Advil's side effects and safety. <u>Advil I</u>, 654 F. Supp. at 571. <u>Advil II</u> concerned a narrower set of Advil advertisements alone that featured an actor who stated, in words or substance, "Like Tylenol, Advil doesn't upset my stomach." <u>Am. Home Products Corp.</u>, 654 F. Supp. at 820.

Both suits were ultimately resolved by entries of consent judgments that enjoined each party from making certain claims about Tylenol and Advil in future advertising. The <u>Advil II</u> Order enjoined American Home Products ("AHP," Pfizer's predecessor) and "all those in privity with it" (namely, Pfizer) from "stating in words or substance in any advertisement that ADVIL is 'like TYLENOL' in the respect of adverse effects on the stomach . . . ." <u>Advil II</u> Order ¶ 1.

After signing the <u>Advil II</u> Order, AHP conducted a study titled the Children's Analgesic Medicine Project ("CAMP Study"). Amended Complaint ¶ 41. The CAMP study compared the safety of Advil's active ingredient, ibuprofen, and Tylenol's active ingredient, acetaminophen, in over 41,000 children suffering from fever and pain, over 14,000 of whom were infants under the age of two. <u>Id.</u>

This suit was filed because the parties now dispute the meaning of the word "ADVIL" in the Advil II Order. Pfizer claims that the Advil II Order unambiguously applies only to the 200 milligram adult Advil tablet on the market at time the Order was drafted. Accordingly, it believes the Order allows it to run comparative stomach safety advertisements for pediatric Advil products. McNeil believes that the Order includes all Advil products that contain the drug ibuprofen, including pediatric Advil.

After the Court denied McNeil's motion to dismiss, both parties filed cross motions for judgment on the pleadings. Each seeks an affirmance that their interpretation of the <u>Advil II</u> Order is correct as a matter of law.

#### III. DISCUSSION

## A. Legal Standard

A motion for judgment on the pleadings under Rule 12(c) of the Federal Rules of Civil Procedure is subject to the same standard of review as a motion to dismiss under Rule 12(b)(6). Bank of N.Y. v. First Millennium, Inc., 607 F.3d 905, 922 (2d Cir. 2010). Thus, the Court accepts the nonmovant's allegations as true and draws all reasonable inferences in the nonmovant's favor. Harris v. Mills, 572 F.3d 66, 71 (2d Cir.2009). In essence, a grant of a motion pursuant to Rule 12(c) is proper if "from the pleadings, the moving party is entitled judgment as a matter of law." Burns Int'l Sec. Servs., Inc. v. Int'l Union, 47 F.3d 14, 16 (2d Cir. 1995) (per curiam).

## B. Discussion

"Consent decrees 'reflect a contract between the parties (as well as a judicial pronouncement), and ordinary rules of contract interpretation are generally applicable."

<u>U.S. ex rel. Anti-Discrimination Ctr. of Metro New York, Inc. v. Westchester Cnty., N.Y., 712</u>

F.3d 761, 767 (2d Cir. 2013) (citing <u>Doe v. Pataki</u>, 481 F.3d 69, 75 (2d Cir.2007)). "Thus, documents that are expressly incorporated in the consent judgment should be considered." <u>S.E.C. v. Levine</u>, 881 F.2d 1165, 1179 (2d Cir. 1989). "[W]here . . . a term of a consent decree is ambiguous, a court may consider extrinsic evidence to ascertain the parties' intent, including the circumstances surrounding the formation of the decree." <u>United States v. Broad. Music, Inc.</u>, 275 F.3d 168, 175 (2d Cir. 2001). Finally, "because consent decrees are normally compromises in

<sup>&</sup>lt;sup>1</sup> The Court notes longstanding tension in case law as to whether consideration of evidence beyond the four corners of the consent decree is proper only after a finding that the decree's terms are ambiguous therein. In <u>United States v. ITT Cont'l Baking Co.</u>, 420 U.S. 223, 238 (1975), the Supreme Court stated that "reliance upon certain aids to construction . . . includ[ing] the circumstances surrounding the formation of the consent order, any technical meaning words used may have had to the parties, and any other documents expressly incorporated in the decree . . . does not in any way depart from the 'four corners' rule'" applied in previous cases interpreting

which the parties give up something they might have won in litigation and waive their rights to litigation, it is inappropriate to search for the 'purpose' of a consent decree and construe it on that basis." <u>United States v. ITT Cont'l Baking Co.</u>, 420 U.S. 223, 238 (1975).

consent decrees. When examining the consent decree at issue in <u>ITT</u>, the Court began with documents that were expressly incorporated therein rather than the language in the decree alone. <u>Id.</u> at 243. The Court then stated that the plain language of the decree was sufficient to decide the issue "[e]ven without the aid of these explanatory documents properly usable to construe this particular order." <u>Id.</u> Notwithstanding its finding on the plain meaning of the text, the Court still proceeded to examine "the circumstances surrounding the order and the context in which the parties were operating." <u>Id.</u>

Following ITT, the Second Circuit has repeatedly stated that extrinsic evidence should only be considered when the text of the consent decree is ambiguous. See e.g. United States v. Broad. Music, Inc., 275 F.3d 168, 175 (2d Cir. 2001) (stating that where "a term of a consent decree is ambiguous, a court may consider extrinsic evidence to ascertain the parties' intent, including the circumstances surrounding the formation of the decree"); King v. Allied Vision, Ltd., 65 F.3d 1051, 1059 (2d Cir.1995) (same).

With respect to documents expressly incorporated, some cases suggest that they are only properly considered if the terms of the decree are ambiguous. <u>Broad. Music, Inc.</u>, 275 F.3d at 175. Others instruct that expressly incorporated documents should be analyzed before concluding that a document's terms are ambiguous. <u>E.E.O.C. v. Local 40</u>, Int'l Ass'n of Bridge, Structural & Ornamental Iron Workers, Joint Apprenticeship Comm., Iron Workers Locals 40 & 361 & Allied <u>Bldg. Metal Indus.</u>, 76 F.3d 76, 80 (2d Cir. 1996); <u>S.E.C. v. Levine</u>, 881 F.2d 1165, 1179 (2d Cir. 1989).

As explained below, the Court concludes that while the text of the consent decree alone is ambiguous, the documents incorporated therein clarify that ambiguity. In the absence of clearer guidance, the Court also analyzes the circumstances surrounding the decree's formation. Because they do not contradict the Court's conclusion as to the consent decree's meaning, the Court need not decide whether such evidence is indeed "extrinsic" and therefore only properly reviewable upon a finding of ambiguity.

# a. The Advil II Order includes pediatric Advil products.

# 1. The <u>Advil II</u> Order incorporates the opinions from the <u>Advil II</u> and <u>Advil II</u> cases.

Before analyzing the language of the <u>Advil II</u> Order, the Court decides which documents are expressly incorporated in it. The first paragraph of the Order states that it is written "in accordance with the Court's Opinion and Order dated December 1, 1987 [<u>Advil II</u>]." Both parties agree that the <u>Advil II</u> opinion is incorporated into the Advil II Order. The Court does as well.

The language of the <u>Advil II</u> Order does not expressly incorporate the <u>Advil I</u> opinion of April 1987. But <u>Advil II</u> relied on the factual findings from <u>Advil I</u> in order to conclude that AHP had engaged in false advertising when it made the claim that Advil was "like Tylenol" with respect to adverse effects on the stomach.

If it were not for their "like Tylenol" claim, the Advil commercials would probably fall within the acceptable range of commercial puffery. But, as the Court has already found after a full trial [in Advil I], Advil is *not* "like Tylenol" in the respect of their effects on the stomach.

Advil II, 675 F. Supp. at 825 (emphasis in original).

Further, both parties urge the Court to view the <u>Advil I</u> opinion as incorporated into the <u>Advil II</u> Order. McNeil attaches it to its brief in support of the motion for judgment on the pleadings and Pfizer quotes it in its arguments urging the Court to interpret the <u>Advil II</u> Order in its favor. Accordingly, with the parties' urgings, the Court concludes that the <u>Advil II</u> opinion is incorporated into the <u>Advil II</u> Order. <u>See ITT</u>, 420 U.S. at 238 ("Since the parties themselves so provided, both the appendix and the complaint are proper aids to the construction of the order and of the agreement of which it is part.").

# 2. The <u>Advil II</u> Order, incorporating the <u>Advil II</u> and <u>Advil II</u> opinions, unambiguously includes all Advil products whose active ingredient is ibuprofen.

The Advil II Order permanently enjoins Pfizer "from stating in words or substance in any advertisement that ADVIL is 'like TYLENOL' in the respect of adverse effects on the stomach, provided, however, that nothing herein shall be construed as preventing defendant from advertising that ADVIL does not cause stomach upset, without a comparison to TYLENOL."

On its face alone, the <u>Advil II</u> Order is ambiguous. Advil could plausibly mean all Advil products, including those in existence at the time of the Order and those that would later come into existence. This sweeping interpretation is supported by the language surrounding the word "ADVIL," barring "words or substance" rather than one particular phrase, "in any advertisement" rather than one particular media format, and "in the respect of adverse effects on the stomach," rather than one particular side effect or disorder. Further, the order contains no limitation on the word Advil or reservation of rights in relation to specific dosages or variations of Advil products. Nonetheless, it is plausible to read the <u>Advil II</u> Order as limiting the definition of Advil to its meaning at the time of drafting: adult Advil. By this interpretation, the <u>Advil II</u> Order could not possibly refer to Infants' and Children's Advil, simply because they did not yet exist.

It is therefore appropriate to examine the incorporated documents from Advil I and Advil II. The expressly incorporated Advil II opinion addresses a complaint that Pfizer's predecessor AHC falsely claimed comparative gastrointestinal safety with Tylenol by stating in advertisements "in haec verba or in substance, 'Like Tylenol, Advil doesn't upset my stomach." Advil II, 675 F. Supp. at 820. The advertisements in question referred to both Advil and Tylenol by their brand names and the court's discussion of them mirrors this language. Id. The opinion thus uses the word "Advil" 57 times, but the word "ibuprofen" only twice: once to describe Advil's

active ingredient, <u>id.</u>, and again when relating McNeil's interpretation of the <u>Advil I</u> opinion ("McNeil further alleges that, as this Court found in the prior action, the mechanisms of action of acetaminophen and ibuprofen are entirely different"). <u>Id.</u> at 820-21.

The Advil I opinion is far more complex. It resolves claims of "falsity in widely published printed materials and television commercials linking ibuprofen with aspirin and unfavorably comparing both to acetaminophen in the respect of causing adverse side effects" and counterclaims of "falsity in . . . comparative advertising of Advil and two of its other OTC analgesic products . . . ." Advil I at 572. Unlike the advertisements in question in the Advil II opinion, which compared brand names alone (Tylenol and Advil), the Advil I opinion analyzed advertisements that compared brand names to active ingredients (Tylenol and ibuprofen). See id. at 574 (describing an advertisement featuring "Extra-Strength Tylenol" on one side of a heavy, dark line and "ibuprofen" on the other side); id. at 583 (describing a representative print advertisement that states "Extra-Strength Tylenol gives you unsurpassed pain relief without the stomach irritation you can get with aspirin or the ibuprofen pain relievers"). In at least one instance, Advil I interchangeably referred to a product by both its brand name and its active ingredient. Compare Advil I at 574 (discussing an advertisement that compared aspirin, ibuprofen, and Tylenol) with id. at 591 (referring to that same advertisement as comparing aspirin, ibuprofen, and acetaminophen). But for the most part, as with Advil II, the Advil I opinion used language that mirrored the underlying advertisements it considered. Thus, Advil I uses the word "Advil" only 25 times, but the word "ibuprofen" 160 times, because the advertisements it considered used the word ibuprofen.

Although both opinions resolve claims of false advertising related to Advil and Tylenol, they address entirely different questions. <u>Advil II</u> answers the narrow question of whether

certain advertisements "tend to give many listeners the erroneous impression that Advil is superior to Tylenol" with respect to adverse stomach effects. Advil II, 675 F. Supp. at 823. The issue of the case, then, was not the equivalence of Advil to Tylenol with respect to adverse stomach effects. As Advil II makes clear, "the Court has already found after a full trial, Advil is *not* 'like Tylenol' in the respect of their effects on the stomach." Id. at 825 (emphasis in original). Rather, the issue of Advil II was whether one particular set of advertisements comparing namebrand Tylenol to namebrand Advil was misleading.

In contrast, the Advil I opinion addressed head-on the substantive truth of whether Advil—or, at the very least, its active ingredient ibuprofen—causes more adverse stomach effects than Tylenol's active ingredient, acetaminophen. On that score, Advil I is unequivocal: "The evidence indisputably establishes that ibuprofen does indeed cause every one of the [adverse] indicated gastrointestinal side effects in at least a minor percentage of users. It is equally clear that in every one of these respects it is . . . significantly inferior to acetaminophen." Advil I, 654 F. Supp. at 576. Elsewhere in Advil I, the Court repeats its finding: "[T]he evidence establishes that in terms of objective gastrointestinal side effects, such as ulceration, hemorrhage and occult bleeding, acetaminophen poses a significantly lower risk than ibuprofen . . . . " Id. at 584 (emphasis in original). To reach that conclusion, Advil I analyzed the mechanisms of action of over-thecounter analgesics, explaining the specific pharmacological processes by which ibuprofen and acetaminophen dull pain in the body. It found that ibuprofen, as a non-steroidal anti-inflammatory drug (NSAID), dulls pain by "inhibit[ing] the body's normal production of prostaglandins . . . . However, since prostaglandins perform a number of beneficial functions, such as protection of the mucous lining of the gastrointestinal tract, ... NSAIDs tend to cause gastrointestinal irritation and ulceration . . . ." <u>Id.</u> at 572-73. Accordingly, the scope of <u>Advil I</u>'s factual findings is not confined to the specific Advil products at issue in the case, but to ibuprofen the drug itself.

At first glance, this differentiation between Advil and ibuprofen seems to favor Pfizer's reading of the <u>Advil II</u> Order. To wit, <u>Advil II</u> focuses on Advil specifically while <u>Advil II</u> focuses on ibuprofen generally. Because the court knew how to differentiate between Advil and ibuprofen, its use of the term Advil in the <u>Advil II</u> Order should not be read broadly to include all Advil products with ibuprofen. This interpretation is flawed, however, for the reasons that follow.

First, as stated above, the court's use of Advil in certain instances and ibuprofen in others was, for the most part, controlled by the underlying advertisements that the parties asked it to evaluate. Where the underlying advertisement compared "Advil" to "Tylenol," the court used brand names alone in its discussion. But where the underlying advertisement compared "Tylenol" to "ibuprofen," the court used both brand names and active ingredient names. The varied use of the two terms thus does not necessarily indicate an intentional differentiation between the specific product on the market at the time of the writing (adult Advil) and its active ingredient (ibuprofen). Further, in at least one instance Advil I did, in fact, use a name brand and active ingredient name interchangeably, albeit when referring to Tylenol. While these observations do not conclusively settle the matter, they offer support for a reading of the Advil II Order as interchangeably using "ibuprofen" and "Advil."

Second, and more damning to Pfizer's interpretation, the <u>Advil II</u> opinion twice rephrases the comparative stomach safety finding of <u>Advil I</u> in terms of "Tylenol" and "Advil," notwithstanding <u>Advil I</u>'s use of "acetaminophen" and "ibuprofen" instead. <u>Compare Advil II</u>, 675 F. Supp. at 825 ("[A]s the Court has already found after a full trial, Advil is *not* 'like Tylenol' in the respect of their effects on the stomach."); <u>id.</u> 825-26 (referring to "the erroneous belief that the

with Advil I, 654 F. Supp. at 576 ("The evidence indisputably establishes that ibuprofen does indeed cause every one of the indicated gastrointestinal side effects in at least a minor percentage of users. It is equally clear that in every one of these respects it is . . . significantly inferior to acetaminophen."). Thus Advil II equates the stomach effects of Advil specifically with those of ibuprofen generally. This observation makes obvious that the Advil II court did indeed use the terms "Advil" and "ibuprofen" interchangeably. And that finding weighs decisively in favor of McNeil's interpretation of the Advil II Order, in which the term "Advil" encompasses not just the specific Advil products contemporaneously on the market, but any Advil product whose active ingredient is ibuprofen.

Pfizer advances a number of unavailing arguments as to why the language of the Advil II Order, including the incorporated Advil I and Advil II opinions, unambiguously supports its interpretation. Principally, it relies on the fact that pediatric Advil products did not exist at the time the Order was drafted as proof that the Order could only have defined "Advil" as adult Advil alone. Pfizer contends that McNeil's reading of the Order would expand it to include all future Advil products containing ibuprofen and the sophisticated parties here would have explicitly included language covering future products had they so desired.

Pfizer cites to one Second Circuit case, <u>VKK Corp. v. Nat'l Football League</u>, 244 F.3d 114, 130 (2d Cir. 2001), for the uncontroversial proposition that courts should not interpret contracts or consent judgments to expand their scope beyond the plain meaning of their written terms. The question before the <u>VKK</u> court was whether the terms "successor" or "affiliate" in a contractual release applied to parties who were not the original assignees to the agreement. To find that they were not, the Second Circuit looked to the definitions of those terms in Black's Law

Dictionary. Here, neither the <u>Advil</u> Orders and opinions nor any supplementary reference aids define the term "Advil," so <u>VKK</u> is inapposite. But as the discussion above explains, notwithstanding the lack of an explicit definition of Advil in the Order, the term is nonetheless unambiguous when read in conjunction with the incorporated opinions. Thus, McNeil's interpretation does not expand the plain meaning of the word Advil to include all Advil products that contain ibuprofen: it is the plain meaning. It was therefore unnecessary for the parties to specify which future, hypothetical Advil products would fall within the scope of the Order.

Moreover, Pfizer's limiting reading of the Order to include only 200 milligram adult Advil would make it virtually meaningless, because it would allow Pfizer to escape its application merely by manufacturing and selling slightly modified versions of the 200 milligram tablet. In Wilder v. Bernstein, 49 F.3d 69, 73 (2d Cir. 1995), the Second Circuit examined a similar issue: whether a settlement decree that applied to "all New York City children whose placement in foster care is the responsibility of the New York City Commissioner of Social Services" included those children placed with non-parental relatives, also called kinship foster care. At the time the decree was signed, kinship foster care was in very limited use. Notwithstanding, the court found that "even if kinship foster care appeared only after the Decree was finalized . . . it is implausible that the City could limit the Decree's reach and dilute its impact merely by establishing new kinds of foster care." Id. Here, too, Pfizer's interpretation of the Advil II Order is implausible because it would so dilute its impact.

Pfizer also urges the Court to turn to the <u>Advil I</u> consent decree to interpret the meaning of Advil in the <u>Advil II</u> Order. The Court declines to do so, because unlike the <u>Advil I</u> decision, the <u>Advil I</u> consent decree is not incorporated into the <u>Advil II</u> Order and "evidence of contemporaneous agreements is not admissible in evidence to contradict a term of the writing."

S.E.C. v. Levine, 881 F.2d 1165, 1179 (2d Cir. 1989). The Advil I consent decree is thus extrinsic evidence that "may generally be considered only if the terms of the judgment, or of documents incorporated in it, are ambiguous." <u>Id.</u> As the Court has concluded, the language of the <u>Advil II</u> Order, when supported by documents incorporated in it, is not ambiguous.

But even if it were, and even if the Court were to examine the Advil I consent decree as extrinsic evidence, it does not support Pfizer's interpretation. Pfizer is correct that the Advil I consent decree includes broad language that enjoins it from making certain advertising claims related to "Advil, any other ibuprofen products, or ibuprofen in general." Cendali Declaration in Support, ECF No. 41, Ex. 6 at ¶ 6. And that isolated statement alone might support an inference that when the parties wanted to refer broadly to ibuprofen and narrowly to Advil, they specifically did so. But context is key. The broad language in that statement precedes a reference to a specific claim that Pfizer is enjoined from making: that "ibuprofen interacts with fewer drugs than acetaminophen or that ibuprofen is comparable or superior to acetaminophen with respect to adverse drug-drug interactions." Id. ¶ 6(b). And that claim itself was discussed in the Advil I decision, not in terms of ibuprofen and acetaminophen, but rather Advil and Tylenol. See Advil I, 654 F. Supp. at 589 ("The truth of the matter is that there simply is no credible support for AHP's claim of Advil's superiority over Tylenol in the respect of drug-drug interactions."). Thus, even assuming that the Court could properly consider the Advil I consent decree in its interpretation of the Advil II Order, the broad language therein that Pfizer points to weighs in favor of the Court's conclusion that the Advil court used the terms Advil and ibuprofen interchangeably in its opinions and orders.

Nor do the circumstances surrounding the formation of the <u>Advil II</u> Order that Pfizer highlights support its interpretation. Pfizer cites to trial transcripts to prove that Judge

Connor only examined the effects of adult Advil and emphasizes that the cases considered only advertisements for adult Advil and scientific and medical evidence on the effect of ibuprofen on adults. It argues that the <u>Advil</u> decisions' use of the present tense constricts the Order's use of "Advil" to the product that was on the market at the time. It also claims that the decisions exclusively referred to Advil as the 200 milligram tablet on the market at the time. Finally, it attaches the pleadings in the <u>Advil</u> cases to prove that the parties defined "Advil" as Advil for adults.

Regardless of the numerous clinical studies that AHP submitted to Judge Connor, the <u>Advil I</u> opinion makes clear that "[b]ecause many of these exhibits were merely 'dumped' into evidence with only the briefest discussion by a witness, or none at all, the Court has not undertaken the mountainous task of reading all of them, but has confined its review to those which the parties deemed sufficiently important to cite in their briefs or proposed findings." <u>Advil I</u>, 654 F. Supp. at 572. Thus the evidence presented in the cases is not a more persuasive factor in interpreting the Advil II Order than the language of the Order and opinions.

Nor does the use of the present tense in the <u>Advil</u> opinions restrict the <u>Advil II</u> Order's scope to products in existence at the time. Though the decisions spoke of a product that AHP "markets," "manufactures," and "sells," that tense merely reflected the court's discussion of the present controversy before it. It would have made little sense for the court to have written that AHP "sold" or "will market" Advil when in fact AHP's marketing of Advil was present and continual.

Further, as the Court has concluded, the <u>Advil</u> opinions did not use the term Advil exclusively to refer to Advil for adults. Instead, they interchangeably used the term to refer to both a specific product and to its active ingredient, ibuprofen. Finally, how the parties defined the term

Advil in their pleadings is irrelevant to how the Order defined Advil, since a consent judgment "must be construed as it is written, and not as it might have been written had the plaintiff established his factual claims and legal theories in litigation." <u>United States v. ITT Cont'l Baking</u> Co., 420 U.S. 223, 236 (citing <u>United States v. Armour & Co.</u>, 402 U.S. 673, 680 (1971)).

# IV. CONCLUSION

For the reasons described above, Pfizer's motion to for judgment on the pleadings is **DENIED** (ECF No. 39) and McNeil's cross motion for judgment on the pleadings is **GRANTED** (ECF No. 44). The Clerk of Court is respectfully requested to close the case.

SO ORDERED.

**Dated: April 27, 2016** 

New York, New York

ANDREW L. CARTER, JR. United States District Judge