UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FERRING PHARMACEUTICALS, INC.,		
Plaintiff,	Civil Action No.:	15-802 (RC)
v.	Re Document No.:	64
ALEX AZAR,[1] in his official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,		
and		
SCOTT GOTTLIEB, in his official capacity as COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION,		
Defendants.		

MEMORANDUM OPINION

DENYING PLAINTIFF'S MOTION TO ENFORCE JUDGMENT

I. INTRODUCTION

This case returns to this Court one year after the grant of summary judgment to Plaintiff Ferring Pharmaceuticals, Inc. ("Ferring") due to Defendant U.S. Food and Drug Administration's ("the FDA") surprise change of position regarding the chemical classification of a molecule within Plaintiff's colon cleansing drug, Prepopik. For years, Ferring and the FDA

[1] Pursuant to Federal Rule of Civil Procedure 25(d), Alex Azar, the current Secretary of the United States Department of Health and Human Services, is automatically substituted as a defendant in this matter.

have agreed that picosulfate is the active moiety[2] within the molecule sodium picosulfate, one of the three active ingredients in Prepopik, and that this active moiety does not exist in any drugs previously approved by the FDA. Based on this understanding, Ferring challenged the FDA's interpretation of a rule that it believed was the only obstacle to obtaining five years of exclusivity for the drug. After the grant of summary judgment to Ferring removing this obstacle, and remand to the FDA for a determination of whether Ferring was entitled to five years of exclusivity for Prepopik, the FDA returned to Ferring with a new conclusion: that the active moiety in sodium picosulfate is actually bis-(p-hydroxyphenyl)-pyridyl-2-methane ("BPHM"), an active moiety found in several drugs that have already been approved. As such, the FDA concluded that Ferring was not entitled to five-year exclusivity for Prepopik.

Ferring now challenges this determination as a violation of the Court's grant of summary judgment and remand to the agency, and requests that this Court order the "FDA to recognize NCE exclusivity of Prepopik, in keeping with the positions the agency has taken repeatedly throughout the regulatory process and ensuing litigation." Mem. P. & A. Supp. Pl.'s Mot. Enforce J. ("Pl.'s Mem.") at 17, ECF No. 64-1. For the reasons set forth below, the Court denies Ferring's motion to enforce the judgment.

II. FACTUAL AND PROCEDURAL BACKGROUND

Prepopik, a fixed-combination drug product used to cleanse the colon prior to colonoscopies, contains three active ingredients: sodium picosulfate, magnesium oxide, and

[2] An "[a]ctive moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance." 21 C.F.R. § 314.3(b).

anhydrous citric acid. A.R. 4, ECF No. 20-3. "Fixed-combinations are drug products that generally include two or more drug substances (active ingredients) in a fixed ratio, synthetically combined into a single dosage form." A.R. 200, ECF No. 20-4. While magnesium oxide and anhydrous citric acid had already been approved in previous New Drug Applications ("NDA") when Ferring submitted its NDA for Prepopik, sodium picosulfate had not been. Therefore, when it submitted its NDA for Prepopik, Ferring also sought five years of exclusivity for the drug as a New Chemical Entity[3] ("NCE"), which if approved would have prevented other drug manufacturers from submitting Abbreviated New Drug Applications ("ANDA") and § 505(b)(2) NDAs[4] of generic versions for Prepopik for five years after the approval of Prepopik's NDA. 21 U.S.C. § 355(j)(5)(F)(ii).

The FDA approved Ferring's NDA for Prepopik in 2012. A.R. 201. However, the agency refused to grant Ferring five years of exclusivity for Prepopik because two of the active ingredients in the drug (magnesium oxide and anhydrous citric acid) existed in drugs previously approved by the FDA. *Id.* Instead, it granted Ferring three years of exclusivity on the ground that its application "contain[ed] reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." 21 U.S.C. § 355(j)(5)(F)(iii); *see* Ex. D, Pl.'s Mot. Enforce J. ("Pl.'s Mot.") at 2, ECF No. 64-5; A.R. 201. The regulation governing the Food, Drug, and Cosmetic Act's five-year exclusivity provision instructs that

[3] A "new chemical entity" is "a drug that contains no active moiety that has been approved by the FDA in any other NDA submitted under section 505(b) of the [A]ct." 21 C.F.R. § 314.108(a).

[4] Section 505(b)(2) NDAs are applications in which some or all of the investigations relied upon to show that the drug is safe and effective "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted." 21 U.S.C. § 355(b)(2).

> [i]f a drug product that contains a new chemical entity was approved after September 24, 1984, in an NDA submitted under section 505(b) of the [A]ct, no person may submit a 505(b)(2) application or ANDA under section 505(j) of the [A]ct for a drug product that contains the same active moiety as in the new chemical entity for a period of 5 years from the date of approval of the first approved NDA . . . .

21 C.F.R. § 314.108(b)(2). In contrast, the three-year exclusivity provision only precludes the FDA from *approving* new ANDAs and § 505(b)(2) applications before the end of the three-year period, rather than altogether prohibiting the submission of those applications. *Compare* 21 U.S.C. § 355(j)(5)(F)(ii), *with id.* § 355(j)(5)(F)(iii).

Ferring submitted a Citizen Petition requesting that the FDA change its exclusivity determination for Prepopik. A.R. 64. A year later, the FDA issued a response to this Citizen Petition and Citizen Petitions filed by two other pharmaceutical companies whose respective fixed-combination drug products had also been denied five-year exclusivity. A.R. 199. The FDA's response stated that it believed that its then-current interpretation of the relevant statute and regulations—that fixed-combination drugs that contain at least one previously approved active moiety cannot be granted exclusivity, even if the drug also contains at least one new active moiety—was "permissible." A.R. 212. However, it acknowledged that its existing interpretation "may result in drug development strategies that are suboptimal from a public health perspective" because, when sponsors submit two NDAs—one for a drug with a single active-ingredient containing the new active moiety and another for a fixed-combination product—"undue importance" may be placed on "the order in which these two NDAs are approved." A.R. 213–14. Therefore, the FDA agreed to consider altering its interpretation of the law, issuing a draft guidance and seeking public comment on a new interpretation of existing law and regulation that would "recognize 5-year NCE exclusivity for a drug substance that does not contain a previously

approved active moiety, even where such a drug substance is approved in a fixed-combination with another drug substance that contains at least one previously approved active moiety." A.R. 214.

Despite the fact that Prepopik met this new standard, the FDA refused to grant it five years of exclusivity because "[e]xclusivity runs from the date of approval of the product" and the agency's old interpretation had been in effect on the date Prepopik's NDA had been approved. A.R. 215. After filing a Petition for Reconsideration and Petition for Stay, which the FDA denied, Ferring filed this action in federal court, alleging that the FDA's denial of its application was contrary to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399b, and the agency's own regulations, and that its refusal to apply the new interpretation was arbitrary and capricious in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). *See* Compl. ¶¶ 58–71, ECF No. 2. As a remedy, Ferring sought "a declaratory judgment declaring that the FDA's determination of the exclusivity period for Prepopik violates the [APA]" and "injunctive relief ordering the FDA to grant the full five years of exclusivity for Prepopik." Compl. ¶ 9.

On first review, the Court denied Ferring all of the relief it requested. *See generally Ferring Pharm. Inc. v. Burwell* ("*Ferring I*"), 169 F. Supp. 3d 199 (D.D.C. 2016). Performing a *Chevron* analysis, at Step One the Court found that it was ambiguous whether the term "drug" in the relevant sentence of the statute referred to drug substances or drug products. *Ferring I*, 169 F. Supp. 3d at 211–12 (citing *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984)). At *Chevron* Step Two, it found that the agency's original construction of the statute was reasonable, even though that construction assigned different meanings to the term "drug" within the same sentence of statutory text. *Id.* at 212–17. It similarly found that the original interpretation was not arbitrary and capricious. *Id.* at 217–19. This holding was in part predicated

on the fact that Ferring had not produced any examples of the original interpretation creating circumstances in which a drug substance's eligibility for five-year exclusivity turned on the order in which NDAs were approved. *Id.* at 218 ("If there were, in fact, situations in which a drug was eligible for five-year exclusivity under FDA's prevailing interpretation but failed to receive it because of the order in which it was approved, those circumstances might render FDA's policy arbitrary and capricious.").

Following the Court's grant of summary judgment to the FDA, Ferring moved for reconsideration on the grounds that it could identify several examples of a single-entity drug substance being denied five-year exclusivity due to the order in which the NDAs for drugs that include that substance were approved. *See* Mem. P. & A. Supp. Pl.'s Mot. Recons. ("Pl.'s Mot. Recons. Mem.") at 1–3, ECF No. 39-1. The Court granted the motion for reconsideration, entered summary judgment for Ferring, and "remand[ed] th[e] action to FDA for further proceedings not inconsistent with [its] opinion." *Ferring Pharm., Inc. v. Burwell* ("*Ferring II*"), No. 15-802, 2016 WL 4734333, at *11 (D.D.C. Sept. 9, 2016).

It is the result of this remand that Ferring now challenges. Throughout the NDA process, the NCE exclusivity Citizen Petition process, and this litigation, the FDA has consistently agreed with Ferring that the active moiety in sodium picosulfate is picosulfate. For example, when Ferring submitted its NDA for Prepopik, the FDA classified the NDA as a "Type 1 – New Molecular Entity" submission. *See* FDA, Drugs@FDA: FDA Approved Drug Products, Prepopik (NDA 202535), https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. The term "new molecular entity" is not defined by statute or regulation, but the FDA defines the term as "an active ingredient that contains no active moiety that has been previously approved by [the FDA] in an [NDA] or has been previously marketed as a drug in the United States." *See* FDA,

Drugs@FDA Glossary, https://www.fda.gov/drugs/informationondrugs/ucm079436.htm. Implied in that classification is the determination that sodium picosulfate contains an active moiety that had not previously been approved because magnesium oxide and anhydrous citric acid contain active moieties that had already been approved. Throughout the course of this litigation, the FDA never altered its determination that sodium picosulfate contains a not previously approved active moiety—until now.

Eight months after the Court remanded this matter back to the FDA for further proceedings consistent with its arbitrary and capriciousness finding, the FDA changed its mind regarding the identity of the active moiety in sodium picosulfate. It now believes, upon "further review," that the active moiety in sodium picosulfate is not picosulfate, but rather BPHM, an active moiety that is also found in other previously approved drug products. Ex. B at 2, Pl.'s Mot., ECF No. 64-3. As such, it concluded that Prepopik was not entitled to five-year NCE exclusivity. Ex. D at 8–9, Pl.'s Mot.

The agency's change in position is based in its new chemical analysis of picosulfate. Following its review of Ferring's application for five-year NCE exclusivity, it explained that "[a]t the time the Prepopik application was submitted, the Agency determined that sodium picosulfate was [an NME]. It was believed that picosulfate was the active moiety of the drug substance sodium picosulfate, and that this active moiety had not been previously approved by FDA." *Id.* at 7.

The agency has given no indication of why this determination was made. It admits that "[i]t is not clear from the administrative record how the Agency determined that sodium picosulfate was considered to be an NME, as no documentation of a structural analysis of this

active ingredient has been found." *Id.*[5] The agency continues that at the time of its approval of Prepopik's NDA and its initial denial of the application of five-year NCE exclusivity, "there was no need to closely examine the structure of picosulfate to more thoroughly assess the assumption that it did not contain a previously approved active moiety," because, using the agency's interpretation of the NCE exclusivity regulations in place at the time, it had already determined that Prepopik did not qualify for five years of exclusivity anyway. App. A at 4, Ex. 1, Defs.' Opp'n.

Now the FDA explains that, following the Court's remand, it has taken a closer look at the chemical properties of sodium picosulfate and "determined that sodium picosulfate is the di-sodium salt of a di-sulfate derivative of [BPHM]," because "[a]fter excluding the salt and ester portions of sodium picosulfate, as FDA's regulations require, what remains is BPHM." Ex. D at 7, Pl.'s Mot. "Amongst chemists, there is a long standing understanding that esters are substances resulting from the splitting-out of water from the combining of an alcohol, and an acid, where the acid may be organic (e.g. acetic acid) or inorganic (e.g. sulfuric acid)." App. A at 4, Ex. 1, Defs.' Opp'n. After performing a "virtual hydrolysis to cleave all ester bonds," and "[e]xamin[ing] the alcohol and acid components" to "determine which are 'responsible for the physiological or pharmacological action of the drug substance,'" the FDA determined that the active moiety in sodium picosulfate is BPHM. *Id.* at 11–12. It therefore concluded that "[d]espite [its] prior statements that sodium picosulfate was an NME and an NCE, it is now evident that

[5] The agency explained that while Prepopik was explicitly described as an NME in its tertiary Chemistry Review and primary Clinical Pharmacology Review, this classification was not discussed in the primary Chemistry, Manufacturing and Controls review. App. A at 3, Ex. 1, Defs.' Opp'n, ECF No. 66-1. The agency believes that the dearth of explanation regarding Prepopik's NME status was likely due to the fact that in 2012, the agency had not yet developed a standard process for determining and documenting NME status. *Id.*

those statements were incorrect because this drug substance contained a previously approved active moiety when it was approved in Prepopik." Ex. D at 8, Pl.'s Mot.

Ferring does not accept this conclusion, claiming that it resulted from a mid-adjudication change in the interpretation of the term "ester" to include "covalently bound sulfur-based appendages." Ex. C at 2, Pl.'s Mot., ECF No. 64-4. It argues that if the agency wanted to change its interpretation of the term "ester," it should have followed the appropriate administrative procedures. *Id.* According to Ferring, the FDA's "sudden reversal is not just an unreasonable break with past practice," but also "an end-run around this Court's" grant of summary judgment and remand order. Pl.'s Mem. at 2. Therefore, it has filed a motion to enforce the Court's prior judgment, requesting that the Court "order FDA to award NCE exclusivity to Prepopik instead of ordering another remand." *Id.* at 16. The motion is now ripe for decision.

III. LEGAL STANDARD

"Within a court's power to administer its decrees is the power to construe and interpret the language of the judgment." *Heartland Hosp. v. Thompson*, 328 F. Supp. 2d 8, 11–12 (D.D.C. 2004) (citing *Sec. & Exch. Comm'n v. Hermil, Inc.*, 838 F.2d 1151, 1153 (11th Cir. 1988)). A motion to enforce a judgment is the usual method of requesting such an interpretation. *Id.* at 11 (citing *Hermil*, 838 F.2d at 1153). "Success on a motion to enforce a judgment gets a plaintiff only the relief to which [the plaintiff] is entitled under [its] original action and the judgment entered therein." *Heartland Reg'l Med. Ctr. v. Leavitt*, 415 F.3d 24, 29 (D.C. Cir. 2005) (internal quotation marks and citations omitted).

"When a district court reverses agency action and determines that the agency acted unlawfully, . . . the appropriate course is simply to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal."

N. Air Cargo v. U.S. Postal Serv., 674 F.3d 852, 861 (D.C. Cir. 2012) (citing *PPG Indus., Inc. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995)). "Indeed, to order the agency to take specific actions is reversible error." *Flaherty v. Pritzker*, 17 F. Supp. 3d 52, 57 (D.D.C. 2014) (citing *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005 (D.C. Cir. 1999)). On remand, agencies are permitted to come to the same conclusion as they had originally come to, as long as it is for a permissible reason. *See Fed. Election Comm'n v. Akins*, 524 U.S. 11, 25 (1998) (noting that, after remand, an agency "might later, in the exercise of its lawful discretion, reach the same result for a different reason" than one rejected by reviewing court); *see also Lone Mountain Processing, Inc. v. Sec'y of Labor*, 709 F.3d 1161, 1164 (D.C. Cir. 2013) ("The Commission may well arrive at the same result it reached originally, . . . but it must do so with more clarity than it showed in the first instance.").

IV. ANALYSIS

In order for Ferring to succeed on its motion to enforce the Court's prior judgment, it must demonstrate that the FDA did not comply with the Court's order. Therefore, the Court must first determine the scope of its prior order. *See Heartland*, 415 F.3d at 29–30. The order at issue in this case was the result of a motion for reconsideration, which was filed "for the limited purpose of addressing one aspect of this Court's March 15, 2016 Memorandum Opinion" granting summary judgment to the FDA. Pl.'s Mot. Recons. Mem. at 1. In that motion, Ferring clarified that there had been "drug products that were denied NCE exclusivity precisely because of the order in which they were approved." *Id.* The Court was persuaded by this new evidence, and granted Ferring's motion, remanding the case to the FDA "for further proceedings not inconsistent with" its opinion. *Ferring II*, 2016 WL 4734333, at * 11. However, the opinion in question, and the analysis leading to it, concerned only whether the FDA's original interpretation

of the five-year NCE exclusivity provisions was arbitrary and capricious. The Court performed no separate analysis, and made no finding, of whether Prepopik was entitled to NCE exclusivity. All the Court found was that the agency's prior interpretation of the relevant statutory and regulatory provisions could not be justified, and therefore, that the FDA could not apply that interpretation to Prepopik when adjudicating Ferring's application for five-year exclusivity.

However, Ferring still believes that FDA's change in position "violates both the letter and spirit of this Court's Order" because the FDA, as well as the Court, had never questioned whether sodium picosulfate contained an active moiety that the FDA had not previously approved. Pl.'s Mem. at 6. And because Ferring, it would seem, relied on the FDA's assumption regarding the non-approval status of sodium picosulfate's active moiety, it believes that the FDA should not be allowed to issue its surprise denial of exclusivity at this late hour. *See id.* at 12. Ferring therefore argues that the FDA's change in position regarding sodium picosulfate's prior approval status violates the law of the case; that the agency is judicially estopped from changing its position in this manner; that the agency's eleventh hour chemical analysis of sodium picosulfate impermissibly retroactively applies a new interpretation of the term "ester" and violates due process; and that the agency's actions are arbitrary and capricious. *See id.* at 7–15. For the reasons set forth below, the Court finds that the FDA's actions on remand do not violate the law of the case and that the FDA is not judicially estopped from asserting its change in position concerning sodium picosulfate's prior approval status. The Court also finds that Ferring's arguments regarding retroactivity, due process, and arbitrary and capriciousness are not suitable for consideration within the context of a motion to enforce judgment.

A. Law of the Case

Ferring's first argument is that the FDA's change in position regarding the active moiety in sodium picosulfate violates the law of the case doctrine because the FDA's actions on remand "undermine the clear thrust of this Court's order instructing FDA to take further proceedings *consistent with the Court's memorandum opinion*." Pl.'s Mem. at 8 (internal quotation marks and citation omitted) (emphasis in original). According to Ferring, the "FDA's latest flip-flops, changing its positions on the identity of the active moiety in sodium picosulfate and whether the active ingredient itself is novel, simply came too late in the day." *Id.* at 7. The FDA counters that "[t]he doctrine of law of the case is inapplicable here because the factual issue of whether sodium picosulfate contains a new active moiety was never raised as a disputed issue to be decided during the litigation and FDA's actions on remand were fully within the scope of the Court's mandate." Defs.' Opp'n at 6, ECF No. 66. The FDA is correct that its determination regarding the active moiety in sodium picosulfate cannot be bound by the law of the case doctrine, though not, as it suggests, because the parties never disputed the issue.

"'Law-of-the-case doctrine' refers to a family of rules embodying the general concept that a court involved in later phases of a lawsuit should not re-open questions decided (i.e., established as the law of the case) by that court or a higher one in earlier phases." *Crocker v. Piedmont Aviation, Inc.*, 49 F.3d 735, 739 (D.C. Cir. 1995). Under the law-of-the-case doctrine, "the same issue presented a second time in the same case in the same court should lead to the same result." *LaShawn A. v. Barry*, 87 F.3d 1389, 1393 (D.C. Cir. 1996) (en banc). "The doctrine of law of the case comes into play only with respect to issues previously determined." *Quern v. Jordan*, 440 U.S. 332, 347 n.18 (1979). "[Q]uestions that merely could have been decided do not become law of the case." *Women's Equity Action League v. Cavazos*, 906 F.2d 742, 751 n.14

(D.C. Cir. 1990) (citing *Bouchet v. Nat'l Urban League*, 730 F.2d 799, 806 (D.C. Cir. 1984)); *see also Alpha/Omega Ins. Servs. v. Prudential Ins. Co.*, 272 F.3d 276, 279 (5th Cir. 2001) ("[U]nlike res judicata, the law of the case doctrine applies only to issues that were actually decided, rather than all questions in the case that might have been decided, but were not."). "[D]icta is not part of the law of the case." *United States v. Singleton*, 759 F.2d 176, 185 (D.C. Cir. 1985) (citing *Nat'l Souvenir Ctr., Inc. v. Historic Figures, Inc.*, 728 F.2d 503, 511 (D.C. Cir.), *cert. denied*, 469 U.S. 825 (1984)). However, "[t]he doctrine encompasses a court's explicit decisions, as well as those issues decided by necessary implication." *Williamsburg Wax Museum, Inc. v. Historic Figures, Inc.*, 810 F.2d 243, 250 (D.C. Cir. 1987). "[A]dherence to the doctrine is not mandatory," but rather left to the district court's sound discretion. *Moore v. Hartman*, 332 F. Supp. 2d 252, 256 n.6 (D.D.C. 2004).

At a basic level, Ferring's argument that the law of the case applies here must fail because the Court never actually found that the active moiety in sodium picosulfate is picosulfate, either explicitly or by necessary implication. Indeed, in neither of its two prior memorandum opinions did the Court even repeat the parties' belief that the active moiety in sodium picosulfate was the not-previously-approved picosulfate. The closest the Court ever came to such a pronouncement was during its description of Ferring's actions during the NDA and NCE exclusivity application processes, when it explained that "[b]ecause sodium picosulfate constituted a new drug substance, Ferring sought five-year exclusivity for PREPOPIK when it submitted its NDA." *Ferring II*, 2016 WL 4734333, at *4. Apart from that, the Court only referenced the fact that sodium picosulfate "had never previously been approved in a NDA," *id*. at *1, a fact which the parties still do not dispute.

The Court never found or stated that picosulfate is the active moiety in sodium picosulfate because the identity of that moiety was irrelevant to the Court's analysis of the agency's interpretation of the NCE exclusivity provisions. Ferring argues that the parties' assumption regarding the active moiety cannot now be revisited because otherwise, "[t]he issue before the Court in this case—the propriety of FDA's original interpretation of the NCE exclusivity statute as applied to fixed-dose combination products—would have been wholly academic if sodium picosulfate were not, in fact, a novel active ingredient." Pl.'s Mem. at 6. Therefore, Ferring argues, it can be inferred that the Court found that the active moiety in sodium picosulfate had not already been approved. But that is not so.

If the FDA had indeed already informed Ferring that BPHM was the active moiety in sodium picosulfate, and had denied Ferring's application for five-year NCE exclusivity based on both its active moiety determination and its application of its prior interpretation of the NCE exclusivity provisions to Prepopik, and Ferring believed that it had legitimate challenges to both grounds of denial, and indeed then challenged both, Ferring's challenge of the FDA's use of its prior interpretation of the exclusivity provisions would have been far from academic.[6] After all, the same arguments regarding retroactivity, due process, and arbitrary and capriciousness that Ferring now promotes to challenge the FDA's decision to recognize sodium picosulfate as an ester would have also been available to Ferring then. As such, it cannot be inferred, from the Court's finding on a completely separate issue, that the Court had already found that sodium

[6] In order to prevail in such a challenge to a denial of exclusivity, Ferring would have had to prevail on both arguments—i.e., that the FDA had erred both in its determination concerning the active moiety in sodium picosulfate and in its interpretations of the NCE exclusivity provisions. Thus, the matter would only have been academic if Ferring had not prevailed on the moiety issue and the Court, in its discretion, had decided not to also reach the exclusivity interpretation issue.

picosulfate contained an active moiety that had not already been approved. The Court simply never made such a finding, either explicitly or implicitly. Indeed, given the obvious scientific complexity that went into determining the active moiety's identity on remand, *see, e.g.*, App. A at 11–12, Ex. 1, Defs.' Opp'n, it is clear that such a determination is more properly made by the agency. *See e.g.*, *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995) ("[C]ourts give a high level of deference to an agency's evaluations of scientific data within its area of expertise."); *Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992) (rationale for deference "particularly strong" when agency evaluates scientific evidence within its technical expertise).[7]

Despite the fact that the law of the case doctrine clearly does not apply to something the Court never addressed, even tangentially, and which, even if it had been tangentially addressed, would have been dicta because such a finding would not have been essential to its holding, *see Singleton*, 759 F.2d at 185 ("dicta is not part of the law of the case"), the Court will still consider and correct several of the parties' assumptions regarding the law of the case doctrine. In its response to Ferring's contention that the law of the case applies, the FDA claims that the doctrine could not apply here because "the factual issue of whether sodium picosulfate contains a new active moiety was never raised as a disputed issue to be decided during the litigation." Defs.' Opp'n at 6. Ferring counters that an issue need not be disputed to become the law of the case, and cites to two cases that support that proposition. *See* Pl.'s Reply at 8, ECF No. 67 (citing *Belizan v. Hershon*, 495 F.3d 686, 693 (D.C. Cir. 2007); *United States v. Turtle Mountain Band of Chippewa Indians*, 612 F.2d 517, 521 (Ct. Cl. 1979)).

[7] Of course, such a finding, if made in a clearly erroneous or arbitrary and capricious manner, could be subject to review under the APA, though not through a motion to enforce a prior judgment that dealt with an entirely separate question. *See* discussion *infra* Section IV.C.

Ferring is correct that an issue need not be disputed to become the law of the case. However, neither of the cases it cites stands for the proposition that issues that have not actually been decided, even implicitly, may become the law of the case. In *Belizan*, the Circuit Court refused to revisit, during the case's second appeal, the district court's affirmative determination that a set of facts did not sufficiently state a claim under a particular act, when that determination had not been challenged during the plaintiffs' first appeal to the circuit. *See Belizan*, 495 F.3d at 693. Likewise, in *Turtle Mountain*, the Court of Claims refused to revisit an explicit decision by the Indian Claims Commission that it had already affirmed, explaining that its prior determination during the first appeal was the law of the case. *See Turtle Mountain*, 612 F.2d at 519–20. In both of these cases, issues that had not been disputed, but that had in fact already been decided, were deemed to be the law of the case. In this case, the question of what the active moiety in sodium picosulfate is was never disputed, never considered, and never decided by the Court. Accordingly, the law of the case doctrine does not apply to the FDA's decision regarding the active moiety in sodium picosulfate on remand.

B. Judicial Estoppel

Ferring also argues that the FDA's switch in position regarding the active moiety in sodium picosulfate is barred by judicial estoppel, which "prevents parties from abusing the legal system by taking a position in one legal proceeding that is inconsistent with a position taken in a later proceeding." Pl.'s Mem. at 8 (citing *Moses v. Howard Univ. Hosp.*, 567 F. Supp. 2d 62, 66 (D.D.C. 2008), *amended by* 601 F. Supp. 2d 1 (D.D.C. 2009), *and aff'd*, 606 F.3d 789 (D.C. Cir. 2010)). The FDA responds that judicial estoppel does not apply because the agency did not intentionally change its position regarding the active moiety in sodium picosulfate in order to gain a tactical advantage in this suit, and because it never "succeeded in persuading [the Court]

to accept [its] earlier position" regarding the active moiety in sodium picosulfate. Defs.' Opp'n at 8–9 (citing *New Hampshire v. Maine*, 532 U.S. 742, 750–51 (2001)). The FDA is correct on both counts, and accordingly, the Court will not grant Ferring the relief it seeks on this ground either.

"[W]here a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position, especially if it be to the prejudice of the party who has acquiesced in the position formerly taken by him." *Maine*, 532 U.S. at 749 (citing *Davis v. Wakelee*, 156 U.S. 680, 689 (1895)). While there is no exhaustive list of what should be considered when deciding whether a party is judicially estopped from asserting a new argument or position, courts should generally consider whether: 1) "a party's later position [is] 'clearly inconsistent' with its earlier position," 2) "the party has succeeded in persuading a court to accept that party's earlier position, so that judicial acceptance of an inconsistent position in a later proceeding would create 'the perception that either the first or the second court was misled,'" and 3) "the party seeking to assert an inconsistent position would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped." *Id.* at 750–51 (internal citations omitted). Additionally, "it may be appropriate to resist application of judicial estoppel 'when a party's prior position was based on inadvertence or mistake.'" *Id.* at 753 (internal citation omitted).

Ferring claims that the FDA's actions "check[] all three of these boxes." *See* Pl.'s Mem. at 9. However, by the Court's count, it only checks one. While the FDA has indeed asserted "clearly inconsistent" positions with respect to its view of whether picosulfate is the active moiety in sodium picosulfate, it is not the case that the FDA "succeeded in persuading the court to accept [its] earlier position." Pl.'s Reply at 9. Indeed, the FDA never made any effort to persuade the Court of the identity of the active moiety in sodium picosulfate. Instead, the FDA

took its earlier statements that the active moiety of sodium picosulfate was picosulfate during the NDA process, assumed those statements were correct, and also assumed, at that time, that those statements would be applicable to the NCE process. The Court never mentioned, nor questioned, this assumption, not because it had been persuaded, but because the question concerning sodium picosulfate's active moiety did not need to be decided to resolve the issues before it.[8] As such, the FDA did not "succeed[] in persuading [this] court to accept [its] earlier position, so that judicial acceptance of an inconsistent position" by this Court on remand would create the perception that this Court had been previously misled. *Maine*, 532 U.S. at 750.

There is no doubt that Ferring is inconvenienced by the FDA's new position that the active moiety in sodium picosulfate can be found in other, previously approved active ingredients. Indeed, had Ferring known that the FDA would argue that the active moiety in sodium picosulfate was BPHM rather than picosulfate, it may have decided not to pursue this litigation in the first place. At the very least, this revelation is a setback. However, this change in position certainly did not give the FDA an unfair advantage throughout the course of this litigation. Indeed, had the FDA staked out this position at the outset, it may have avoided litigating two dispositive motions regarding its prior interpretation of the NCE statutory and regulatory provisions, depending on how Ferring had chosen to respond.[9] The FDA represents that its prior position regarding the active moiety in sodium picosulfate was the result of

[8] Granted, if the FDA had denied exclusivity both because of its interpretation of the NCE provisions and because it believed the active moiety in sodium picosulfate is BPHM, and the Court had upheld the FDA's decision regarding the active moiety in sodium picosulfate, the Court may not have had to reach the regulatory argument. But these are alternate arguments that do not depend on each other.

[9] And if the FDA had prevailed on the moiety issue, it could have avoided this Court's finding that its prior interpretation of the NCE exclusivity provisions was arbitrary and capricious, which led to it having to grant exclusivity to new drugs from applicants that had not challenged the FDA's interpretation before this Court. *See* Pl.'s Mem. at 2 n.1.

"inadvertence or mistake," which courts may consider when deciding whether a party is judicially estopped from asserting a new position. *Maine*, 532 U.S. at 753. Given that the change in position did not benefit FDA and, in fact, may have damaged it with respect to potentially unnecessary litigation and adverse consequences with respect to third parties, that interpretation is plausible.

Because the FDA's actions do not meet the three criteria set forth in *Maine*, and because it appears that the FDA's late change in position may have been due to inadvertence or mistake, the Court does not find that the FDA is judicially estopped from determining that the active moiety in sodium picosulfate is BPHM, thereby denying Prepopik five years of exclusivity. Accordingly, the Court cannot grant Ferring the relief it seeks on this basis either.

C. Other Challenges to the Agency's Actions on Remand

Ferring also asserts that the process through which the FDA determined that the active moiety in sodium picosulfate is BPHM was defective. First, it contends that the agency's decision that sodium picosulfate contained an ester amounts to retroactive rulemaking because it "adopt[ed] a new, industry-wide interpretation of a statutory term in the context of an adjudication and then appl[ied] it retroactively" to Prepopik. Pl.'s Mem. at 10–11. Second, it argues that this change in interpretation violates the Due Process Clause of the Fifth Amendment to the United State Constitution because the agency did not provide Ferring with "notice and some kind of hearing before final deprivation of a property interest." *Id.* at 13 (citing *Henke v. Dep't of the Interior*, 842 F. Supp. 2d 54, 61 (D.D.C. 2012)). Last, it alleges that the "FDA's new interpretation of the term 'ester' was arbitrary and capricious." *Id.* at 15. The FDA responds that these merits arguments concerning the agency's decision on remand are not properly raised in a

motion to enforce the prior judgment, and also fail on the merits. Defs.' Opp'n at 10–13. Because Defendant is right as to its former argument, the Court need not consider the latter.

In support of its position that Ferring's merits arguments concerning the agency's decision on remand are not properly raised in a motion to enforce the prior judgment, the FDA cites *Heartland Reg'l Med. Ctr. v. Leavitt*, 415 F.3d 24 (D.C. Cir. 2005). *See* Defs.' Opp'n at 10. In *Heartland*, the plaintiff hospital attempted to enforce a prior judgment which ordered the U.S. Department of Health and Human Services ("HHS") *to consider and respond to suggestions* for reasonable alternatives to its then-current definition of the term "urban area," a criterion relevant to the hospital's qualification for a specific type of Medicare reimbursement. *Id.* at 27–28. On remand, HHS considered and rejected the alternative definitions, thereby preventing the plaintiff hospital from receiving the benefit (designation as a hospital outside of an "urban area") that it sought. *Id.* at 27.

In response to the results of that remand, the plaintiff hospital filed a motion to enforce the court's previous order, seeking a declaratory judgment that it qualified for the reimbursement as well as an award of the reimbursement itself, and also filed a separate APA challenge to the agency's actions on remand. *Id.* at 28. The district court denied the motion to enforce the judgment. Concluding that it could only enforce what it had already ordered, the district court found that the agency had complied with the previous order by considering, and then rejecting, alternative definitions to the term "urban area." *Id.* The D.C. Circuit affirmed, explaining that "nothing on the face of that decision compelled HHS to grant Heartland SCH status and reimbursement." *Id.* Rather, by considering and responding to reasonable alternatives, the agency had fulfilled its obligations under the order. *Id.* The court further clarified that "whether or not the agency's post-*Heartland I* rejection of the alternatives was arbitrary is a determination that

must be made in Heartland's separate APA action challenging HHS's post-remand decisions," because "[n]othing in *Heartland I* itself addresses that question, and therefore a motion to enforce the *Heartland I* judgment is not the proper means to answer it." ***Id.*** at 30. The court also indicated that the question of whether an agency's actions on remand constituted impermissible retroactive rulemaking was best left to determination in the separate APA action, rather than a motion to enforce. *See id.*; *see also Flaherty v. Pritzker*, 17 F. Supp. 3d 52, 59 (D.D.C. 2014) (explaining that the court would soon address plaintiffs' challenge to an agency's decision on remand, not in response to plaintiffs' motion to enforce a prior judgment, but in response to its supplemental complaint).

Ferring attempts to distinguish this case from *Heartland* by pointing out that the Court's order in this case "rel[ied] on all parties' shared understanding that sodium picosulfate contained a novel active moiety." Pl.'s Reply at 12. However, as explained above, the Court did not "rely" on the parties' shared understanding that picosulfate was the active moiety in sodium picosulfate in reaching its decision, but rather focused on the issue presented to it: whether the application of the FDA's original interpretation of the NCE five-year exclusivity provision to Prepopik was arbitrary and capricious, violating the APA. The identity of the active moiety in sodium picosulfate was not essential to the Court's reasoning in reaching its decision, nor was it actually decided by the Court. Accordingly, although this remand gave Ferring the right to have its application adjudicated without the application of a particular arbitrary and capricious rule, it did not dictate a result in Ferring's favor. Nor did it constrain the FDA's decisionmaking process beyond the non-application of the rule that the Court had deemed arbitrary and capricious. On remand, agencies are permitted to come to the same conclusions as they had come to in the first instance, as long as they come to those conclusions for permissible reasons. *See Fed. Election*

Comm'n v. Akins, 524 U.S. 11, 25 (1998) (noting that, after remand, the agency "might later, in the exercise of its lawful discretion, reach the same result for a different reason" than the one rejected by the reviewing court); *see also Lone Mountain Processing, Inc. v. Sec'y of Labor*, 709 F.3d 1161, 1164 (D.C. Cir. 2013) ("The Commission may well arrive at the same result it reached originally, . . . but it must do so with more clarity than it showed in the first instance."). If there is a post-remand arbitrary and capricious, or otherwise invalid, final agency action that Ferring wishes to challenge, it may do so, but not through a motion to enforce the Court's prior judgment.

V. CONCLUSION

For the foregoing reasons, Ferring's Motion to Enforce Judgment (ECF No. 64) is **DENIED**. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: February 13, 2018

RUDOLPH CONTRERAS
United States District Judge