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

REPLY BRIEF OF APPELLANT LUPIN PHARMACEUTICALS, INCORPORATED

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INTRODUCTION

Lupin respectfully submits this reply brief in support of reversal of the judgment of the District Court. On *de novo* review, this Court should conclude that, under *Chevron* Step 2, FDA reasonably adopted its "single bundle of patents rights" approach for reissued patents, leading to the conclusion that Mylan and Watson cannot be eligible for 180-day exclusivity. Under *Chevron* Step 1, Teva's 180-day exclusivity period was triggered by its 2008 final court decision that the original patent was invalid. Thus, there are no remaining 180-day exclusivity rights in connection with generic versions of Celebrex. Lupin (and any other ANDA sponsor that is able to satisfy substantive ANDA approval requirements) is entitled to receive final approval at this time.

ARGUMENT

1. Teva criticizes "plaintiffs' attempt to divide-and-conquer the Agency's letter decision by splitting the relevant inquiry into "'separate and distinct questions'". Teva Br. at 31. In its administrative decision, FDA treated the current controversy as involving two issues. JA-46, 49. Lupin took the same approach in its opening brief, as did Mylan and Watson. FDA also addressed this case as presenting two questions, FDA Br. at 26-27. Under Teva's simplistic framing of the issues, practically ***every*** case could be reduced to a single question:

whether the plaintiff is entitled to prevail. That approach obfuscates the real issues before a court and does not provide a helpful framework for analysis.

2a. Throughout its brief, Teva makes much of the statute's silence on reissued patents. FDA notes that the statute is "ambiguous." FDA Br. at 37. They are correct, but only in part. Lupin agrees that the statute is silent, and therefore ambiguous, on the treatment of reissued patents generally. Thus, FDA reasonably adopted its "single bundle of rights" approach for reissued patents, an interpretation entitled to deference under Step 2 of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984).

Importantly, however, the statute is not silent with regard to the court decision trigger when a reissued patent is involved. Under the plain statutory language, Teva's 2008 final court decision on the original patent triggered its 180-day exclusivity stemming from the original patent. Under *Chevron* Step 1, the only plausible construction of the statute is the court decision trigger refers to a decision on ***the*** patent that was the subject of the Paragraph IV certification that is the basis for exclusivity. Here, that is the original patent. *See* Lupin Br. at 5-6.

2b. Contrary to FDA's assertion (JA-50), there is no "incongruity" with that view. The conclusion that Teva's 180-day exclusivity period was triggered and has expired, and the continued existence of the original patent in the form of the reissued patent, are not mutually exclusive. Under Lupin's interpretation,

nothing prevents FDA from implementing 180-day exclusivity in a workable manner when reissued patents are involved. This is clearly not a situation where FDA must create an "extra-statutory exception" to avoid an absurd result, such as "shared exclusivity" to avoid an exclusivity "stand-off." *See Apotex Inc. v. Food and Drug Administration*, 414 F. Supp. 2d 61, 73 (D.D.C.), *aff'd*, 226 Fed. Appx. 4 (D.C. Cir. 2006).

2c. Determining the validity of FDA's interpretation of the statute begins with *Chevron* Step 1 by assessing whether Congress has spoken directly to the precise question at issue. *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1067 (D.C. Cir. 1998) (quoting *Chevron*, 467 at 842-43). Under *Chevron* Step 1, this Court looks to the entire statute and should not permit a construction of the statute that produces an absurd result. *Mova*, 140 F.3d at 1067-68. Here, there is nothing absurd about a determination that the 2008 court decision on the original patent triggered Teva's 180-day exclusivity rights from the "bundle" of patent rights.

2d. Lupin's interpretation is hardly "incongruous," much less "irreconcilable" and "internally inconsistent," Teva Br. at 61. Even if there arguably is some "tension" (Teva Br. at 52) among the different aspects of Lupin's interpretation, that is hardly a reason to reject Lupin's interpretation outright. In addressing other disputes involving 180-day exclusivity, courts have noted flaws

with every approach and interpretation proffered. *E.g.*, *Mova*, 140 F.3d at 1072-74 (involving FDA's former "successful defense" regulation on eligibility for 180-day exclusivity); *Apotex*, 414 F. Supp. 2d at 74 (involving whether multiple 180-day exclusivity periods are potentially available).

3. Teva's statement that "[i]t thus is irrelevant how FDA would have addressed exclusivity in 2008, because FDA does not make piecemeal exclusivity determinations at cherry-picked points in time" (Teva Br. at 38) misses the point. Lupin agrees with FDA and Teva (FDA Br. at 31-32; Teva Br. at 38-39) that May 30, 2014 was the appropriate date for a final FDA decision on 180-day exclusivity. However, FDA made the wrong decision on that date. On May 30, 2014, under *Chevron* Step 1, FDA should have decided that Teva's 180-day exclusivity rights were triggered by the final court decision on the original patent in 2008 and ran out in 2008.

4. Teva argues that, even if the 2008 court decision on the original patent were relevant, it was not sufficient to serve as the court decision trigger because that decision did not address all claims of the original patent. Teva Br. at 44-45. Remarkably, Teva does not cite any authority or even precedent for its assertion that this is the "only sensible view," Teva Br. at 44. It is far too late in the 30-year history of the Hatch-Waxman Amendments to make such an assertion. FDA effectively rejected Teva's contention in the very first paragraph of its decision

letter. JA-41 (describing controversy as one where "a final court decision has issued determining that the original patent is invalid or not infringed").

5. FDA states that tying the court decision trigger to a final court decision on the reissued patent, not on the original patent, rewards the conduct that Congress sought to encourage. FDA Br. at 24-25. Teva makes much of 180-day exclusivity as the statutory reward for challenging patents on innovator drug products being copied. Teva Br. at 56-58. Neither FDA nor Teva explain how treating Teva's 2008 court decision on the original patent as the court decision trigger – as compelled by the plain statutory language – would in any way diminish the exclusivity incentive.

6. FDA criticizes Lupin's argument that the interpretation that there is no remaining 180-day exclusivity best serves the Congressional purpose of getting reasonable priced generic drugs on the market as quickly as possible, Lupin Br. at 10. FDA then purports to extend Lupin's "logic" to the ridiculous conclusion that exclusivity should never be granted. FDA Br. at 34-35. That line of argument is obviously without merit. Lupin's only point is that, in the face of competing interpretations, an interpretation (such as Lupin's) that supports open generic competition advances Congressional intent.

7. Other than labeling Lupin's interpretation an "incongruity" (JA-50), FDA does not explain the purported deficiencies with that approach. FDA is

regulating directly from the statute. If FDA believes it must depart from the plain language of the statute, its interpretation must be justified so that this Court can review FDA's decision. Because FDA has not explained its reasoning, at a minimum FDA's decision should be vacated and the matter remanded for further consideration. *See Teva Pharmaceuticals, U.S.A., Inc. v. United States Food and Drug Administration*, 182 F.3d 1003, 1011 (D.C. Cir. 1999) (involving 180-day exclusivity court decision trigger and declaratory judgment actions).

CONCLUSION

For the reasons discussed, this Court should reverse the judgment of the District Court.

August 8, 2014

Respectfully submitted,

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Dated: August 8, 2014

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CERTIFICATE OF FILING AND SERVICE

I hereby certify that on this 8th day of August, 2014, I caused this Reply Brief of Appellant Lupin Pharmaceuticals, Incorporated to be filed electronically with the Clerk of the Court using the CM/ECF System, which will send notice of such filing to the following registered CM/ECF users:

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