IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FERRING PHARMACEUTICALS, INC.,

Plaintiff,

v.

SYLVIA M. BURWELL, *et al.*,

Defendants.

Civil Action No. 15-0802 (RC)

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PAR PHARMACEUTICAL, INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Local Rule 7(h), and the Court's March 15, 2016 Order (D.I. 28), Par respectfully moves this Court to enter summary judgment affirming the FDA's refusal to retroactively apply its new interpretation of the five-year NCE exclusivity provisions under 21 U.S.C. § 355(j)(5)(F)(ii).

I. INTRODUCTION

This case concerns Ferring's challenge to the FDA's refusal to grant Ferring a five-year new chemical entity ("NCE") exclusivity for its Prepopik product. This Court already ruled that the FDA's previous interpretation of the relevant statute was not arbitrary and capricious, *see* D.I. 29, and requested additional briefing on the FDA's decision not to apply its new interpretation retroactively, *see* D.I. 28. Therefore, the sole issue remaining is whether the FDA's new interpretation must apply retroactively to grant Ferring a five-year NCE exclusivity for Prepopik.

Retroactive application of the FDA's new interpretation would violate basic notions of equity and fairness. Accordingly, the FDA denied Ferring's request for additional exclusivity partly because it would "impose a burden on the ANDA sponsors, who relied on [the FDA's] existing interpretation in filing their applications." A.R. 215; *see also* D.I 21 at 22. The FDA is correct. Par (the ANDA sponsor here) would suffer an unfair burden because, in developing its generic version of Prepopik, Par relied on the FDA's longstanding interpretation that five-year NCE exclusivity does not apply to drug products with at least one previously-approved active ingredient. Rockwell Decl. ¶ 4. Par also relied on the FDA's initial decision to grant Ferring just a three-year exclusivity for Prepopik, the FDA's denial of Ferring's Citizen Petition again asking for NCE exclusivity, and the FDA's denial of Ferring's request for reconsideration of its Citizen Petition. Rockwell Decl. ¶¶ 5, 6, 25.

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Par has invested, and continues to invest, significant time, money, and other resources to develop a generic version of Prepopik, and to defend itself in litigation concerning patents that allegedly cover Prepopik. Rockwell Decl. ¶¶ 10–17, 22–25. These investments are based on Par's reasonable reliance on longstanding FDA interpretations. If the FDA's new interpretation is applied retroactively, however, then approval of Par's ANDA would be unexpectedly delayed until as late as 2020 [redacted] and its legal costs associated with defending against Ferring's patent lawsuit would be wasted.

This Court should deny Ferring's request.

II. FACTS AND PROCEDURAL HISTORY

The three active ingredients in Ferring's Prepopik product have been available in the same doses and combinations for decades. Only one of Prepopik's three active ingredients (sodium picosulfate) had never been approved by the FDA before, although it was approved and marketed in Europe for decades. *See* Ex. A at 2 (Public Assessment Report for Picolax, Lay Summary) ("A national licence had previously been granted [for Picolax] in the UK on 22nd December 1980 (PL 03194/0014).").

Even though two of the active ingredients in Prepopik were previously FDA-approved, Ferring filed its New Drug Application ("NDA") for Prepopik asking for a five-year NCE exclusivity. *See* D.I. 29 at 1. On July 16, 2012, the FDA denied Ferring's request, based on its longstanding interpretation of the relevant statutory provisions on exclusivity. A.R. 201. Since at least April 28, 1988, the FDA had interpreted its exclusivity provisions in the same manner. The FDA granted five-year NCE exclusivity only if a new drug product contains "no active moiety that was previously approved by the Agency." A.R. 323–324; A.R. 829 ("[F]or over 25

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years, FDA had consistently applied this interpretation to determine that certain fixed-combinations such as . . . Prepopik would be ineligible for 5-year NCE exclusivity."); A.R. 831 n.12. This interpretation was codified and published in 1994. *See* 21 C.F.R. § 314.108; 59 Fed. Reg. 50338 (Oct. 3, 1994). Therefore, Ferring could not have been surprised when it received only a three-year exclusivity for Prepopik.

On January 29, 2013 Ferring challenged the FDA's old interpretation of its exclusivity provisions. Ferring, along with other NDA holders, submitted a Citizen Petition challenging the FDA's exclusivity determination for Prepopik, and suggesting an alternative interpretation that would award Ferring a five-year NCE exclusivity for the product. A.R. 62. That petition was denied on February 21, 2014. *See* A.R. 830. Ferring petitioned for reconsideration on March 21, 2014, and that too was denied on October 10, 2014. A.R. 829–842.

[redacted] One of the factors that motivated Par to pursue a generic version of Prepopik, instead of other potential projects available at the time, was that, in accordance with the FDA rules, Prepopik did ***not*** have five years of NCE exclusivity. Rockwell Decl. ¶ 4; Ex. B at Par-Prepopik 0034265.

After formally authorizing and pursuing any new generic drug development project, Par periodically reviews the business and legal landscape, and evaluates whether the project should continue. Rockwell Decl. ¶ 6. One of the factors that led Par to continue the generic Prepopik project was the FDA's denial of Ferring's requests for NCE exclusivity. A.R. 829–42; Rockwell Decl. ¶ 6. [redacted]

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[redacted] Par successfully developed a generic version of Prepopik [redacted]. Rockwell Decl. ¶ 7. [redacted] *Id.* ¶ 9.

After the FDA denied Ferring's Citizen Petition, it published proposed guidance describing a new interpretation of its exclusivity provisions, and sought public comment thereon. A.R. 830 ("In [FDA's] original response to Ferring . . . FDA disagreed with [Ferring] that FDA's longstanding interpretation was impermissible. . . . FDA also issued a draft guidance for industry . . . [that] proposed to adopt a new interpretation . . . under which certain fixed-combination products (such as Stribild and Prepopik) would be eligible for 5-year NCE exclusivity."). On October 10, 2014 [redacted] the FDA published new guidance adopting its new interpretation. A.R. 829–830 ("Simultaneously with this response, the Agency will issue the Exclusivity Guidance in final form . . . .").

After the FDA acknowledged receipt of Par's ANDA for review on or about [redacted], Par promptly notified Ferring of its Paragraph IV certification, as required under 21 U.S.C. § 355(j)(2)(B). Rockwell Decl. ¶ 7. Then, on February 20, 2015, Ferring filed a patent-infringement action against Par under 35 U.S.C. § 271(e)(2). *See* Complaint, *Ferring Pharm. Inc. v. Par Pharm., Inc.*, No. 1:15-cv-00173-RGA, D.I. 1 (D. Del. Feb. 20, 2015) (Ex. C). By statute, a 30-month regulatory stay for the FDA to approve Par's ANDA is currently in place. *See* 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stay will expire on or about [redacted], making Par eligible for final approval of its ANDA as of that expiration date. Rockwell Decl. ¶

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19.

Ferring appealed the FDA's refusal to grant it five-year NCE exclusivity for Prepopik in this Court on June 1, 2015. *See* D.I. 1. On March 15, 2016, this Court denied Ferring's motion for summary judgment, ruling that the FDA's old exclusivity interpretation was not arbitrary or capricious. *See* D.I. 28, 29. The Court also denied, without prejudice, Ferring's request for retroactive application of the FDA's new exclusivity interpretation for Prepopik. *Id.* The Court requested renewed cross-motions for summary judgment directed to the narrow issue of whether the FDA must apply its new interpretation retroactively to Prepopik, thus making it eligible for a five-year NCE exclusivity. *See* D.I. 29 at 32; D.I. 28. The sole issue remaining in this case is whether the FDA's new interpretation applies retroactively, as requested by Ferring to preserve its monopoly.

III. ARGUMENT

A. Legal Standards

In general, "[r]etroactivity is not favored in the law," and "congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 208, 208 (1988). Giving a new rule prospective-only effect acts to "protect the settled expectations of those who had relied on the preexisting rule." *Williams Nat. Gas Co. v. FERC*, 3 F.3d 1544, 1554 (D.C. Cir. 1993).

As explained by this Court, there are five factors used to determine whether retroactivity is proper:

> (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.

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D.I. 29 at 31 (quoting *Retail Wholesale Dep't Store Union v. NLRB*, 466 F.2d 380, 390 (D.C. Cir. 1972)). These "factors 'boil down . . . to a question of concerns grounded in notions of equity and fairness.'" *Id.* (quoting *Cassell v. FCC*, 154 F.3d 478, 486 (D.C. Cir. 1998); *Clark-Cowlitz Joint Operating Agency v. FERC*, 826 F.2d 1074, 1082 n.6 (D.C. Cir. 1987) (en banc)). Therefore, a court must determine if "the inequity in applying" the new rule "outweighs the interests that might be furthered if it were applied." *Id.* (quoting *Retail Union*, 466 F.2d at 390).

Here, equity and fairness militate in favor of affirming the FDA's decision. Retroactive application of the FDA's new interpretation would be inequitable and unfair because Par reasonably relied on the FDA's old interpretation. Also, retroactive application would heavily burden Par in the form of sunk resources that may not be recouped based on a potentially changed competitive landscape. Further, retroactive application would grant Ferring an extension of Prepopik's monopoly, and keep Par's low-cost generic version of Prepopik away from the American public for years.

B. Par reasonably relied on the FDA's longstanding interpretation.

The Court should affirm the FDA's refusal to retroactively extend Ferring's regulatory exclusivity for Prepopik because Par reasonably relied on the FDA's old interpretation, and continues to reasonably rely on that interpretation. The "more consistently an agency has followed one view of the law, the more likely it is that private parties have reasonably relied to their detriment on that view." *Clark-Cowlitz*, 826 F.2d at 1083 (citations omitted). For instance, in *RKO General, Inc. v. FCC*, the D.C. Circuit found that the FCC's new determination should not apply retroactively because it was inconsistent with the FCC's prior statements and practice, which had been recognized for decades. 670 F.2d 215, 223–24 (D.C. Cir. 1981) (citations omitted); *see also Boston Edison Co. v. Fed. Power Comm'n.*, 557 F.2d 845, 849 (D.C. Cir.

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1977) (reversing agency's retroactivity determination because when an agency changes its standard, it must "apply the changed standard only to those actions taken by the parties after the new standard has been proclaimed as in effect").[1]

Here, the FDA adopted a new interpretation of its exclusivity rules partly because the 20-year old interpretation, if maintained, could be detrimental to the pharmaceutical industry. A.R. 213 ("In light of these recent changes, we understand that our current interpretation . . . may result in drug development strategies that are suboptimal from a public health perspective."); A.R. 220; A.R. 212 ("We further conclude that recent changes in drug development, particularly in the field of fixed-combination development in the last 20 years . . . warrant revisiting our current policy."). But from the time Par first decided to pursue a generic version of Prepopik [redacted] to the time it filed an ANDA [redacted], the FDA's old interpretation was in effect (as it had been for over twenty years). A.R. 323–24; A.R. 829; 21 C.F.R. § 314.108; 59 Fed. Reg. 50338 (Oct. 3, 1994). Par's reliance on the FDA's longstanding interpretation was buttressed by the FDA's initial denial of Ferring's request for five-year NCE exclusivity in July 2012, the denial of Ferring's Citizen Petition in February 2014, and the denial of Ferring's petition for rehearing in October 2014. Rockwell Decl. ¶¶ 4-6; A.R. 201, 829–30.

Par pursued a generic version of Prepopik with a reasonable expectation that the FDA

[1] When analyzing retroactivity, other circuits also consider the degree to which the old rule was reasonably relied on. *See, e.g.*, *De Niz Robles v. Lynch*, 803 F.3d 1165, 1177 (10th Cir. 2015) ("Really, then, [the second and third] factors direct our attention to the question whether the petitioner can claim reasonable reliance on some past rule or decision . . . ." (citations omitted)); *Acosta-Olivarria v. Lynch*, 799 F.3d 1271, 1275 (9th Cir. 2015) ("Because [the five-factor test] requires that a court look at an individual's own reliance, this retroactivity analysis is applied 'on a case-by-case basis' . . . ." (citations omitted)); *McDonald v. Watt*, 653 F.2d 1035, 1044 (5th Cir. 1981) ("In general, the ill effect of retroactivity is the frustration of the expectations of those who have justifiably relied on a prior rule . . . ." (citing *Retail Union*, 466 F.2d at 390)); *N.C. Utils. Comm'n v. FERC.*, 741 F.3d 439, 449–50 (4th Cir. 2014) ("In reviewing [an agency's discretion to determine whether to apply a new policy on rehearing], we consider the parties' reliance interests . . . ." (citation omitted)).

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would continue to apply its old, longstanding interpretation to deny Ferring five-year NCE exclusivity for the drug. Rockwell Decl. ¶¶ 4–6. Par's reliance was reasonable because the FDA's prior interpretation was applied consistently for over 20 years, and because the FDA likewise consistently applied it to Ferring's requests. The FDA's new interpretation is exactly the kind of change in practice, policy, or standard that the D.C. Circuit said cannot be applied retroactively. *See RKO Gen.*, 670 F.2d at 223–24. It would be manifestly unfair and inequitable to Par for Ferring to receive an additional two years of exclusivity for Prepopik. This Court should affirm the FDA's retroactivity decision.

C. Par would be unfairly burdened if Prepopik gets additional, retroactive exclusivity.

The Court should uphold the FDA's refusal to retroactively grant Ferring five-year NCE exclusivity for Prepopik. [redacted]

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Here, the FDA's retroactivity determination should be affirmed because [redacted] Granting Ferring its request for retroactive five-year NCE exclusivity will have cascading effects culminating in harm to Par.

First, the FDA will be required to rescind acceptance of Par's ANDA, forcing Par to wait until at least July 16, 2016 before it can re-submit its ANDA. *Id.* ¶ 18. This is because NCE exclusivity prohibits generic companies from filing ANDAs during the first four years after a NDA is approved. *See* 21 C.F.R. § 314.101(e)(2)(ii); 21 U.S.C. §§ 355(c)(3)(E)(iii), 355(j)(5)(F)(iii).[2] But the delay in submitting an ANDA is not the only harm. If Par re-submits its ANDA on July 16, 2016, then generic approval, marketing, and sale could be delayed until January 16, 2020.[3] Rockwell Decl. ¶ 19.

Second, withdrawal and resubmission of Par's ANDA could allow other generic competitors, who failed to match Par's investment in diligent product development and ANDA filing, to be placed on equal competitive footing with Par. *Id.* ¶¶ 20–24. This is because, on July 16, 2016, Par, and potentially multiple other ANDA applicants, are free to submit ANDAs with Paragraph IV certifications to become "First Applicants" eligible to share the 180-day

[2] Unlike five-year NCE exclusivity, three-year exclusivity prohibits FDA ***approval***, but not receipt, of an ANDA. *See* 21 U.S.C. § 355(j)(5)(F)(iii), 21 C.F.R. § 314.108(b)(4). Thus, an ANDA may be received, reviewed, and even tentatively approved during the three-year period, and the ANDA may receive final approval after the three-year exclusivity period.

[3] When an ANDA with a Paragraph IV certification is submitted any time between the fourth and fifth years of an applicable NCE exclusivity period, the 30-month stay of FDA approval of the ANDA may be extended so the stay lasts until 7.5 years after approval date of the branded drug. 21 U.S.C. § 355(j)(5)(F)(ii). Here, 7.5 years after Prepopik's July 16, 2012 approval is January 16, 2020.

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exclusivity period [redacted]. *Id.* [redacted]

Third, in addition to a delay in ANDA approval [redacted], forcing Par to withdraw and re-submit its ANDA would likely result in dismissal of Ferring's patent lawsuit against Par (filed on February 20, 2015), which has already proceeded nearly through the end of fact discovery,[4] resulting in a waste of legal fees and judicial resources. *Id.* ¶¶ 15–19. [redacted] Adding insult to injury, if Par re-submits its ANDA, Ferring could sue Par again based on Par's second ANDA filing, requiring more legal fees, costs, and judicial resources. *See* 21 C.F.R. § 314.95; 21 U.S.C. § 355(j)(5)(B)(iii); Rockwell Decl. ¶¶ 13, 15–19.

If an extension of Ferring's regulatory exclusivity for Prepopik had been reasonably foreseeable, Par would have considered allocating its resources to other projects, or delaying investment in a generic version of Prepopik. Rockwell Decl. ¶¶ 5, 25. Instead, Par invested significant resources in the generic Prepopik project, including fees associated with pursuing regulatory approval of Par's ANDA. *Id.* ¶¶ 11–13. If Ferring obtains a retroactive five-year NCE exclusivity for Prepopik, most of these costs will be sunk. *Id.* ¶ 14. And the sole reason for Par's losses will be its reasonable reliance on the FDA's longstanding regulatory

[4] Fact discovery closes on April 8, 2016. *See Ferring Pharm. Inc. v. Par Pharm., Inc.*, No. 15-00173-RGA, D.I. 82 (D. Del. Feb. 9, 2016) (Ex. D).

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interpretation, which this Court ruled was not arbitrary or capricious. *See* D.I. 28.

Generic drug manufacturers' business decisions about whether and when to invest in the development of a given generic drug, as well as when to submit an ANDA, are significant strategic decisions in terms of time, money, and human resources. Investing money and assigning personnel to develop one drug means that opportunities to develop other generic drugs are lost or delayed. Unexpected and unpredictable extensions of the exclusivity periods can be devastating to a generic drug manufacturer's business. Rockwell Decl. ¶ 10. [redacted] If the FDA had granted Ferring a five-year NCE exclusivity when Prepopik was approved in 2012, Par likely would have delayed developing a generic version of Prepopik at that time, and would have invested its time, money, and personnel resources in other commercial projects. *Id.* ¶¶ 5, 25. If Ferring receives retroactive NCE exclusivity for Prepopik, then Par may not fully recoup its actual investments in its generic version of Prepopik in view of a potentially changed competitive landscape, nor recover the foregone opportunities for other commercial projects. So retroactively granting five-year NCE exclusivity for Prepopik threatens to undermine the substantial investments and efforts Par expended (and continues to expend) to bring a low-cost generic version of Prepopik to the American public, while providing Ferring with an undeserved windfall. *Id.* ¶ 26.

V. CONCLUSION

For the foregoing reasons, Par's motion for summary judgment should be granted. A proposed order is attached for the convenience of the Court.

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Dated: April 5, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

In accordance with LCvR 5.3, I hereby certify that on April 5, 2016 I caused to be served a copy of: (1) Par's Motion for Leave to File Under Seal; (2) Par's Motion for Summary Judgment; (3) Par's Memorandum of Points and Authorities in Support of Its Motion for Summary Judgment (FILED UNDER SEAL); (4) Declaration of Brandon Rockwell in Support of Par's Motion for Summary Judgment and Motion for Leave to File to Seal (FILED UNDER SEAL); (5) Proposed Order Granting Par's Motion for Summary Judgment; and (6) Proposed Order Granting Par's Motion for Leave to File Under Seal, by electronic mail to the counsel of record listed below.

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