No. 14A_____
(13-854)

IN THE SUPREME COURT OF THE UNITED STATES

TEVA PHARMACEUTICALS USA, INC., ET AL.,

Petitioners,

v.

SANDOZ, INC., ET AL.,

Applicants-Respondents.

On Writ of Certiorari
to the United States Court of Appeals for the Federal Circuit

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PETITIONERS' RESPONSE TO RESPONDENTS' APPLICATION FOR IMMEDIATE TRANSMISSION OF THE COURT'S JUDGMENT

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January 26, 2015

RULE 29.6 STATEMENT

The parent companies of Teva Pharmaceuticals USA, Inc. are: Orvet UK Unlimited, Teva Pharmaceutical Holdings Cooperative U.A., Ivax LLC (f/k/a IVAX Corporation), Teva Pharmaceuticals Europe, B.V., and Teva Pharmaceutical Industries Ltd.; Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Pharmaceuticals USA, Inc.

Teva Pharmaceutical Industries Ltd. has no parent company, and no publicly traded company owns 10% or more of Teva Pharmaceutical Industries Ltd.

The parent companies of Teva Neuroscience, Inc. are: IVAX Corporation, Teva Pharmaceuticals USA, Inc., Orvet UK Unlimited, Teva Pharmaceutical Holdings Cooperative U.A., Ivax LLC (f/k/a IVAX Corporation), Teva Pharmaceuticals Europe, B.V., and Teva Pharmaceutical Industries Ltd.; Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Neuroscience, Inc.

Yeda Research and Development Co. Ltd. is wholly owned by Yeda Trust; no publicly traded company owns 10% or more of Yeda Research and Development Co. Ltd.

PETITIONERS' RESPONSE TO APPLICATION

Petitioners Teva Pharmaceuticals USA, Inc., *et al.* (collectively "Teva"), respectfully submit this response to respondents' application requesting that this Court issue its judgment forthwith. This application came on the heels of Teva's request to the District Court to restore the status quo ante—the injunction, in effect pending appeal, that the Federal Circuit had erroneously set aside. *See* Attachment A. Granting respondents' request to issue this Court's judgment early threatens to terminate the District Court's jurisdiction and block the District Court from granting Teva's request to restore the injunction.

Teva would have no objection to issuing the judgment early if the District Court's authority to rule on Teva's request were preserved, and on Saturday Teva offered respondents a proposal to that end. Respondents declined to agree or to make any counter-proposal. In light of that refusal, Teva submits that this Court should grant respondents' application only after the District Court rules on Teva's motion or the District Court's opportunity to rule on that motion is preserved.

This Court's judgment—a decision *in Teva's favor*—should not be used to block the District Court from restoring the parties to the position they were in before the Federal Circuit ruled. Respondents' desire to rush does not justify depriving Teva of its rights as the owner of a lawfully issued patent that has been upheld by the District Court. Any desire to rush carries particularly little weight here, as respondents currently lack the FDA approval necessary to sell an infringing product anyway.

1. When the Federal Circuit rendered its erroneous decision invalidating the '808 patent and refused to stay its mandate, the District Court was compelled to cut short the injunction protecting Teva against patent infringement. *Compare* J.A. 59a-62a, 102a-104a *with* Pet. App. 73a-82a.[1] That injunction had been entered in July 2012, and respondents never challenged the propriety of the injunction or sought to stay it pending appeal. Had the Federal Circuit's mandate not issued—and had respondents not vigorously opposed any attempt to recall and stay it, *see* Nos. 13A458, 13A1003—the injunction would still be in force today.

Accordingly, once this Court issued its decision making clear that the Federal Circuit had invalidated the '808 patent on an erroneous basis, Teva returned to the District Court on Friday morning to request that the injunction be reinstated pending the remand, and asked for expedited briefing. *See* Attachment A. At 6 p.m. that day, respondents filed their application with this Court, which if granted would frustrate Teva's request for relief: once this Court issues its mandate and the Federal Circuit recalls *its* mandate, the District Court would lose jurisdiction over the judgment, including the injunctive component. *See, e.g.*, *Griggs v. Provident Consumer Discount Co.*, 459 U.S. 56, 58, 59-60 (1982) (district court and court of appeals cannot simultaneously have power to modify the same judgment).

2. The action needed by the District Court is simple: the District Court need merely restore the judgment to how it stood during the appeal to the Federal

[1] The original injunction was set to last until the '808 patent expires on September 1, 2015. Teva prevailed on appeal as to other patents, so the Federal Circuit's mandate allowed the injunction to last until those patents expired on May 24, 2014.

Circuit, an appeal that now resumes under the proper standard laid down by this Court. Indeed, because this Court has vacated the Federal Circuit judgment that forced the District Court to change the injunction, undoing the change and restoring the status quo ante should be virtually automatic. The only reason any action by the District Court is needed is that injunctions must comply with certain requirements as to form and specificity. *See* Fed. R. Civ. P. 65(d). But as noted above, respondents have declined to offer any assurance that granting them what they seek—early issuance of the judgment—will not block the District Court from performing even that simple task.

Thus, while Teva has no objection to beginning work immediately on the remand ordered by this Court, leaving Teva with no way to reinstate the District Court's injunction would be unacceptable. The injunction was set aside *only* because of the Federal Circuit decision, which in a key respect "was wrong," slip op. 16, and has now been set aside. Respondents cannot continue to benefit from that erroneous decision while they pursue their appeal under the proper standard. They were enjoined during their previous appeal, and they should be enjoined during the remanded appeal unless they can secure a final judgment that the patent is invalid. They cannot overcome the law of the case, and win a second chance to challenge the injunction pending appeal, by virtue of their *loss* in this Court.

To provide Teva with adequate protection, this Court should do one of two things. Either the Court should issue the judgment immediately but make clear that the Federal Circuit shall not impede the District Court from ruling on Teva's

request,[2] or the Court should deny the application without prejudice until after the District Court rules or the parties reach an agreement that preserves the District Court's ability to do so. Teva has sought expedited briefing from the District Court and will be ready to be heard as quickly as the District Court sees fit.

3. Withholding the judgment long enough for the District Court to rule—and in no event more than 19 days from today—would not cause respondents or the public interest any cognizable hardship.

First, for reasons having nothing to do with patent law, none of the respondents is lawfully able to market a generic version of Copaxone® at this time. Respondents' applications for approval were submitted to the Food and Drug Administration in 2007 and 2009, respectively, and Teva's patents have not posed any impediment to approval since May 24, 2014. *See* J.A. 59a-60a, 122a. But the FDA has not approved those applications. Respondents' assertion that failure to issue the judgment *now*, rather than in 19 days, will harm the public depends entirely on the unsupported notion that respondents will succeed on two fronts: that they will in fact secure the FDA approval that, to date, has not been forthcoming, *and* that they will succeed in convincing the Federal Circuit, under a more deferential standard, to overturn the District Court's decision upholding the patent.

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[2] Once the Federal Circuit recalls its mandate and regains jurisdiction, the District Court could rule on Teva's request pursuant to Fed. R. Civ. P. 62.1 and Fed. R. App. P. 12.1, which allow for "indicative rulings" during a pending appeal. This Court could make clear that once the Federal Circuit regains jurisdiction, the Federal Circuit should, pursuant to those Rules, take whatever action is needed to put into effect any ruling by the District Court granting Teva relief. Respondents' rejection of Teva's proposal indicates that they plan to oppose such relief in the District Court *and* Federal Circuit.

Second, because the parties have not previously briefed application of the clear-error standard in detail, new briefing will be needed before any decision on remand. And because respondents are the appellants in the court of appeals, respondents are free to begin work on their opening brief on remand even before this Court's judgment issues. Issuing this Court's judgment 19 days early thus is not likely to materially affect the timing of the Federal Circuit's *decision*.

CONCLUSION

The judgment of this Court should be issued once Teva's ability to seek reinstatement of the injunction is adequately protected, not to exceed the ordinary 25-day period. The application should therefore be granted subject to an instruction that the Federal Circuit shall not interfere with the reinstatement motion in the District Court, or else the application should be denied without prejudice.

Respectfully submitted.

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