UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FERRING PHARMACEUTICALS, INC.,	:		
	:		
Plaintiff,	:	Civil Action No.:	15-0802 (RC)
	:		
v.	:	Re Document Nos.:	30, 35, 36, 37, 38,
	:		39, 40, 41, 42, 48,
SYLVIA M. BURWELL, *et al.*,	:		49, 53, 57
	:		
Defendants.	:		

MEMORANDUM OPINION

GRANTING PLAINTIFF'S MOTION FOR RECONSIDERATION; DENYING AS MOOT PAR PHARMACEUTICAL, INC.'S MOTION TO INTERVENE; DENYING AS MOOT THE PARTIES' RENEWED MOTIONS FOR SUMMARY JUDGMENT; DENYING AS MOOT PAR PHARMACEUTICAL, INC.'S MOTION FOR SUMMARY JUDGMENT; GRANTING THE PARTIES' MOTIONS TO SEAL; AND DENYING PAR PHARMACEUTICAL, INC.'S MOTION FOR A PROTECTIVE ORDER

I. INTRODUCTION

Plaintiff Ferring Pharmaceuticals, Inc. ("Ferring") is the manufacturer of PREPOPIK, a fixed-dose combination drug product that contains three drug substances: sodium picosulfate, magnesium oxide, and anhydrous citric acid. When it submitted a New Drug Application ("NDA") for PREPOPIK to the U.S. Food and Drug Administration ("the FDA"), Ferring sought a five-year period of marketing exclusivity because one of the drug substances, sodium picosulfate, had never previously been approved in a NDA. The Federal Food, Drug, and Cosmetics Act ("FDCA") provides for a five-year period of marketing exclusivity when a drug application is approved "for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application." 21 U.S.C. § 355(j)(5)(F)(ii). During that five-year period, "no application may be submitted . . . which refers to the drug for which the subsection (b) application was submitted." *Id.* Because PREPOPIK's other two active

ingredients had previously been approved for market, the FDA applied its then-existing interpretation of the FDCA and determined that PREPOPIK was not entitled to a five-year period of marketing exclusivity because the finished "drug product" included active ingredients that had previously been approved in other drug products. Ferring filed a Citizen Petition challenging the FDA's interpretation and, in response, the FDA—acknowledging the policy concerns Ferring and two other pharmaceutical companies raised regarding the agency's interpretation—concluded that the FDCA could reasonably be read to refer to "drug substances" (the individual active ingredients of the drug). The FDA announced that it would change its interpretation and permit five-year exclusivity for fixed-combination drug products that contained a novel drug substance, even if that drug product also contained other previously approved drug substances. But the FDA also concluded that it would apply its interpretation only prospectively, and declined to alter its exclusivity determination for PREPOPIK.

Ferring challenged the FDA's prior interpretation as contrary to the plain language of the FDCA, or an unreasonable interpretation of statutory ambiguity, under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). In an earlier Memorandum Opinion, the Court held that the FDA's prior interpretation was a reasonable interpretation of the FDCA's ambiguous language under *Chevron* Step Two, and that the interpretation was not arbitrary and capricious. *See Ferring Pharm., Inc. v. Burwell*, --- F. Supp. 3d ----, No. 15-0802, 2016 WL 1060199, at *7–14 (D.D.C. Mar. 15, 2016). At that time, the Court declined to reach Ferring's claim that, even if the FDA's prior interpretation was permissible, the agency's refusal to apply its new interpretation retroactively was arbitrary and capricious. *Id.* at *14–15. The Court noted that, at the administrative level, the FDA's initial response to Ferring's Citizen Petition had cited the D.C. Circuit's decision in *Retail, Wholesale & Department Store Union v.*

NLRB, 466 F.2d 380 (D.C. Cir. 1972) as support for its retroactivity conclusion. *See Ferring*, 2016 WL 1060199, at *14. The Court directed the parties to file renewed motions for summary judgment addressing that line of cases. *See id.* at *15.

The parties have now filed those renewed motions for summary judgment. In addition, Ferring has moved for reconsideration of one aspect of the Court's Memorandum Opinion. And, in the midst of briefing, Par Pharmaceutical, Inc., a company that has filed an Abbreviated New Drug Application ("ANDA") for approval to market a generic version of PREPOPIK, filed a motion to intervene and a related motion for a protective order. As explained below, the Court will grant Ferring's motion for reconsideration, deny as moot Par's motion to intervene and the parties' renewed summary judgment motions, and deny Par's motion for a protective order.

II. FACTUAL BACKGROUND

The Court previously surveyed the relevant statutory and factual background in full, and assumes familiarity with its prior Memorandum Opinion.

A. Statutory Background

The FDCA requires that all new prescription drugs be approved by the FDA before they can be marketed. *See* 21 U.S.C. § 355(a). Generally, when a pharmaceutical manufacturer submits an NDA for approval, it must support that application with full reports of clinical studies that demonstrate that the product is safe and effective. *See id.* § 355(b). In 1984, Congress enacted the Hatch-Waxman Amendments, which "created a new system for protecting both the interests of drug manufacturers who produce new drugs and the interests of generic drug manufacturers and their consumers." *Abbott Labs. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990); *see* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). The amendments simplified the approval process of generic versions of a previously

approved drug by providing for the submission of two new types of drug applications. In one, called an Abbreviated New Drug Application ("ANDA"), a pharmaceutical manufacturer may rely on the FDA's finding that a previously approved drug—referred to as the "listed drug"—is safe and effective, so long as the applicant can demonstrate that the proposed generic drug is the "same as" the reference listed drug in several essential respects. *See generally* 21 U.S.C. § 355(j)(2)(A). In the other, called a "505(b)(2) application," a pharmaceutical manufacturer may rely on investigations that "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" to show that the drug is safe and effective. *Id.* § 355(b)(2).

Notwithstanding the availability of these less onerous approval avenues, Congress also put in place incentives to promote the development of new drugs. As relevant to this case, the Hatch-Waxman Amendments established a five-year marketing exclusivity period for certain types of drugs, protecting a manufacturer from the submission of an ANDA or 505(b)(2) application and, thus, from generic competition. As amended, the FDCA provides that:

> If an application submitted under subsection (b) of this section [21 U.S.C. § 355(b)] for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection [concerning ANDAs] which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section . . . .

Id. § 355(j)(5)(F)(ii); *see id.* § 355(c)(3)(E)(ii) (parallel provision providing the same five-year exclusivity period to prevent the filing of a 505(b)(2) application).

Even if a drug is not eligible for a five-year period of marketing exclusivity, the Hatch-Waxman Amendments provide for a shorter, three-year period of exclusivity for certain changes to previously approved drugs. If an applicant submits one or more new clinical studies in

support of a change in the conditions of an approved drug's use, the FDCA confers a three-year period of marketing exclusivity, so long as the FDA considers those studies to have been essential to the agency's approval of the change. 21 U.S.C. § 355(j)(5)(F)(iii); *see also id.* § 355(c)(3)(E)(iii). Unlike the five-year exclusivity provision, which prohibits the FDA from even *accepting* an application during the exclusivity period, the three-year exclusivity provision only precludes the FDA from making a new ANDA or 505(b)(2) application *effective* before the end of the three-year period. *Compare id.* § 355(j)(5)(F)(ii), *with id.* § 355(j)(5)(F)(iii).

The two clauses of the five-year exclusivity provision relevant to this case are what the parties refer to as the "eligibility" and the "bar" clauses. *See* A.R. at 203, ECF No. 26-4; Pl.'s Mem. Supp. Summ. J. at 13 ("Pl.'s Mem. Supp."), ECF No. 20-1. The "eligibility clause" describes whether a drug is eligible for five-year exclusivity. To be eligible, a drug must be "a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of [§ 355]." 21 U.S.C. § 355(j)(5)(F)(ii). If a drug meets that requirement, it will bar the types of ANDAs or 505(b)(2) applications identified in the "bar clause." Specifically, "no application may be submitted . . . which *refers to the drug for which the subsection (b) application was submitted* before the expiration of five years from the date of the approval of the application." *Id.* (emphasis added).

The meaning of the word "drug" as used in the five-year exclusivity provision (or the other exclusivity provisions, for that matter) is not defined in section 355. Until recently, the FDA read the term "drug" in the "eligibility clause" to refer to a finished "drug product"—that is, "a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." 21 C.F.R. § 314.3(b). The FDA codified its interpretation of the five-year exclusivity provision

in 21 C.F.R. § 314.108, proposed in 1989 and finalized in 1994.[1] *See* Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872 (July 10, 1989) [hereinafter "Proposed Rule"]; *see also* Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338 (Oct. 3, 1994) [hereinafter "Final Rule"].

At the time it promulgated the regulation, however, the FDA acknowledged that the statute posed a potential problem for the exclusivity holder, and that the Act "is ambiguous as to which ANDA[s] or 505(b)(2) applications are affected by an innovator's exclusivity." Proposed Rule, 54 Fed. Reg. at 28,897. Specifically, under a narrow interpretation of the "bar clause," in which the "protection offered by exclusivity is that exclusivity covers only specific drug products . . . , an innovator's exclusivity could lose its value as soon as FDA approved a second full new drug application for a version of the drug." *Id.* That is because "an ANDA could be approved by reference to the *second approved version of the drug*"—a separate drug product—"which would not be covered by exclusivity." *Id.* (emphasis added). Thus, "[d]epending upon the meaning of the phrase 'refer to' and the word 'drug,'" the FDA was concerned that the five-year exclusivity provision and the other exclusivity provisions in the Hatch-Waxman Amendments "could be interpreted to allow ANDA[s] and 505(b)(2) applicants, once FDA approved subsequent new drug applications for different versions of the same drug, to

[1] The regulation provides that:

> If a drug product that contains a new chemical entity was approved after September 24, 1984, in an application submitted under section 505(b) of the act, no person may submit a 505(b)(2) application or abbreviated new drug application under section 505(j) of the act 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 new drug application . . . .

21 C.F.R. § 314.108(b)(2).

circumvent the innovator's exclusivity by 'referring to' the subsequent versions of the innovator's drug." *Id.*

By contrast, FDA noted that a possible "broader interpretation" of the bar clause "is that it covers the active moieties in new chemical entities . . . rather than covering only specific drug products," which "would protect the new active moiety of a new chemical entity . . . from generic competition even after FDA had approved subsequent full new drug applications for subsequent versions of the drug."[2] *Id.* Because the FDA did not "believe that Congress intended the exclusivity provisions to discourage innovators from making improvements in their drug products nor from authorizing the marketing of competitive products," the FDA concluded that the "broader interpretation of the scope of exclusivity should be applied." *Id.* The FDA has coined this interpretation its "umbrella policy," which it describes as providing that "5-year NCE [new chemical entity] exclusivity does not attach only to the first approved drug product that was eligible for 5-year NCE exclusivity, but also to the line of products containing the same active moiety." A.R. at 206. And, although it is not quite spelled out in the proposed rule's preamble, the FDA now acknowledges that its umbrella policy resulted from the agency's interpretation of "drug" in the bar clause to mean "drug substance." *Id.* at 225. A "[d]rug substance" is defined in relevant part as "an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body." 21 C.F.R. § 314.3(b).

[2] An active moiety is defined as "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. § 314.108(a).

Taken together, then, prior to 2014, the FDA interpreted the five-year exclusivity provision to provide that only *drug products* containing no previously approved drug substances were eligible for exclusivity. Once eligible, however, the FDA interpreted the bar clause to bar all ANDAs and 505(b)(2) applications referencing that drug product or any later-approved products containing the product's *drug substances*, in order to preserve the innovator's exclusivity to the greatest extent possible.

B. Factual & Procedural History

Ferring's drug product PREPOPIK is intended for use in cleansing the colon in preparation for colonoscopy in adults. Compl. ¶ 32, ECF No. 2. PREPOPIK is a fixed-dose combination drug product. *Id.* Fixed-dose combination drug products "generally include two or more drug substances (active ingredients) in a fixed ratio, synthetically combined in a single dosage form." A.R. at 200. PREPOPIK in fact contains three different active ingredients: sodium picosulfate, magnesium oxide, and anhydrous citric acid. *Id.* at 201; Compl. ¶ 32. Two of these ingredients, magnesium oxide and anhydrous citric acid, had previously been approved in an NDA. By contrast, sodium picosulfate, a stimulant laxative, had never previously been approved in any NDA. A.R. at 201. Because sodium picosulfate constituted a new drug substance, Ferring sought five-year exclusivity for PREPOPIK when it submitted its NDA. *See* Pl.'s Mot. Summ. J. Ex. 3 at 2, ECF No. 20-6. Ferring alleges that it was unable to seek a NDA for sodium picosulfate as a single-ingredient drug product because picosulfate's therapeutic benefit is realized only in combination with the other active ingredients. A.R. at 70, ECF No. 26-2. Ferring points out that the FDA did not require factorial studies—which are employed to evaluate the contribution of each of a drug product's individual substances to the drug's overall efficacy—because of "serious ethical concerns" that "each component as a stand alone

would result in inadequate colon cleansing for colonoscopy." Pl.'s Mot. Summ. J. Ex. 2 at 40, ECF No. 20-5; A.R. at 70.

The FDA approved Ferring's NDA for PREPOPIK on July 16, 2012, *see* Compl. ¶ 33; A.R. at 201, but, consistent with its interpretation of the five-year exclusivity provision, the FDA only awarded Ferring three-year exclusivity because the drug product contained two active moieties (magnesium oxide and anhydrous citric acid) that had previously been approved. *See* Pl.'s Mot. Summ. J. Ex. 3 at 3; A.R. at 201. Ferring submitted a Citizen Petition on January 29, 2013 requesting that the FDA change its exclusivity determination. A.R. at 64. Two other pharmaceutical companies filed similar Citizen Petitions around the same time. *See generally id.* at 98–140, ECF No. 26-3; *id.* at 144–58. In short, Ferring argued that the FDA's denial of five-year exclusivity was inconsistent with Congress's intent in passing the Hatch-Waxman Amendments, as discerned from the relevant legislative history, *id.* at 70–76, and that the interpretation also conflicted with various other FDA policies, *id.* at 76–94.

On February 21, 2014, the FDA issued a single response to all three companies' Citizen Petitions. *Id.* at 199. In that response, the FDA summarized its prior interpretation of the FDCA and its own regulation. *Id.* at 207–09. Although the FDA stated that it believed its "current interpretation of the relevant statute and regulations is permissible," the agency acknowledged that "Petitioners have articulated an alternative interpretation of the relevant statute and regulations that would also be permissible," and asserted that "in either the eligibility or the bar clause, FDA may reasonably interpret 'drug' narrowly to mean 'drug product' or broadly to mean 'drug substance.'" *Id.* at 212. The agency further explained that "recent changes in drug development, particularly in the field of fixed-combination development in the last 20 years, and the importance of fixed-combinations to key therapeutic areas—such as HIV, cardiovascular

disease, tuberculosis, and cancer—warrant[ed] revising [its] current policy," particularly as "fixed-combinations containing new active moieties are becoming more prevalent in drug development." *Id.* The FDA conceded that its existing interpretation "may result in drug development strategies that are suboptimal from a public health perspective" because if sponsors "prefer to submit two NDAs"—one for a single-entity drug containing the new active moiety and another for a combination product—"undue importance" may be placed on "the order in which these two NDAs are approved." *Id.* at 213–14. Additionally, "in some situations, such a strategy may not be available if a new active moiety does not clinically lend itself to approval in a single-entity drug product." *Id.* at 214.

As a result, the FDA "agree[d] that the increasing importance of fixed-combinations for certain therapeutic areas means that it would be in the interest of public health to encourage the development of fixed-combinations as a policy matter," and determined that "[o]ne way to accomplish this goal would be to adopt a new interpretation of the relevant statutory and regulatory authorities that would encourage the development of fixed-combinations that contain novel drug substances . . . irrespective of whether the fixed-combination also includes a drug substance that contains a previously approved active moiety or moieties." *Id.* at 214. To that end, the FDA issued draft guidance and proposed to seek public comment on a new interpretation which 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." *Id.*

Despite proposing to alter its interpretation of the five-year exclusivity provision, the FDA declined to recognize five-year exclusivity for PREPOPIK and the other drugs sponsored

by the companies that had filed the Citizen Petitions. *See id.* at 216. The agency concluded that "[e]xclusivity runs from the date of approval of a product," and noted that the agency's existing interpretation had been in effect when the drugs at issue were approved. *Id.* at 215. The agency based its decision on several factors, including that its "existing interpretation of these provisions is longstanding and has been consistently applied in many prior cases presenting similar facts," that the agency wished to "avoid any unnecessary disruptions to the regulated industry," and that the new interpretation "could impose a burden on the ANDA sponsors, who relied on [the agency's] existing interpretation in filing their applications." *Id.* The agency also concluded that applying its new interpretation to the companies' drugs would not further the goals of the Hatch-Waxman Amendments because the products had "already . . . been developed and approved." *Id.*

Ferring filed a Petition for Reconsideration and Petition for Stay, arguing that the FDA's new interpretation is the correct one—indeed, the only one in line with congressional intent—and that, in any event, it was arbitrary and capricious for the agency to decline to apply its new interpretation to Ferring's products. *See id.* at 1–42. The FDA denied that petition. *See id.* at 829–42.

Ferring then initiated this APA action, alleging that the FDA's action was contrary to the FDCA and the agency's own regulations, and that its decision was arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A). *See* Compl. ¶¶ 58–71. In its prior Memorandum Opinion, the Court rejected many of these claims. The Court first held that the term "drug" as used in the FDCA was ambiguous at *Chevron* Step One. *See Ferring*, 2016 WL 1060199, at *7–9. At *Chevron* Step Two, the Court concluded that the FDA's construction of the statute was reasonable and served the FDCA's purpose, even though that interpretation read the term "drug" in the eligibility and bar clauses to have different meanings. *Id.* at *9–12. The Court similarly

rejected Ferring's argument that the interpretation was arbitrary and capricious. *Id.* at *12–14. Specifically, the Court rejected Ferring's contention that the FDA's interpretation and umbrella policy, in combination, created circumstances in which a drug substance's eligibility for the five-year exclusivity period turned arbitrarily on the order in which NDAs were approved. *Id.* at *13. The Court conceded that "[i]f there were, in fact, situations in which a drug was eligible for five-year exclusivity under the FDA's prevailing interpretation but failed to receive it because of the order in which it was approved, those circumstances might render the FDA's policy arbitrary and capricious." *Id.* But, as the Court explained, in each of the examples Ferring identified a drug substance was first approved as a single-entity product and then only later approved as part of a fixed-combination drug product—in other words, in "a straightforward application of the FDA's umbrella policy." *Id.*

Finally, the Court declined to rule on the question of whether the FDA acted arbitrarily and capriciously in refusing to apply its new interpretation retroactively. *Id.* at *14–15. The Court explained that, although the parties' memoranda cited little law on this question, at the administrative level the FDA had relied on the D.C. Circuit's decision in *Retail, Wholesale & Department Store Union v. NLRB*, 466 F.2d 380 (D.C. Cir. 1972)—a decision that the D.C. Circuit has described as "provid[ing] the framework for evaluating retroactive applications of rules announced in agency adjudications." *Ferring*, 2016 WL 1060199, at *14 (quoting *Clark-Cowlitz Joint Operating Agency v. FERC*, 826 F.2d 1074, 1081 (D.C. Cir. 1987) (en banc)). The Court therefore ordered the parties to "file renewed motions for summary judgment that more fully address the retroactivity issue." *Id.* at *15.

Ferring has since moved for reconsideration of the Court's determination that the FDA's prior interpretation of the five-year exclusivity provision was not arbitrary and capricious. *See*

Pl.'s Mot. Recons., ECF No. 39. Ferring now identifies several examples that, Ferring claims, demonstrate that a single-entity drug substance's ability to receive five-year exclusivity can turn arbitrarily on the order in which NDAs including that drug substance are approved. *See* Pl.'s Mem. Supp. Mot. Recons. at 1–3 ("Pl.'s Mem. Supp. Recons."), ECF No. 39-1. In addition, the parties have filed their renewed motions for summary judgment, analyzing whether the FDA should have applied its new interpretation of the five-year exclusivity provision retroactively to Ferring's benefit. *See generally* Defs.' Renewed Cross-Mot. Summ. J., ECF No. 37; Pl.'s Renewed Mot. Summ. J., ECF No. 38.

Since the Court issued its Memorandum Opinion, Par Pharmaceutical, Inc. ("Par") has also filed a motion to intervene.[3] *See* Par Pharmaceutical, Inc.'s Mot. Intervene ("Par's Mot. Intervene"), ECF No. 35. Par has developed and submitted an ANDA seeking FDA approval of a generic version of PREPOPIK. *Id.* at 2. Moreover, Par is a "First Applicant" for a generic version of PREPOPIK, which means that the company is eligible for a 180-day period of generic market exclusivity before the FDA would be able to approve competing generic versions of PREPOPIK. *Id.*; *see* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb). On February 20, 2015—before this lawsuit was filed—Ferring filed a patent-infringement action against Par in the United States District Court for the District of Delaware, which remains pending. *See* Complaint, *Ferring Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, No. 15-cv-00173 (D. Del. Feb. 20, 2015), ECF No. 1. Par now seeks to interve as a matter of right under Federal Rule of Civil Procedure 24(a)(2) or permissive intervention under Rule 24(b)(1)(B). *See* Par's Mot. Intervene at 1. Par

[3] As discussed *infra* in Part III.B, Par claims that its motion to intervene and other filings contain sensitive and confidential business and financial information, and thus has moved to file these documents under seal. Unless otherwise noted, the Court will cite to the redacted versions of Par's filings.

also seeks a protective order to keep confidential certain information it claims constitutes proprietary business information. *See* Movant-Intervenor Par Pharmaceuticals Inc.'s Mot. Protective Order, ECF No. 36. In addition, Par has anticipatorily filed a motion for summary judgment discussing the retroactivity question. *See generally* Par Pharmaceutical, Inc.'s Mot. Summ. J., ECF No. 41. Ferring opposes Par's motion to intervene, motion for a protective order, and motion for summary judgment.

III. ANALYSIS

A. Ferring's Motion for Reconsideration

The Court first considers Ferring's motion asking the Court to reconsider its conclusion that the FDA's prior interpretation of the five-year exclusivity provision was not arbitrary and capricious.

1. Legal Standard

A district court has "broad discretion to hear a motion for reconsideration brought under Rule 54(b)." *Isse v. Am. Univ.*, 544 F. Supp. 2d 25, 29 (D.D.C. 2008). While different jurisdictions "'apply a variety of different standards when confronted with a motion for reconsideration,' this jurisdiction has established that reconsideration is appropriate 'as justice requires.'" *Lyles v. District of Columbia*, 65 F. Supp. 3d 181, 188 (D.D.C. 2014) (citation omitted) (quoting *Cobell v. Norton*, 355 F. Supp. 2d 531, 539 (D.D.C. 2005)). "[A]sking 'what justice requires' amounts to determining, within the Court's discretion, whether reconsideration is necessary under the relevant circumstances." *Cobell*, 355 F. Supp. 2d at 539. "Considerations a court may take into account under the 'as justice requires' standard include whether the court 'patently' misunderstood the parties, made a decision beyond the adversarial issues presented, made an error in failing to consider controlling decisions or data, or whether a controlling or significant change in the law has occurred." *Isse*, 544 F. Supp. 2d at 29. In general, "a court will

grant a motion for reconsideration of an interlocutory order only when the movant demonstrates: (1) an intervening change in the law; (2) the discovery of new evidence not previously available; or (3) a clear error in the first order." *Stewart v. Panetta*, 826 F. Supp. 2d 176, 177 (D.D.C. 2001) (quoting *Zeigler v. Potter*, 555 F. Supp. 2d 126, 129 (D.D.C. 2008)).

Cobell also suggests that, because "the decision whether to reconsider its interlocutory rulings is within the Court's discretion," the Court "may nevertheless elect to grant a motion for reconsideration if there are other good reasons for doing so," even "if the appropriate legal standard does not indicate that reconsideration is warranted." 355 F. Supp. 2d at 540; *accord Isse*, 544 F. Supp. 2d at 29. The district court's discretion is limited, however, "by the law of the case doctrine and 'subject to the caveat that where litigants have once battled for the court's decision, they should neither be required, nor without good reason permitted, to battle for it again.'" *Singh v. George Wash. Univ.*, 383 F. Supp. 2d 99, 101 (D.D.C. 2005) (quoting *In re Ski Train Fire in Kaprun, Austria, on Nov. 11, 2004*, 224 F.R.D. 543, 546 (S.D.N.Y. 2004)).

In addition to showing a clear error, a change in the law, the discovery of new evidence, or another good reason to grant the motion, the party seeking reconsideration must also show that "some harm would accompany a denial of the motion to reconsider." *Isse*, 544 F. Supp. 2d at 29. For "justice to require reconsideration, logically, it must be the case that, some sort of 'injustice' will result if reconsideration is refused." *Cobell*, 355 F. Supp. 2d at 540.

2. Analysis

In its first motion for summary judgment, Ferring argued that the FDA's prior interpretation of the five-year exclusivity provision was arbitrary and capricious because, in combination with the agency's umbrella policy, it created circumstances in which a drug substance's eligibility for exclusivity turned arbitrarily on the order in which NDAs were

approved. *See* Pl.'s Mem. Supp. Summ. J. at 25–27, ECF No. 20-1. Ferring pointed to several examples in which a NDA for a single-entity version of a drug substance was approved shortly before a NDA for a fixed-combination drug product, which then was able to share in the single-entity's exclusivity period as a result of the umbrella policy. *Id.* at 25–26. Ferring hypothesized that in each such case, "if the order of the approvals had been reversed and the fixed-dose combination drug product had been approved just hours before the single-ingredient product, *none* of the products would have been awarded NCE exclusivity, because each would have contained a previously approved active ingredient." *Id.* at 26 (emphasis in original).

In order to "satisfy the arbitrary and capricious standard" an agency "must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so." *Indep. Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996). The scope of a court's "arbitrary and capricious" review "is narrow" and "a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983). To satisfy the standard, an agency "must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Id.* (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). Arguments that an agency has acted arbitrarily and capriciously and that an agency's interpretation fails *Chevron* Step Two "overlap," *Nat'l Ass'n of Broad. v. FCC*, 789 F.3d 165, 171 (D.C. Cir. 2015), and a court's analysis is "often 'the same, because under *Chevron* step two, [the court asks] whether an agency interpretation is arbitrary or capricious in substance,'" *Agape Church, Inc. v. FCC*, 738 F.3d 397, 410 (D.C. Cir. 2013) (quoting *Judulang v. Holder*, 132 S. Ct. 476, 483 n.7 (2011)).

In its prior Memorandum Opinion, the Court believed that the sequence Ferring identified was simply a necessary outgrowth of the FDA's umbrella policy: that is, manufacturers generally developed a new, novel drug substance, obtained approval of that drug substance in a single-entity version, and then sought protection under the umbrella policy for any later drug products which incorporated that novel drug substance with other, previously approved drug substances. *See Ferring*, 2016 WL 1060199, at *13. The Court noted that "[i]f there were, in fact, situations in which a drug was eligible for five-year exclusivity under the FDA's prevailing interpretation but failed to receive it because of the order in which it was approved, those circumstances might render the FDA's policy arbitrary and capricious." *Id.* But the Court explained that in each of the examples Ferring specifically raised in its memorandum, the NDA for each of the single-entity drug products was submitted well before the NDA for the relevant combination-drug product. *Id.* The Court found that this general progression—from single-entity versions to incorporation in a fixed-combination drug product—accorded with the umbrella policy's effort to ensure that innovators would not be discouraged from "making improvements in their drug products." *Id.* (quoting Proposed Rule, 54 Fed. Reg. at 28,897). Thus, it appeared to the Court that the FDA was not treating similarly situated drug substances differently and that there did not exist examples in which the temporal sequence of drug product approvals was outcome determinative. And, as the Court explained, Ferring's PREPOPIK was not an apt comparator to any drugs whose single-entity versions might have lost out on exclusivity. What distinguished PREPOPIK was not the sequence in which the NDA was approved, but that its drug substance, sodium picosulfate, could not ethically be tested (and therefore could not be approved) in a single-entity form, and thus "was never even *eligible* for five-year exclusivity under the FDA's prevailing policy." *Id.* (emphasis in original).

In its motion for reconsideration, however, Ferring now provides three examples that lead the Court to doubt the factual basis for its prior conclusion. *See* Pl.'s Mem. Supp. Recons. at 1–3. In each instance, a drug substance that had never been previously approved was included as part of a fixed-combination drug product (a fixed-combination drug product that did not receive five-year exclusivity because it contained other, previously approved drug substances). *Id.* And, in each case, a single-entity version of the drug substance was later approved, but did not receive the benefit of a five-year exclusivity period, because the drug substance had been previously approved as part of the fixed-combination product. *Id.*

Take, for example, Gilead Sciences, Inc.'s product STRIBILD. That product, approved on August 27, 2012, contains four active ingredients: elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate. A.R. at 201. When it was approved, emtricitabine and tenofovir disoproxil fumarate had previously been approved as part of other drug products, but elvitegravir and cobicistat had not. *Id.* For that reason, STRIBLID, like PREPOPIK, did not receive a five-year period of marketing exclusivity. *Id.* at 216. Yet, unlike PREPOPIK's sodium picosulfate, elvitegravir and cobicistat could safely be used in single-entity forms. On September 24, 2014—over two years after STRIBLID had been approved—those drug products were each approved in a single-entity form.[4] But because elvitegravir and cobicistat had already been approved as part of

[4] *See* NDA Approval Letter from Debra Birnkrant, MD, Dir., Div. of Antiviral Prods., Ctr. for Drug Evaluation & Research, to Christophe Beraud, PhD, Gilead Sciences, Inc. (Sept. 24, 2014) (approving elvitegravir under brand name VITEKTA), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/203093Orig1s000ltr.pdf; NDA Approval Letter from Debra Birnkrant, MD, Dir., Div. of Antiviral Prods., Ctr. for Drug Evaluation & Research, to Christophe Beraud, PhD, Gilead Sciences, Inc. (Sept. 24, 2014) (approving cobicistat under brand-name TYBOST), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/203094Orig2s000ltr.pdf.

STRIBLID, those drugs did not receive a five-year period of marketing exclusivity.[5] A second example is similar: Organon USA's product NuvaRing contains the active ingredients ethinyl estradiol and etonogestrel, only the former of which had previously been approved in another product.[6] When a single-entity version of etonogestrel was approved in July 2006, it did not receive a five-year period of marketing exclusivity as a direct result of the approval of NuvaRing.[7] In both of these cases, the single-entity version of a drug substance, which was approved second, lost out on a period of five-year exclusivity solely because that drug substance had first been approved as part of a fixed-combination product.

These newly highlighted examples now show that, even if the FDA's prior interpretation is reasonable under *Chevron* Step Two from a conceptual standpoint, that interpretation produces circumstances that fail to treat "similar cases in a similar manner." *Indep. Petroleum Ass'n of Am.*, 92 F.3d at 1258. Indeed, this case is not unlike *Abbott Laboratories v. Young*, 920 F.2d 984

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[5] *See* Exclusivity Summary for NDA 203093 at 2 (denying five-year exclusivity for single-entity product VITEKTA [elvitegravir] because the drug substance was contained in STRIBLID), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/203093Orig1s000AdminCorres.pdf (page 3 of PDF document); Exclusivity Summary for NDA 203094 at 2–3 (denying five-year exclusivity for single-entity product TYBOST [cobicistat] because the drug substance was contained NDA 203100 [for STRIBLID]), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/203094Orig1Orig2s000AdminCorres.pdf (pages 3–4 of PDF document); *see also* U.S. Dep't of Health & Human Servs., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* at ADA 65 (36th ed. 2016) (listing exclusivity period for VITEKTA ending September 24, 2017—three years after approval), *available at* http://www.fda.gov/downloads/drugs/developmentapprovalprocess/ucm071436.pdf; *id.* at ADA 41 (same for TYBOST).

[6] *See* NDA Approval Letter from Florence Houn, MD, MPH, FACP, Dir., Office of Drug Evaluation III, Ctr. for Drug Evaluation & Research, to Edwina Muir, Organon, Inc. (approving NuvaRing, containing active ingredients etonogestrel and ethinyl estradiol), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2001/21187ltr.pdf.

[7] *See* Exclusivity Summary for NDA 21-529 at 2–3 (denying five-year exclusivity for single-entity etonogestrel product because the drug substance was contained in NuvaRing), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021529s000_AdminCorres.pdf.

(D.C. Cir. 1990). There, the D.C. Circuit considered a related provision of the Hatch-Waxman Amendments' exclusivity provisions which makes a drug eligible for exclusivity only if it has "no active ingredient (including any ester or salt of the active ingredient) . . . which has been approved in any other [NDA]." *Id.* at 986 (alteration in original) (quoting then-current 21 U.S.C. § 355(j)(4)(D)(i)). In that case, Abbott Labs sought approval of a drug the active ingredient of which was a salt form of a previously approved active ingredient. *See id.* at 986. The D.C. Circuit was faced with interpreting the term "active ingredient," among others, to determine whether Abbott's second application—for the salt form of a previously approved active ingredient—should receive a period of exclusivity. *See id.* at 987–89.

After rejecting the government's proffered interpretation, *see id.* at 988, the circuit also rejected the interpretation Abbott Labs urged, which focused on active ingredient in the *second-approved* application, alone, *see id.* at 988–89. Abbott Labs asserted that because the salt form had not yet been approved (nor had an ester or salt *of that salt*), the active ingredient was eligible for an exclusivity period. As the circuit explained, that reading would mean that a drug with a salt as its active ingredient would be eligible for a period of exclusivity (because neither the salt itself, nor an ester or salt-form of that salt would have been previously approved as an active ingredient), notwithstanding the fact that the active ingredient was, itself, *a salt of* a previously approved drug. *Id.* at 989. By contrast, if the order of approvals was switched—that is, if the salt-form was approved before its non-salt form—the second application for the non-salt form would *not* receive exclusivity because a salt of that active ingredient *had been* approved previously. *Id.* Thus, it appeared to the circuit that under Abbott Labs' interpretation a drug's eligibility for an exclusivity period depended on the "entirely serendipitous" incident of whether the salt- or non-salt form of an active ingredient was approved first. *Id.* And the circuit pointed

out that it had "not been offered *any* scientific, technical, economic, or other explanation why Congress would intend the grant of a ten year market exclusivity to depend on the temporal sequence in which . . . applications were approved." *Id.* (emphasis in original).

The temporal sequence in which drug applications are approved is similarly outcome determinative here: under the FDA's prior interpretation certain drug substances lost out on a five-year period of marketing exclusivity solely because they had been first approved as part of a fixed-combination drug product. To resist this conclusion, the FDA focuses on the *fixed-combination* products in Ferring's examples, arguing that the fixed-combination products were never, themselves, eligible for exclusivity on their own because they contained other, previously approved drug substances. *See* Defs.' Opp'n to Pl.'s Mot. Recons. at 2 ("Defs.' Opp'n"), ECF No. 44. The FDA rightly points out that those drug products could only share in an exclusivity period as a result of the umbrella policy. *Id.* Yet, the FDA overlooks the *single-entity* drug products in each of Ferring's examples. Those products *would* have been eligible for a five-year period of marketing exclusivity had they been approved before the fixed-combination product. Those drug substances are the proper comparators when determining whether similar cases are treated in a similar manner. In fact, the FDA concedes that the exclusivity determination for the single-entity products might have changed depending on the order in which the drug products were approved. *See* Defs.' Opp'n at 3 ("If the manufacturers in question had sought approval for the single-ingredient products before seeking approval for the fixed-combination products, the agency's exclusivity determination might have been different."). The relevant point is that certain drug substances received a five-year period of marketing exclusivity—in which later fixed-combination drug products that included those drug substances were able to share, as a

consequence of the umbrella policy—while others were denied the same marketing exclusivity period because a fixed-combination drug product was approved first.

And the FDA fails to provide a "legitimate reason" for treating those drug substances differently from ones that were first approved in their single-entity forms. *Indep. Petroleum Ass'n of Am.*, 92 F.3d at 1258. If a drug substance is sufficiently novel to warrant protection under a five-year exclusivity period—and sufficiently novel that other products containing that drug substance should also be protected through the umbrella policy—it is not apparent why timing, or the order in which the drugs were approved, should alter that assessment. Indeed, in its response to Ferring's Citizen Petition, the FDA acknowledged that its prior interpretation "may place undue importance on the order in which . . . two NDAs are approved." A.R. at 213–14. So far as the FDA points out in its briefing here, the agency did not otherwise attempt to justify this temporal distinction. The FDA's response in opposition to Ferring's motion—to the extent it does not constitute a *post hoc* rationalization—is similarly unconvincing. The agency asserts that the "different outcomes" are "simply . . . the result of FDA applying its then-current interpretation." Defs.' Opp'n at 3. That reasoning is wholly circular, however, and the FDA fails to substantively *justify* those differing outcomes with a legitimate reason that would serve Congress's purpose in enacting the exclusivity period.

Ultimately, like in *Abbott Laboratories*, the FDA has failed to "offer[] *any* scientific, technical, economic, or other explanation [for] why Congress would intend the grant of . . . market exclusivity to depend on the temporal sequence in which . . . applications were approved." 920 F.2d at 989 (emphasis in original). Thus, the FDA's prior interpretation was arbitrary and capricious. Consequently, the Court finds that there is good reason to correct a clear error in its prior opinion, that Ferring would be harmed by the Court's failure to do so, and that Ferring's

motion for summary judgment should have been granted. *See Isse*, 544 F. Supp. 2d at 29. In light of the Court's conclusion, it will remand this action to the FDA for further proceedings not inconsistent with this opinion. *See Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) (explaining that "the proper course, except in rare circumstances, is to remand to the agency"); *see also Amerijet Int'l, Inc. v. Pistole*, 753 F.3d 1343, 1353 (D.C. Cir. 2014) (noting that remand is the "usual remedy"); *cf. Council for Urological Interests v. Burwell*, 790 F.3d 212, 223–24 (D.C. Cir. 2015) (remanding to agency in light of conclusion that interpretation failed at *Chevron* Step Two).

B. The Remaining Motions

In light of the Court's determination that the FDA's prevailing interpretation of the five-year exclusivity provision was arbitrary and capricious at the time it denied Ferring's request for exclusivity, the Court need not consider Ferring's alternative argument that the agency erred in failing to apply its new interpretation retroactively. This conclusion also moots Par's motion to intervene. Par seeks to intervene "solely for the purpose of submitting a motion for summary judgment directed to the retroactivity issue, and to reserve its right to appeal the final decision of this Court." *See* Par's Mot. to Intervene at 12. Now that it is unnecessary to reach that retroactivity issue, Par's motion will be denied as moot.

Par's motion to intervene and its anticipatory motion for summary judgment did include material that Par contends is confidential business and financial information. For that reason, Par filed a motion for a protective order, and sought to seal each of its filings.[8] *See* Movant-Intervenor

[8] Par also filed redacted versions of these filings. *See, e.g.*, ECF Nos. 35, 40. Ferring filed its own responses under seal, out of an abundance of caution, although Ferring disputes that the material is confidential, *see, e.g.*, ECF Nos. 42, 48, and has also filed redacted versions of these filings, *see, e.g.*, ECF Nos. 43, 52.

Par Pharmaceutical, Inc.'s Mot. Protective Order, ECF No. 36; *see also, e.g.*, Movant-Intervenor Par Pharmaceutical, Inc.'s Mot. File Under Seal, ECF No. 30. Some of the information, including Par's discussion of the resources it expended developing and submitting its ANDA for a generic version of PREPOPIK, is quite general. In addition, in other instances Par has not redacted information that seemingly discloses some of the information it claims is confidential. The Court therefore questions whether all of the information Par seeks to seal, or protect through its proposed Protective Order, is confidential. Nevertheless, the Court has reviewed the sealed material and some of it is undoubtedly confidential, proprietary information. Moreover, because the Court does not reach the retroactivity issue—and therefore does not discuss or rely on any of the information Par provides—the need for public access to the information is at a minimum. Ferring also had access to the information and was able to respond to it in its now-mooted briefing. Therefore, at this time the Court will grant the parties' motions to seal.[9] *See, e.g.*, *United States v. Hubbard*, 650 F.2d 293, 318 (D.C. Cir. 1980) (setting forth various factors a court should consider in sealing material and noting, in particular, that unsealing was not warranted where "[n]one of the documents at issue . . . was either used in the examination of witnesses during the protracted public hearing . . . or specifically referred to in the trial judge's public decision . . . or included as part of the publicly available stipulated record").

As for the Protective Order, Ferring raised initial concerns that the proposed order, as written, restricted access to the confidential material only to counsel of record listed in this action—and to the exclusion of Ferring's patent counsel in the Delaware patent action and other

[9] If this case were to return to this Court for a determination on the retroactivity question following appeal, the Court would reconsider whether narrower, tailored redactions are necessary to ensure the utmost public access to information relevant to the Court's decision in this case.

attorneys assisting counsel of record in this case. *See* Pl.'s Mem. Opp'n Par's Mot. Protective Order & Mots. Seal at 2, ECF No. 43. Ferring argued that it could not effectively respond to Par's factual contentions—particularly regarding this case's impact on the pending patent action—without assistance from those attorneys. *Id.* Par has now clarified that it seeks only to restrict the *use* of the information disclosed in this action in the patent action, or other venues beyond this case. *See* Par Pharmaceutical, Inc.'s Reply Supp. Par's Mot. Protective Order at 1 ("Par's Reply Supp. Protective Order"), ECF No. 56; *see also* ECF No. 54 at 3 (reproducing letter from Par's counsel explaining that "Par's concern centers around *use* of its confidential information, particularly in the patent case" (emphasis in original)). Par has also permitted Ferring's patent counsel and other attorneys to access the materials for purposes of responding to its filings in this case. *See* Par's Reply Supp. Protective Order at 2–3; *see also* ECF No. 54 at 2 ("Par agrees that all of the Hogan Lovells attorneys working on this lawsuit can have immediate access to Par's sealed filings as if these attorneys are 'counsel of record' under Paragraph 5(a) of the Proposed Protective Order."); *id.* at 3 ("Par will not object to Womble Carlyle's [Ferring's patent counsel] access to Par's sealed filings as if those attorneys are 'counsel of record' under Paragraph 5(a) of the Proposed Protective Order . . . .").

Thus, for purposes of this case the bell cannot be unrung. Par filed the information it thought relevant, without knowing whether the Court would grant Par's Protective Order, and granted access to Ferring's patent counsel for purposes of responding to Par's arguments. Presumably, Par concluded that it was in its strategic interest to share that information. It is not this Court's obligation to police any potential improper use of the information in a separate civil action outside of this district. To the extent the information has been ruled irrelevant to the Delaware patent action, and Ferring attempts to use the information in that case, it is up to the

district judge there to decide whether to exclude it. For that reason, the Court finds a Protective Order unwarranted in this case and will deny Par's motion.

IV. CONCLUSION

For the foregoing reasons, Ferring's motion for reconsideration (ECF No. 39) is **GRANTED**, Par's motion to intervene (ECF Nos. 30, 35) is **DENIED AS MOOT**, Ferring and the FDA's respective renewed motions for summary judgment (ECF Nos. 37, 38) are **DENIED AS MOOT**, Par's motion for summary judgment (ECF No. 40, 41) is **DENIED AS MOOT**, the parties' motions to seal (ECF Nos. 42, 48, 49, 53, 57) are **GRANTED**, and Par's motion for a protective order (ECF No. 36) is **DENIED**. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: September 9, 2016

RUDOLPH CONTRERAS
United States District Judge