RECORD NOS. 14-1522(L); 14-1529; 14-1593

In The
United States Court of Appeals
For The Fourth Circuit

MYLAN PHARMACEUTICALS, INCORPORATED,

Plaintiff – Appellant,

and

WATSON LABORATORIES, INCORPORATED;
LUPIN PHARMACEUTICALS, INCORPORATED,

Intervenors/Plaintiffs – Appellants,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendant – Appellee,

TEVA PHARMACEUTICALS USA, INCORPORATED,

Intervenor/Defendant – Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA AT CLARKSBURG

BRIEF OF APPELLANT
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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT
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No. 14-1529 Caption: Mylan Pharmaceuticals, Inc. v. U. S. Food and Drug Administration

Pursuant to FRAP 26.1 and Local Rule 26.1,

Lupin Pharmaceuticals, Inc.
(name of party/amicus)

who is appellant, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☑ YES ☐ NO
If yes, identify all parent corporations, including grandparent and great-grandparent corporations:
Lupin, Inc. - parent
Lupin Atlantis Holding S.A. ("LAHSA") - grandparent
Lupin Ltd. - great-grandparent

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☑ YES ☐ NO
If yes, identify all such owners:
Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Ltd., the latter being a publicly traded corporation in the Republic of India. No publicly traded corporation owns more than 10% of the stock in Lupin Ltd.

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation (Local Rule 26.1(b))? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐ YES ☑NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐ YES ☑NO
If yes, identify any trustee and the members of any creditors' committee:

Signature: /s/ John H. Tinney, Jr. Date: 6/10/2014

Counsel for: Lupin Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

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I certify that on 6/10/2014 the foregoing document was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by serving a true and correct copy at the addresses listed below:

/s/ John H. Tinney, Jr. 6/10/2014
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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTE

RULE

OTHER AUTHORITIES

JURISDICTIONAL STATEMENT
STATEMENT OF ISSUES
STATEMENT OF THE CASE AND FACTS

Lupin Pharmaceuticals, Inc. (Lupin) incorporates by reference these sections of the brief of Appellants Mylan Pharmaceuticals, Inc. (Mylan) and Watson Laboratories, Inc. (Watson) (Mylan/Watson Brief).

SUMMARY OF ARGUMENT

This case presents two separate questions arising from a Food and Drug Administration (FDA) decision letter.

As to the first question, FDA correctly concluded that the statute is silent on the effect of reissued patents on 180-day exclusivity. Therefore, FDA adopted its "single bundle of patent rights" approach. The district court agreed that FDA's approach was reasonable and, therefore, lawful under "Step 2" of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984). Upon *de novo* review, this Court should uphold FDA's decision for the reasons stated by the district court.

As to the second issue, the plain language of the Federal Food, Drug and Cosmetic (FDC Act) controls under *Chevron* "Step 1," *id.*, thereby compelling the conclusion that a 2008 court decision holding the original patent invalid triggered Teva Pharmaceuticals USA, Inc.'s (Teva) 180-day exclusivity period. Even when analyzed under *Chevron* "Step 2," the only reasonable, and therefore permissible,

interpretation of the statute is that the 2008 court decision triggered Teva's 180-day exclusivity. Upon *de novo* review, this Court should conclude that FDA's decision cannot stand. Accordingly, the district court's judgment, which upheld FDA's approach, should be reversed.

ARGUMENT

In its decision letter, FDA correctly identified two discrete issues: "Reissued Patents and 180-Day Exclusivity," JA-46; and "Effect of a Court Decision on the Original Patent that Occurred Before the Patent was Reissued," JA-49. The district court upheld FDA's interpretation on both issues.

Lupin submits this brief because it agrees with appellants Mylan and Watson on some – but not all – aspects of FDA's and the district court's treatment of these two issues. As discussed below, the district court correctly upheld FDA's single bundle of rights approach for 180-day exclusivity in situations involving original and reissued patents. On this issue, Lupin disagrees with Mylan and Watson.

As to the second issue, the district court erred in upholding FDA's decision that the 2008 court decision of invalidity on the original patent did not trigger Teva's 180-day exclusivity. On this issue, Lupin agrees with the views set forth in the Mylan/Watson Brief. Lupin presents additional views in support of this conclusion below.

Standard Of Review

The district court consolidated Mylan's motion for preliminary injunction with a final hearing on the merits under Rule 65(a)(2), Fed. R. Civ. P., treating the motion as one for summary judgment. This Court reviews such rulings in Administrative Procedure Act (APA) cases *de novo*, without deference to the district court's resolution of the issue. *Friends of Back Bay v. United States Army Corps of Engineers*, 681 F.3d 581, 587 (4th Cir. 2012).

I. FDA's Single Bundle Of Rights Approach For Original And Reissued Patents Is A Permissible Interpretation Of The FDC Act

FDA stated that, under its single bundle of patent rights approach, "subsequent paragraph IV certifications to a reissued patent that references the original patent should not be the basis for separate periods of 180-day exclusivity." JA-49. The district court properly upheld FDA's interpretation.

The district court began its review of FDA's approach with the two-step inquiry set out in *Chevron:* whether "Congress has directly spoken to the precise question at issue"; and, if not, "whether the agency's answer is based on a permissible construction of the statute." JA-329 (quoting *Chevron*, 467 U.S. at 842-43). Noting that Congress has not addressed the precise question presented here, JA-329, and that the statute is ambiguous with respect to 180-day exclusivity periods for reissued patents, JA-331, the district court applied a *Chevron* Step 2 analysis of FDA's single bundle of patent rights approach, JA-335. The district

court noted that FDA's decision is consistent with the statutory treatment of reissued patents generally. JA-336. The district court also noted that FDA's decision comports with its prior decisions, JA-338, and that treating an original and reissued patent as having a single bundle of rights is a reasonable interpretation that allows FDA to administer its statute in a predictable manner, JA-339. The district court, therefore, concluded that FDA's single bundle of rights interpretation is a reasonable interpretation of the FDC Act and also satisfies the APA's arbitrary and capricious standard of review. *Id*.

On *de novo* review, this Court should uphold the district court. Under this analysis, the only 180-day exclusivity rights associated with the original and reissued patents stem from Teva's first Paragraph IV certification to the original patent in 2003. Mylan and Watson have no "shared" 180-day exclusivity rights based on being among the first abbreviated new drug application (ANDA) sponsors to submit Paragraph IV certifications to the reissued patent. Thus, Mylan and Watson are not entitled to 180-day exclusivity.

II. FDA's Decision That The 2008 Court Decision Did Not Trigger Teva's 180-Day Exclusivity Period Is Contrary To The Plain Language Of The Statute

The second issue before this Court is whether the 2008 court decision of patent invalidity on the original patent served as the trigger for Teva's 180-day exclusivity rights. The only reasonable and permissible interpretation of the FDC

Act is that, contrary to FDA's decision letter and the district court's decision upholding it, the 2008 court decision ***did*** trigger Teva's 180-day exclusivity rights. Therefore, there are no remaining 180-day exclusivity rights that block final approvals for Lupin or any other ANDA sponsor that is able to satisfy substantive ANDA approval requirements.

The Mylan/Watson Brief sets forth arguments why the 2008 court decision triggered Teva's 180-day exclusivity rights. Lupin supports those arguments; here, Lupin presents additional arguments on why the district court's decision was erroneous as a matter of law.[1]

With a court decision "holding ***the patent which is the subject of the certification*** to be invalid or not infringed," the ANDA applicant's 180-day exclusivity begins to run. Former 21 U.S.C. § 355(j)(5)(B)(iv) (emphasis added) (full text appears in the Addendum).[2] Under the unambiguous language of this

[1] Appellate courts – including this Court – have reversed district courts on many occasions in cases involving FDA's interpretations of the law related to generic drug approvals, including the following: *Teva Pharmaceuticals USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010); *Teva Pharmaceuticals USA, Inc. v. Leavitt*, 548 F.3d 103 (D.C. Cir. 2008); *Teva Pharmaceuticals USA, Inc. v. Food and Drug Administration*, 441 F.3d 1 (D.C. Cir. 2006); *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001); *Serono Laboratories, Inc. v. Shalala*, 158 F.3d 1313 (D.C. Cir. 1998); and *Granutec, Incorporated v. Shalala*, 139 F.3d 889 (table), 1998 WL 153410 (4th Cir. 1998).

[2] This matter is governed by provisions of the FDC Act before its amendment by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), Pub. L. No. 108-173.

provision of the statute, Teva's first Paragraph IV certification on the original patent is plainly a certification on "***the*** patent" (emphasis added). The 2008 court decision should have triggered Teva's 180-day exclusivity rights based on its first Paragraph IV certification to the original patent.

In issuing its decision letter, however, FDA ignored the plain language of former 21 U.S.C. § 355(j)(5)(B)(iv), concocted an apparent ambiguity, and relied upon *Chevron* Step 2 to decide that the 2008 court decision did not trigger Teva's exclusivity. JA-50-51. The district court accepted FDA's manufactured ambiguity when, in fact, there is none. By ignoring the plain, unambiguous language of the statute, the district court repeated and compounded FDA's error in contravention of *Chevron* Step 1. Thus, FDA's and the district court's reasoning was erroneous as a matter of law.[3]

The district court and FDA both appear inordinately concerned that FDA's approach (not treating the 2008 court decision as a triggering event) "is fair to the ANDA applicants who first took on the risk of litigation by certifying to the original patent." JA-338, quoting JA-51. In other words, it seems that both FDA and the district court thought Teva deserved a generic exclusivity period as a

[3] The district court did not discuss Lupin's view that, under *Chevron* Step 1, the only permissible interpretation is that the 2008 court decision on the original patent triggered Teva's 180-day exclusivity, even though that argument was before the district court, *see* Reply Memorandum of Lupin Pharmaceuticals, Inc. (Docket 87, JA-13) at 6.

reward for being the first ANDA applicant to challenge the original patent. However, Teva's failure to receive a meaningful reward under the only permissible interpretation of the statute is immaterial – a fact recognized even in FDA's letter. In the Mircette situation cited by FDA, JA-47, and by the district court, JA-338, Barr Laboratories, Inc. did not get full benefit from its 180-day exclusivity rights, which were triggered by a court decision about four months before it received final ANDA approval.[4]

Instead of looking to the plain statutory language as *Chevron* Step 1 requires, the district court erroneously concluded that "here, the FDA has provided a well-reasoned explanation for its decision." JA-337. To support its reasoning, the district court quoted from FDA's decision letter: "[FDA] believe[s] that considering a court decision on the original patent not to be a triggering event in these cases is consistent with the statutory scheme." JA-337-38 (quoting JA-51). Yet FDA and the district court never should have reached these "beliefs" and "well-reasoned explanation[s]" because the language of former 21 U.S.C.

[4] The interpretation urged by Lupin – that Teva's 180-day exclusivity was triggered and expired in 2008 – does not undermine the 180-day exclusivity reward. The current situation is different from the one addressed in *Ranbaxy Laboratories, Ltd. v. Leavitt*, 459 F. Supp. 2d 1, 9-10 (D.D.C. 2006). There, the court held that allowing innovator drug sponsors to delist their patents from FDA's *Orange Book* effectively vitiated the 180-day exclusivity rights of ANDA sponsors, contrary to "the plain and undisputed intent of Congress" in providing the 180-day exclusivity reward for the first ANDA sponsor to challenge an *Orange Book* patent.

§ 355(j)(5)(B)(iv) is plain – Teva's Paragraph IV certification was to "the patent" that the court held invalid in 2008, thereby unequivocally triggering Teva's exclusivity. Under *Chevron* Step 1, that clear, unambiguous language controls. FDA and the district court erred in failing to follow *Chevron* Step 1.

Even assuming for discussion purposes that the question of whether the 2008 court decision triggered Teva's 180-day exclusivity rights in 2008 cannot be answered under *Chevron* Step 1, there are several problems with FDA's interpretation that was upheld by the district court under *Chevron* Step 2. Under *Chevron* Step 2, the FDA's approach to the court decision trigger here is not "based on a permissible construction of the statute," *Chevron*, 467 U.S. at 843, and the district court erred as a matter of law in upholding it.

First, FDA's interpretation that the 2008 final court decision of invalidity did not trigger the 180-day exclusivity period for the bundle of patent rights for the original and reissued patents effectively reads the court decision trigger out of the statute in the current situation. Under FDA's interpretation, the 2008 court decision on the original patent cannot serve as the trigger for Teva's 180-day exclusivity because the patent was reissued. Yet, under FDA's single bundle of patent rights approach, the reissued patent is of no relevance, so there is no 180-day exclusivity period associated with the reissued patent. Putting all this together, there is effectively no court decision trigger for the original and reissued patents.

This construction of the FDC Act violates the well-accepted principle that a court must review a statute to "fit, if possible, all parts into an harmonious whole." *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). A reviewing court must give effect to every provision, clause, and word of a statute if at all possible. *See*, *e.g.*, *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012). FDA's interpretation, upheld by the district court, violates these rules of construction and has the effect of eliminating the court decision trigger from the FDC Act.

Second, FDA's reasoning is internally inconsistent. After stating several times in unequivocal terms that there will only be a single 180-day exclusivity period attached to the single bundle of rights associated with an original patent and a reissued patent, JA-48-49, FDA's decision has the effect of granting a second, completely new, period of 180-day exclusivity, despite the fact that Teva already had a 180-day exclusivity period associated with the original patent. The fact that Teva received no benefit from its 180-day exclusivity period tied to the original patent is immaterial; that exclusivity period existed, was triggered, and expired in 2008.

Third, the internal inconsistency in FDA's reasoning, which reasoning the district court endorsed, undercuts FDA's contention that its approach is

"predictable," JA-49. If anything, FDA's approach is unpredictable, which supports the conclusion that it is not a reasonable interpretation.

Fourth, the original patent remains in FDA's *Orange Book*. But for the fortuitous circumstance that the patent was reissued, there would be no question that the 2008 Federal Circuit decision that the original patent was invalid served as the court decision trigger for Teva's 180-day exclusivity. That fact adds to the unpredictability of FDA's approach and further supports the conclusion that FDA's interpretation is not a reasonable one that can withstand scrutiny under *Chevron* Step 2.

Finally, the interpretation that there is no remaining 180-day exclusivity best serves the Congressional goal behind the Hatch-Waxman Amendments – getting reasonably priced generic drugs on the market as quickly as possible. *See In Re Barr Laboratories, Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). Under FDA's interpretation, approved by the district court, no generic version of Celebrex will be available until December 2014, with full generic competition not available until June 2015. By stark contrast, under Lupin's interpretation, full generic competition, resulting in lower prices, could begin immediately.

CONCLUSION

For the reasons discussed above, this Court should reverse the judgment of the district court. The district court should be directed to enter judgment recognizing that there are no remaining 180-day exclusivity rights in connection with generic versions of Celebrex. As a result, Lupin (and any other ANDA sponsor that is able to satisfy substantive ANDA approval requirements) is entitled to receive final approval at this time.

July 3, 2014

Respectfully submitted,

LUPIN PHARMACEUTICALS, INC.

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ADDENDUM

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Former 21 U.S.C. § 355(j)(5)(B)(iv), before its amendment by the MMA § 1102(a)(1):

> (**iv**) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after–
>
> > (**I**) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
> >
> > (**II**) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

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Dated: July 3, 2014

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CERTIFICATE OF FILING AND SERVICE

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