No. 13A1003

IN THE SUPREME COURT OF THE UNITED STATES

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA NEUROSCIENCE, INC., and YEDA RESEARCH AND DEVELOPMENT CO., LTD.,

Applicants,

v.

SANDOZ INC. and MOMENTA PHARMACEUTICALS INC.,

Respondents,

and

MYLAN PHARMACEUTICALS INC., MYLAN INC., and NATCO PHARMA LTD.,

Respondents.

RESPONDENTS' JOINT OPPOSITION TO TEVA'S SECOND APPLICATION TO RECALL AND STAY THE MANDATE

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RULE 29.6 STATEMENT

Respondent Sandoz Inc. states that it is an indirect wholly-owned subsidiary of Novartis AG and that no other publicly held company owns 10% or more of the stock of Sandoz Inc.

Respondent Momenta Pharmaceuticals Inc. is a publicly held corporation. As of December 31, 2013, BlackRock Inc., a publicly held corporation, owned 10% or more of Momenta's stock. No parent corporation or other publicly held corporation owns more than 10% of Momenta's stock.

Respondent Mylan Inc. states that it is a publicly held corporation and that no parent corporation or publicly held corporation owns more than 10% of its stock. Respondent Mylan Pharmaceuticals Inc. is wholly owned by Mylan Inc.

Respondent Natco Pharma Ltd. states that it is a publicly held corporation and that no parent corporation or publicly held corporation owns more than 10% of its stock.

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INTRODUCTION

Under the guise of an application to recall and stay the court of appeals' mandate, Teva seeks an injunction barring Sandoz and Mylan from going to market with their multiple sclerosis drug products, as permitted by the district court's final judgment. What is ultimately at stake in this litigation is whether Sandoz and Mylan should be prevented from launching their products during the 15-month period between May 24, 2014 and September 1, 2015 (when Teva's now-invalid patent otherwise would have expired). Therefore, granting Teva the extraordinary relief it seeks would, as a practical matter, decide the ultimate merits of this litigation for Teva. That is far broader relief than warranted by this Court's grant of review of the legal question posed by Teva: what is the appropriate standard of appellate review of a district court's construction of a patent claim. Yet before this Court has even received briefing on that legal question—much less decided the appropriate standard of review or whether Teva's concededly ambiguous patent claim could survive under that standard—Teva seeks to alter the current injunction and enjoin respondents on the presumption that the patent will ultimately be held not indefinite. Teva's application should be denied.

First, the relief Teva seeks—to "restore" the district court's original injunction (Stay Appl. 1)—cannot be obtained with a recall and stay of the Federal Circuit's mandate. Teva cites no authority to support its assertion to the contrary. The injunction Teva actually seeks would require affirmative relief under the All Writs Act, which requires a much greater showing than would a stay of the mandate. Teva has neither requested such extraordinary affirmative relief nor

made any attempt to carry that high burden. And it could not do so on the record before this Court. That alone warrants denial of Teva's application.

Second, Teva has not met even the less demanding, but still stringent, standard for a recall and stay of the mandate. The grant of certiorari to decide the legal question of the standard of review for claim construction does not mean there is a "fair prospect" that the *invalidity judgment* will be reversed. Indeed, Teva devotes only a few sentences to asserting that it might prevail if this Court were to adopt a more deferential standard of review.

Teva could not satisfy its burden even if it tried. If this Court applies de novo review to claim construction, the judgment will stand. And Teva has not shown that this Court is likely to reject de novo review: the Court already has recognized that claim construction—like the interpretation of other legal instruments—is a legal issue, even when informed by expert evidence.

Moreover, the judgment of invalidity is likely to stand even under a more deferential standard of appellate review. The court of appeals held the patent at issue indefinite because a critical claim term is ambiguous, the specification provides nothing to resolve the ambiguity, and the prosecution history contains irreconcilable statements as to the meaning of that term. If this Court were to conclude that a district court's determinations regarding "historical fact" warrant deference (as some amici proposed to the en banc Federal Circuit in *Lighting Ballast*), the ultimate conclusion that the patent is invalid would remain unchanged. The critical "evidence" on which Teva relies is a litigation expert's post

hoc attempt to explain away inconsistencies on the face of the patent documents, not a "historical fact" about the meaning of a claim term at the time of the invention. Even if this Court endorsed a clear-error standard of review for any "factual findings" subsidiary to claim construction, Teva's patents would still be indefinite. The district court clearly erred in relying on expert declarations that directly contradicted the patent and its prosecution history. Expert evidence cannot cure irreconcilable inconsistency in the patent documents, and such post hoc evidence certainly cannot provide the public notice required for patent claims to be definite.

Teva also fails to show that it would face irreparable harm without an injunction or a stay. The only possible harm Teva identifies is a monetary one—that Sandoz and Mylan will enter the market and that Teva will sell less Copaxone®, at a lower price, from May 24, 2014 to September 1, 2015. Although Teva's declarant asserts that it is difficult to estimate the loss of revenue Teva might suffer, Teva has publicly quantified the potential loss in a statement to its investors. If Teva ultimately prevails in this litigation, a court could assess Teva's actual losses and award damages. And both Sandoz and Mylan have sufficient cash reserves to satisfy any such judgment.

Finally, the balance of harms does not favor an injunction or a stay. Such an order would harm both Sandoz and Mylan—and the public—by extending Teva's monopoly over a product that the Federal Circuit has held is not covered by a valid patent. Indeed, any order prohibiting Sandoz and Mylan from launching their

generic products would not only decide this litigation for Teva in every practical sense, but also effectively extend Teva's monopoly for years to come. That is because Teva recently has obtained FDA approval for a new formulation of Copaxone® that Teva claims is protected by separate patents expiring in 2030. Teva is acting swiftly to switch existing Copaxone® patients to its new formulation. Every day that Sandoz and Mylan are restrained from competing, Teva switches more patients and diminishes the potential market for generic products. Teva has failed to satisfy the demanding standard for an injunction or stay, and it should not be permitted to use such an order in this case to extend its patent grant beyond its expiration to a different product.

Teva's application to recall and stay the mandate should be denied.

BACKGROUND

1. Pursuant to the Hatch-Waxman Act, Sandoz and Momenta (together, Sandoz) and Mylan and Natco (together, Mylan) each filed abbreviated new drug applications ("ANDAs") seeking FDA approval to market their own versions of Teva's Copaxone®, a drug used to treat multiple sclerosis. In response, Teva brought this suit against Sandoz and Mylan for patent infringement. Pet. App. 4a.

Copaxone® is a form of copolymer-1. Copolymer-1 is not new; it was invented in 1967 and first patented in 1974. C.A. JA49258; C.A. JA344; C.A. JA26052-26053. But the original patent expired before copolymer-1 was marketed. To obtain new patent protection, Teva contended it had improved copolymer-1 by selecting portions of copolymer-1 with particular "molecular weights" or "average molecular

weights." According to Teva, the effectiveness and reduced toxicity of the substance claimed depends on its precise molecular weight. C.A. JA18180, C.A. JA18199.

As such, an accurate understanding of the meaning of "molecular weight" in the claims is essential to defining the claimed substance. Because a sample of copolymer-1 "consists of a mixture of individual polymer molecules that have varying molecular weights," the "molecular weight" of a sample necessarily refers to an average molecular weight. Pet. App. 4a. But as Teva conceded, there are several different ways to describe that average, including weight average molecular weight (M_w), number average molecular weight (M_n), or peak molecular weight (M_p). Pet. App. 4a. The "average molecular weight" value of any single sample of copolymer-1 will generally be different depending on whether what has been determined or described is weight average molecular weight, number average molecular weight, or peak molecular weight. A skilled artisan thus cannot know the bounds of the asserted claims—or determine whether a copolymer-1 sample is covered by the patent—without knowing which type of average molecular weight is claimed.

Yet neither the patents' claims nor their common specification identifies the type of "molecular weight" or "average molecular weight" used in the claims. And on two separate occasions during prosecution of claims reciting this term, Teva gave conflicting definitions to the United States Patent and Trademark Office ("Patent Office"), once stating that the term meant "weight average" and later stating the term meant "peak." Claim 1 of the '808 patent—the only asserted claim extending

past May 24, 2014—is representative of the claims with this "molecular weight" ambiguity:

> A method of manufacturing copolymer-1 comprising reacting protected copolymer-1 * * *, treating said trifluoroacetyl copolymer-1 * * *, and purifying said copolymer-1 to result in copolymer-1 having *a molecular weight of about 5 to 9 kilodaltons*.

C.A. JA346 (emphasis added).

2. The district court nevertheless held the asserted claims not indefinite. Although the court acknowledged that the claims "are silent as to the meaning" of "average molecular weight," it construed "average molecular weight" as "peak molecular weight." Pet. App. 42a, 62a. In so doing, the district court relied on declarations of Teva's expert, Gregory Grant, that were prepared for this litigation and that purported to interpret the patents' specification and prosecution history. In essence, Grant opined, and the district court ruled, that one of Teva's two conflicting statements to the Patent Office about the meaning of "average molecular weight" should be disregarded. Grant also opined, and the district court ruled, that a figure in the specification disclosed peak molecular weight even though, as Grant conceded, the figure actually displayed data closer to weight average molecular weight. When the district court ruled, Grant had not testified or been cross-examined in court. Indeed, the district court held no evidentiary hearing and observed no live testimony before construing the claims and ruling on their indefiniteness. After a bench trial on other issues, the district court enjoined

Sandoz and Mylan from launching their products until expiration of the '808 patent on September 1, 2015. Pet. App. 78a-81a.

3. In a unanimous decision, the court of appeals held that a subset of the asserted claims (the "Group I" claims) were invalid for indefiniteness. Pet. App. 8a. The court recognized that it was "undisputed that Group I claims contain an ambiguity because their plain language does not indicate which average molecular weight measure is intended." Pet. App. 8a. And it rejected Teva's argument that the prosecution history and specification resolved that ambiguity.

As to the prosecution history, the court of appeals concluded that two of Teva's "prosecution statements directly contradict[ed] each other and render[ed] the ambiguity insoluble." Pet. App. 8a-9a. In particular, in prosecuting one patent, Teva overcame an indefiniteness rejection by asserting that one skilled in the art would understand "average molecular weight" to refer to "*peak*" molecular weight. Pet. App. 9a. Yet when prosecuting a related patent, Teva overcame the same objection by asserting that "average molecular weight" meant "*weight*" average molecular weight. Pet. App. 9a.

The court of appeals further held that "[t]he specification does not resolve the ambiguity." Pet. App. 9a. Citing Grant's declarations, Teva contended that the specification's reference to the Size Exclusion Chromatography (SEC) method for determining molecular weight implied "peak" molecular weight and that Figure 1 of the patents confirmed this. Pet. App. 8a-10a. But the court noted that the specification's reference to the SEC method resolved nothing because all the experts

(including Grant) agreed that other types of average molecular weight also can be obtained from the data generated by the SEC method. Pet. App. 10a. Moreover, the court explained, Figure 1 (reproduced below from the court's opinion) actually contradicted Grant's declarations. The curves in Figure 1 of the patent show the distribution of molecular weights in different samples of copolymer-1, but "the peaks of the curves in Figure 1 do not correspond to the values denoted as 'average molecular weight' in the figure's legend," as they would if the "average molecular weight" referred to peak molecular weight. Pet. App. 10a. Indeed, Grant conceded that "the 7.7 kDa value [stated in Figure 1] is closer to the M_w [weight average molecular weight] than to the M_p [peak molecular weight] of the corresponding batch," refuting Teva's contention that peak molecular weight was the intended measure. Pet. App. 10a.

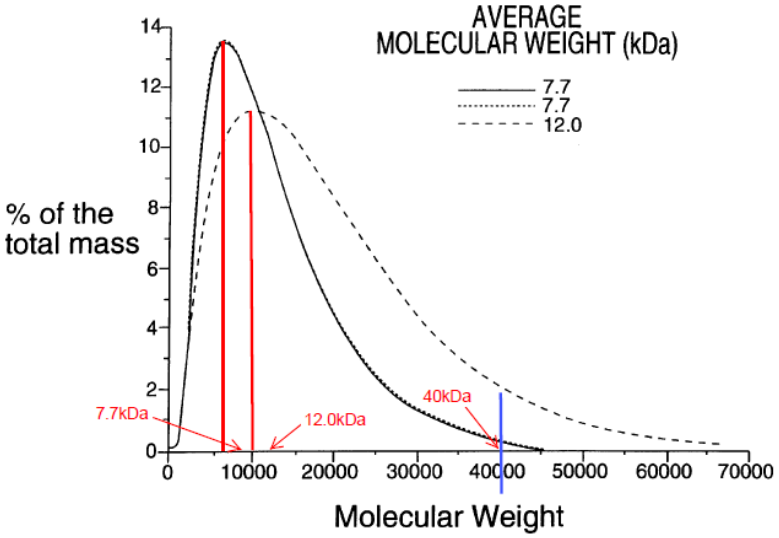

FIG. 1

Pet. App. 11a.

Because the patents and their prosecution history provided no indication as to which type of molecular weight Teva claimed, the court of appeals held that the Group I claims are indefinite and invalid. Those claims include the '808 patent's sole claim—and the only claim with a September 1, 2015 expiration date. The court of appeals went on, however, to affirm the validity and infringement of other ("Group II") claims, which the court held did not depend on average molecular weight. The Group II claims expire on May 24, 2014.

4. On September 16, 2013, after obtaining a three-week extension of the deadline for filing a rehearing petition, Teva sought rehearing and rehearing en banc. Teva thereafter filed what it called a "motion to correct the judgment" (which repeated its rehearing petition arguments), as well as a motion to stay the mandate pending a petition for a writ of certiorari. The Federal Circuit denied both motions, without dissent or calling for a response, and it issued its mandate to the district court.

5. On November 4, 2013, Teva asked the Chief Justice to recall and stay the mandate. Appl. to Recall and Stay Mandate, *Teva Pharm. USA, Inc. v. Sandoz Inc.*, No. 13A458 (U.S. Nov. 4, 2013). The Chief Justice denied that application.

6. After return of the mandate to the district court, the district court modified the terms of the injunction and entered the modified judgment, without objection from Teva. Modified Final Judgment, *Teva Pharm. USA, Inc. v. Sandoz Inc.*, No. 08-cv-7611, Dkt. No. 355 (S.D.N.Y. Dec. 20, 2013). As a result, Sandoz and Mylan presently are barred from marketing copolymer-1 only until May 24, 2014.

7. Teva waited until the ninetieth day to file its certiorari petition. Respondents filed their opposition nearly two weeks before it was due. On March 31, 2014, this Court granted certiorari. It is now too late for this Court to resolve this case this Term.

8. Meanwhile, Teva has asked the Patent Office to reissue the '808 patent. The reissue process allows the Patent Office to replace an unexpired patent with a new, "reissued" one, where the existing patent "is defective as a result of an error in the patent which was made without deceptive intention." 35 U.S.C. § 251; Manual of Patent Examining Procedure ("MPEP") § 201.05 (8th ed. Rev. 9, Aug. 2012); *see* MPEP § 201.05 (9th ed., Mar. 2014) ("A reissue application is an application for a patent to take the place of an unexpired patent that is defective."). To establish the Patent Office's grounds to consider a reissue application, the reissue applicant must submit an oath or declaration, under penalty of perjury, that identifies "at least one error * * * being relied upon as the basis for reissue." 37 C.F.R. § 1.175; MPEP § 1414. In other words, the applicant must swear that there is an error in the patent and that the applicant made a mistake in its original patent.

When Teva first sought reissue in August 2013, its oath was based on the Federal Circuit's ruling, stating only that "a panel of the Federal Circuit Court of Appeals has held that the sole patent claim is invalid for indefiniteness" and that the proposed reissue claim "addresses the error perceived by the court." Reissue Application Declaration, *In re Reissue Application of U.S. Patent No. 5,800,808*,

Appl. No. 13/964,856 (Aug. 12, 2013). The Patent Office rejected this oath as insufficient because it admitted no error. Non-Final Rejection, *In re Reissue Application of U.S. Patent No. 5,800,808*, Appl. No. 13/964,856 (Jan. 3, 2014). To cure this deficiency, on February 13, 2014, while its certiorari petition was pending, Teva submitted a new oath conceding that "Claim 1 is invalid under 35 U.S.C. 112, second paragraph, for indefiniteness." Amendment to Reissue Application Declaration, *In re Reissue Application of U.S. Patent No. 5,800,808*, Appl. No. 13/964,856 (Feb. 13, 2014). Only with that change did the examiner in the Patent Office accept Teva's oath as sufficient to create grounds to consider Teva's reissue application. Final Rejection, *In re Reissue Application of U.S. Patent No. 5,800,808*, Appl. No. 13/964,856 (Apr. 3, 2014). Ultimately, the Patent Office rejected the reissue application as indefinite and for double-patenting. *Ibid.*

In its reply in support of its certiorari petition in this Court, Teva downplayed its concession to the Patent Office, which is fundamentally inconsistent with its position in this Court. Cert. Reply 5 n.3. But Teva's conduct is not akin to pleading in the alternative. Teva has submitted an unqualified statement to a government agency, under penalty of perjury, that the only patent claim that extends beyond May 24, 2014, is invalid for indefiniteness.

REASONS THE STAY SHOULD BE DENIED

I. The Relief Teva Seeks Would Require An Injunction, Not Merely A Recall And Stay Of The Mandate, And Teva Cannot Justify That Extraordinary Relief

Teva's request seeks the wrong relief in this Court. A recall and stay of the mandate cannot "restore" an injunction that no longer exists. *Contra* Stay Appl. 1.

Following return of the mandate to the district court, that court modified the injunction. Although Teva said it would file a petition for a writ of certiorari, it did not ask the district court to delay modifying the injunction pending its petition. Teva acceded to the modification that it now seeks to undo.

Under these circumstances, even the extraordinary relief of recalling and staying the mandate would not be enough. In the ordinary course, once the appellate mandate issues, the district court may carry out proceedings consistent with the court of appeals' decision, even while this Court reviews that decision. *Aetna Cas. & Sur. Co. v. Flowers*, 330 U.S. 464, 467 (1947). Although a subsequent recall of the mandate deprives the district court of power to carry out *further* proceedings, a recall cannot undo what the district court already has done: modify the injunction consistent with the mandate of the court of appeals. *See* 16 Charles Alan Wright et al., Federal Practice and Procedure § 3938 (2d ed. 2013). Indeed, in an opinion accompanying this Court's denial of relief similar to what Teva seeks, Justice Powell explained that "[o]rdinary linguistic usage suggests that an order, once executed, cannot be 'stayed.' *Affirmative* action then becomes necessary to restore the status quo." *Graddick v. Newman*, 453 U.S. 928, 936 (1981) (Powell, J.) (emphasis added). Tellingly, Teva cites no authority to support its assertion that a recall and stay of the mandate would require the district court to take affirmative

steps to "restore the original injunction in force before the mandate issued." Stay Appl. 21; *see* Stay Appl. 1, 3, 9.[1]

Rather than a recall and stay of the mandate, "[w]hat the applicant would require in order to achieve the substantive relief that it seeks is an original writ of injunction." *Ohio Citizens for Responsible Energy, Inc. v. Nuclear Regulatory Comm'n*, 479 U.S. 1312, 1313 (1986) (Scalia, J., in chambers). Unlike a stay, an original writ of injunction is "an order *altering* the legal status quo." *Turner Broad. Sys., Inc. v. FCC*, 507 U.S. 1301, 1307 (1993) (Rehnquist, C.J., in chambers) (emphasis in original); *see Hobby Lobby Stores, Inc. v. Sebelius*, 133 S. Ct. 641, 642 (2012) (Sotomayor, J., in chambers) (same). An original writ of injunction is required because the relief Teva seeks would require "judicial intervention" to alter the existing injunction. *Lux v. Rodrigues*, 131 S. Ct. 5, 6 (2010) (Roberts, C.J., in chambers) (internal quotation marks omitted); *see Graddick*, 453 U.S. at 936. The judgment and injunction presently in place runs only until May 24, 2014. Prohibiting Sandoz and Mylan from launching their generic products after that date would require affirmative alteration of the current final judgment—and that would require a new injunction.

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[1] In a separate opinion in *Graddick*, then-Justice Rehnquist questioned Justice Powell's "linguistic usage" argument. 453 U.S. at 943. But Justice Rehnquist did not question that any request for such affirmative relief, whatever it is labeled, must meet the All Writs Act's exacting requirements. Indeed, he applied that rigorous standard—that the right to relief be "indisputably clear" and be exercised only in aid of the Court's jurisdiction—when applicants applied to him for such relief. *Turner Broad. Sys., Inc. v. FCC*, 507 U.S. 1301, 1307 (1993).

This Court's authority to issue such an injunction arises from the All Writs Act, 28 U.S.C. § 1651(a). *Hobby Lobby*, 133 S. Ct. at 642. But "'such power is to be used sparingly.'" *Ibid.* (quoting *Turner Broad. Sys.*, 507 U.S. at 1303). Unlike a stay that "suspend[s] judicial alteration of the status quo," injunctive relief "grants judicial intervention" and "therefore demands a significantly higher justification than that required for a stay." *Lux*, 131 S. Ct. at 6 (internal quotation marks omitted). The Court therefore orders injunctive relief "only when it is necessary or appropriate in aid of our jurisdiction and the legal rights at issue are indisputably clear." *Hobby Lobby*, 133 S. Ct. at 642-643 (internal quotation marks and alteration omitted); S. Ct. R. 20.1 ("Issuance by the Court of an extraordinary writ authorized by 28 U.S.C. § 1651(a) is not a matter of right, but of discretion sparingly exercised.").

Teva makes no effort to satisfy this demanding standard, and its failure to make the request for an injunction is itself sufficient reason to deny that relief. As in *Ohio Citizens*, this Court should "not consider counsel to have asked for such extraordinary relief where, as here, he has neither specifically requested it nor addressed the peculiar requirements for its issuance." *Ohio Citizens*, 479 U.S. at 1314. But even if the Court were to consider Teva's application under the All Writs Act, Teva could not meet its standards. At best, Teva has asserted that there is a "fair prospect" this Court will alter the legal rule applicable to appellate review of claim construction, not that a different rule will require a different result. Stay Appl. 9. Such a "fair prospect" comes nowhere close to "indisputably clear." And as

set forth below, the '808 patent's concededly ambiguous claim is likely to be held indefinite under any standard of appellate review. Accordingly, Teva cannot demonstrate a "right to relief [that] is 'indisputably clear.'" *Lux*, 131 S. Ct. at 7.

II. Even If A Recall And Stay Of The Mandate Could Achieve The Relief Teva Seeks, Teva Cannot Satisfy The Standard For A Recall And Stay

Even if a recall and stay of the mandate could provide the relief Teva seeks, Teva has not satisfied its burden to show that such relief is warranted. Particularly where, as here, the applicant has not sought relief first in the lower courts, a stay will not be granted "[e]xcept in the most extraordinary circumstances." S. Ct. R. 23.3. Teva can show no such extraordinary circumstances.

A. Teva has not shown that there is a "fair prospect" that the invalidity judgment will be reversed

Teva asserts that it is likely to prevail simply because this Court granted certiorari. Stay Appl. 8, 10. But the grant of certiorari is not enough to warrant the extraordinary relief of a recall and stay of the mandate. *Conkright v. Frommert*, 556 U.S. 1401, 1402 (2009) (Ginsburg, J., in chambers) (rejecting second stay application, noting that "[a] 'reasonable probability' of a grant is only one of the hurdles an applicant must clear. Relief is not warranted unless the other factors also counsel in favor of a stay."). Teva must show a "fair prospect" that a majority of the Court will reverse the judgment below.

Teva fails to carry its burden. Indeed, Teva's own "fair prospect" heading claims only a fair prospect that this Court will adopt a different legal test for appellate review of claim construction. Stay Appl. 10. Teva studiously avoids explaining how a different standard of review would mandate restoration of its

indefinite patent, devoting only a few sentences to how it might prevail under a different standard. Stay Appl. 12. That is far from sufficient.

Under the correct inquiry, Teva is not entitled to a recall and stay of the mandate. The court of appeals correctly held the Group I claims invalid for indefiniteness, and that judgment would be the same under any standard of review.

1. The invalidity judgment will stand if this Court affirms de novo review

Teva simply assumes the grant of certiorari means that this Court will reject the de novo standard of review. But that prejudges the merits, which have not yet been briefed, much less considered. Just because this Court granted certiorari on a question deemed worthy of en banc consideration by the Federal Circuit does not indicate which standard of review this Court ultimately will adopt. *See Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, No. 2012-1014, 2014 WL 667499 (Fed. Cir. Feb. 21, 2014) (en banc). If, upon full consideration of the merits, this Court affirms that the standard of review of a district court's construction of a patent claim is de novo, then Teva does not dispute that the invalidity judgment here will stand.

And de novo review of this fundamentally legal question would flow logically from this Court's decision in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 387 (1996). There, this Court concluded that claim construction "is a question of law, to be determined by the court." *Id.* at 384 (internal quotation marks omitted). That conclusion was supported by precedent, history, and policy. *Id.* at 377-391. It was consistent with long-established precedent holding that "construing the letters-

patent" is "a question of law, to be determined by the court." *Winans v. Denmead*, 56 U.S. (15 How.) 330, 338 (1854). To be sure, the *Markman* Court described its task as "classify[ing] a mongrel practice" as either an issue of "fact" or one of "law"; but that was merely a characterization of the question the Court set out to answer. *Markman*, 517 U.S. at 378. The Court's conclusion was that claim construction is a question of law. *Id.* at 391.

That conclusion is consistent with the rule applied in other areas of law, where "interpreting a set of legal words" is "purely legal." *Buford v. United States*, 532 U.S. 59, 65 (2001). Courts consistently hold that the meaning of written documents, such as land patents, deeds, wills, or other agreements, is an issue of law subject to de novo review. *See Brown v. Huger*, 62 U.S. (21 How.) 305, 318 (1859); *Maritimes & Ne. Pipeline, LLC v. Echo Easement Corridor, LLC*, 604 F.3d 44, 47 (1st Cir. 2010); *Terran v. Kaplan*, 109 F.3d 1428, 1432 (9th Cir. 1997); *Smoot v. Boise Cascade Corp.*, 942 F.2d 1408, 1411 (9th Cir. 1991). Statutory and constitutional interpretations similarly are subject to de novo review, even when they require historical inquiries. *See, e.g.*, *District of Columbia v. Heller*, 554 U.S. 570, 576 (2008); *al-Marri v. Rumsfeld*, 360 F.3d 707, 711 (7th Cir. 2004). Rule 52(a) does not require otherwise, as that rule "does not apply to conclusions of law." *Pullman-Standard v. Swint*, 456 U.S. 273, 287 (1982). Just as this rationale led to *Markman*'s conclusion that claim construction is a legal question for the court, it likewise may well lead this Court to conclude that de novo appellate review applies to that same question.

2. Even if deference were accorded to a district court's determinations regarding "historical facts," there is no "fair prospect" of reversal of the invalidity judgment

Contrary to Teva's assumption (Stay Appl. 10, 12), even if this Court were to accord deference to a district court's determinations regarding "historical facts" (as some amici had pressed in the en banc Federal Circuit in *Lighting Ballast*), that would not change the outcome here, because the expert "evidence" Teva submitted consisted of merely legal opinion, not "historical fact." *Contra* Stay Appl. 12.

Teva conceded below that the patent claims at issue are ambiguous on their face because they do not specify which type of molecular weight is claimed. Pet. App. 8a ("It is undisputed that Group I claims contain an ambiguity because their plain language does not indicate which average molecular weight measure is intended."). On appeal, the court of appeals properly looked to the patents and their prosecution history when holding the terms indefinite. Pet. App. 8a-10a.

First, the court of appeals observed that, during prosecution of its patents before the Patent Office, Teva gave two flatly contradictory definitions of "average molecular weight." Pet. App. 9a. As discussed above, in one instance, Teva told the Patent Office that one of ordinary skill in the art would understand "average molecular weight" to mean "peak" molecular weight. Pet. App. 9a (quoting C.A. JA3258). Yet in another, Teva told the Patent Office that "average molecular weight" meant "weight average molecular weight." Pet. App. 9a (quoting C.A. JA3229). No matter what an expert might later say in litigation, "Teva's two definitions cannot be reconciled." Pet. App. 9a.

Second, the court of appeals looked to the patents' common specification and determined that it too provided no guidance regarding the meaning of "average molecular weight." Pet. App. 9a-10a. The court of appeals recognized that Figure 1 of the patent contradicted the opinion of Teva's expert that the figure referred to "peak" molecular weight. Pet. App. 9a-10a. Even a cursory examination of the patent demonstrated that "the peaks of the curves in Figure 1 do not correspond to the values denoted as 'average molecular weight' in the figure's legend." Pet. App. 10a. Indeed, those reported "average molecular weight" values were closer to "weight average molecular weight" than to "peak" molecular weight—as even Teva's expert admitted. Pet. App. 10a; *see* C.A. JA5824-5825.

Teva's contrary "evidence" consisted solely of written declarations of its paid expert. *See* Stay Appl. 12. While those declarations contained undisputed background information about "polypeptide[s] and molecular weight" generally, Pet. App. 94a-118a, the purported "facts" on which Teva relied were Teva's expert's litigation-driven "interpretation" of the patent documents themselves—an attempt to disregard Teva's inconsistent statements on the face of the specification and prosecution history. *See* C.A. JA1016-1018, JA7097-7101 (Grant declarations discussing "average molecular weight"). That is not "evidence" about "the *historical* meaning of a claim term to one of ordinary skill in the art at the time of the invention." U.S. En Banc Amicus Br. at 15, *Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, No. 2012-1014, 2014 WL 667499 (Fed. Cir. June 11, 2013) (emphasis added). Nowhere did the expert contend that "average molecular weight"

had an established meaning at the time of the invention. *Contra* Stay Appl. 12. In fact, Teva admitted that the term was ambiguous and had no fixed meaning. Pet. App. 8a.

As such, the "evidence" Teva cites is not the kind of "historical fact" evidence that the United States and some other amici have contended could support findings warranting deference on appeal. *Contra* Stay Appl. 10. Quite the opposite: the United States has explained that courts "must exercise care to distinguish relevant and probative expert testimony (e.g., testimony about the accepted meaning of a claim term in the relevant art at the time of the invention) from irrelevant opinion (e.g., an expert's present, subjective understanding of a patent claim)." U.S. En Banc Amicus Br. at 20, *Lighting Ballast*, *supra*. Because Teva's expert declarations offered only the latter, there is no "fair prospect" that the invalidity judgment will be different if this Court were to accord deference to a district court's conclusions regarding "historical facts."

3. Even under clear-error review, there is no "fair prospect" the invalidity judgment will be reversed

Teva similarly has not carried its burden to show a "fair prospect" that the invalidity judgment would be reversed even under a "clear error" regime.

For one thing, Teva contends that the "central question in this case was a factual one: how would a person of ordinary skill in the art at the time of the invention have understood a scientific claim term? If there is a definite answer to that manifestly factual question, then the patent is not indefinite." Stay Appl. 12. But the ultimate issue of indefiniteness is a legal question. *Markman*, 517 U.S. at

384. And that is so even if all subsidiary factual findings are accorded clear-error review. *Cf. Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2253 (2011) (Breyer, J., concurring) (warning against conflation of ultimate legal determinations and subsidiary factual issues in assessing and reviewing patent invalidity).

For another, even under clear-error review of any subsidiary "factual findings," no deference would be owed to what the district court did here, where the evidence Teva relies on as "credit[ed]" by the district court consisted of expert declarations that directly contradicted the legal documents. As this Court has recognized, "expert evidence" cannot be used to construe a patent to expand what is described on "the face of the papers" themselves. *U.S. Indus. Chems., Inc. v. Carbide & Carbon Chems. Corp.*, 315 U.S. 668, 677-678 (1942). That is particularly true where the expert declaration seeks to resolve an irreconcilable conflict in a patent's prosecution history or to trump a patent's specification. Such a result would deprive the public of clear notice of what constitutes infringement and would undermine the statutory requirement that patent claims must "particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b) (2012) (formerly 35 U.S.C. § 112 ¶ 2); *see United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942); *Permutit Co. v. Graver Corp.*, 284 U.S. 52, 60 (1931).

Consistent with these principles, the en banc Federal Circuit has recognized that courts "should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and

the prosecution history, in other words, with the written record of the patent." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). The en banc court of appeals cautioned that such expert testimony "poses the risk that it will be used to change the meaning of claims in derogation of the indisputable public records consisting of the claims, the specification and the prosecution history, thereby undermining the public notice function of patents." *Id.* at 1319 (internal quotation marks omitted). And this Court likewise has held that "[i]t is inadmissible to enlarge the scope of the original patent by recourse to expert testimony * * * ." *U.S. Indus. Chems.*, 315 U.S. at 678.

Applying these principles here, the district court's "factual findings" cannot save these patents, even under clear-error review. To overcome the conceded ambiguity of the claims, Teva's expert contradicted the patent's specification and purported to explain away the irreconcilable prosecution history. For example, with regard to one of Teva's two irreconcilable definitions of "average molecular weight" in the prosecution history, Grant contradicted the public record by saying that one of skill in the art reading the prosecution history "would have understood that to be a misstatement." C.A. JA7100. Moreover, because his readings of the "peaks" in Figure 1 of the specification did not correspond to the "average molecular weight" values denoted in that figure's legend, Grant opined that Figure 1 was erroneous and that his calculation fell within an unspecified "margin of error." C.A. JA3115-

3116.[2] A district court should not give weight to "expert evidence" that contradicts the written record of the patent documents and the prosecution history; nor should a court of appeals give deference to a district court's reliance on any such "evidence," even under clear-error review.

Simply put, the court of appeals properly refused to allow a litigation expert to determine the ultimate meaning of the patent instruments. That outcome would not change under any standard of review.[3]

B. Teva will not suffer irreparable harm in the absence of a stay

1. Teva bears the burden of establishing present irreparable harm

As the party seeking the stay (or, more properly, the injunction), Teva has the present burden to show irreparable harm. This Court has held that injunctions are *not* automatic in patent cases, even upon a final determination that a patent is

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[2] Grant did not explain what he meant by a "margin of error," but he asserted that a 100% or 200% error could fall within a "margin of error." C.A. JA3099.

[3] The possibility of a change in the substantive standard for determining indefiniteness provides an additional reason to doubt that Teva ultimately will prevail on the merits. Under Federal Circuit precedent, a patent is not indefinite as long as it is "amenable to construction, however difficult that task may be," and a court may invalidate a claim for indefiniteness only if the claim is "insolubly ambiguous, and no narrowing construction can properly be adopted." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). In *Nautilus, Inc. v. Biosig Instruments, Inc.*, No. 13-369 (to be argued April 28, 2014), this Court is considering whether that standard is faithful to 35 U.S.C. § 112(b), which requires that a patent contain "one or more claims particularly pointing out and distinctly claiming the subject matter which the [applicant] regards as the invention." Because Teva's claims could not survive under the Federal Circuit's current standard, which is very generous to vague patents, they would, *a fortiori*, fail to survive any more rigorous standard that this Court might adopt in *Nautilus*.

valid and has been infringed. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393-394 (2006). Thus where, as here, a patent holder seeks to block the entry of a competing generic drug, courts do not issue injunctions without a specific showing of irreparable harm. *Contra* Stay Appl. 13; *see, e.g.*, *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1010-1011 (Fed. Cir. 2009) (affirming the district court's finding of no irreparable harm where "the plaintiffs had not shown that the defendants were unable to respond in money damages"); *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1347-1348 (Fed. Cir. 2006) (rejecting plaintiff's argument that "the sharp economic consequences of open competition from generic drugs establish the inadequacy of monetary damages and irreparable harm," and reasoning that "we do not doubt that generic competition will impact [plaintiff's] sales * * *, but that alone does not establish that [its] harm will be irreparable").

And this Court evaluates whether to grant a stay (or, more correctly, an original writ injunction) on the basis of the record that exists today, not the record that may have existed in the past. As members of the Court have explained, an "applicant must demonstrate * * * a likelihood that irreparable harm [will] result *from the denial of a stay*." *Conkright*, 556 U.S. at 1402 (emphasis added); *see Rubin v. United State*s, 524 U.S. 1301, 1301 (1998) (Rehnquist, C.J., in chambers) ("An applicant for stay first must show irreparable harm *if a stay is denied*.") (emphasis added). Teva thus is incorrect in contending that Sandoz and Mylan's decision not to contest the entry of an injunction two years ago (after they had lost in the district court) means that they must agree to the entry of a new stay or injunction now that

they have prevailed in the court of appeals, the original injunction has been modified in their favor, and the patent is nearing its expiration. *Contra* Stay Appl. 13. Indeed, Teva implicitly acknowledges that showing irreparable harm is its burden by submitting a new declaration—a declaration it failed to submit last fall when it sought a stay in the Federal Circuit and this Court.

2. Teva's potential harms are not irreparable

a. Teva has failed to demonstrate that its claimed potential harm is irreparable. The mere loss of money can be compensated by a damages award, and thus does not constitute irreparable harm. *Sampson v. Murray*, 415 U.S. 61, 90 (1974) ("The key word in this consideration is irreparable. Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough.") (internal quotation marks omitted); *Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1578-1579 (Fed. Cir. 1996) (affirming denial of motion for preliminary injunction against a generic drug manufacturer where "calculating lost profits would be a relatively simple task" and the defendants "have adequate assets to satisfy any judgment likely to be awarded").

Here, any harm Teva would suffer as a result of the marketing of competing generic drugs could be remedied by a money judgment. The only basis for irreparable harm that Teva identifies is set forth in the declaration of Teva's Vice President of Marketing, John Hassler. But nothing in that declaration demonstrates that Teva's claimed injury is irreparable. First, Hassler states that Teva invested "hundreds of millions" of dollars to develop Copaxone®, suggesting that continuing its monopoly is necessary to recoup those costs. Hassler Decl. 2.

Not so. According to industry sources, Copaxone® has generated revenues of at least $40 billion over the last twenty years; in 2013 alone, Teva profited by over $2 billion from Copaxone® sales. Teva has been paid in full for its development costs.

Next, Hassler asserts that generic competition will lead to an irreversible decline in Teva's market share and in the price it can charge. Hassler Decl. 3-5. Even if true, that does not establish that the resulting harm could not be remedied by money damages. Indeed, Teva has refuted similar claims of irreparable harm in other cases, explaining that "a 'drastic' loss of market share or revenue as a result of competition * * * would not constitute irreparable harm. Loss of market share and revenue is a classic example of harm that is compensable by money damages." Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction at 36 ["Teva's Eisai Opposition"], *Eisai Co. Ltd. v. Teva Pharm. USA, Inc.*, No. 05-5727 (D.N.J. Feb. 29, 2008). Teva was right then, and its newfound contrary view is unconvincing.

Hassler also states that "precision in estimating lost market share and revenue [is] very difficult." Hassler Decl. 3. But here that also is not true. Teva has publicly quantified its expected losses from generic competition. In a December 2013 statement to investors, Teva calculated the amount it expects to lose if Copaxone® faces generic competition as early as June 1, 2014. Teva Pharm. Indus. Ltd., *Teva Provides 2014 Financial Outlook* (Dec. 10, 2013).[4] That statement

[4] *Available at* http://ir.tevapharm.com/phoenix.zhtml?c=73925&p=irol-newsArticle&ID=1883417&highlight.

provides considerable detail and a narrow range for its expected losses, including a loss of net revenues of approximately $500 million for 2014. *Ibid.* Teva also concludes that each month that generic entry into the market is delayed will result, on average, in approximately $78 million in additional net revenues. *Ibid.*

More importantly, whether or not it is possible to *estimate* Teva's losses from generic competition now, it certainly is within the ability of a district court to hear evidence to determine the appropriate *measure* of those losses once they occur. Teva currently has 100% of the market for Copaxone®. A court should be able to calculate any decrease in the price of Copaxone® attributable to the advent of competition. This calculation will be aided by the fact that, should Teva ultimately prevail, Teva at worst faces the prospect of reduced revenue from sales of its drug during a period of just over a year. As Teva concedes, the patents that the court of appeals upheld will shield it from competition until May 2014 at the earliest, and the patent at issue here will expire in September 2015. Stay Appl. 4. This case therefore differs from one in which a patentee might suffer an erosion in the price "[d]uring the growth stage of a product," resulting in a loss that is difficult to calculate and hence irreparable. *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930-931 (Fed. Cir. 2012). Teva has not attempted to show that a court would be unable to calculate an appropriate damages award to compensate it for any lost revenue due to generic competition during that finite period of time.

Teva suggests that there are "serious questions about respondents' ability to pay money damages" should the district court's ruling ultimately be upheld. Stay

Appl. 16. That suggestion is unfounded. As explained in the confidential declaration of Samuele Butera and the declaration of Tony Mauro, respondents have ample resources to satisfy any judgment. Teva certainly has "not establish[ed] that recoupment will be impossible." *Conkright*, 556 U.S. at 1402.

b. The purported non-economic harms described in the Hassler declaration are not irreparable either. Hassler contends that the introduction of a generic Copaxone® competitor may undermine Teva's ability to provide patient treatment support and to educate healthcare providers about multiple sclerosis and using Copaxone®, and that Teva may terminate employees engaged in these efforts. Hassler Decl. 6-9. It is difficult to see how not spending money on marketing efforts would constitute harm to Teva. Teva has elsewhere attacked arguments paralleling those it now advances, describing as "without merit" the "assertion that a variety of potential business consequences flowing from reduced profits and revenues, such as reduced expenditures on clinical studies and potential sales force layoffs, should be found to constitute irreparable harm." Teva's Eisai Opposition, *supra*, at 37-38 (discussing *Eli Lilly*, 82 F.3d at 1578). Indeed, the absence of merit is particularly true here, where Teva's "patient outreach" today is geared towards "trying to convert patients to a new, more concentrated form of Copaxone" that Teva claims is covered by new patents until 2030. *See* Andrew Pollack, *Supreme Court to Hear Appeal of Generic Drug Case*, N.Y. Times, Apr. 1, 2014, at B3. There thus is no reason to believe that "patient outreach" will continue in earnest once that conversion has been completed and the patents at issue here expire.

3. Teva's claims are undermined by its failure to act with urgency

Finally, Teva's "delay in filing [its] petition * * * vitiates much of the force of [its] allegations of irreparable harm." *Beame v. Friends of the Earth*, 434 U.S. 1310, 1313 (1977) (Marshall, J., in chambers). Teva points out that it filed this application soon after the petition for a writ of certiorari was granted. Stay Appl. 15. But that ignores the delay that occurred *before* Teva filed its certiorari petition. "Were the injury" to Teva from a generic launch truly irreparable, "one would think that [Teva] would have filed [its] petition for certiorari with dispatch, so that this matter could have been resolved by the entire Court" this Term. *Beame*, 434 U.S. at 1313. Instead, as in *Beame*, Teva "waited the maximum time, 90 days, after the Court of Appeals denied rehearing and rehearing en banc before filing [its] petition." *Ibid.* Had Teva "filed [its] petition for certiorari with dispatch," this case could have been heard on the merits this Term, resulting in a decision before, or at least very shortly after, the May 24, 2014 expiration of the other patents covering Copaxone®.

C. The balance of the equities forecloses Teva's request

Even if Teva could show that it faces irreparable injury, it would not be entitled to an injunction or a stay because any injury to Teva would be outweighed by the injury to respondents, patients, and third party payors (including the federal government). Justices often look to "balance the equities—to explore the relative harms to applicant and respondent, as well as the interests of the public at large." *Conkright*, 556 U.S. at 1402 (internal quotation marks omitted); *see Barnes v. E-*

Systems, Inc. Grp. Hosp. Med. & Surgical Ins. Plan, 501 U.S. 1301, 1305 (1991) (Scalia, J., in chambers).

1. An injunction or stay would cause severe harm to respondents

Teva ignores the immense harm that Sandoz and Mylan would suffer if they were barred from entering the market with their competing products, and it identifies no avenue of recourse for them if such an order were to turn out to have been improvidently granted.

What is more, the harm to Sandoz and Mylan from an injunction or stay is likely to extend well beyond the duration of any such order as a result of Teva's ongoing efforts to undercut the present Copaxone® market before the introduction of a generic alternative. Until a few months ago, Copaxone® had been administered only in daily 20-milligram injections—the version of the drug that Sandoz and Mylan intend to produce. But on January 28, 2014, Teva obtained FDA approval to market a version of the drug that is administered in 40-milligram injections three times a week. Glatiramer Acetate, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, U.S. Food & Drug Admin.[5] The 40-milligram version purportedly is covered by separate patents, not at issue in this litigation, that will not expire until 2030. *Ibid.*

Because that 40-milligram version is shielded from imminent generic competition, Teva has made efforts to move the Copaxone® market to that version,

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[5] http://www.accessdata.fda.gov/scripts/Cder/ob/docs/obdetail.cfm?Appl_No=020622&TABLE1=OB_Rx (last visited Apr. 9, 2014).

because "the more patients it converts ahead of generic approvals, the higher the probability insurers won't force those customers to switch back to daily shots once generics become available." David Wainer, *Teva's Early Copaxone Conversion Effort Convincing Analysts*, Wash. Post, Mar. 11, 2014. Indeed, Teva even has created financial incentives for patients to use the new 40-milligram version by pricing it thousands of dollars per year lower than the 20-milligram formulation. *See* Pollack, *supra*, at B3; *see also* Mauro Decl. ¶ 22 (explaining the practical difficulties of switching patients and payors back to the original formulation after they have adopted a new one).

Simply put, Teva is aggressively moving to cannibalize the 20-milligram market that Sandoz and Mylan are seeking to enter: by February 28, 2014—after only one month on the market—Teva already had switched 8.7% of Copaxone® users to the 40-milligram formulation. Wainer, *supra*. Teva's chief science officer, Michael Hayden, said earlier this year that the company expects to switch nearly half of existing patients to the new version of Copaxone® in order to protect its market from generic competition. Simon King, *Physician Views: How Will Neurologists Embrace Teva's New Version of Copaxone? What About Potential Generic Versions Later This Year?*, FirstWord Pharma, Feb. 3, 2014. And analysts have remarked that investors "may have failed to understand just how comprehensive Teva's patient outreach system has been." Wainer, *supra* (internal quotation marks omitted).

As a practical matter, an injunction or stay delaying competition would decide this litigation for Teva. It would give Teva more time to implement its switching strategy without competition from Sandoz or Mylan for the 20-milligram product, thereby allowing Teva to continue its aggressive efforts to decimate the generic market for that product. The Court should not countenance Teva's plan to lock up the market not just for fifteen more months, but for fifteen years after that.

2. An injunction or stay would not be in the public interest

An injunction or stay also would harm patients and payors (including the federal government) because it would allow Teva to continue charging monopoly prices for Copaxone®, a product that the Federal Circuit has held not to be covered by a valid patent. Over the last decade, the annual cost of Copaxone® has "roughly quadrupled * * * to about $60,000 a year." Pollack, *supra*, at B3. As one doctor remarked, "'The prices would go up 10, 20, 30 percent at a time for no apparent reason.'" *Ibid.* (quoting Dr. John R. Corboy, co-director of the Rocky Mountain Multiple Sclerosis Center at the University of Colorado). Teva has increased the price of Copaxone® by at least 24.7% since October 2012. *See* Teva Pharm. Indus. Ltd., Annual Report for Year Ending Dec. 31, 2013 at 65 (Feb. 10, 2014) (reporting price increases for Copaxone® of 4.9% in October 2012 and 9.9% in January 2013); David Wainer, *Teva Braces for Tussle with Insurers Over Copaxone's Heir*, Bloomberg News (Mar. 2, 2014), http://www.bloomberg.com/news/2014-03-02/teva-braces-for-tussle-with-insurers-over-copaxone-s-heir.html (reporting price increase for Copaxone® of 9.9% in January 2014).

One of the primary reasons that Congress enacted the Hatch-Waxman Act was to allow generic-drug manufacturers to launch their products as quickly as possible upon the expiration of valid patents or the invalidation of invalid ones. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670-671 (1990); *see Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (noting that the statute "is designed to speed the introduction of low-cost generic drugs to market"). Litigation under Paragraph IV, in particular, is intended to encourage generic manufacturers to challenge invalid patents so that the generic product can be available to consumers as quickly as possible. *See Arkansas Carpenters Health & Welfare Fund v. Bayer AG* (*In re Ciprofloxacin Hydrochloride Antitrust Litig.*), 544 F.3d 1323, 1338 (Fed. Cir. 2008); *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1327-1328 (Fed. Cir. 2005). An injunction or stay would frustrate that congressional purpose.

Teva attacks the proposition that "whatever makes patented inventions available more cheaply will serve the public interest." Stay Appl. 17. That argument begs the question, which is whether Copaxone® *is* a patented invention. Teva's patent has been determined to be invalid and that judgment is likely to remain regardless of how this Court resolves the legal question Teva has presented. Accordingly, the harm to competition, and to individuals with multiple sclerosis,

would be a significant, real cost to an injunction or stay, and it is appropriate for this Court to consider it in evaluating the public interest.[6]

III. If A Stay Or Injunction Is Ordered, That Relief Should Be Conditioned On The Posting Of Substantial Bonds

Teva has not shown that an injunction or stay is appropriate. But if such an order were to be issued, it should be conditioned on the posting of substantial bonds—one for Sandoz and one for Mylan—to ensure that Sandoz and Mylan can be fully compensated in the event it is determined that the injunction was improvidently granted.[7] Absent a bond, Sandoz and Mylan will be without recourse for any injuries they suffer if wrongly enjoined. *See Russell v. Farley*, 105 U.S. 433, 437 (1881); *W.R. Grace & Co. v. Local Union 759, Int'l Union of United Rubber, Cork, Linoleum & Plastic Workers of Am.*, 461 U.S. 757, 770 n.14 (1983) ("A party injured by the issuance of an injunction later determined to be erroneous has no action for damages in the absence of a bond.").

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[6] Teva suggests that an injunction will help patients by allowing it to continue its marketing efforts, which "educat[e] physicians and other healthcare providers" and "inform[ ] them concerning the benefits and uses of Copaxone®." Hassler Decl. 6. That ignores the fact that respondents would engage in similar promotional efforts that would equally serve a "public health function" by "increas[ing] public awareness of MS." Hassler Decl. 9; *see* Mauro Decl. ¶¶ 15-17.

[7] One bond should be issued in the name of both Sandoz Inc. and Momenta Pharmaceuticals, Inc., for the sum of the damages set forth in their respective supporting declarations, Declaration of Samuele Butera, paragraphs 6 and 12, and Declaration of Richard P. Shea, paragraphs 10, 15, and 17. The other bond should be issued in the name of Mylan Inc. and Mylan Pharmaceuticals Inc. on behalf of respondents Mylan Inc., Mylan Pharmaceuticals Inc. and Natco Pharma Ltd., for the sum of the damages set forth in the supporting Confidential Declaration of Robert Tighe, paragraphs 3 and 13.

This Court has authority to condition a stay on a bond under 28 U.S.C. § 2101(f), and it has done so in the past. *Appalachian Power Co. v. Public Serv. Comm'n*, 46 U.S.L.W. 3356 (1977) (Burger, C.J.) (granting stay on condition of $46,401,000 bond); *cf.* Fed. R. App. P. 41(d)(2)(C). Indeed, a preliminary injunction, which is effectively the relief Teva now seeks, *must* be secured with a bond. Fed. R. Civ. P. 65(c).

Courts "should take care that the bond is set high enough to cover the losses that their handiwork could cause." *Roche Diagnostics Corp. v. Medical Automation Sys., Inc.*, 646 F.3d 424, 428 (7th Cir. 2011). As Judge Easterbrook has explained, "courts should err on the high side" because "[t]he fee for a solvent firm * * * to post a bond * * * is a very small fraction of the sum involved," and "an error in the other direction produces irreparable injury, because the damages for an erroneous * * * injunction cannot exceed the amount of the bond," even if actual losses are greater. *Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 888 (7th Cir. 2000). Here, the harm to Sandoz and Mylan from being wrongly stayed or enjoined from launching would be hundreds of millions of dollars. *See* Confidential Declaration of Samuele Butera; Confidential Declaration of Richard P. Shea; Confidential Declaration Of Robert Tighe In Support Of Mylan's Bond. The information that justifies those amounts is highly sensitive, as it includes forecasts of sales, revenues, and costs. Accordingly, Sandoz and Mylan are filing accompanying motions for leave to file supporting declarations under seal, to be viewed only by the Court and the parties' outside counsel, in accordance with the protective orders entered in this case by the

district court. Stipulated Protective Order, *Teva Pharms. USA, Inc. v. Sandoz Inc.*, No. 08-cv-7611, Dkt. No. 41 (S.D.N.Y. Apr. 10, 2009); Stipulated Protective Order, *Teva Pharms. USA, Inc. v. Mylan Pharms. Inc.*, No 09-cv-08824, Dkt. No. 54 (S.D.N.Y. June 11, 2010).

CONCLUSION

The application to recall and stay the mandate should be denied.

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