IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FERRING PHARMACEUTICALS INC., Plaintiff, v. THOMAS E. PRICE, M.D., in his official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and SCOTT GOTTLIEB, M.D., in his official capacity as COMMISSIONER OF FOOD AND DRUG ADMINISTRATION, Defendants.	Supplemental to Civil Action No. 1:15-cv-802 (RC) **ORAL HEARING REQUESTED**

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF FERRING PHARMACEUTICALS INC.'S MOTION TO ENFORCE JUDGMENT

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FDA has changed its legal positions early and often in this drawn-out affair. But the agency throughout *has* consistently maintained two critical points: that picosulfate is the active moiety in sodium picosulfate (one of the three active ingredients in Ferring's Prepopik), and that neither sodium picosulfate nor its active moiety has ever previously been approved by FDA. For nearly eight years of administrative proceedings and litigation, no one—not this Court, not Ferring, and certainly not FDA—ever disputed that Prepopik contained a novel active ingredient. Until last month.

As this Court will remember, the question in this case is whether Prepopik was eligible for five-year new chemical entity (NCE) exclusivity based on its new active ingredient, sodium picosulfate, notwithstanding the presence of two other active ingredients (magnesium oxide and anhydrous citric acid) that were not novel. FDA originally had denied Ferring's request for exclusivity, on the ground that NCE exclusivity was not warranted unless *all* of the active ingredients in a drug product are novel. And although FDA changed its position after Ferring petitioned the agency, it refused to apply its new interpretation to Prepopik, on the ground that new agency policies should not be applied retroactively to drugs approved before the new policy was announced.

This Court found FDA's original interpretation of the NCE exclusivity statute to be arbitrary and capricious, and entered an order remanding to the agency "for further proceedings consistent with the Court's memorandum opinion." D.E. 59. That order took effect in March, after FDA pursued, but then withdrew, an appeal to the D.C. Circuit.

On remand, however, FDA performed its most elaborate flip-flop yet. Although the agency expressly relied on this Court's order to grant NCE exclusivity to several other applicants

who had suffered from the agency's arbitrary interpretation,[1] the agency yet again withheld NCE exclusivity from Prepopik—by reversing course on its longstanding position about the identity of the active moiety in sodium picosulfate. And in sharp contrast to the position it took on retroactivity in the first administrative proceeding and before this Court, FDA decided to apply *this* new policy retroactively to Prepopik, even though it had been approved years earlier.

That sudden reversal is not just an unreasoned break with past practice. It also creates an end-run around this Court's order.

I. FACTUAL AND PROCEDURAL HISTORY

As this Court will recall from our prior briefing, the NCE statute provides that if a drug contains an "active ingredient (including any ester or salt of the active ingredient)" that has not previously been approved, the drug product is entitled to NCE exclusivity. 21 U.S.C. § 355(j)(5)(F)(ii). FDA's regulations simplify this long statutory phrase into the more efficient term "active moiety." *See* 21 C.F.R. § 314.108(b)(2); *see also* id. § 314.108(a) (defining "active moiety" 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 … of the molecule, responsible for the physiological or pharmacological action of the drug substance.").

[1] On the same day that FDA denied exclusivity to Prepopik, it granted NCE exclusivity to four other similarly-situated products: Pfizer's Duavee, Gilead's Stribild, and GlaxoSmithKline's Breo Ellipta and Anoro Ellipta. Subsequent letter decisions memorializing these decisions expressly cite this Court's opinion as the basis for doing so. *See, e.g.*, FDA, Letter Regarding Docket No. FDA-2016-P-3082 (June 9, 2017) ("To minimize the possibility of further legal challenge, the Agency has determined that, consistent with the holding in *Ferring Pharmaceuticals*, Duavee is eligible for 5-year NCE exclusivity…."), *available at* https://www.regulations.gov/document?D=FDA-2016-P-3082-0026. Even so, FDA stated that the agency's "decision not to appeal should not be construed to mean that the Agency agrees with the District Court's analysis or reasoning." FDA, Letter Regarding Docket No. FDA-2017-P-1278 (June 26, 2017), *available at* https://www.regulations.gov/document?D=FDA-2017-P-1278-0003.

Throughout the drug approval process, throughout the NCE exclusivity citizen petition process, and throughout this lawsuit, FDA consistently took the position that the active moiety in sodium picosulfate was picosulfate, and that picosulfate had never previously been approved. Indeed, as early as 2009, before Ferring even submitted its New Drug Application (NDA), FDA described sodium picosulfate as a new molecular entity (NME). Ex. A at 5. As with NCEs, an NME designation is reserved for drugs containing an active moiety that has not previously been approved. *See* FDA, *Drugs@FDA Glossary* (an NME is "an active ingredient that contains no active moiety that has been previously approved by [FDA] in an [NDA] or has been previously marketed as a drug in the United States.").[2]

Two years later, in 2011, when Ferring submitted its NDA, FDA formally classified the Prepopik NDA as "Type 1 – New Molecular Entity." *See* FDA, *Drugs@FDA FDA Approved Drug Products: Preopoik (NDA 202535)*.[3] FDA confirmed Prepopik's NME classification in the public Drugs@FDA database following approval of Ferring's NDA in July 2012.[4] And to this day, Prepopik remains listed as a new molecular entity in that database.

FDA's determination that picosulfate is the active moiety of sodium picosulfate was not limited to the NME context. Throughout its consideration of Ferring's NCE request, FDA repeatedly took the position that the active moiety of sodium picosulfate was picosulfate, and that picosulfate was a novel active moiety. D.E. 21 Ex. A at 3. FDA continued to take that position throughout this lawsuit. *See* D.E. 21 at 9, 22. Those repeated representations unsurprisingly led the Court to adopt that finding in its final Opinion. D.E. 60 at 8 ("sodium

[2] *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=glossary.page (last visited July 14, 2017).
[3] *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process (last visited July 14, 2017).
[4] *See id.*

picosulfate, a stimulant laxative, had never previously been approved in any NDA."). That position was critical to the Court's resolution of the case: If sodium picosulfate were *not* in fact a novel active ingredient, meaning that it contained no previously approved active moiety, Ferring's bid for NCE exclusivity would have been doomed from the start, and there would have been nothing arbitrary about FDA's denial of exclusivity.

FDA initially appealed this Court's decision. D.E. 61. Before its opening brief was due, however, FDA voluntarily dismissed its appeal without explanation. D.E. 63-1. That resulted in a remand to the agency, pursuant to this Court's order. D.E. 59.

On remand, FDA suddenly, and radically, changed its tune. On April 5, 2017, Ferring received a brief letter from a Supervisor for the Orange Book Staff at FDA stating that upon "further review," the active moiety of sodium picosulfate appeared to be bis-(p-hydroxyphenyl)-pyridyl-2-methane (BPHM), which was also the active moiety in another previously approved drug product. Ex. B at 2. The letter continued: "Based on the foregoing, it appears that Prepopik does not contain any active ingredient which contains no previously approved active moiety." *Id.* FDA gave Ferring fourteen days to respond with any arguments it wished to make before the Agency "finalizes its remand decision." *Id.*

Ferring responded on April 19, pointing out that FDA's newfound position regarding sodium picosulfate's active moiety was a dramatic reversal of an essential premise of FDA's nearly decade-long treatment of Prepopik, both at the agency level and in the courts. Ex. C at 1–2. Ferring noted that the time for a new chemical analysis of picosulfate had long passed. *Id.* at 2. Ferring also noted that FDA had long recognized picosulfate to be the active moiety of sodium picosulfate, and that FDA had recognized sodium picosulfate to be a novel active ingredient, both in the context of its NME decision for Prepopik and in the context of the NCE

exclusivity dispute. Ferring also observed that, in order to reach its new position, FDA appeared to be staking out a new position regarding what constitutes an "ester" as that term is used in the NCE exclusivity statute. Specifically, FDA appeared to be suggesting that an "ester" for NCE exclusivity purposes could be a sulfur-based structure. Ferring pointed out to FDA that the agency had never previously taken this position. Ferring requested that the agency finalize the award of NCE exclusivity, in keeping with the scope of the remand order. *Id*. at 3, 9.

FDA responded to Ferring's letter on June 9. Ex. D. In its response, FDA acknowledged that it had previously "determined that sodium picosulfate was a new molecular entity (NME)." *Id.* at 7. But FDA circularly asserted that, "[d]espite the Agency's prior statements that sodium picosulfate was an NME and an NCE, it is now evident that those statements were incorrect because this drug substance contained a previously approved active moiety when it was approved in Prepopik." *Id.* at 8. To reach that conclusion, FDA took the position Ferring surmised it would: that the term "ester" as used in the NCE exclusivity statute could be interpreted to include a functional group containing a central *sulfur* atom rather than the usual carbon atom. *Id*.

FDA purported to refute Ferring's assertion that the agency had never previously identified an "ester" for purposes of the NCE exclusivity statute based on the existence of a functional group with a central sulfur atom. *Id.* However, the agency was unable to provide any examples of NCE exclusivity decisions that turned on the presence of a so-called "sulfur ester" in the drug product itself. The only two examples FDA could muster of the agency's recognition of sulfur-containing esters are not relevant to the interpretation of the NCE exclusivity statute. First, both products were approved before the enactment of the NCE exclusivity statute (and therefore had no bearing on the agency's interpretation of "ester" in that statute). And second,

both examples involved purported "esters" that were formed in the body after ingestion of the drug product—not present in the drug product itself. *Id.* at 8 n.37.

On this flimsy basis, FDA denied NCE exclusivity to Prepopik—again.

II. ARGUMENT

FDA's decision on remand violates both the letter and spirit of this Court's Order, necessitating this motion.

"A motion to enforce judgment is the usual method for requesting a court to interpret its own judgment. . . . Courts grant motions to enforce judgments when a prevailing plaintiff demonstrates that a defendant has not complied with a judgment entered against it." *Heartland Hosp. v. Thompson*, 328 F. Supp. 2d 8, 11 (D.D.C. 2004), *aff'd sub nom. Heartland Reg'l Med. Ctr. v. Leavitt*, 415 F.3d 24 (D.C. Cir. 2005); *see also Mass. Union of Pub. Hous. Tenants, Inc. v. Pierce*, No. 78-1895, 1983 WL 150 (D.D.C. Oct. 19, 1983) (noting that district courts have ancillary jurisdiction to enforce and protect judicial decrees).

Here, FDA's actions on remand directly contravene the central premise upon which this Court's judgment rested: that sodium picosulfate contained an active moiety (picosulfate) that had never been previously approved. D.E. 60 at 8. The 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. By changing its position on this critical issue after the agency lost this case, and after both this Court and Ferring relied on the agency's original position, FDA has run afoul of both the law of the case doctrine and judicial estoppel principles. FDA's ill-considered decision also constitutes retroactive rulemaking, violates Ferring's due process rights, and constitutes arbitrary and capricious agency decisionmaking in violation of the APA.

A. FDA's Decision Violates Core Principles of the Law of the Case Doctrine and Judicial Estoppel.

FDA's unexpected about-face on remand implicates two related legal doctrines: law of the case and judicial estoppel.

Law of the Case. The law of the case doctrine provides that "a court should not reopen issues decided in earlier stages of the same litigation." *Agostini v. Felton*, 521 U.S. 203, 236 (1997). That doctrine, which is invoked at the Court's discretion, is based on the fundamental rule-of-law commitment that "the *same* issue presented a second time in the *same case* in the *same court* should lead to the *same result*." *See LaShawn A. v. Barry*, 87 F.3d 1389, 1393 (D.C. Cir. 1996) (en banc) (emphasis in the original). That is, the doctrine serves "to maintain consistency and avoid reconsideration of matters once decided during the course of a single continuing lawsuit." 18B Charles Alan Wright *et al.*, Federal Practice & Procedure Jurisprudence § 4478 (2d ed. 2017). "The 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). And the doctrine binds administrative agencies' actions on remand in the same fashion as a decision of a court of appeals binds a trial court. *See* Wright, *supra* § 4478.3 ("An administrative agency is bound by the mandate of a reviewing court much as a lower court is bound by the mandate of a higher court."); *Atl. City Elec. Co. v. FERC*, 329 F.3d 856, 858–859 (D.C. Cir. 2003) (per curiam) ("The holding of our opinion [delineating FERC's authority on remand] was plain. . . . Lest there be any doubt, we so hold once more.").

The principles underlying the law of the case doctrine point in only one direction here: 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. If

allowed to stand, FDA's actions would undermine the clear thrust of this Court's order instructing FDA to take "further proceedings *consistent with the Court's memorandum opinion*," D.E. 59 (emphasis added). That order rested on the shared understanding that "sodium picosulfate, a stimulant laxative, had never previously been approved in any NDA." D.E. 60 at 8.[5] And that shared understanding—which FDA never wavered from during its years-long review process—was not some idle afterthought. The novelty of sodium picosulfate was the key prerequisite for Prepopik to warrant NCE exclusivity. FDA was thus required on remand to conduct itself "consistent with the Court's memorandum opinion"—not contrary to it. FDA was not entitled simply to change its mind about the active moiety of sodium picosulfate on remand.

Judicial Estoppel. FDA's decision also implicates basic judicial estoppel principles. That doctrine "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." *Moses v. Howard Univ. Hosp.*, 567 F. Supp. 2d 62, 66 (D.D.C. 2008), *amended*, 601 F. Supp. 2d 1 (D.D.C. 2009), *and aff'd*, 606 F.3d 789 (D.C. Cir. 2010). Judicial estoppel rests on the commonsense notion that a litigant cannot induce a court or another party to accept one legal position and then jettison that position later, for tactical advantage. As the Supreme Court described it in *New Hampshire v. Maine*, "where 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." 532 U.S. 742, 749 (2001).

While judicial estoppel is often applied in the context of two different proceedings, the

[5] By referring to the novelty of the active ingredient "sodium picosulfate," the Court's decision was predicated on the fact that sodium picosulfate's active moiety, picosulfate, had not previously been approved.

doctrine also can be applied to different *phases* of the same lawsuit. *See Intellivision v. Microsoft Corp.*, 484 F. App'x 616, 620 (2d Cir. 2012) ("Hoffman argues that the doctrine of judicial estoppel requires that a party's prior representation be adopted by a *different* court in a '*prior separate proceeding*,' rather than by the same court in an earlier phase of the same proceeding. However, the Supreme Court has recognized that no such requirement exists."); *see also New Hampshire*, 532 U.S. at 749 (observing that judicial estoppel "generally prevents a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase") (quoting *Pegram v. Herdrich*, 530 U.S. 211, 228 n.8 (2000)).

Though there are no "inflexible prerequisites or an exhaustive formula for determining the applicability of judicial estoppel," courts "typically" look to the following three factors, among other context-specific considerations, when deciding whether to apply that doctrine: (1) whether "a party's later position" is "'clearly inconsistent' with its earlier position," (2) "whether the party has succeeded in persuading a court to accept that party's earlier position," and (3) "whether 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 750–751. Judicial estoppel applies to both issues of fact and law. Wright, *supra* § 4477.

FDA's most recent change in position checks all three of these boxes. First, as discussed at greater length below, FDA's newfound position is clearly inconsistent with its previous, longstanding position. Second, as this Court's order reflects, FDA succeeded in persuading this Court to accept the agency's previous position—that sodium picosulfate was a novel active ingredient—and to issue an opinion consistent with that position. And third, FDA's actions, if not estopped, would impose on Ferring substantial costs in terms of the time and effort it took to

pursue NCE exclusivity, through the previous administrative process, and through a proceeding before this Court. (Not to mention the time and resources this Court expended on the parties' previous submissions.) And there can be no doubt that FDA's actions are patently unfair; FDA's last minute effort to re-characterize its decision is precisely the "classic 'heads I win, tails you lose' approach to dispute resolution" that courts routinely condemn. *See, e.g.*, *Metro. Edison Co. v. Pa. Pub. Util. Comm'n*, 767 F.3d 335, 367 (3d Cir. 2014).

FDA doubtless will respond that judicial estoppel against the government presents a higher bar for success. *See New Hampshire*, 532 U.S. at 755–756. That bar is easily surpassed here. This does not involve a situation where FDA has taken two different positions in two different proceedings involving two different private parties in two different Circuits; the government is entitled to that degree of inconsistency. Here, however, FDA has changed its position as it relates to *Ferring alone*, on remand from the very lawsuit where it took precisely the opposite position.

B. FDA's Conduct Violates Principles of Retroactivity.

FDA also apparently did not contemplate some of the other significant legal ramifications of its June 9 letter to Ferring. For one thing, the agency's new interpretation of "ester" as including a sulfur-based functional group reflects a brand new agency policy. As far as Ferring can tell, FDA has never previously identified an "ester" for NCE exclusivity purposes that had a central sulfur atom. To the contrary, the agency had taken the position in the context of its treatment of Prepopik itself that there was no "ester" that required removal for determining the active moiety for NCE exclusivity purposes; instead, the agency identified picosulfate as the active moiety.

FDA's application of its new policy in the context of the very same adjudication where it

was announced violates basic principles prohibiting retroactive rulemaking. It is impermissible for an agency to adopt a new, industry-wide interpretation of a statutory term in the context of an adjudication and then apply it retroactively to the regulated entity. Unlike for rulemakings, which apply only prospectively, there is normally a "presumption of retroactivity for adjudications," because adjudications generally clarify existing law in a particular application. *Qwest Servs. Corp. v. FCC*, 509 F.3d 531, 539 (D.C. Cir. 2007). But, when agencies mix rulemaking with adjudication, there is the potential to work on the regulated party a "manifest injustice"—in which case that presumption of retroactivity gives way. *Id.* at 537. In order to ferret out such instances, the D.C. Circuit applies a five-factor test to determine whether an agency position announced during an adjudication may be applied retroactively:

> (1) whether the particular case is one of first impression, (2) whether the new rule represents an abrupt departure from well established practice or merely attempts to fill a void in an unsettled area of law, (3) the extent to which the party against whom the new rule is applied relied on the former rule, (4) the degree of the burden which a retroactive order imposes on a party, and (5) the statutory interest in applying a new rule despite the reliance of a party on the old standard.

Retail Wholesale & Dep't Store Union v. NLRB, 466 F.2d 380, 390 (D.C. Cir. 1972); *see also Clark-Cowlitz Joint Operating Agency v. FERC*, 826 F.2d 1074, 1098 (D.C. Cir. 1987) (en banc) (Mikva, J., dissenting) (noting that the first four *Retail Union* factors "gauge the litigants' personal interest in not being judged under a newly announced standard"). FDA's retroactive application of its new policy on so-called "sulfur esters" in the same adjudication in which it was announced constitutes a textbook violation of the *Retail Union* test.

1. First impression. FDA has never before held that a sulfur-based functional group can qualify as an "ester" in the context of an NCE exclusivity determination. To the contrary, FDA had long taken the position that sodium picosulfate would not be considered to contain an ester for NCE exclusivity purposes.

2. Departure from established practice. FDA's newfound interpretation departed dramatically and without warning from the agency's practice—both in this case, and more generally. FDA for *years* treated this active moiety as novel, establishing a micro-practice in this case alone. This change in position is more than mere gap-filling, but instead reflects an abrupt departure from a previous agency position that was unforeseeable.

3. Reliance. Ferring has spent more than five years seeking exclusivity in agency proceedings and in litigation before this Court and the D.C. Circuit. It would be an understatement to say that Ferring relied on FDA's long-standing treatment of sodium picosulfate as a novel active ingredient.

4. Burden. It is equally an understatement to say that FDA's new interpretation burdens Ferring substantially. It eviscerates a key component of Ferring's NCE exclusivity argument. It also has a significant commercial impact on Ferring's product, owing to the resultant diminishment in exclusivity.[6]

5. "Statutory interest" despite reliance. Finally, FDA points to no statutory interest in applying its newfound interpretation retroactively. Nor is there any. *See, e.g.*, *Gilbert v. Fed. Mine Safety & Health Review Comm'n*, 866 F.2d 1433, 1443 (D.C. Cir. 1989) (holding impermissible retroactive application of newly announced rule when "the Commission d[id] not even purport to identify a statutory interest sufficient to overcome the factors that weigh against retroactive application"); *see also Yakima Valley Cablevision, Inc. v. FCC*, 794 F.2d 737, 746

[6] Although the five-year NCE exclusivity period for Prepopik is set to expire on July 16, 2017, Ferring still stands to lose out significantly if FDA continues to deny NCE exclusivity even after this date. Among other things, the methodology for calculating the 30-month stay under Hatch Waxman is different where an ANDA applicant provides its Paragraph IV notice before expiration of the NCE exclusivity period, as several ANDA filers have done for Prepopik. *See* 21 U.S.C. § 355(j)(5)(F)(ii) (recognizing 7.5 year stay for patent litigation for NCE drug products).

(D.C. Cir. 1986) ("Obviously, in many instances, a retroactive change in policy is perfectly appropriate; however, the law requires that an agency explain why it has decided to take this rather extraordinary step."). In fact, FDA itself previously took the position—in this proceeding—that a new NCE exclusivity policy cannot be applied to already-approved drug products. D.E. 60 at 11 (noting FDA's argument that NCE exclusivity runs from the date of approval). So to review the bidding, FDA in this same case has taken both the position that the agency's now-current interpretation of the exclusivity statute *cannot* be applied retroactively—even though Ferring actively *sought* its retroactive application, *see generally* D.E. 38—and the position that the agency's newfound interpretation of the term "ester" *can* be applied retroactively, when Ferring actively *opposes* it. The only continuity between these two positions is, of course, that FDA refuses to grant Ferring NCE exclusivity.

All of the *Retail Union* factors thus counsel against retroactivity, in order to protect Ferring from what would otherwise be an unfair, and dispositive, surprise relating to a new interpretation of "ester" for NCE exclusivity purposes. As not one of these factors favors FDA, and as the countervailing harm to Ferring is enormous, application of the *Retail Union* factors is straightforward. Retroactive application is not warranted here.

C. FDA's Conduct Violates Principles of Due Process.

Allowing FDA to spring its newly devised interpretation of "ester" on Ferring at the eleventh hour would also violate fundamental due process principles. The Due Process Clause of the Fifth Amendment to the United States Constitution "requires, at minimum, that the government provide notice and some kind of hearing before final deprivation of a property interest." *Henke v. Dep't of the Interior*, 842 F. Supp. 2d 54, 61 (D.D.C. 2012). And that property interest can take the form of a statutory entitlement, such as Ferring's entitlement to

exclusivity for Prepopik. *See Mpras v. District of Columbia*, 74 F. Supp. 3d 265, 270 (D.D.C. 2014) ("For due process purposes, 'to have a property interest in a benefit, a person clearly must have more than an abstract need or desire' and 'more than a unilateral expectation of it; he must, instead, have a legitimate claim of entitlement to it.'") (alteration omitted). As such, FDA owed Ferring the Constitution's baseline guaranty of due process of law.

By announcing its brand new "ester" interpretation on remand, years after the agency took a contrary position on Prepopik, FDA flouted these deep-seated values. Even the agency recognizes the problematic nature of this conduct, stating "[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," and that "[p]reviously, the Agency incorrectly believed the Prepopik contained a drug substance that had not been previously approved in the US, and was thus an NME. FDA regrets this error and apologizes for informing Ferring of this determination almost 5 years after Prepopik's approval and after litigation related to the exclusivity determination." Ex. D at 7–8. In essence, FDA moved the goalposts on Ferring after the company spent years pursuing NCE exclusivity. This conduct is unlawful. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012) ("To defer to the agency's interpretation in this circumstance would seriously undermine the principle that agencies should provide regulated parties 'fair warning of the conduct . . . prohibit[ed] or require[d].'"); *Satellite Broad. Co. v. FCC*, 824 F.2d 1, 3–4 (D.C. Cir. 1987) ("Traditional concepts of due process . . . preclude an agency from penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule. . . . Otherwise the practice of administrative law would come to resemble 'Russian Roulette.'").

D. FDA's Conduct on Remand Was Arbitrary and Capricious

Finally, in addition to being procedurally improper, FDA's new interpretation of the term "ester" was arbitrary and capricious. An agency decision is arbitrary and capricious if the agency "offered an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983); *see also Clark Cty. v. FAA*, 522 F.3d 437, 441–442 (D.C. Cir. 2008). To survive arbitrary and capricious review, "an agency action must be the product of reasoned decisionmaking." *Fox v. Clinton*, 684 F.3d 67, 75 (D.C. Cir. 2012). "[N]o deference is owed to an agency action that is based on an agency's 'purported expertise' where the agency's explanation for its action 'lacks any coherence.'" *Id*. at 75. As the D.C. Circuit has noted: "Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusions, we must undo its action." *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999).

Here, the little explanation FDA provided to support its about-face was completely illogical. In its June 9 letter, FDA stated categorically that "FDA treats the combined product of an alcohol and sulfuric acid, like sodium picosulfate, as an ester." Ex. D at 8. In support of this contention, however, the agency cited to only two products: Topicort (Desoximetasone) Ointment and Dyazide (hydrochlorothiazide/triamterene) Capsules. *Id.* n. 37. *Neither* of them supports the principle for which they are cited. First, both products were approved before the enactment of the Hatch-Waxman Amendments in 1984—that is, before the existence of the NCE exclusivity provisions. *See* FDA, *Drugs@FDA FDA Approved Drug Products: Topicort (NDA 017856) Approval History*[7]; FDA, *Drugs@FDA FDA Approved Drug Products: Dyazide (NDA*

[7] *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process (last visited July 14, 2017).

016042).[8] As a result, they bear no relevance to FDA's interpretation of the word "ester" as used in that statute. Second, both references to so-called "sulfur esters," as explained in those products' labeling,[9] describe metabolites—substances formed in the body *after* ingestion of a drug. The relevant active ingredients of the referenced products did not themselves contain sulfur, let alone a sulfur ester. As a result, neither example provides any support for how FDA treats so-called "sulfur esters" in an active ingredient for purposes of NCE exclusivity. FDA's explanation simply does not stand up to arbitrary and capricious review. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

E. FDA Should Be Ordered to Recognize NCE Exclusivity for Prepopik.

Courts have wide latitude to fashion appropriate remedies for—and impose adverse outcomes on—agencies who fail to adhere to a binding order. *See, e.g.*, *N.C. Fisheries Ass'n v. Daley*, 27 F. Supp. 2d 650, 667 (E.D. Va. 1998) (entering a specific fishing quota after the Secretary of Commerce failed to comply with the court's remand order). Based on FDA's demonstrated commitment to stonewalling Ferring's bid for NCE exclusivity, Ferring respectfully requests that the Court order FDA to award NCE exclusivity to Prepopik instead of ordering another remand.

[8] *See id.*

[9] *See* FDA, Topicort® Cream (desoximetasone) Approved Labeling (Apr. 1999), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/17856slr024,18309slr013_topicort_lbl.pdf; FDA, DYAZIDE® (hydrocholorothiazide/triamterene) Capsules Approved Labeling (Feb. 2011), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/016042s078lbl.pdf.

III. CONCLUSION

For the foregoing reasons, Ferring requests this Court to enforce its earlier judgment and order FDA to recognize NCE exclusivity for Prepopik, in keeping with the positions the agency has taken repeatedly throughout the regulatory process and ensuing litigation.

Respectfully submitted,

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