launch Package is pasted below as Figure 1.)

Figure 1

The box contains two side panels with additional information. One side panel contains, in very small, cramped font (in a space that is 1.5 inches by 4 inches), the full FDA-required 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.*

PTX 3 at 4; PTX 425. Just below the Indications for Use statement, there is a sentence asking consumers to "[p]lease refer to the package insert for test instructions and for more information on the Weeks Estimator feature." PTX 3 at 4. The word ovulation appears only on the top of the box in an image promoting an entirely different Clearblue product called the "Advanced Ovulation Test." PTX 3 at 5. (An image of the side panel containing the Indications for Use statement is pasted below as Figure 2.)



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.
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%

Figure 2

2. The Television Commercial

From August 28, 2013 to December 2, 2013, SPD ran a nationally televised commercial promoting the Weeks Estimator (the "Television Commercial"), Daly DT ¶ 70, which aired thousands of times on at least 65 different networks and was projected to reach millions of women aged 18-49 each month, PPF ¶ 60. The Television Commercial shows two women sitting around a kitchen table engaging in the following dialogue:

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

PTX 5-6. As the first woman says "It's like two tests in one," an image of the Weeks Estimator appears on screen with the digital screen prominently displaying "Pregnant // 1-2 Weeks.*" PTX 5-6.[5] After the second woman says, "I think I'm going to cry," the commercial cuts to an image for two seconds showing three large digital screens (containing the words "Pregnant // 1-2 weeks," "Pregnant // 2-3 weeks," and "Pregnant // 3+ weeks") in an arc over an image of the product with the phrase "ESTIMATED WEEKS SINCE OVULATION (UP TO 3+)" in grayish blue font below the arc and above an image of the product. PTX 5-6. As this screen is displayed, a voiceover says: "The new Clearblue pregnancy test also estimates how many weeks. Weeks Estimator. Only from Clearblue." PTX 5-6. Beginning at 6 seconds into the commercial and continuing to the end of the 15-second commercial, small white font appears at the bottom of the screen stating:

> *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.

PTX 5-6.

[5] An image of this screen is pasted below as Figure 4 in Section III.A.3.a.

3. Other Launch Advertising

Prior to and after the launch of the Weeks Estimator, SPD maintained a dedicated webpage promoting the Weeks Estimator. Feldman DT ¶¶ 47-50; PTX 17. The top of the webpage displays the Clearblue logo next to the phrase: "The ONLY Pregnancy Test that Estimates Weeks." PTX 17 at 1. Just below that banner, the webpage prominently states "NEW! Pregnancy Test with Weeks Estimator," with an image of the product showing "Pregnant // 1-2 weeks" in the digital display window. PTX 17 at 1. The first prose script on the webpage is a paragraph stating:

> 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. It's like 2 tests in 1! This is the latest innovation in home pregnancy testing providing information that you can trust. Knowing more helps you prepare for the exciting future ahead – 78% of women surveyed said they believe it is important to know how far along they are.

PTX 17 at 1. Just below this paragraph, the webpage has a line break with an additional paragraph; the third sentence of that paragraph states: "It uses two separate testing strips to estimate how many weeks based on time since ovulation (1-2 weeks, 2-3 weeks, 3+ weeks)." PTX 17 at 1.

SPD also hired a celebrity spokesperson, Tamera Mowry-Housley, of "Sister, Sister" fame, to appear as a guest on the television show "The Doctors" to promote the Weeks Estimator. Suarez DT ¶¶ 2-6. After announcing that she and her husband are planning to have a baby, she says: "I am the new spokesperson for Clearblue. It's the pregnancy test. I am. I can't wait to use it . . . because it actually estimates how many weeks of pregnancy you're in." PTX 10. SPD contends that Ms. Mowry-Housley spoke "off script" and was not authorized to make this statement, Suarez DT ¶ 6, but internal emails reveal that SPD's marketing firm was "beyond pleased with how well this pitched placement delivered," PTX 269; Tr. 773:3-16.

In addition, SPD promoted the Weeks Estimator through a number of other channels, including presentations made to retailers, internet advertising (e.g., web banners), retailer circulars, retailer websites, and in-store advertising (e.g., side-wing displays and shelf trays).

PPF ¶ 63-64; PTX 18-24, 100, 215-216. These advertisements similarly convey the message that the product estimates "weeks pregnant" without any indication that this estimate differs from a doctor's estimate. *See, e.g.*, PTX 19 (Walgreens advertisement stating: "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."); PTX 18 (point-of-sale displays stating "First pregnancy test to estimate weeks" and "How far along are you?"); *see also* Tr. 1070:1-1071:5 (noting that the shelf display messages shown in PTX 18 were designed to sit next to each other).

H. The Revised Advertising

As described in detail in the Court's March 24, 2015 Memorandum and Order, following complaints from C&D, the FDA reached out to SPD with concerns about its launch advertising. *Church & Dwight III*, 2015 U.S. Dist. LEXIS 67187, at *15-16. For example, the FDA stated that it had informed SPD "not [to] talk about weeks pregnant" and "[p]lacing 'weeks' in the result window is the same as saying weeks pregnant." PTX 412; Tr. 344:14.

SPD then submitted a "mitigation proposal" to address some of the FDA's concerns. *Id.*; *see also* DTX 17; Tr. 354:4-355:5. In response to FDA objections to the Television Commercial, SPD proposed, among other things, adding language to the disclaimer and removing dialogue about a doctor's visit. DTX 017 at 3. The FDA found these changes insufficient, noting that even with the proposed changes the commercial

> still does not convey the limitations of [the] Week Estimator completely, nor does it clearly state that the device can only estimate weeks since ovulation (and not weeks of pregnancy) and therefore does not present a balanced and accurate description of [SPD's] product to customers. Further . . . [SPD is] required to communicate a complete and unmodified (i.e., unparaphrased) Indication For Use (IFU) statement in all of [its] promotional materials.

DTX 17 at 4. SPD also requested 10 days to take down the Television Commercial, but the FDA required it to do so in 6. DTX 17 at 4. Based on other feedback from the FDA, SPD revised the product's package and made a number of other changes to its advertising as described below.

1. Revised Package

The Revised Package began appearing on store shelves in February 2014. Daly DT ¶ 65. The front of the box is substantially similar to the Launch Package but with two key differences. First, in the top right-hand corner, instead of a yellow strip with the term "NEW," there is a gray strip with the phrase: "Only Test That // Estimates Weeks // Since Ovulation*." PTX 4 at 2. This phrase is separated onto three lines, with "Estimates Weeks" in larger, bold lettering on the middle line. Second, the digital screens to the right of "Advanced Digital[6] // Pregnancy Test // With Weeks Estimator" contain only the words "Pregnant // 1-2"; "Pregnant // 2-3"; "Pregnant // 3+"; and "Not Pregnant." PTX 4 at 2. Just below these four digital screens is the phrase "Weeks Along." PTX 4 at 2. On the side panel, the Indications for Use statement now appears with an asterisk in front of it—an apparent reference to the asterisk appearing after the phrase "Only Test That Estimates Weeks Since Ovulation*" on the front of the box. PTX 4 at 3. Otherwise, this and the other side panel are the same as the Launch Package. PTX 4 at 3-4. (An image of the front of the Revised Package is pasted below as Figure 3.)

Figure 3

[6] "Digital" appears after "Advanced" as opposed to under the digital screens in the Launch Package.

2. Internet-Only Commercial

As noted, SPD ceased airing the Television Commercial at the FDA's direction and replaced it with an Internet-Only Commercial, which is substantially similar to the Televised Commercial but with the following modifications. PTX 9. First, the dialogue is changed as follows:

> 1st Woman: I have something to tell you: I'm pregnant!
>
> 2nd Woman: Really?
>
> 1st Woman: I took this Clearblue test. It's like two tests in one.
>
> Voice over: Only Clearblue tells you if you are pregnant and estimates how many weeks since ovulation.
>
> 2nd Woman: Oh my God, I think I'm going to cry!
>
> Voice over: Weeks estimator, only from Clearblue.

PTX 9. During the voice over, the commercial cuts to the same image of the three large digital screens (with "Pregnant // 1-2," "Pregnant // 2-3," and "Pregnant // 3+") in an arc over an image of the product with the phrase "ESTIMATED WEEKS SINCE OVULATION (UP TO 3+)" in grayish blue font below the arc and above the product. PTX 9. Following this image, the commercial cuts to an image of the Revised Package in the center of the screen with "Weeks Estimator" in large, pink lettering jumping out of the box, distracting the eye from the rest of the packaging. PTX 9. The commercial ends with the full Indications for Use statement on screen for 15 seconds, but this is the only disclaimer that appears during the commercial. PTX 9.

3. Other Revised Advertising

SPD replaced the original webpage for the Weeks Estimator in December 2013 with a new webpage. Daly DT ¶ 78. The new webpage is substantially similar to the old webpage, but with the following modifications: (1) the image of the Launch Package has been replaced with an image of the Revised Package; (2) the word "New" no longer appears on the page; (3) and the word "weeks" no longer appears in the digital screen for the Weeks Estimator. DTX 173. In addition, the first paragraph of prose script on the webpage has been 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! This is the latest

innovation in home pregnancy testing providing information that you can trust. Knowing more helps you prepare for the exciting future ahead.

DTX 173. That is, "since ovulation" was added following "number of weeks," and the phrase "78% of women surveyed said they believe it is important to know how far along they are" was deleted.

I. SPD's Intentional Deception

As discussed in the conclusions of law, Lanham Act jurisprudence soundly presumes that consumers are in fact deceived if an advertiser sets out to deceive them. Based on the facts set forth in the following paragraphs, the Court finds that SPD's staff engaged in such intentional deception prior to and after the launch of the Weeks Estimator. Time and again, SPD'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. Rather than clarify its product advertising, SPD's staff sought to exploit the confusion.

To begin with, SPD's staff were fully aware that the medical community uses a standard convention for expressing pregnancy duration based on the number of weeks since a woman's LMP, whether actual or conventionalized (i.e., using a standard follicular phase of two weeks). PPF ¶ 8; *see also* PTX 122 at 1. For example, in a peer-reviewed article analyzing the use of hCG to estimate the date of fertilization, Dr. Sarah Johnson, SPD's Head of Clinical and Medical Affairs, observed that "[h]istorically, pregnancy is dated using the first day of the last menstrual period (LMP)." PTX 51 at 1. Similarly, a report that SPD submitted to the FDA as part of the 510(k) process recognized that "[t]raditionally, gestational age has been estimated from a woman's recollection of her LMP. . . . Standard clinical practice dictates that gestational age determined by ultrasound is also extrapolated to an estimated LMP date." PTX 55 at 5.[7]

Consistent with these pre-trial statements, SPD's witnesses acknowledged at trial—often with considerable reluctance—the existence of the LMP convention. After one such longwinded

[7] Similarly, many studies that SPD offered into evidence reference the convention for dating pregnancy based on weeks since LMP. *See, e.g.*, DTX 113 ("Pregnant woman are routinely assigned a delivery date of about 280 days after the onset of their last menstrual period.").

explanation, the Court pointedly asked Dr. Joanna Pike, SPD's Senior Global Pregnancy Product Manager, "If someone says to you or you read somewhere I am four weeks pregnant without any further explanation, what would you assume that means?" Tr. 1184:2-4. Dr. Pike, withdrawing deeper into her chair, provided a convoluted answer before finally acknowledging that "I think in general you may – you may – this, it is time since LMP because it is widely used," which she hesitantly admitted was "[t]he truth." Tr. 1184:22-1185:3. The truth it was.

To his credit, when asked on cross-examination if he "kn[ew] the convention used by medical doctors to date pregnancy," Mark Gittins, SPD's Chief Compliance Officer, provided one of the few straightforward answers on this topic: "The convention is to date pregnancy from the first day of last menstrual period." Tr. 265:1-4. He further acknowledged that the product in issue provides an estimate that differs from how a doctor expresses pregnancy duration. Tr. 277:22-25.

Aware of the convention, SPD staff members recognized that the Weeks Estimator's result was likely to confuse consumers. For example, Dr. Pike provided the following analysis in an email to her colleagues:

> We should not suggest in US that the product tells you 'Weeks Pregnant' when we have been constrained by FDA to say 'weeks since ovulation'. Indeed, even outside of US, this product doesn't tell you weeks pregnant – if you are 1-2 weeks by [the Weeks Estimator] then you are 3-4 weeks pregnant because the universal convention for dating pregnancy is from the LMP not from ovulation. . . . 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.

PTX 52 at 1. At trial, Dr. Pike first attempted to escape the plain meaning of these words by arguing that she was conveying the FDA's views, not her own. Pike DT ¶ 7. The email considered as a whole—particularly the statement that the convention for dating pregnancy is from LMP even outside the FDA's jurisdiction—belies this explanation. In her cross-examination, Dr. Pike also tried to explain the final sentence about consumer confusion as "using a bit of hyperbole here because [she] was very strongly trying to kill" an advertising mockup showing a baby "bump" she did not like. Tr. 1166:17-1167:15. Based on her tone, demeanor,

and unconvincing explanations, the Court found Dr. Pike's attempt to contradict the plain meaning of her email lacking credibility. Her email was candid. Her testimony about the email was not.

In addition to its own staff, members of SPD's U.S. Advisory Board, which was created "[t]o allow SPD to obtain external expert advice on product strategy and launch plans," PTX 53 at 6, also highlighted the existence of the LMP convention and the possible confusion that might result from the discrepancy between the product's estimate and a doctor's estimate based on the convention. For example, one Board member stated at an early meeting "that LMP was currently the pregnancy-related time measurement that most women understood and that pregnancies were dated from this point by obstetricians. He added that it was important not to contradict this clinician-defined measurement." PTX 53 at 10. At a subsequent meeting, another Board member raised concerns about the digital display screens containing "Pregnant 1-2," etc., noting: "Need to be clearer what this means, i.e. from time of conception NOT LMP, we are Not saying what we are doing." PTX 69 at 30; *see also* PTX 472 at 13 (Stewart Wilson Depo. Tr. 71:12-72:7). At yet another meeting, a different Board member "suggested that medical professionals are behind the time[s] when it comes to dating pregnancy using LMP" and that "there could be an opportunity to change the way doctors date pregnancy," but "there was acknowledgment that this would be a large undertaking." PTX 54 at 11.

Despite awareness of the LMP convention and warnings about confusion from the FDA, its in-house scientific staff, and its Advisory Board, SPD advertised the Weeks Estimator in ways that were intended to obfuscate the distinction between the Week's Estimator's result of weeks since ovulation and the estimate of pregnancy duration a doctor would provide.

Perhaps the most glaring example of this deceptive behavior revolves around the Television Commercial. Ryan Daly, Clearblue's Worldwide Marketing Director, acknowledged at trial that it would be untrue to "communicat[e] to consumers that this product can estimate weeks of pregnancy the same way that a doctor does, or would give the same result as a doctor." Tr. 715:18-716:5. Nonetheless, the very story board for the Television Commercial is entitled

"Before the Doctor Visit," PTX 238 at 2, Tr. 1170:2-7, and an internal SPD PowerPoint presentation described the Television Commercial as "Best Friends with the insight of knowing it before the doctor visit," PTX 209 at 10. Unsurprisingly, SPD's market research revealed that viewers believed the product can tell you how far along you are before you go to the doctor, PTX 110 at 8; PTX 111 at 13-19; Tr. 1062:22-1065:1, which, as discussed in greater detail below, necessarily implies that the product will provide the same estimate one would get *from* a doctor's visit.

Prior to airing the advertisement, Mr. Daly explained to his colleagues that "I know we are being told by some that the FDA will be waiting for this ad, but I really struggle with that given their setup . . . they have a pharma ad division but none for [over-the-counter products]. Net, I view the risk as low." PTX 211 at 1. In other words, he thought the likelihood of getting caught airing an ad that contravened FDA requirements was minimal because the FDA did not have resources to police advertising for over-the-counter products.[8] Instead, he was concerned the networks would get cold feet about the product's ability to substantiate its advertising message:

> To me the thing that keeps me up at night is network clearance. Particularly around the area of replacing your Dr … Now I think the copy does a great job of not pushing this as a replacement to Dr, and our supers will cover us, but some could get shy should they read the entire intended for use statement. So for this, I think we need to be very careful … I want us to see everything that we plan to send the TV stations. Only give them what they ask for.

PTX 211 at 1 (ellipses in original). (To obtain clearance to air a commercial on network television, advertisers are typically required to submit "substantiation" for the commercial's advertising messages. PPF ¶ 35.) At trial, Mr. Daly provided a farfetched explanation[9] for this

[8] The FDA ultimately did object to the Television Commercial, noting it "conveys the message that the Weeks Estimator product can be used for measuring the number of weeks of pregnancy and pregnancy progression because of the dialogue between the 2 women ('I'm pregnant. 2 weeks. You already went to the doctor? Not yet.'), whereas the Indications for Use statement includes the following limitation: 'This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy'. Therefore the TV commercial may be misleading to a consumer who may understand the device measures pregnancy progression and duration." PTX 136 at 2.

[9] Mr. Daly's lack of credibility revealed itself repeatedly, from his description of something referred to internally as the "Bedford puke," PTX 211 at 1, an apparent shorthand for the dangers of providing too much

email, unconvincingly stating that it expressed his concern about overwhelming the networks with too much information: "We have technical people who will sometimes provide hundreds of pages of information when you only really need one page." Tr. 718:3-8. Rather than give the networks the full Indications for Use statement, which is less than a page long, SPD gave the networks a substantially truncated version that omitted the warning: "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 can not be substituted for a doctor's determination of gestational age." Tr. 719:8-720:15. It was also the truncated version of the Indications for Use statement that was used as a "super" (disclaimer text at the bottom of the screen), and that Mr. Daly believed would "cover" SPD. And when asked where in the commercial it communicates the message that the product's estimate is different from a doctor's estimate, Mr. Daly answered: "Again, you're looking at one medium, and when you actually have a pack that a consumer can potentially pick up in great detail, it discusses the, you know, the fact that this is a different method. We also call attention to our website at the end of the ad to provide further information. I think you can't just take it – you know, you can't take one specific execution and sum up what someone would take away from that." Tr. 712:4-11.

Unfortunately, Mr. Daly was not the only SPD staff member who exhibited such disregard for truthful advertising. Anticipating a likely complaint from the FDA or C&D regarding the Television Commercial, SPD's staff discussed creating a backup commercial that correctly identified a key problem with the ad: "Back up plan is Best Friends with no mention of 'knowing before doctor visit.'" PTX 209 at 12; PTX 257 at 1; Tr. 761:8-763:7; *see also* PPF ¶ 37. Kirsten Suarez, Clearblue's Brand Manager, similarly surmised: "Is our guess that First Response would challenge the doctor portion so we're solving for that? Can we not wait to receive a letter and then edit? I'm guessing we'd have time between receipt of the letter and actual need to traffic in new copy/pull from the networks." PTX 257 at 1. The Court finds that

information to regulators and broadcasters, Tr. 720:16-721:22, to his statement that SPD prepared shelf trays that "were shipped to one single retailer," Daly DT ¶ 81, which just happened to be Target, Tr. 1066:8-19; 1067:4-12.

these communications show that SPD staff knew precisely what was false or misleading about the commercial, but they chose to air it anyway. At trial, Ms. Suarez unconvincingly explained: "I thought the fact that we included a doctor was good because we wanted to ensure that women still got prenatal care, and here we are showing her still going to the doctor." Tr. 763:2-7.

Ms. Suarez also made other troubling statements about the Weeks Estimator's advertising that suggest a deliberate attempt both to evade FDA limitations and convey a false message about the product. For example, she made the following statement about promotional materials developed for CVS: "One last thing, 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." PTX 214 at 1. This statement also reveals that SPD's staff knew that placing the word "pregnant" in proximity to "weeks" would suggest that the product provides an estimate of weeks pregnant.[10] In another email, Ms. Suarez recognized that SPD could not advertise the product as estimating "how far along," but that it could refer to survey results indicating that women want to know how far along they are because "[w]e can't say we're doing it, just that women want to know." PTX 260 at 1. In yet another email she responded to a suggestion that an advertisement should say "Find out how far along you are," with the following: "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 as you had, or we need to use the 'estimate weeks' language." PTX 358 at 4-5.[11]

SPD staff also believed that consumers did not have a good understanding of ovulation. For example, in response to Dr. Pike's suggestion that consumers know what ovulation is, Ms. Suarez replied: "Trust me, it doesn't really make sense to them. The other slides in that deck

[10] The FDA shared the same view: "In the letter we say you should not talk about weeks pregnant. Placing 'weeks' in the result window is the same as saying weeks pregnant." PTX 412 at 1.

[11] Ms. Suarez also explained that she was not concerned that consumers would misinterpret the advertising as suggesting that the product provides the same estimate of weeks pregnant as a doctor because "it actually didn't seem like that big of a deal to me." Tr. 802:23-24.

show how they 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 anything." PTX 62 at 2.[12] She subsequently stated: "Ryan/I/our PR agency/US team doesn't want to talk 'ovulation' other than when we have to, like on a graph, because people do not connect that to when they got pregnant." PTX 62 at 1; Tr. 751:5-25, 756:17-757:5; *see also* PTX 259 at 4; Tr. 1257:8-11. Similarly, a summary of a meeting between Dr. Johnson and colleague Fiona Humberstone with SPD's outside marketing firm discussing the product's advertising contains the heading: "Why doesn't weeks estimate match my doctor's estimate?" PTX 59 at 2. Under that heading, it is noted that "[t]he data doctors use [is] measured from last menstrual period (LMP) whereas our data measures since the egg was fertilized," and "[o]verall lack of consumers' understanding of ovulation may cause confusion. Need to address the reason why [healthcare providers] use different method without saying it is wrong or suggesting that Weeks Estimator takes the place of seeing [a healthcare provider]." PTX 59 at 2. Thus, although SPD did eventually add the word "ovulation" to its advertising, these communications reveal why SPD did not want to use ovulation in the launch advertising and why it downplayed ovulation in the revised advertising.

Attempting to counter the evidence that it set out to intentionally deceive consumers, SPD repeatedly suggested that it had tried in vain to include a conversion chart on the outside of the product's packaging that would mitigate consumers' confusion regarding how the product's estimate of weeks differs from a doctor's estimate of weeks pregnant. To begin with, SPD provided a shifting reason for the absence of the conversion chart. SPD initially stated in its brief in support of its motion *in limine* to dismiss all false advertising claims that the FDA "prohibited" or "forbade" it from "placing the LMP/ovulation conversion chart on the outside of the box." Dkt. No. 224 at 21 n. 9; *see also* Dkt. No. 232 at 9. By the time of SPD's pre-trial briefing, its contention that the FDA forbade placing the chart on the outside of the box had softened into an explanation that SPD "*understood* the FDA's instruction to remove 'accuracy'

[12] The "deck" referred to is a PowerPoint presentation admitted as PTX 61.

information from the outside of the box to require removal of all performance information concerning the estimation of weeks function, including the Conversion Chart." Dkt. No. 307 ¶ 34 (emphasis added). Finally, at trial, Dr. Johnson stated that it was only after doing a "deep" read of the Clearance Letter that SPD's staff determined that they had to remove the conversion chart from the outside of the package. Tr. 1194:16-23, 1203:17-24; *see also* Johnson DT ¶ 28 (interpreting Hold Letter). Because SPD often overstated other instances of the FDA and broadcasters "requiring" or "mandating" as opposed to "permitting" or "allowing" certain conduct, *compare* Daly DT ¶ 72, *with* Tr. 700:13-705:20, the Court does not credit SPD's explanation for the removal of the conversion chart. Similarly, it is not at all clear from the FDA's Hold and Clearance Letters that the FDA intended to prohibit SPD from including the conversion chart on the outside of the box. *See, e.g.,* DTX 1 at 5.

Moreover, while SPD frequently pushed back against the FDA regarding other changes that it did not like, it did not ask the FDA to clarify whether the FDA actually wanted SPD to remove the conversion chart, nor did it object to the removal based on concerns that the conversion chart was needed to avoid consumer confusion. Instead, SPD relied on its own claimed interpretation of the FDA's communications to decide that it had to remove a conversion chart that it now argues would have mitigated consumer confusion regarding its product. SPD also failed to offer any alternative suggestions to the FDA to retain the primary message of the conversion chart in other forms. Regardless, SPD's own staff were concerned about confusion *even with* the conversion chart on the outside of the package: Dr. Pike's assessment that putting "weeks pregnant" on the product's packaging was likely to confuse consumers—because it did not align with the "universal" convention for pregnancy dating—was made in the context of assuming that the chart would be "readily visible" on the package. PTX 52; Tr. 1194:24-1198:9.

In sum, SPD was aware that the Weeks Estimator's result did not align with the standard convention for dating pregnancy; SPD was warned by the FDA, its U.S. Advisory Board, and in-house scientific staff about the possibility of consumer confusion; and yet SPD developed

advertising that was intentionally designed to mislead consumers about the difference between the product's estimate of weeks since ovulation and a doctor's estimate of weeks pregnant.[13]

J. What the Court Is Not Deciding

Before addressing its conclusions of law, the Court takes this opportunity to note a factual finding that it is not making: when pregnancy begins "as a biological matter" (to use SPD's terminology). Although the parties spent much time pursuing this red herring—with experts testifying on behalf of SPD that pregnancy begins at fertilization and on behalf of C&D that it begins at implantation—the Court concludes that even if this were a factually answerable question, it need not decide it because it has little, if any, bearing on the key legal issues in this case. The key issue is whether SPD's advertising communicates the message that the Weeks Estimator provides an estimate of weeks pregnant that is consistent with a doctor's estimate of weeks pregnant and, if so, whether this message is false. When pregnancy begins "as a biological matter" is, therefore, beside the point.

III. CONCLUSIONS OF LAW

As described above, doctors use a standard convention for expressing pregnancy duration based on weeks since a woman's LMP. SPD's Clearblue Advanced Pregnancy Test with Weeks Estimator tells a woman if she is pregnant and provides an estimate of weeks since a woman last ovulated. Under the Lanham Act, the Court must determine whether SPD's advertising conveys the false message that the product provides an estimate of weeks that is consistent with a doctor's estimate of weeks pregnant. Based on its findings of fact and conclusions of law, the Court concludes that it does and that C&D is entitled to injunctive relief. The Court also concludes, however, that C&D failed to present sufficient evidence to establish its claim for breach of contract.

[13] SPD's intentional deception extended to other aspects of its advertising not directly relevant here, such as touting the fact to U.S. retailers that 15% of European purchasers of the product had used the product to track their pregnancy despite the FDA's explicit restrictions on making such statements. PTX 117; Tr. 1085:21-1091:2.

A. False Advertising under the Lanham Act[14]

Stated succinctly, the elements of a Lanham Act claim require a plaintiff to demonstrate that the defendant's advertising message[15] (1) is false, either literally or impliedly, (2) is material, and (3) causes or is likely to cause injury to plaintiff. *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 255 (2d Cir. 2014) ("*Merck Eprova II*").[16] Due to the complexity of the doctrine, the Court briefly elaborates the legal standard necessary to satisfy each of these elements.

Starting with the first element, falsity may be premised on one of two theories: (a) the advertising is "literally false as a factual matter," or (b) it is impliedly (i.e., misleadingly) false, which means that, "although the advertisement is literally true, it is likely to deceive or confuse consumers." *Id.* (quoting *S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 238 (2d Cir. 2001)). To establish literal falsity, a plaintiff must show that (i) the advertisement makes an express statement of falsity (i.e., it is "false on its face") or (ii) the advertisement is "false by necessary implication," meaning 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, 148, 158 (2d Cir. 2007). 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." *Merck Eprova II*, 760 F.3d at 256 (quoting *Tiffany (NJ) Inc. v. eBay, Inc.*, 600 F.3d 93, 112 (2d Cir. 2010)). But if an advertising message is impliedly false, a plaintiff generally must show evidence of consumer confusion, unless there is evidence that the defendant intended to deceive the public through "deliberate conduct" of an "egregious nature," in which

[14] C&D also brought a claim for false advertising under Section 349 of New York's General Business Law, which the parties agree imposes the same liability standard as the Lanham Act. *See* Dkt. No. 308 at 6; Dkt. No. 291 at 72 n.15; Dkt. No. 368 at 15 n.4; Dkt. No. 371 at 6.

[15] In many Lanham Act cases, the parties and courts often refer to the messages or statements in the challenged advertising as "claims," i.e., claims about what the product does. But using "claim" for an advertising statement or message is unnecessarily confusing in light of the legal usage of "claim," which generally means "[t]he aggregate of operative facts giving rise to a right enforceable by a court" or "[t]he assertion of an existing right; any right to payment or to an equitable remedy, even if contingent or provisional." *Black's Law Dictionary* 281-82 (9th ed. 2009). To avoid confusion, the Court uses the term "message" in lieu of "claim."

[16] The statute also requires proof that the allegedly false advertising was placed in interstate commerce, 15 U.S.C. § 1125(a), which, as a practical matter, is rarely contested.

case "a presumption arises that 'consumers are, in fact, being deceived.'" *Id.* (quoting *Johnson & Johnson * Merck Consumer Pharmaceuticals Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 298-99 (2d Cir. 1992)).

Furthermore, only unambiguous messages can be literally false. *Time Warner*, 497 F.3d at 158. Thus, as a practical matter, the court must first determine whether the challenged advertising conveys an unambiguous message, either by express statement or necessary implication; if so, the Court must determine whether that message is literally false. But if the advertising does not convey an unambiguous message, the Court generally must look to consumer surveys to determine what message is conveyed to consumers and then determine whether the message conveyed is false. *Id.*

Turning to the second Lanham Act element, materiality, the Second Circuit requires a plaintiff to show that "the defendants misrepresented an inherent quality or characteristic of the product." *Merck Eprova II*, 760 F.3d at 255 (citing *S.C. Johnson*, 241 F.3d at 238).

Finally, for liability as opposed to damages, the third element—injury—turns on "whether it is likely that [defendant's] advertising has caused or will cause a loss of [plaintiff's] sales, not whether [plaintiff] has come forward with specific evidence that [defendant's] ads actually resulted in some definite loss of sales." *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d Cir. 1980) (citing *Parkway Baking Co. v. Freihofer Baking Co.*, 255 F.2d 641, 649 (3d Cir. 1958); *Ames Publ'g Co. v. Walker-Davis Publ'ns, Inc.*, 372 F. Supp. 1, 13 (E.D. Pa. 1974); 2 J.T. McCarthy, *Trademarks and Unfair Competition* § 27:5 at 249-50 (1973)).

1. Launch Package

Beginning with the Launch Package, the Court concludes that the package's advertising message is unambiguous and literally false. And even if the message were ambiguous, C&D is entitled to a presumption of consumer confusion in light of SPD's intentional deception and, furthermore, it has shown evidence of consumer confusion.

a) Literal Falsity

As noted, a piece of advertising need not make an express statement of falsity to be literally false under the Lanham Act; rather, "[i]f the words or images, considered in context, necessarily imply a false message, the advertisement is literally false and no extrinsic evidence of consumer confusion is required." *Time Warner*, 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)). Although the Launch Package does not make an express statement that the Weeks Estimator provides an estimate of weeks pregnant that is consistent with a doctor's estimate of weeks pregnant, the Launch Package's words and images, considered in context, necessarily imply this unambiguous message, which is false.

First, the Court concludes that the Launch Package, considered in context, necessarily implies an unambiguous message. Considered together, the name of the product ("Clearblue Advanced *Pregnancy* Test with *Weeks* Estimator") and the digital screens ("*Pregnant* // 1-2 *Weeks*," etc.), without any clarification, necessarily imply that the product tells a woman whether she is pregnant and, if she is pregnant, how many weeks pregnant she is. Moreover, the Weeks Estimator is a home pregnancy test—i.e., an over-the-counter medical device—that is marketed to women for use before they see a doctor about their pregnancy, and women have historically relied on their doctors for an estimate of pregnancy duration. Thus, in the context of a home pregnancy test that also provides an estimate of "weeks," the overriding message to consumers is that this is an estimate of weeks pregnant that is consistent with a doctor's estimate of weeks pregnant. *Cf. Avis Rent A Car Sys., Inc. v. Hertz Corp.*, 782 F.2d 381, 384-85 (2d Cir. 1986) (Friendly, J.) ("[T]he evidence pointed unmistakably to an interpretation that Hertz was speaking of cars available for rental and not of total cars owned. Hertz and Avis have made their reputation as companies that *rent* cars, not companies that sell or merely own cars."). A caduceus in the lower right-hand corner of the box augments this message.[17]

[17] The caduceus is a conventionalized symbol of the medical profession. *See Webster's Third New Int'l Dictionary* 312 (1961) (defining caduceus as "a conventionalized representation of a staff with two snakes curled around it and with two wings at the top" and as "one of the symbols of a physician").

Second, the Court concludes that this unambiguous message is false. Because doctors use a standard convention for expressing pregnancy duration based on weeks since a woman's LMP, while the Weeks Estimator provides an estimate of weeks since ovulation, the message that the product provides the same estimate of weeks pregnant as a doctor is false.

SPD's attorneys and witnesses devoted considerable energy to evading, downplaying, or refusing to acknowledge the existence of the standard convention for expressing pregnancy duration. These efforts to avoid acknowledging the existence and import of a standard convention—one that even its own staff described as "universal"—do not suffice to render its advertising truthful; indeed, other courts have rejected similar attempts to evade the import of words bearing a conventional meaning in a given context. *See Johnson & Johnson v. GAC Int'l, Inc.*, 862 F.2d 975, 982 (2d Cir. 1988) ("A word that has no meaning except that which is assigned to it cannot be untrue. But where, as here, a 'coined' word incorporates words that do have preexisting meanings and connotations, we see no reason to allow any greater leeway for deceptiveness."); *Merck Eprova AG v. Gnosis S.p.A.*, 901 F. Supp. 2d 436, 453 (S.D.N.Y. 2012) ("*Merck Eprova I*") ("[W]hile the Court found Dr. Siegel to be credible, his testimony was largely irrelevant to this action, as it spoke to a theoretical use of the contested terms that bordered on the aspirational, not to how those terms are actually used. . . . But, even if *some* terms are misused, he ultimately did not dispute that these terms are consistently used in the way Merck contends they should be." (citations omitted)).

SPD also argues that the Launch Package cannot convey a message that is false by necessary implication because of the Indications for Use statement on the side of the package. But the entire statement is 206 words long, separated into four paragraphs, and printed in minuscule font. Stacey Feldman, C&D's Vice President of Marketing for Women's Health and Personal Care, credibly testified that in her experience very few consumers will read the Indications for Use statement on the side panel, Feldman DT ¶¶ 20-21, and even Ryan Daly, Clearblue's Worldwide Marketing Director, testified that "the statement in its entirety on the pack [is] fairly long," hence why he opted to provide what he considered to be a shorter, "more

consumer-friendly version" to the broadcasters, Tr. 709:8-13. Moreover, as many courts have found, "[a] footnote or disclaimer that 'purports to change the apparent meaning of the claims and render them literally truthful, but which is so inconspicuously located or in such fine print that readers tend to overlook it, will not remedy the misleading nature of the claims.'" *Smithkline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 906 F. Supp. 178, 182 (S.D.N.Y. 1995) (quoting *Am. Home Prods. Corp. v. Johnson & Johnson*, 654 F. Supp. 568, 590 (S.D.N.Y. 1987)). Stated differently, a lengthy disclaimer on the side of a box that is unlikely to be noticed by consumers cannot remedy advertising "that necessarily conveys a false message to the consumer." *Novartis Consumer Health, Inc.*, 290 F.3d at 598.

Similarly, SPD routinely pointed to the package insert for the product as eliminating any possibility of consumer confusion. The same disclaimer points discussed above apply to this insert. Moreover, the Court finds SPD's argument unpersuasive for two additional reasons. First, the product is wrapped in cellophane plastic so the package insert is not available to the consumer until the consumer has purchased the product and, therefore, the Lanham Act injury is complete by the time the consumer reads the package insert. *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *40 n.6. Second, the Court agrees with Ms. Feldman's observation that "many consumers will not review with care most of the information contained in the Package Insert," which is "particularly likely because SPD's extensive advertising campaign will have already deceived many consumers who purchase the Weeks Estimator to believe that it will tell them how long they have been pregnant, and the digital readout of the results on the Product test stick will not appear to such consumers to require interpretation." Feldman DT ¶ 16.

b) Implied Falsity

Alternatively, even if the Launch Package's advertising were ambiguous, the Court concludes that the Launch Package is impliedly false; that is, it is "likely to mislead or confuse consumers." *Time Warner*, 497 F.3d at 153 (citing *Coca-Cola v. Tropicana Prods., Inc.*, 690 F.2d 312, 317 (2d Cir. 1982)). "'[P]laintiffs alleging an implied falsehood are claiming that a

statement, whatever its literal truth, has left an impression on the listener [or viewer] that conflicts with reality'—a claim that 'invites a comparison of the impression, rather than the statement, with the truth.'" *Id.* (quoting *Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 229 (2d Cir. 1999)).

As noted above, because the Court finds that SPD intentionally set out to deceive consumers and that this conduct was of an egregious nature, C&D is entitled to a presumption "that consumers are, in fact, being deceived." *Merck Eprova II*, 760 F.3d at 256 (quoting *Smithkline Beecham Corp.*, 960 F.2d at 298-99). In such cases, "the burden shifts to the defendant to demonstrate the absence of consumer confusion." *Id.* Having failed to come forward with any evidence demonstrating an absence of consumer confusion, SPD has not rebutted this presumption. Thus, C&D satisfies its burden of demonstrating that the Launch Package deceives consumers.

But even if C&D had not come forward with evidence of SPD's intentional deception, C&D has provided evidence of both actual confusion and likelihood of confusion. First, C&D introduced an April 2014 news report from the CBS affiliate in Los Angeles, California, reporting that an expectant mother who had purchased the Launch Package believed the product provided an estimate of weeks pregnant that was consistent with how her doctor would estimate weeks pregnant. PTX 120. The woman became concerned, wondering if her "baby was not developing correctly," when her doctor told her that she was further along in her pregnancy than the estimate provided by the product. PTX 120.[18] SPD's public relations agency brought the news story to SPD's attention, but it recommended that SPD "make no proactive statement at this time and let the story fade away." PTX 226A at 2. In response, Procter & Gamble's Communications Manager for Personal Health Care suggested the following: "My thinking is

[18] SPD did not object to this exhibit when it was admitted into evidence. Tr. 458:2-17. However, SPD appeared surprised that the exhibit was already in evidence when it was discussed at a later stage of trial, Tr. 1092:1-1093:2, suggesting it intended to object to the exhibit, which it never did. Even if the hearsay objection were not waived, C&D did not offer the exhibit for the truth of the matter asserted, Tr. 1092:15-:1093:2, and the Court is not relying on it for this purpose.

that we make the confusion a story, and how we're helping bring pregnancy testing into the 21st century with better science, so good that it's helping doctors reframe 'the way they've always done it?'" PTX 226A at 1. Despite this suggestion, SPD did nothing to address the confusion. Tr. 1097:1-21.

C&D also pointed to approximately 340 complaints made to SPD's consumer "care line" as examples of consumer confusion. PTX 65-67; Patrizio DT ¶ 67.[19] However, of these, only 30 were from consumers located in the United States and only 17 reflect that the complaining consumer mistakenly believed that the product estimates pregnancy duration the same way a doctor would. Sammel DT ¶ 11; Patrizio DT ¶ 50, 67; PTX 65-67. Because the present lawsuit concerns only U.S. advertising, the 310 non-U.S. complaints have little bearing on this case. In addition, the Court agrees with SPD that 30 complaints represents a small percentage when compared to the roughly 1,866,215 Weeks Estimators sold to U.S. consumers from August 2013 to June 2014. Cristobal DT ¶ 7. At the same time, the Court does not agree with SPD that the small number of complaints demonstrates an absence of confusion because many deceived consumers may not even know about the care line or may not be inclined to call it. In short, although these few consumer complaints are evidence of actual confusion, they are of modest weight.[20]

Second, C&D presented evidence of likelihood of confusion in the form of Hal Poret's consumer surveys, which focused on the Weeks Estimator's Launch and Revised Packaging. For the Launch Package, Mr. Poret concluded that 19.0% or 21.9% (depending on the base used)

[19] SPD objected to the consumer complaints on relevance and hearsay grounds, and the Court indicated that it would admit the exhibits for what they may be permissibly considered for. *See* Dkt. No. 335 at 143; Tr. 120:7-12. It is unclear from SPD's objections to C&D's proposed findings of fact whether it maintains this objection. *See* PPF ¶ 77. In any event, the objection is overruled because the consumer complaints are not offered to prove that the Week's Estimator does or does not estimate pregnancy duration the same way a doctor would; they are offered only to show the declarant's—i.e., the consumer's—state of mind. *See Fun-Damental Too v. Gemmy Indus. Corp.*, 111 F.3d 993, 1003-04 (2d Cir. 1997) ("The testimony in question was not offered to prove that Fun-Damental was actually selling to some retailers at lower prices, but was probative of the declarant's confusion.").

[20] C&D also pointed to comments made on social media, such as Facebook, as examples of actual consumer confusion. SPD countered that the comments are inadmissible and/or unreliable. Because of the other available evidence of consumer confusion, the Court need not determine whether the social media comments are admissible or, if admissible, how much weight they should be given.

of participants answered both that the product estimates the number of weeks a woman is pregnant and that the product's estimate of weeks is the same as a doctor's estimate of weeks pregnant. Poret DT ¶ 106. Mr. Poret explained that this is a conservative figure, i.e., favorable to SPD, because he "assumed that a respondent was deceived only if that respondent answered *both* that the Product estimates the number of weeks a woman is pregnant and that the Product's estimate of weeks is the same as a doctor's." Poret RT ¶ 61. Even this conservative figure reveals that a substantial number of participants understood the Launch Package to communicate the message that the Weeks Estimator provides an estimate of weeks pregnant that is consistent with the estimate a doctor would provide. *See Merck Eprova AG v. Brookstone Pharm., LLC,* 920 F. Supp. 2d 404, 419-20 (S.D.N.Y. 2013) (finding 11% is a "substantial percentage"). As noted above, this message is false.

Using a scattershot approach, SPD criticized Mr. Poret's survey on myriad grounds—from the survey population he used to the design of his questions to the way he coded his answers. "The evidentiary value of a survey depends on its underlying objectivity as determined through many factors, such as 'whether [the survey] is properly "filtered" to screen out those who got no message from the advertisement, whether the questions are directed to the real issues, and whether the questions are leading or suggestive.'" *Novartis Consumer Health, Inc.*, 290 F.3d at 591 (quoting *SmithKline Beecham Corp.*, 960 F.2d at 300). Bearing this standard in mind, and upon a careful review of Mr. Poret's testimony, consideration of how he fared on cross-examination, and based as well on the testimony of SPD's survey expert, Sarah Butler, the Court concludes that Mr. Poret's survey is reliable and that SPD's criticisms are meritless.

In sum, the Court concludes that C&D has established Lanham Act liability with respect to the Launch Package on multiple grounds: (1) the Court concludes that the Launch Package necessarily implies an unambiguous message that is false; (2) in light of SPD's intentional deception, C&D is entitled to a presumption, which SPD did not rebut, that the Launch Package in fact deceives consumers; and (3) the Launch Package is misleadingly false in light of the evidence of (a) actual confusion and (b) likelihood of confusion.

2. Revised Package

As noted above, the only differences between the Revised and Launch Package are the insertion of "Only Test That Estimates Weeks Since Ovulation*," the removal of "weeks" from the digital screens, and the insertion of "Weeks Along" just below the digital screens. PTX 4 at 2. Both parties pointed to competing evidence regarding the degree to which consumers do or do not understand the meaning of "ovulation" and its relationship to how a doctor dates pregnancy, and thus the degree to which adding "since ovulation" to the front of the box would clarify that the Weeks Estimator provides an estimate that does not align with a doctor's estimate. The Court need not resolve this dispute—and thus, the Court need not determine whether adding "since ovulation" alters the package's unambiguous message—because it concludes that, regardless, the Revised Package is impliedly false.

As a preliminary matter, it is unclear from the case law whether C&D is entitled to the presumption of consumer confusion as to all of SPD's advertising based on SPD's intentional deception that is directly tied to only specific pieces of advertising. On the one hand, an advertiser who has learned the error of its ways and has modified its advertising accordingly should not be forever held to account for prior instances of bad conduct. On the other hand, evidence of prior intentional deception may be probative of whether subsequent corrections were sincerely implemented. The Court notes, for example, that even though SPD added the phrase "since ovulation" to the Revised Package, this phrase is not displayed prominently, which is consistent with SPD's internal emails stating that it did not want to use the word "ovulation" in relation to the Weeks Estimator because "US women do not have a clear enough understanding of ovulation." PTX 59; *see also* PTX 62 (SPD's marketing team "doesn't want to talk 'ovulation' other than when we have to, like on a graph, because people do not connect that to when they got pregnant.").

Regardless of whether C&D is entitled to the presumption of consumer confusion based on SPD's intentional deception, C&D presented evidence that this Court found persuasive of likelihood of consumer confusion based on Mr. Poret's surveys. For the Revised Package, Mr.

Poret concluded that 16.0% or 17.3% (depending on the base used) of participants answered both that the product estimates the number of weeks a woman is pregnant and that the product's estimate of weeks is the same as a doctor's estimate of weeks pregnant. Poret DT ¶ 106. Thus, Mr. Poret's survey reveals that a substantial number of participants understood the Revised Package to communicate the message that the Weeks Estimator provides an estimate of weeks pregnant that is consistent with a doctor's estimate. As noted, this message is false.

3. Television Commercial

Turning to the Television Commercial, as with the Launch Package, the Court concludes that the commercial's advertising message is unambiguous and is literally false. And even if the message were ambiguous, C&D is entitled to a presumption of consumer confusion in light of SPD's intentional deception and, furthermore, it has shown evidence of consumer confusion.

a) Literal Falsity

The Court has little difficulty concluding that the Television Commercial necessarily implies an unambiguous message that is false. Although the Television Commercial does not make an express statement that the Weeks Estimator provides an estimate of weeks pregnant that is consistent with a doctor's estimate, the Court finds that this is the clear takeaway from the commercial. As with the Launch Package, the proximity of the words "weeks" and "pregnant" in the digital screens and the repeated message that the product is a home pregnancy test that also provides an estimate of "weeks" ("The new Clearblue *pregnancy* test also estimates how many *weeks*") suggest in the overall context of the commercial that the product provides an estimate of weeks pregnant that is consistent with a doctor's estimate of weeks pregnant. The dialogue between the two women only further augments this unambiguous message when the first woman states that she knows she is two weeks pregnant despite not having gone to the doctor yet because she used the Weeks Estimator. This exchange communicates to the viewer that the woman received the same estimate of weeks pregnant from the product that she would have received had she gone to the doctor—which is false.

SPD argues that the "super," or disclaimer, at the bottom of the screen combined with the phrase "Estimated Weeks Since Ovulation," which appears for two seconds at the bottom of the screen showing the arc of digital screens, makes the commercial literally truthful or, at a minimum, ambiguous. However, SPD intentionally omitted language from the super clarifying that the estimate of pregnancy duration from a doctor is different from the Weeks Estimator's result. Moreover, the super at the bottom of the screen is in small, whitish font that blends in to the white background such that even the Court failed to notice it upon first viewing. (An image of the screen shot containing this disclaimer is pasted below as Figure 4.) The phrase "Estimated Weeks Since Ovulation" at the bottom of the chart, which appears for two seconds, is similarly inconspicuous. As noted above, such inconspicuous disclaimers are insufficient to offset the overriding message of the advertisement.

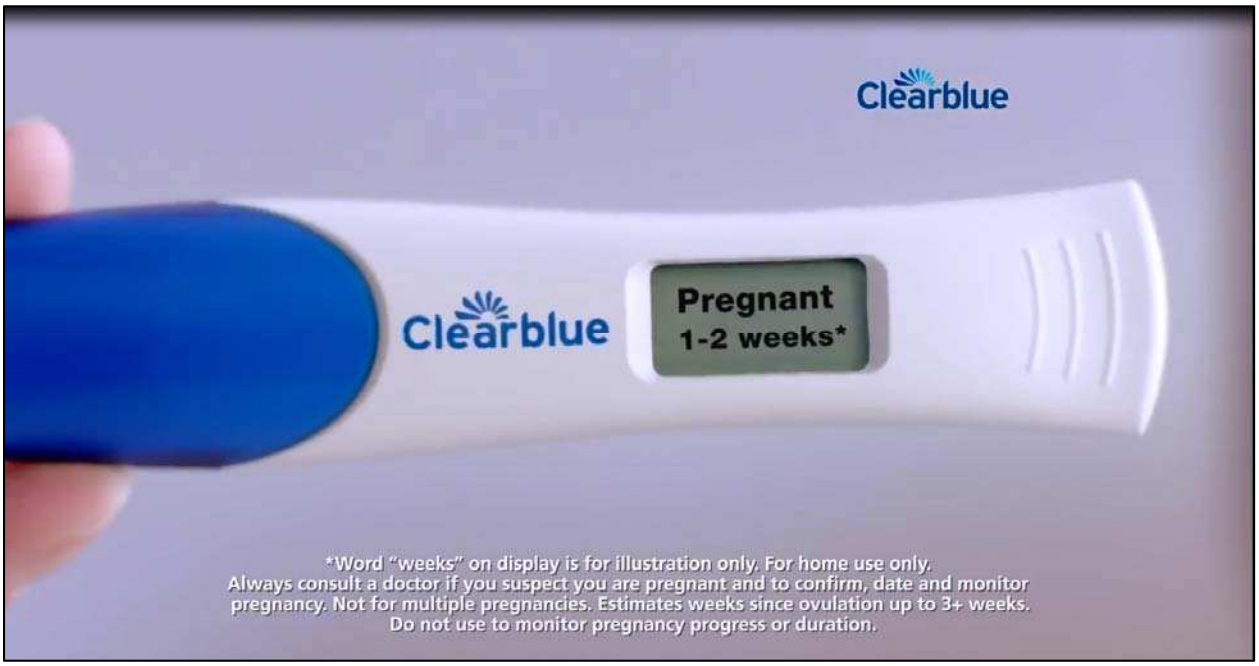


Figure 4

b) Implied Falsity

Even if not false by necessary implication, the Television Commercial is misleadingly false. As with the Launch Package, C&D is entitled to a presumption of consumer confusion in light of SPD's intentional deception, exemplified by Mr. Daly's and Ms. Suarez's emails and

testimony regarding the Television Commercial. SPD failed to come forward with any evidence that consumers are not misled by the Television Commercial, thus the Court presumes that the commercial deceived consumers.

C&D also presented evidence of likelihood of consumer confusion based on Dr. Bruce Isaacson's consumer surveys, but the Court need not rely on this evidence in light of the Court's finding that the Television Commercial is literally false and that SPD engaged in intentional deception regarding the Television Commercial.

4. Other Advertising

Finally, the Court concludes that much of the other advertising C&D cited is just as literally false as the Launch Package. The webpage prominently asserts that the product "is the FIRST and ONLY pregnancy test that not only tells you if you are pregnant but also estimates the number of weeks." PTX 17. The paragraph on the initial webpage concludes by noting that "78% of women surveyed said they believe it is important to know how far along they are." PTX 17. Without any other qualification, and given the context, the necessary implication is that this product provides an estimate of weeks pregnant that is consistent with a doctor's estimate. Similarly, courts have recognized that false advertising made in the context of presentations to retailers falls within the Lanham Act's ambit. *See, e.g.*, *Symantec Corp. v. CD Micro, Inc.*, No. 02-406-KI, 2003 U.S. Dist. LEXIS 25608, at *8 (D. Or. Feb. 3, 2003) ("The important point is that the misrepresentations must be made to an entity who purchases plaintiff's product, not whether that entity is the ultimate consumer."). And the presentations made to retailers as well as internet advertising (e.g., web banners), retailer circulars, retailer websites, and in-store advertising (e.g., side-wing displays, shelf trays) convey the message that the product estimates "weeks pregnant," which, in context, conveys the message that the estimate is the same as a doctor's estimate of weeks pregnant. *See, e.g.*, PTX 19 (Walgreens advertisement stating: "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."); PTX 18 (point-of-sale displays stating "First pregnancy test to estimate weeks" and "How far along are you?").

To the extent this other advertising is ambiguous, C&D is entitled to a presumption of consumer confusion in light of SPD's intentional deception as reflected in, among other things, Ms. Suarez's emails discussed above.[21]

5. Materiality

The Second Circuit consistently applies a materiality standard that requires showing only "'that the defendants misrepresented an inherent quality or characteristic of the product.'" *Merck Eprova II*, 760 F.3d at 255 (quoting *S.C. Johnson*, 241 F.3d at 238); *see also Time Warner*, 497 F.3d at 153 n.3 ("Under either theory [of falsity], the plaintiff must also demonstrate that the false or misleading representation involved an inherent or material quality of the product." (citing *S.C. Johnson & Son, Inc.*, 241 F.3d at 238; *NBA v. Motorola, Inc.*, 105 F.3d 841, 855 (2d Cir. 1997)); *Fur Info. & Fashion Council, Inc. v. E.F. Timme & Son, Inc.*, 501 F.2d 1048, 1051 (2d Cir. 1974) (stating Lanham Act Section 43(a) "was intended to apply only to misrepresentations relating to the inherent qualities of defendant's own goods").

The Weeks Estimator's ability to estimate weeks is, as the product's name conveys, an inherent quality or characteristic of the product as it is the key feature that differentiates it from the many other home pregnancy tests on the market. Indeed, much of SPD's marketing for the Weeks Estimator touted the message that it is the *only* pregnancy test with this feature. *See, e.g.*, PTX 17 (SPD's webpage stating "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."); *see also* Tr. 1061:11-16; PTX 110 at 5, 7 (discussing consumer reaction to Television Commercial, noting: "The new weeks estimator feature piques her interest in the product and makes her want to try."). Such marketing strongly suggests that SPD itself believed that the weeks estimating feature was an inherent quality or characteristic of

[21] C&D's post-trial briefing did not contain any specific arguments regarding the Internet-Only Commercial, nor did it offer any evidence during trial of consumer confusion regarding the Internet-Only Commercial.

the product. *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 312 (1st Cir. 2002) ("It seems reasonable to infer from defendants' aggressive marketing strategy highlighting the 'cashmere' nature of the blazers that defendants themselves believed cashmere to be an inherent and important characteristic of the blazers."). For these several reasons, the Court concludes that the weeks estimating function, which SPD misrepresented, is an inherent quality or characteristic of the product.

6. Injury

A Lanham Act plaintiff must also show injury, but, for liability purposes,

> [t]he statute 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. The correct standard is whether it is likely that [defendant's] advertising has caused or will cause a loss of [plaintiff's] sales, not whether [plaintiff] has come forward with specific evidence that [defendant's] ads actually resulted in some definite loss of sales.

Carter-Wallace, 631 F.2d at 190; *see also Vidal Sassoon, Inc. v. Bristol-Myers Co.*, 661 F.2d 272, 278 (2d Cir. 1981) ("Although Sassoon offered no evidence of actual sales loss directly traceable to the alleged misrepresentations, proof of diversion of sales is not required for an injunction to issue pursuant to § 43(a)."). And, "[t]o prove a likelihood of injury[, plaintiff] must also show a logical causal connection between the alleged false advertising and its own sales position." *Id.* at 190; *see also Vidal Sassoon*, 661 F.2d at 278; *Brookstone Pharm., LLC*, 920 F. Supp. 2d at 429; *L & J. G. Stickley, Inc. v. Cosser*, No. 5:02-CV-1542, 2008 U.S. Dist. LEXIS 7463, at *10 (N.D.N.Y. Jan. 31, 2008); *Telebrands Corp. v. Media Grp*, No. 97 Civ. 6768 (RPP), 1997 U.S. Dist. LEXIS 20474, at *9 (S.D.N.Y. Dec. 24, 1997).

As an initial matter, "[i]n cases where, as here, the district court has found literal falsity, [the Second Circuit has] never required a finding of extrinsic evidence of injury to consumers or to the plaintiff." *Merck Eprova II*, 760 F.3d at 259. Because the Court finds that the Launch Package, Television Commercial, and comparable other advertising are false by necessary implication (i.e., literally false), C&D need not provide extrinsic evidence of injury.

But even if that were not the case, C&D provided evidence showing a logical causal connection between SPD's false advertising and its own sales position. From 2001 to 2011 First Response's market share (excluding sales at Wal-Mart) increased from 12.0 "dollar share points" (market share in terms of dollar sales) to 29.8 dollar share points in 2011. PTX 29; Feldman DT ¶¶ 62 n.11, 70. (Each dollar share point is equal to approximately $2.6 million in retail sales for C&D on an annual basis. Feldman DT ¶ 68.) And in the year and a half preceding the launch of the Weeks Estimator, First Response's market share across all outlets continued to grow from 28.8 dollar share points at the beginning of 2012 to 32.4 dollar share points in August 2013. PTX 28; Feldman DT ¶¶ 64-80. Clearblue's market share, in contrast, went from approximately 16 dollar share points at the beginning of 2012 to 12.5 dollar share points in August 2013. PTX 28; Feldman DT ¶¶ 64-80.

SPD then launched the Weeks Estimator in August 2013 with an extensive marketing campaign, budgeting over $30 million for advertising, which it boasted was the "highest marketing investment ever seen in the category." PPF ¶ 53. SPD described the goal of this large investment as follows: "enabl[e] Clearblue to attain a dominant share of voice leadership of 60% v. First Response 30% and ept (10%)," PTX 100 at 7, with the aim of becoming "the Pregnancy Test market leader behind this innovative launch. (we are currently the #2 brand behind First Response***)," PTX 100 at 3-4.

Although Clearblue did not replace First Response as the number one home pregnancy test brand in terms of dollar share points, it gained market share while First Response lost market share. Within three months of the product's launch, the Weeks Estimator went from 0 to 9 dollar share points, and the Clearblue brand as a whole gained 7.7 dollar share points to reach a total of 20.2 dollar share points. PTX 28; *see also* Feldman DT ¶ 62. First Response's market share, in contrast, declined 2.4 dollar share points during these three months and continued to decline to 29.7 dollar share points by January 18, 2014. PTX 28. Dr. Tulin Erdem credibly testified that

> [t]his sharp change in the market cannot be attributed to any feature of the Product besides the "weeks estimator" feature. First, the core of SPD's advertising for the Product was the promotion of the "weeks estimator" feature. Second, the other

> function of the Product – the detection of pregnancy – was unchanged from the Clearblue digital pregnancy tests that had long been on the market before the launch of the Weeks Estimator.

Erdem DT ¶ 62.

SPD's internal marketing documents similarly attributed Clearblue's market gain and First Response's market loss to its marketing campaign for the Weeks Estimator. *See, e.g.*, PPF ¶ 92; PTX 107, 102, 108, 109; Erdem DT ¶¶ 57-61. For example, a member of SPD's marketing team sent an email in September 2013 noting: "Great News – SPD and Clearblue set all-time share records in September behind the holistic marketing plan launch and is on track to deliver the year!" Erdem DT ¶ 58; PTX 107 at 1. And, as noted, the key message of this holistic marketing plan was that the "Clearblue Advanced Digital Pregnancy Test with Weeks Estimator gives women the reassurance of knowing much more of their pregnancy because it is the only test that can also tell you how far along you are." PTX 209 at 9; *see also* PTX 100 at 4-5 ("Advantage versus First Response and E.P.P.: delivers the only pregnancy test to also estimate the # of weeks' pregnant"; "Strategies: Drive trade-up by filling the unmet need to know # of weeks' pregnant"). Indeed, both parties conducted market research showing that consumers were attracted to the idea of a pregnancy test that could estimate weeks pregnant, *see* Feldman DT ¶¶ 58-59; PTX 25, 26, 112, 113, and that SPD's Television Commercial "was highly persuasive, and effective in motivating consumers to purchase the Product. In particular, '[t]he relevancy of the information regarding the weeks estimator accuracy' was found to be 'driving the desire for the target audience to purchase the product.'" Feldman DT ¶ 61 (quoting PTX 27 at 8, 70); *see also* PTX 26.

Despite this evidence, SPD argues that C&D failed to establish a logical causal connection between the Weeks Estimator's false advertising and C&D's sales position because it did not conduct the type of "rigorous" analysis—particularly regression analysis to control for a host of independent variables—that SPD believes is necessary. SPD's argument is more appropriate in the damages phase of this case and has little bearing on merits liability for injunctive purposes because C&D need only show a "logical causal connection" and need not

"come forward with specific evidence that [defendant's] ads actually resulted in some definite loss of sales." *Carter-Wallace*, 631 F.2d at 190; *see also EFCO Corp. v. Symons Corp.*, 219 F.3d 734, 740 n.5 (8th Cir. 2000) ("Symons attacks Hancock's damage analysis for failing to account for all possible market forces. This criticism is more appropriate to a discussion of damages than causation, for it addresses what amount of EFCO's loss is attributable to Symons' conduct, rather than whether Symons[] caused the loss in the first instance."). In *Carter-Wallace*, for example, it was irrelevant for purposes of liability and injunctive relief "[t]hat much of the decline in Johnson's Baby Oil sales may be due to competition from lower priced baby oils" or "that the total pecuniary harm to Johnson might be relatively slight." *Id.* at 191. In any event, Dr. Erdem refuted most, if not all, of SPD's experts' hypothesized explanations for First Response's market decline.[22]

The Court finds SPD's other criticisms of Dr. Erdem's analysis equally unavailing. For example, Dr. Cox, one of SPD's expert witnesses, contends that "First Response did not experience a *significant* change in share of units sold at the time of the alleged false advertising." Cox DT ¶ 13 (emphasis added). But C&D need only show that it has been or is likely to be harmed, not that this harm is significant. In any event, at $2.6 million in annual sales per dollar share point, even the loss of just one dollar share point is significant in terms of revenue. And it is particularly significant in terms of relative market share given that C&D and SPD generally have only 20-30 share points each and bitterly compete with each other for *every* share point they have. Moreover, it is likely that C&D's countervailing actions, such as offering rebates and other promotions, mitigated the decline in its market share. Feldman DT ¶ 79; Tr. 583:8-584:4.

[22] For example, Dr. Cox argued that "Ms. Feldman testified that the Weeks Estimator had a price advantage over C&D's First Response products," Cox DT ¶ 26 (citing Feldman Dep. Tr. 268), and, therefore, "it is important to determine what portion of C&D's alleged decline was attributable to relative price and promotional pricing by SPD (digital and analog products) and other competitors," Cox DT ¶ 27. But, as Dr. Erdem testified, "Clearblue home pregnancy test kits have been priced lower than First Response pregnancy tests for the past several years when comparing digital to digital and analog to analog, and the Weeks Estimator is in fact more expensive than Clearblue's other home pregnancy test kits." Erdem RT ¶ 56. Moreover, after the launch of the Weeks Estimator, "First Response's relative price arguably continued to grow, but at a much slower rate than it had between March 2013 and July 2013." Erdem RT ¶ 57.

Dr. Cox also posited that because it was an exciting new product that was extensively advertised, the Weeks Estimator arguably grew the home pregnancy test market as a whole, suggesting that C&D should not complain about any decline in market share as its sales were larger than they would have been without the Weeks Estimator. Cox DT ¶ 28. This argument is unconvincing: Even if the whole pie grew because of the new product, but C&D's share of that pie grew at a smaller rate than it would have in the absence of SPD's false advertising, C&D would still have lost sales on account of the false advertising.

In short, the Court concludes that C&D established a logical causal connection between SPD's false advertising and its market harm that is sufficient to establish SPD's liability for false advertising under the Lanham Act, and it finds SPD's arguments to the contrary unavailing.

7. False Advertising Conclusion

In sum, C&D has successfully shown that SPD's advertising message is false, either literally or impliedly, is material, and causes or is likely to cause injury to C&D. The trial also reinforced the Court's prior observation that the Lanham Act and the FDCA complement each other, allowing the expertise, perspective, and resources of market competitors to augment those of the FDA. *Church & Dwight III*, 2015 U.S. Dist. LEXIS 67187, at *16-29. As the discussion of SPD's intentional deception reveals, SPD considered the FDA's limited resources when weighing the risk of airing a deceptive television commercial—a fact the Supreme Court cited as a basis for rejecting FDCA preclusion and preemption arguments in *POM Wonderful*, 134 S. Ct. at 2239, and *Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009). Moreover, the trial confirmed that "competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely upon certain sales and marketing strategies. Their awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators." *POM Wonderful*, 134 S. Ct. at 2238. The FDA had to make its decisions regarding the Weeks Estimator's labeling largely in advance of the product's launch, without the benefit of consumer surveys or other evidence of possible consumer confusion. C&D's Lanham Act suit brought this additional evidence to light and revealed the ways in which the product's

packaging causes consumer confusion. As previously noted, "[a]llowing Lanham Act suits takes advantage of synergies among multiple methods of regulation. This is quite consistent with the congressional design to enact two different statutes, each with its own mechanisms to enhance the protection of competitors and consumers." *Id.* at 2239.

B. Injunctive Relief

C&D asks the Court to permanently enjoin SPD from advertising the Weeks Estimator as providing an estimate of weeks that is consistent with a doctor's estimate of weeks pregnant. "Indeed, '[i]n most cases, after a full trial finding false advertising, a final injunction is appropriate.'" *Fresh Del Monte Produce Inc. v. Del Monte Foods Co.*, 933 F. Supp. 2d 655, 660 (S.D.N.Y. 2013) (quoting 5 J.T. McCarthy, *McCarthy on Trademarks and Unfair Competition* § 27:37 (4th ed. 2012)). Relatedly, C&D asks the Court to require SPD to undertake corrective advertising. To obtain a permanent injunction, a plaintiff must satisfy a four-factor test, which requires demonstrating

> (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006). Because the "first and second factors in the *eBay* test often blend together," *Fresh Del Monte*, 933 F. Supp. 2d at 664, the Court addresses them together, but otherwise addresses each factor separately.

1. Irreparable Injury and Inadequacy of Damages at Law

"To demonstrate irreparable harm in a Lanham Act case, a party 'must show two things: (1) that the parties are competitors in the relevant market, and (ii) that there is a logical causal connection between the alleged false advertising and its own sales position." *CJ Prods. LLC v. Snuggly Plushez LLC*, 809 F. Supp. 2d 127, 149 (E.D.N.Y. 2011) (quoting *Zeneca Inc. v. Eli Lilly & Co.*, No. 99 Civ. 1452 (JGK), 1999 U.S. Dist. LEXIS 10852, at *104-105 (S.D.N.Y. July 19, 1999)); *see also Coca-Cola Co.*, 690 F.2d at 316. "Harm might be irremediable, or irreparable, for many reasons, including that a loss is difficult to replace or difficult to measure,

or that it is a loss that one should not be expected to suffer." *Salinger v. Colting*, 607 F.3d 68, 81 (2d Cir. 2010).

There is no dispute that the parties are direct competitors in the market for home pregnancy tests. PPF ¶ 1. And, as noted in Part III.A.6., C&D has established a logical causal connection between SPD's false advertising and its own sales position. Moreover, SPD's argument that C&D must control for numerous independent variables to account for every possible factor that may have affected its market share demonstrates the difficulty of fully quantifying the loss of market share that C&D suffered as a result of its direct competitor's false advertising.

Both parties also position themselves as "innovators" in the market for home pregnancy tests. Feldman DT ¶ 82. SPD falsely advertises the Weeks Estimator as offering an innovative feature that is highly attractive to consumers, which has likely increased consumers' perceptions of Clearblue as being more innovative than First Response. Erdem DT ¶ 98. Indeed, Clearblue's internal marketing documents reveal that it believed the Television Commercial, which the Court concludes conveys a false message, produced a "halo effect" for the Clearblue brand. PTX 111 at 1 ("I just received topline data which show great results for the TV copy! . . . 'Week estimator/can tell you how far along you are' is well recalled (67%) and identified as the main idea of the copy (58%). It generates high differentiation (88%) with a halo effect on the brand."); *see also* PTX 256 (discussing Television Commercial's halo effect); Tr. 758:10-759:13. SPD staff explained that a "halo effect" is the benefit conferred on the parent brand from positive advertising related to a product marketed under that brand. Tr. 758:18-759:8; *see also* Erdem RT ¶ 61 n.24. Thus, while innovation is a key distinguisher between the First Response and Clearblue brands, it is difficult if not impossible to quantify the harm to C&D caused by SPD's falsely advertising its product as possessing an innovative feature that it did not in fact possess.

Moreover, falsely advertising a product within a given category may cause harm to that category as a whole. Consumers who purchase the Weeks Estimator and then learn that it does not actually estimate weeks pregnant the way a doctor does may lose confidence in home

pregnancy tests as a whole and may question innovative features offered by other brands. *See, e.g., N. Am. Olive Oil Ass'n v. Kangadis Food Inc.*, 962 F. Supp. 2d 514, 518-19 (S.D.N.Y. 2013) ("In addition, Kangadis's labeling allegedly induces consumers to purchase a product that is not what it seems, and thus may cause consumers to lose faith in olive oil products in general. These types of harms are quintessentially irreparable, as '[i]t is virtually impossible to prove that so much of one's sales will be lost or that one's goodwill will be damaged as a direct result of a competitor's advertisement.'" (quoting *Coca-Cola*, 690 F.2d at 316)); *see also Tripledge Prods., Inc. v. Whitney Res., Ltd.*, 735 F. Supp. 1154, 1166 (E.D.N.Y. 1990). Therefore, the Court concludes that it will be difficult to replace or measure the harm to C&D's loss of market share, goodwill, and brand equity caused by SPD's false advertising.

2. Balance of Hardships

As extensively discussed above, the Court concludes that C&D has been and likely continues to be injured by SPD's false advertising, while SPD can claim no protected interest in its false advertising because parties cannot "assert an equitable interest in the perpetuation of an advertising campaign that is literally false." *Reckitt v. Benckiser Inc. v. Motomco Ltd.*, 760 F. Supp. 2d 446, 456-57 (S.D.N.Y. 2011) (citing *Zeneca*, 1999 U.S. Dist. LEXIS 10852, at *118). Moreover, when asked at trial if it would "be damaging to consumer confidence in the weeks estimator or the Clearblue brand for SPD to disseminate advertising stating clearly that the estimate that this product – that the estimate that the weeks estimator provides is different from a doctor's estimate of weeks of pregnancy," Mr. Daly avoided providing an answer. Tr. 1123:16-1125:4. SPD may, of course, continue to advertise its product, but it must do so in a way that is truthful and not misleading. *Zeneca*, 1999 U.S. Dist. LEXIS 10852, at *119.

3. Public Interest

"Finally, the Court must 'ensure that the public interest would not be disserved by the issuance of a preliminary injunction.'" *Juicy Couture, Inc. v. Bella Int'l, Ltd.*, 930 F. Supp. 2d 489, 505 (S.D.N.Y. 2013) (quoting *Salinger*, 607 F.3d at 80). On this point, "[t]he Second Circuit has long held that there is a 'strong interest in preventing public confusion.'" *Id.* (quoting

ProFitness Phys. Therapy Ctr. v. Pro-Fit Ortho. and Sports Phys. Therapy P.C., 314 F.3d 62, 68 (2d Cir. 2002)). The Court concludes that providing greater clarity in advertising an over-the-counter medical device would not disserve the public interest.

4. Unclean Hands

SPD previously asserted an unclean hands defense to C&D's request for injunctive relief. Dkt. No. 308 at 15-16. But SPD did not assert this defense in its post-trial brief and instead converted much of its unclean hands defense into an argument for attorney's fees, which is meritless in light of the Court's liability finding. Dkt. No. 371 at 34-35. Thus, it appears that SPD has abandoned its unclean hands defense, but, even if not abandoned, it is meritless.

5. Scope of Injunctive Relief

Based on the above analysis, the Court concludes that C&D is entitled to injunctive relief. Broadly speaking, SPD is permanently enjoined from communicating—either literally or impliedly—that the Weeks Estimator provides an estimate of weeks pregnant that is the same as a doctor's estimate of weeks pregnant. In light of the complexity surrounding such injunctive relief, however, the Court hereby orders the parties to meet and confer to see if they can reach agreement on the specific language of a permanent injunction order. *Accord Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp.*, 348 F. Supp. 2d 165, 185 (S.D.N.Y. 2004) (directing parties to submit proposals for corrective advertising following finding of false advertising liability). To assist those discussions, the Court provides the following guidance.

First, as previously noted, injunctive relief in false advertising cases generally extends to the messages conveyed in the false advertising and is not limited to the specific pieces of advertising containing those messages. *Church & Dwight II*, 2014 U.S. Dist. LEXIS 158551, at *9-10 (citing *Am. Home Products Corp. v. Johnson & Johnson*, 577 F.2d 160, 164 (2d Cir. 1978); *Santana Prods, v. Bobrick Washroom Equip., Inc*., 249 F. Supp. 2d 463, 522-23 (E.D. Pa. 2003), *rev'd on other grounds*, 401 F.3d 123 (3d Cir. 2005)); *see also S.C. Johnson*, 241 F.3d at 241 ("Rule 65(d) does not require the district court to 'predict exactly what [Clorox] will think of next' or to describe all possible, permissible future commercials that Clorox may produce

involving Ziploc Slide-Loc storage bags." (quoting *Sterling Drug, Inc. v. Bayer AG*, 14 F.3d 733, 748 (2d Cir. 1994))). Therefore, the Court's determination that C&D is entitled to injunctive relief is not limited to the specific pieces of advertising presented to the Court, but extends as well to other forms of advertising that currently exist or that SPD may develop in the future.

Second, because the Court concludes that both the Launch and Revised packaging contain false advertising, SPD will be prohibited from marketing or distributing either the Launch or Revised packages in their current form and will be required to recall all Launch and Revised packages currently on store shelves. *Telebrands Corp. v. Wilton Indus.*, 983 F. Supp. 471, 477 (S.D.N.Y. 1997) (ordering recall of products containing false advertising); *Playskool, Inc. v. Product Dev. Grp., Inc.*, 699 F. Supp. 1056, 1063 (E.D.N.Y. 1988) (same). The Court has considered the burden and expense of such a recall, but finds it appropriate in light of the nature of the product, *Playskool*, 699 F. Supp. at 1063, as well as the degree of SPD's intentional deception.

Third, corrective advertising is often awarded in false advertising cases "to counteract the false impression that may have been placed by the ad in consumer's minds." *Linotype Co. v. Varityper, Inc.*, No. 89 Civ. 4747 (MJL), 1989 U.S. Dist. LEXIS 9105, at *8 (S.D.N.Y. Aug. 4, 1989); *see also Merck Eprova v. Gnosis S.P.A.*, No. 07 Civ. 5898 (RJS), 2013 U.S. Dist. LEXIS 49798, at *6 (S.D.N.Y. Mar 7, 2013) ("[C]ourts have long ordered defendants to engage in corrective advertising campaigns following their infliction of Lanham Act injuries."). In light of the legal and factual findings above, the Court will consider ordering SPD to engage in a corrective advertising campaign to explain the difference between the product's estimate of weeks since ovulation and a doctor's estimate of pregnancy duration based on weeks since LMP. *Merck Eprova I*, 901 F. Supp. 2d at 463; *Merck Eprova II*, 760 F.3d at 264.

With these points in mind, the parties shall submit a proposed permanent injunction order no later than three weeks from the date of this Opinion and Order. If the parties are unable to reach an agreement, C&D shall submit a proposed permanent injunction order and the parties shall submit letters no longer than three pages in length setting forth their respective positions

regarding the wording of the permanent injunction order. The Court will not entertain a rehashing of arguments previously made.

C. Breach of Contract

Finally, C&D also brought a claim for breach of contract against SPD based on a settlement agreement between the parties. "Under New York law, a breach of contract claim requires proof of (1) an agreement, (2) adequate performance by the plaintiff, (3) breach by the defendant, and (4) damages." *Fischer & Mandell LLP v. Citibank, N.A.*, 632 F.3d 793, 799 (2d Cir. 2011) (citing *First Inv. Corp. v. Liberty Mut. Ins. Co.*, 152 F.3d 162, 168 (2d Cir. 1998); *Harsco Corp. v. Segui*, 91 F.3d 337, 348 (2d Cir. 1996)). "[P]arties to an express contract are bound by an implied duty of good faith, but breach of that duty is merely a breach of the underlying contract." *Cruz v. Fxdirectdealer, LLC*, 720 F.3d 115, 125 (2d Cir. 2013) (quoting *Harris v. Provident Life & Accident Ins. Co.*, 310 F.3d 73, 80 (2d Cir. 2002) (internal quotation marks omitted). And, moreover, "New York law . . . does not recognize a separate cause of action for breach of the implied covenant of good faith and fair dealing when a breach of contract claim, based upon the same facts, is also [pleaded]." *Id.* (quoting *Harris*, 310 F.3d at 81) (internal quotation marks omitted).

First, C&D argues that SPD breached Section 2.7(ii) of the Settlement Agreement, which requires SPD to negotiate in good faith with C&D for 30 days after C&D provides written notice of a challenge to certain SPD advertising. PTX 33 at 7. Section 2.7(ii) also provides that "[d]uring the 30-day negotiation period, the advertising Party shall indicate whether it asserts that the challenged Advertising Claim is subject to one or more of the covenants-not-to-challenge provided for" in the Settlement Agreement. PTX 33 at 7. C&D provided SPD with written notice of its proposed challenge on August 23, 2013, PTX 34, and SPD responded on September 19, 2013, PTX 35. SPD's letter asserted that Section 2.5 of the Settlement Agreement barred C&D's challenge, but C&D complains that SPD did not specify which of the two Section 2.5 covenants it invoked. C&D further argues that SPD did not engage in a meaningful effort to negotiate the dispute during the 30-day window. But SPD's response letter

was provided within the 30-day window, stated the section of the settlement agreement relied on, and provided responses to a number of specific criticisms listed in C&D's letter. And aside from this letter, C&D offers no other evidence of SPD's failure to comply in good faith with Section 2.7. Thus, there is insufficient evidence to find it more likely than not that SPD breached Section 2.7(ii) of the agreement.

Second, C&D argues that SPD invoked Section 2.5, and thus forced C&D to engage in arbitration before bringing suit, without a good-faith basis for doing so.[23] Section 2.5 provides that C&D

> hereby grants SPD . . . a covenant-not-to-challenge, worldwide: (1) any Advertising Claim for [the Weeks Estimator] on the ground that it is ineffective at . . . (B) estimating the range of number of weeks (*e.g.*, 1-2 weeks, 2-3 weeks or 3+ weeks) since ovulation for which it was cleared by the FDA or the range of number of weeks since commencement of pregnancy for which it was cleared by the FDA if the FDA actually clears the product for the intended use of estimating the number of weeks from the commencement of pregnancy . . . <u>provided that</u> FDA did not prohibit SPD from making that claim and the claim clearly indicates whether it relates to the accuracy of the pregnancy test function or the accuracy of the weeks estimator function.

PTX 33 at 6. But in its post-trial briefing, SPD argues that it "viewed C&D as challenging the Product's effectiveness at 'estimating the range of number of weeks . . . since ovulation,'" and that "SPD justifiably and in good faith relied upon [this] *different* covenant in an attempt to bar C&D's claims." Dkt. No. 371 at 32 n.18. The only evidence C&D provides to contradict SPD's explanation is the Settlement Agreement, SPD's communications with the FDA, and correspondence between SPD and C&D leading up to the initial arbitration. But C&D's initial letter to SPD did not specify why its challenge to the Weeks Estimator's advertising was permitted under Section 2.5, and, moreover, C&D's letter references certain advertising messages discussing ovulation, PTX 34. Similarly, SPD's response letter does not specify which of the two Section 2.5 covenants it relied upon. PTX 35. In fact, based on the correspondence

[23] Much of the background and ultimate resolution of the arbitration is summarized in the Court's Memorandum & Order dated October 28, 2014, which denied SPD's motion *in limine* to limit the scope of the case to the pieces of advertising attached to C&D's Complaint. *Church & Dwight II*, 2014 U.S. Dist. LEXIS 158551.

that C&D provides, it appears that the earliest point at which C&D specified which Section 2.5 covenant provided the basis for its challenge was in October 17, 2013, which was after C&D had commenced arbitration against SPD. PTX 40; PTX 38. Based on this correspondence, it could be that these two parties were ships passing in the night, failing to understand which of the Section 2.5 covenants was at issue. In addition, C&D had the availability to call witnesses to augment or clarify this limited documentary record, but it failed to do so. Therefore, the Court concludes that there is not enough evidence to find it more likely than not that SPD lacked a good-faith basis for invoking Section 2.5 and forcing C&D to commence arbitration.

Third, C&D argues that SPD breached the implied covenant of good faith and fair dealing by invoking the covenant requiring arbitration for certain claims. But this good faith and fair dealing argument substantially overlaps with the second breach of contract argument noted above. Because C&D pleads a breach of contract claim on the same facts, it cannot bring a separate claim for breach of the implied duty of good faith and fair dealing.

Therefore, because there is an absence of evidence from which the Court could find that SPD breached the parties' Settlement Agreement, C&D's breach of contract claim fails.

IV. CONCLUSION

For the reasons provided above, the Court concludes that (1) SPD engaged in false advertising in violation of the Lanham Act; (2) SPD engaged in intentional deception of an egregious nature; (3) C&D is entitled to a permanent injunction; (4) SPD engaged in false advertising in violation of New York State law; and (5) C&D failed to prove that SPD breached the parties' prior settlement agreement.

In accordance with this Opinion and Order, the parties shall submit a proposed permanent injunction order no later than three weeks from the date of this Opinion and Order. If the parties are unable to reach an agreement, C&D shall submit a proposed permanent injunction order and the parties shall submit letters no longer than three pages in length setting forth their respective positions regarding the wording of the permanent injunction order.

In addition, no later than three weeks from the date of this Opinion and Order, the parties shall also submit a proposal for how to proceed with the damages phase of this case.

This resolves Dkt. Nos. 254, 265, 267, 269, 271, 273.

SO ORDERED.

Dated: July 1, 2015
New York, New York

ALISON J. NATHAN
United States District Judge