IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FERRING PHARMACEUTICALS INC., Plaintiff, v. SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and ROBERT CALIFF, M.D., in his official capacity as COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION, Defendants.	Civil Action No. 1:15-cv-802 (RC) **ORAL HEARING REQUESTED**

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S RENEWED MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Ferring petitioned FDA to revise its interpretation of the new chemical entity (NCE) exclusivity provision of the federal Food, Drug and Cosmetic Act (FDCA) to permit novel drug substances to receive NCE exclusivity even if approved for the first time as part of a fixed-dose combination drug product. The agency adopted the interpretation Ferring advocated. But FDA decided to apply its new construction of the statute *only to drug products approved after FDA announced its new interpretation*. Because PREPOPIK was approved before FDA announced its new interpretation in a Citizen Petition Response in February 2014, the agency concluded that it would subject Ferring's drug product to its *prior* interpretation. Ferring subsequently challenged FDA's decision to apply its old interpretation to any future exclusivity determinations relating to PREPOPIK.

This Court has asked the parties to provide further briefing on whether FDA's refusal to apply its new interpretation to Ferring was permissible under a line of D.C. Circuit cases regarding the retroactive application of agency decisions.[1] The short answer is that FDA's refusal to apply its interpretation retroactively was improper, as a matter of law.

This is not your typical retroactivity case. In most retroactivity cases, the regulated party *opposes* retroactive application of a new rule, arguing that it would work an injustice to permit an agency to impose a new rule on a regulated party without advance notice. *See, e.g., Retail Wholesale & Dep't Store Union v. NLRB*, 466 F.2d 380 (D.C. Cir. 1972) (*Retail Union*). In this case, however, the regulated party – Ferring – actively *sought* a change in FDA's interpretation, and thus *requested* retroactive application of FDA's new rule. As a result, several of the *Retail*

[1] In order to preserve its remaining arguments for appeal, Ferring incorporates by reference its original summary judgment briefing, including its statutory and regulation-based arguments. In addition, Ferring is separately filing a motion for reconsideration on one particular issue addressed in the Court's March 15, 2016 Opinion.

Union factors either are neutral or do not apply. The factors that do apply, moreover, all tilt heavily in favor of Ferring. And even if FDA were correct that its decision could be applied only "prospectively," even a prospective application would include Ferring, because no generic drug companies had even filed applications referencing Ferring's drug product at the time of FDA's decision, let alone had any such applications been approved by FDA.

STATEMENT OF FACTS

The background facts are repeated in the summary judgment papers. *See* Dist. Ct. Doc. 20-1, at 1-9 (July 23, 2015) (Ferring Mem. in Supp. of Mot. for Summ. J. 1-9). The short version: Ferring submitted a Citizen Petition to FDA in January 2013 seeking 5-year NCE exclusivity for its drug PREPOPIK. Ferring explained in its Citizen Petition that the NCE statute mandated that the 5-year NCE exclusivity period applied to any drug product containing previously-approved ingredients, so long as that drug product *also* contains a novel ingredient. *See* A.R. 62-96. There is no dispute that PREPOPIK satisfies this standard: one of its three active ingredients (sodium picosulfate) had not previously been approved by FDA, nor had the active component of that active ingredient (picosulfate).

FDA responded to Ferring's Citizen Petition in February 2014. A.R. 199-216. And in that response, FDA agreed to adopt Ferring's interpretation of the NCE provision, announcing that it would issue a draft guidance document abandoning its previous interpretation and explaining its new one. Under the new interpretation, a drug product containing previously-approved ingredients can still qualify for the five-year period of NCE exclusivity so long as it also contains a novel ingredient. FDA refused, however, to apply its new rule to PREPOPIK, citing purported concerns about "disruption to regulated industry." A.R. 215. At the time FDA

denied Ferring's Citizen Petition, however, there were no existing abbreviated new drug application (ANDA) filers that had referenced PREPOPIK. A.R. 21, 835.

Ferring sought reconsideration of the agency's refusal to apply its new interpretation to PREPOPIK, as did another drug company in a similar position. A.R. 001-42. FDA denied both reconsideration petitions in October 2014. A.R. 832-842. On the same day, FDA finalized the guidance document outlining its new rule and confirmed that the rule would be applied only "prospectively," by which it meant: not to Ferring. A.R. 217-227. PREPOPIK is thus still limited to three years of exclusivity.

ARGUMENT

FDA's refusal to apply its new interpretation of the NCE exclusivity statute to Ferring was unlawful. Whether this Court applies the long line of cases addressing the retroactive application of agency decisions in adjudications or applies the APA's arbitrary-and-capricious analysis, the end result is the same: FDA had no legal basis for denying relief to Ferring. And even if FDA were correct in granting only "prospective" relief, that by definition included PREPOPIK.

I. THE *RETAIL-UNION* FACTORS STRONGLY FAVOR RETROACTIVE APPLICATION OF FDA'S NEW INTERPRETATION TO FERRING.

A. Adjudications Are Presumptively Retroactive.

"[T]he Administrative Procedure Act generally contemplates that when an agency proceeds by adjudication, it will apply its ruling to the case at hand; when, on the other hand, it employs rulemaking procedures, its orders ordinarily are to have only prospective effect." *Clark-Cowlitz Joint Operating Agency v. FERC*, 826 F.2d 1074, 1082 (D.C. Cir. 1987) (en banc). This dispute arose in the context of an adjudication, because FDA announced and explained its new interpretation in its response to Ferring's Citizen Petition on issues involving its treatment of

PREPOPIK. A.R. 212-216; *cf. Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, No. 5:03-00887-MRP PLA, 2009 WL 8727693, at *11 (C.D. Cal. Feb. 17, 2009) ("When a citizen petition challenges a drug approval, the process will closely resemble an adjudicatory proceeding.").

Courts "start with the presumption of retroactivity for adjudications." *Qwest Servs. Corp. v. FCC*, 509 F.3d 531, 539 (D.C. Cir. 2007). *See also* 4 K. Davis, Administrative Law Treatise § 20:8, at 30 (2d ed. 1983) ("[A]n agency having rulemaking power is forbidden … to make new law in an adjudication if it is to be limited to prospective effect.") (cited in *Clark-Cowlitz*, 826 F.2d at 1080). However, an agency properly refrains from retroactively applying a new rule emerging from the adjudicatory context when to do so would work a "manifest injustice." *Qwest Servs.*, 509 F.3d at 537.

The case law on retroactivity in this Circuit was largely built around a familiar fact pattern: an agency would announce an unexpected new rule in the context of an adjudication, and the regulated entity would argue to the court that application of that new rule in the same adjudication in which it was announced worked an injustice. In order to protect regulated entities from policymaking by surprise, the D.C. Circuit developed a set of five factors to assist courts in "deciding whether to grant or deny retroactive force to newly adopted administrative rules":

> (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 Union, 466 F.2d at 389-390; *see also Clark-Cowlitz*, 826 F.2d at 1081(quoting and analyzing these factors); *Williams Nat. Gas Co. v. FERC*, 3 F.3d 1544, 1553-54 (D.C. Cir. 1993) (same).

These five factors are designed to ferret out both the beneficial and adverse effects of imposing a new rule retroactively versus prospectively. "In general, the ill effect of retroactivity is the frustration of the expectations of those who have justifiably relied on a prior rule; the ill effect of prospectivity is the partial frustration of the statutory purpose which the agency has perceived to be advanced by the new rule." *McDonald v. Watt*, 653 F.2d 1035, 1044 (5th Cir. 1981) (citing *Retail Union*, 466 F.2d at 390). Determining which "side of this balance preponderates is in each case a question of law, resolvable by reviewing courts with no overriding obligation of deference to the agency decision." *Retail Union*, 466 F.2d at 390. And this balancing boils down to "concerns grounded in notions of equity and fairness." *Clark-Cowlitz*, 826 F.2d at 1082 n.6.

The retroactivity cases are not a perfect fit in the present case, because unlike the vast majority of retroactivity cases, Ferring is affirmatively *seeking* application of the agency's new policy – and in fact lobbied to bring it about. As a result, the second, third, and fourth *Retail Union* factors (all of which are designed to protect Ferring, the regulated party) are neutral or do not apply. And the first and fifth *Retail Union* factors strongly favor Ferring. The FDA's decision to deny Ferring the benefit of its new interpretation therefore was unsustainable.

1. FDA's Interpretation Is New.

The first *Retail Union* factor – whether the case is one of "first impression" – is something of a misnomer, because it asks not whether the agency is considering an issue for the first time, but rather whether the agency is endorsing a new rule. *See Clark-Cowlitz*, 826 F.2d at 1082 n.6 (clarifying meaning of first factor). This factor "*points in favor of retroactive application of a rule in the adjudication in which the new rule or principle is announced*." *Id.* (emphasis in original). The reasoning is simple: "*parties who challenge old doctrines should be*

rewarded for bringing about the change in the law." *Id.* (emphasis in original). *See also Retail Union*, 466 F.2d at 390 ("to deny the benefits of a change in the law to the very parties whose efforts were largely responsible for bringing it about might have adverse effects on the incentive of litigants to advance new theories or to challenge outworn doctrines.").

This factor decisively cuts against FDA's decision to deny Ferring the benefits of a change in policy that Ferring specifically sought, and ultimately provoked. Ferring was the entity that expended considerable effort to "challenge old doctrines," and to persuade FDA that its interpretation of the five-year NCE provision should be revised. A.R. 213. FDA's new interpretation should be applied retroactively so that the party who advanced the interpretation and persuaded the agency to adopt it actually benefits from it.

2. The Statutory Interest Served By The New Policy Weighs In Ferring's Favor.

The fifth *Retail Union* factor – the statutory interest served by applying the new rule – also tilts heavily in favor of Ferring. This Court need not take Ferring's word for it; the agency itself made the case for Ferring in its response to Ferring's Citizen Petition. FDA admitted that its previous interpretation resulted in drug development strategies that were "suboptimal from a public health perspective," and that the previous approach placed "undue importance on the order in which" new drug applications (NDAs) are approved. A.R. 213-214. FDA also acknowledged the benefits of fixed-dose combination drug products for HIV treatment, and recognized that "combination therapies are an important modality in many disease settings, including cancer, cardiovascular disease, and infectious diseases." A.R. 212-213 (citation and internal quotation marks omitted). FDA concluded "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 revisiting our current policy." *Id.* The agency therefore found that it "would be in the interest of public health to encourage the development of fixed-combinations as a policy matter." A.R. 214. In short, FDA *itself* has already identified the many ways in which the new interpretation serves statutory interests. The fifth factor thus tilts heavily in favor of Ferring.

3. The Other *Retail Union* Factors Are Either Neutral Or Inapplicable In These Special Circumstances.

The remaining three *Retail Union* factors all ask, in one form or another, whether it would be unfair to the party against whom the new interpretation is applied for it to be applied retroactively: Is the new interpretation a departure from prior established practice? Did the party against whom the rule is applied rely on the old interpretation? How much of a burden would fall on the party if the interpretation were applied retroactively? *See Retail Union*, 466 F.2d at 390. Courts sometimes condense these factors into shorthand: when there is a "substitution of new law for old law that was reasonably clear," the new rule may be given prospective-only effect in order to "protect the settled expectations of those who had relied on the preexisting rule." *Public Serv. Co. of Colo. v. FERC*, 91 F.3d 1478, 1488 (D.C. Cir. 1996); *see also Williams Nat. Gas Co.*, 3 F.3d at 1554. But that principle was set up to protect parties to the agency adjudication who do not want the new policy applied to them. *See id.* Here, Ferring specifically *asked* for the new interpretation to be applied to PREPOPIK. Indeed, to the extent "expectations" play a role here, Ferring's expectation was that if FDA was persuaded by Ferring's advocacy – which plainly it was – the interpretation Ferring sought would apply to Ferring's drug.

4. FDA's Justifications For Refusing To Apply Its New Interpretation to Ferring Are Meritless.

The agency purported to justify its refusal to apply the new interpretation to Ferring by making three related observations: (1) FDA's previous interpretation was "longstanding"; (2) the new interpretation might cause "unnecessary disruption to regulated industry"; and (3) if the new interpretation were applied to drug products "for which ANDAs already have been filed," then "it could impose a burden on the ANDA sponsors, who relied on our existing interpretation in filing their applications." A.R. 215.

The three justifications given by the agency do not withstand even minimal scrutiny. FDA's first and second justifications appeal vaguely to the value of avoiding "unnecessary disruption to regulated industry" caused by a "departure" from "longstanding" practice. Notably, these concerns do not relate to actual ANDA filers for PREPOPIK, as there were none as of February 2014, when FDA denied Ferring's Citizen Petition. A.R. 21, 835.[2] Instead, the first and second justifications related to concerns about unknown third parties who might have wished to someway file ANDAs to PREPOPIK. But *any* change causes disruption. *See Landgraf v. USI Film Prods.*, 511 U.S. 244, 270 n.24 (1994). And administrative law recognizes that legal progress is inherently disruptive of expectations. If an agency is to do more than capriciously play favorites in "carving out an exception to the rule of retroactivity," *Clark-Cowlitz*, 826 F.2d

[2] FDA's actions must be evaluated based on the administrative record as of February 21, 2014, when the agency denied Ferring's Citizen Petition. *See, e.g., Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985) ("[T]he focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court."); *Commercial Drapery Contractors, Inc. v. U.S.*, 133 F.3d 1, 7 (D.C. Cir. 1998) (APA review limited to the administrative record except in extraordinary circumstances not present here); 21 C.F.R. § 10.30(j) (noting that "[t]he administrative record . . . is the exclusive record for the Commissioner's decision. The record of the administrative proceeding closes on the date of the Commissioner's decision unless some other date is specified.").

at 1084, it must identify an interest more compelling than merely avoiding speculative and undifferentiated regulated-industry disruption.

And another thing: in order for reliance on settled law to cut against retroactive application of a new interpretation, it must be "reasonabl[e]" reliance. *See, e.g.*, *Clark-Cowlitz*, 826 F.2d at 1083; *Qwest Servs.*, 509 F.3d at 540; *see also McDonald*, 653 F.2d at 1043. Generic drug manufacturers who had not yet submitted an ANDA for a generic version of PREPOPIK at the time FDA issued its Citizen Petition Response could not *reasonably* have relied on the belief that FDA's exclusivity interpretation was frozen in amber. The vague and hypothetical expectations of unidentified future applicants who *might* someday wish to file ANDAs, which *might* (or might not) be approved by FDA, which *might* (or might not) be able to overcome patent rights, and which *might* (or might not) result in "first filer" status such that they could enter the market as soon as Ferring's exclusivity expired and any Orange Book listed patents were found invalid or not infringed, do not rise to the level of "settled expectations" and we doubt FDA would be in a hurry to argue otherwise. Prospective applicants' aspirational plans could be affected by any number of intervening events: legislative changes, regulatory challenges, competition by other generic applicants, the development of newer and better drug products targeted to the same indication, and new patents, to name a few. It would not have been "reasonable" for parties who had not even filed their ANDAs yet to "rely" on some expectation that *if* they did file an application, and *if* it were granted, and *if* they beat out the other generics, and *if* they overcame Ferring's patent rights, that they would be permitted to enter the market based on an NCE exclusivity period that was in effect at one time but had been revised *before they even filed their initial applications*.

Indeed, D.C. Circuit law makes clear that even actual applicants (which again, did not exist at the time FDA issued its decision) have no right to have their applications evaluated under the law that existed when they filed their applications – let alone the law that existed at some earlier time when they first began formulating their plans. *See Bergerco Canada v. United States Treasury Dep't*, 129 F.3d 189, 194 (D.C. Cir. 1997) ("We have rejected any such broad view of applicants' rights.") (citing *DIRECTV, Inc. v. FCC*, 110 F.3d 816, 825-26 (D.C. Cir. 1997) and *Chadmoore Commc'ns, Inc. v. FCC*, 113 F.3d 235, 240-41 (D.C. Cir. 1997)); *see also Pine Tree Med. Assocs. v. Secretary of Health & Human Servs.*, 127 F.3d 118, 121 (1st Cir. 1997) ("[T]he mere filing of an application is not the kind of completed transaction in which a party could fairly expect stability of the relevant laws as of the transaction date."). And here, where the third parties FDA referenced had not even filed their ANDAs yet, those precedents have even more force. "Although hope springs eternal, hope is no surrogate for reliance." *Clark-Cowlitz*, 826 F.2d at 1084; *cf. Public Serv.*, 91 F.3d at 1490 ("Not only is the producers' 'detrimental reliance' purely notional; if it were real it would not have been reasonable.").

Any potential future ANDA applicants who were hypothetically waiting in the wings as of February 2014 – when FDA issued its Citizen Petition Response – still would have been able to file an ANDA application and make use of whatever planning they might have done before FDA issued its Citizen Petition Response; it would just have to be a little later than they might have hoped. And of course, generic manufacturers were on notice as early as January 2013, when Gilead and Ferring filed their Citizen Petitions, that FDA's NCE exclusivity policy was under administrative challenge. A.R. 62-96.

Finally, FDA's third concern – the burden on ANDA sponsors if the interpretation were applied to drug products "for which ANDAs already have been filed" – simply does not apply to

PREPOPIK. A.R. 215. There is nothing in the administrative record to suggest that, at the time FDA issued its initial Citizen Petition Response, FDA had received *any* ANDAs that sought to rely on PREPOPIK as a reference listed drug. A.R. 21, 835. The agency thus could have awarded five-year exclusivity to PREPOPIK in February 2014 (when the agency denied Ferring's Citizen Petition) without imposing a burden on any existing ANDA filers for PREPOPIK, *because there were no such ANDA filers*. The third justification therefore is irrelevant.

5. FDA's Refusal to Apply Its New Interpretation to PREPOPIK was Unlawful.

For the foregoing reasons, under a straightforward application of the *Retail Union* factors, the agency could, as a matter of law, have applied its new interpretation retroactively to Ferring. And those same factors also make clear that retroactive application not was only permissible; it was *required*. This is true both under the *Retail Union* cases themselves, *see, e.g., Qwest Servs. Corp. v. FCC*, 509 F.3d at 539-41 and *Public Serv.*, 91 F.3d at 1490, and under a more traditional arbitrary and capricious analysis.

As far as the *Retail Union* cases go, an agency deciding whether to apply a new rule retroactively must weigh "the interests that might be furthered" by retroactivity against its potential "inequity." *Retail Union*, 466 F.2d at 390. Here, the first and fifth factors strongly favor retroactivity, and the remaining factors are neutral or inapplicable. And FDA's purported justification for denying retroactive application – to protect the interests of third parties who had not yet even filed ANDA applications, let alone had them granted – simply is not legally sustainable. FDA's decision therefore fails judicial scrutiny under *Retail Union*. *See, e.g., Qwest Servs.*, 509 F.3d at 541 (vacating agency order where it had "offered only an unsustainable theory of manifest injustice to support its decision against retroactivity, pointing to

nothing else in the record that would support a departure from the presumption of retroactivity").

This case is thus the reverse of *McDonald v. Watt*, 653 F.2d 1035, 1044 (5th Cir. 1981); there, the court found "the prospectivity side of the scale full and the retroactivity side empty," leading the court to conclude that the agency abused its discretion by applying a new rule retroactively. 653 F.2d at 1046. Here, by contrast, the prospectivity side of the scale is empty and the retroactivity side is full, leading to the conclusion that the FDA abused its discretion in *not applying* its new interpretation retroactively. In the face of the strong interests favoring retroactive application, and given that the reasons articulated by FDA in denying retroactive application are meritless, FDA erred as a matter of law by deciding against retroactive application of its new interpretation to PREPOPIK. *See id.*

The agency's decision also fails under the more traditional APA arbitrary-and-capricious analysis, for the same reasons. FDA justified its prospective-only decision by citing "unnecessary disruption to the regulated industry." A.R. 215. But as we have explained, the "regulated industry" writ large had no reasonable expectation that FDA's policy would be forever frozen in time as of some arbitrary point months or years before they even filed ANDAs to PREPOPIK. FDA's three justifications – the only ones contained in the administrative record, and thus the only ones available to the agency in this Court – fail to stand up to even minimal scrutiny. *See Amerjet Int'l. v. Pistole*, 753 F.3d 1343, 1350 (D.C. Cir. 2014) ("a fundamental requirement of administrative law is that an agency set forth its reasons for decision"); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 50 (1983) ("An agency's action must be upheld, if at all, on the basis articulated by the agency itself," not on the basis of "*post hoc* rationalizations for agency action."). FDA's decision also was arbitrary and capricious for the same reason that it was an abuse of discretion; the agency badly misjudged the

balance that should have been struck in this case. *See* 5 U.S.C. § 706(2)(A).

B. Even If FDA's Action Contained Elements of a "Rulemaking," Application of the New Interpretation to Ferring Was Appropriate.

As previously noted, FDA's decision here is best reviewed as an adjudication, because the Citizen Petition was an outgrowth of FDA's approval of PREPOPIK. *See Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, No. 5:03-00887-MRP PLA, 2009 WL 8727693, at *11 (C.D. Cal. Feb. 17, 2009) ("When a citizen petition challenges a drug approval, the process will closely resemble an adjudicatory proceeding.").

FDA may respond that its new interpretation has at least some of the trappings of a rulemaking, because Ferring's Citizen Petition prompted it to issue a separate draft guidance advancing its new interpretation. But guidance documents are not rulemakings; they simply set forth the agency's position on a particular issue as of that point in time. *See* 21 C.F.R. § 10.115 (d) ("Guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA."). In addition, the draft guidance here was not necessary to or otherwise related to FDA's decision relating to PREPOPIK; instead, it was only issued for the purpose of ensuring that FDA's new interpretation could be applied to *other* applicants in the future. *See* 21 C.F.R. § 10.115(e) (guidance documents only required when disseminating new regulatory expectations "to a broad public audience."). Ferring's Citizen Petition challenged a decision by FDA regarding FDA's regulatory treatment of PREPOPIK, and it was in the context of that adjudication that FDA devised and announced its new interpretation, all at Ferring's prompting. A.R. 215. These are all facets of adjudication.

At best, then, FDA's actions here are a hybrid – a proceeding with certain general rulemaking elements, *prompted by* and an outgrowth of an adjudicative proceeding. *See, e.g.*, *Qwest Servs.*, 509 F.3d at 536 (applying *Retail Union* factors to adjudication portion of quasi-

rulemaking quasi-adjudication). Even if this Court were to treat FDA's new interpretation as a rulemaking, despite its adjudicative origins, the D.C. Circuit permits retrospective rulemaking so long as it is not impermissibly retroactive. "A rule is retroactive if it 'takes away or impairs vested rights acquired under existing law, or creates a new obligation, imposes a new duty, or attaches a new disability in respect to transactions or considerations already past.' " *Marrie v. SEC*, 374 F.3d 1196, 1207 (D.C. Cir. 2004) (citations omitted). As noted above, no third parties had any "vested rights" or received any new obligations or duties here. And as we have explained, this case presents one of those rare circumstances where retrospective application of the agency's new interpretation is plainly warranted: this is an interpretation the regulated party *advanced* and specifically *requested* be applied to its circumstances. There are no countervailing considerations preventing retrospective application, and FDA was wrong to conclude otherwise.

II. Even If FDA Were Permitted to Apply Its New Interpretation Only "Prospectively," That Would Include PREPOPIK.

For all of the reasons we have explained, here and in our initial memorandum, FDA was wrong to refuse to apply its new NCE interpretation to the very party who sought it. But even assuming FDA could justify a prospective-only application of its new interpretation, applying the new exclusivity interpretation going forward would by definition include PREPOPIK.

A law is not considered to have "retroactive" application "merely because it is applied in a case arising from conduct antedating the statute's enactment, or upsets expectations based on prior law." *Landgraf*, 511 U.S. at 269 (citation omitted). Even *prospective* statutes, after all, "may unsettle expectations and impose burdens on past conduct; a new property tax or zoning regulation may upset the reasonable expectations that prompted those affected to acquire the property; a new law banning gambling harms the person who had begun to construct the casino before the law's enactment or spent his life learning to count cards." *Id.* at 269 n.24. In order to

determine whether a law is retrospective, then, "the court must ask whether the new provision attaches new legal consequences to events *completed* before its enactment." *Id.* at 269 (emphasis added).

Here, there were no ANDA filers for PREPOPIK at the time FDA issued its Citizen Petition Response. So FDA's new NCE exclusivity policy did not attach any new legal consequences to any *completed* events. *Id.* That could not have happened until (at the very earliest) an ANDA was filed or (more likely) an ANDA was approved – either way, *after* the new policy was announced. The relief Ferring requested from FDA – an extension of its exclusivity period – thus should be viewed as having *prospective* application at the time FDA denied the request. The mere fact that potential future ANDA applicants might have someday wanted to file an application seeking permission to market a generic version of PREPOPIK does not make the requested extension retrospective. "If every time a man relied on existing law in arranging his affairs, he were made secure against any change in legal rules, the whole body of our law would be ossified forever." *Id.* at 269 n.24 (*quoting* Lon L. Fuller, *The Morality of Law* 60 (1964)).

Even if FDA was correct in applying its new interpretation only "prospectively," then, it should have applied it to PREPOPIK.

CONCLUSION

For all of the foregoing reasons, and those in Plaintiff's initial motion and memorandum, Plaintiff's Renewed Motion for Summary Judgment should be granted.

Respectfully submitted,

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