No. 13A_____
(13-854)

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., MOMENTA PHARMACEUTICALS, INC.,
MYLAN PHARMACEUTICALS INC., MYLAN, INC.,
AND NATCO PHARMA, LTD.,

Respondents.

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

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APPLICATION TO RECALL AND STAY THE FEDERAL CIRCUIT'S MANDATE PENDING THIS COURT'S JUDGMENT IN NO. 13-854

Elizabeth J. Holland
KENYON & KENYON LLP
One Broadway
New York, NY 10004-1050

William G. James, II
KENYON & KENYON LLP
1500 K St., N.W.
Washington, DC 20005

Alan M. Dershowitz
1575 Massachusetts Ave.
Cambridge, MA 02138

Jay P. Lefkowitz, P.C.
John C. O'Quinn
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005

Henry C. Dinger
John C. Englander
Daryl L. Wiesen
Nicholas K. Mitrokostas
GOODWIN PROCTER LLP
Exchange Place
Boston, MA 02109

William M. Jay
Counsel of Record
GOODWIN PROCTER LLP
901 New York Ave., N.W.
Washington, DC 20001
(202) 346-4000
wjay@goodwinprocter.com

David M. Hashmall
GOODWIN PROCTER LLP
620 Eighth Ave.
New York, NY 10018

April 4, 2014

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.

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APPLICATION TO RECALL AND STAY THE FEDERAL CIRCUIT'S MANDATE PENDING THIS COURT'S JUDGMENT IN NO. 13-854

To the Honorable John G. Roberts, Jr., Chief Justice of the United States and Circuit Justice for the Federal Circuit:

Applicants, Teva Pharmaceuticals USA, Inc., et al. (collectively "Teva"), respectfully seek an order recalling and staying the mandate of the U.S. Court of Appeals for the Federal Circuit, and thus requiring the District Court to restore the original injunction in force before the mandate issued, until the sending down of this Court's judgment in No. 13-854, in which the Court granted certiorari on March 31, 2014. Pertinent portions of the petition appendix in No. 13-854 ("Pet. App."), including the decision and orders below, are appended to this application as Appendix 1.

INTRODUCTION

In this case, the Federal Circuit declared invalid a key patent protecting a multibillion-dollar prescription drug treatment, Copaxone®. It did so solely because the court of appeals reviewed *de novo* and disagreed with factual findings made by the District Court in upholding the patent. This Court has now granted certiorari to decide whether the Federal Circuit should have reviewed deferentially, as mandated by Fed. R. Civ. P. 52(a)(6), instead of *de novo*. But the Federal Circuit did more than declare invalid the patent (No. 5,800,808, or the '808 patent); it also insisted on issuing its mandate, and it thus compelled the District Court to modify the permanent injunction that protected Teva against irreparable harm. Once Teva's other Copaxone® patents expire on May 24, 2014, Teva's innovative and

widely prescribed treatment for multiple sclerosis will lose protection unless the Federal Circuit's mandate is recalled. This Court's intervention is needed before that date, to ensure that its decision on the merits next Term will not come effectively too late to prevent irreparable harm to Teva.

Before filing its petition for certiorari, Teva requested that the Federal Circuit hold its mandate, and when that request was denied and the mandate issued, Teva applied to Chief Justice Roberts, as Circuit Justice, to recall and stay the mandate. Respondents opposed those requests on various grounds, but they emphasized two in particular: They contended that there was little chance the Court would grant certiorari in this case, because the Federal Circuit was considering the same legal issue *en banc* and because this case supposedly presented a poor vehicle. And they argued that any harm to Teva was not imminent, because Teva's product is protected by other patents until May 2014 and this Court would surely deny certiorari by then. Teva's applications for a stay were denied at that time. Pet. App. 87a; No. 13A458.

But this Court has now granted certiorari, choosing this case as the vehicle to decide the important question presented. It took up that question after a closely divided *en banc* Federal Circuit invoked principles of *stare decisis* and declined to reconsider the merits of its erroneous standard of review, despite the urging of (among others) the United States. Indeed, even the prevailing litigant in the case before the *en banc* Federal Circuit did not fully defend the existing rule. Given the

widespread criticism of the Federal Circuit's rule and the Court's decision to grant certiorari, there is at least a fair prospect—if not a strong probability—of reversal.

Accordingly, Teva should not now be left without the injunction that the District Court granted to protect Teva against irreparable harm. Respondents have publicly declared their intent to launch generic versions of Teva's product—which indisputably would infringe the '808 patent—as soon as the other patents expire in May. Defendants never contested in the District Court or the Federal Circuit that such a launch would result in irreparable injury to Teva, including irreversible price erosion, changes to the reimbursement rates insurers would pay for Copaxone®, and consequent reductions in support and education for Copaxone®. That injury could not be undone even if this Court were to reverse the Federal Circuit, and thus reinstate the injunction, in early 2015—by which time respondents' products likely would have been on the market for nearly a year. To preserve the parties' status as it was before the Federal Circuit put its incorrect ruling into effect, this Court should recall the Federal Circuit's mandate and stay it pending this Court's consideration of the case on the merits. The effect of that order should be to require the District Court to restore the original injunction in force before the issuance of the mandate compelled the District Court to modify it.

STATEMENT

Teva is a pharmaceutical company that markets Copaxone®, a drug widely prescribed for the treatment of multiple sclerosis. The active drug ingredient in Copaxone® is referred to in this case as "copolymer-1." Copolymer-1 is a mixture of polymer chains of four amino acids. The individual polymer chains that make up

copolymer-1 vary in length and molecular weight. The inventions claimed in the patents asserted in this case all reflect the inventors' discovery that, contrary to the prevailing understanding at the time of the invention, mixtures of relatively low molecular weight chains of copolymer-1 promised therapeutic effectiveness against multiple sclerosis with an improved side effect profile. Copaxone® is protected by a number of patents; several expire in May 2014, but one, the '808 patent, expires on September 1, 2015. The gap between those two expiration dates is the crucial period for purposes of this application.

Respondents are generic drug companies that have sought FDA approval to market generic formulations of Copaxone® before the expiration of the patents asserted in this case. Teva sued respondents in the Southern District of New York under 35 U.S.C. § 271(e)(2) for infringing these patents. Respondents denied infringement and asserted various invalidity defenses, including that the asserted patent claims were invalid for failing to satisfy the definiteness requirement of 35 U.S.C. § 112.

Respondents' indefiniteness defense turned on the construction of the terms "average molecular weight" and "molecular weight" in the asserted patent claims. Respondents argued that all of the asserted claims characterized the pertinent molecular-weight characteristics of copolymer-1 in terms of the "average molecular weight" of the molecules that comprised copolymer-1. Respondents contended that at the time of the invention, a person of ordinary skill in the art would have known of several distinct types of average molecular weight, and that it was impossible to

discern which type was to be used in practicing the claimed invention. Respondents argued that the claims were invalid for indefiniteness under 35 U.S.C. § 112. *See* Pet. App. 4a-5a, 7a.

Based on expert evidence, the District Court rejected respondents' contention and made a factual finding that a skilled artisan would understand "average molecular weight" to mean "peak molecular weight." *Teva Pharm. USA, Inc. v. Sandoz Inc.*, 810 F. Supp. 2d 578, 586-90 (S.D.N.Y. 2011). Before making that finding, the District Court had received evidence from Teva's expert witness, Dr. Grant, and respondents had an opportunity to cross-examine him at deposition. The District Court deemed Dr. Grant credible and made findings agreeing with his conclusion about the meaning of "average molecular weight." As a result, the District Court rejected respondents' contention that the asserted claims were indefinite and upheld the claims' validity. *Id.* at 590-96.

After a lengthy bench trial, the District Court found that respondents' products infringed all of the asserted patents and ruled that none of the claims in those patents was invalid. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 876 F. Supp. 2d 295 (S.D.N.Y. 2012). Following that finding, respondents chose not to oppose Teva's request for injunctive relief; in particular, respondents did not dispute that Teva would suffer irreparable injury from respondents' infringement during the term of the asserted patents. Accordingly, the District Court entered a permanent injunction under 35 U.S.C. § 283, enjoining respondents from launching their generic formulations of Copaxone® until September 1, 2015, when the last of the

asserted patents—the '808 patent—will expire. See Pet. App. 73a-82a. All of the other asserted patents expire on May 24, 2014. On appeal, respondents again did not challenge the propriety of injunctive relief, but argued only that the patents were all invalid and were not infringed.

The Federal Circuit affirmed the District Court's infringement findings and most of its validity rulings. Pet. App. 12a-24a. But the Federal Circuit undertook an independent review of the evidence considered by the District Court in support of its construction of the claim term "average molecular weight." Expressly noting that its review was *de novo*, *id.* at 7a, 10a, the court found, contrary to the District Court, that a person of ordinary skill in the art would not understand "average molecular weight" to mean "peak molecular weight," but would in fact be unable to discern what definition of "average molecular weight" should apply. The court therefore held that the patent claims relying on "average molecular weight," including the sole claim of the '808 patent, were invalid as indefinite. *Id.* at 6a-11a; *see id.* at 3a nn.1-2.

Teva petitioned for rehearing en banc, arguing that by reviewing the District Court's findings *de novo* and not for clear error as required by Fed. R. Civ. P. 52(a)(6) and the decisions of this Court, the panel had erred as a matter of law. Teva noted that the Federal Circuit had granted rehearing en banc on the same question in another case, *Lighting Ballast Control LLC v. Philips Electronics North America Corp.*, No. 2012-1014. The Federal Circuit nonetheless denied Teva's rehearing petition on October 18, 2013. Pet. App. 84a-85a.

Teva then filed a motion for a stay of the Federal Circuit's mandate pending the filing and disposition of a petition for a writ of certiorari. The Federal Circuit denied that motion as well, Pet. App. 87a, and it issued its mandate minutes later. Teva applied to the Chief Justice to recall and stay the mandate. Respondents opposed that relief on the grounds, inter alia, that this Court was highly unlikely to grant certiorari and that Teva's other patents would prevent them from launching before May 2014. The Chief Justice denied the application. No. 13A458 (Nov. 13, 2013).

Compelled to act by the Federal Circuit's mandate, the district court amended its injunction to permit respondents to launch a product that would infringe the '808 patent once the other patents expire on May 24, 2014. *See* Modified Final J., No. 1:08-cv-7611-WHP-AJP, ECF No. 355 (S.D.N.Y. Dec. 20, 2013). Respondents accordingly began to inform the public that they planned to launch generic products as soon as they were no longer enjoined. *See, e.g.*, Thomson Reuters StreetEvents, *Edited Transcript of Mylan Inc. at Cowen Health Care Conference*, Mar. 4, 2014, at 3, http://www.alacrastore.com/thomson-streetevents-transcripts/Mylan-Inc-at-Cowen-Health-Care-Conference-T5299086 (quoting John Sheehan, Mylan Inc. EVP and CFO, as stating: "We will bring Copaxone to market at market formation here later this year, in May of 2014.").

Teva then filed its petition for a writ of certiorari.[1] During the briefing on

[1] Teva also requested that the Patent and Trademark Office reissue the '808 patent to correct the basis on which the Federal Circuit ruled. To date, the PTO has declined to do so, most recently issuing a rejection of the reissue claims based on arguments advanced before the PTO by one of the respondents here.

that petition, the Federal Circuit decided by a vote of 6-4 to adhere to its longstanding rule that all claim construction rulings are reviewed *de novo*, with no deference to the district court. *Lighting Ballast*, 2014 WL 667499 (Fed. Cir. Feb. 21, 2014).

On March 31, 2014, this Court granted the petition for a writ of certiorari to decide whether the Federal Circuit's standard of review is correct. Pet. i.

REASONS FOR STAYING THE FEDERAL CIRCUIT'S MANDATE

Ordinarily, an applicant seeking a stay of a court of appeals' mandate must demonstrate "(1) 'a reasonable probability' that this Court will grant certiorari, (2) 'a fair prospect' that the Court will then reverse the decision below, and (3) 'a likelihood that irreparable harm [will] result from the denial of a stay.'" *Maryland v. King*, 133 S. Ct. 1, 2 (2012) (Roberts, C.J., in chambers) (citation omitted; brackets in original). Irreparable harm for these purposes is gauged on the assumption that the applicant's position on the merits is correct. *Barnes v. E-Systems, Inc. Grp. Hosp. Med. & Surgical Ins. Plan*, 501 U.S. 1301, 1302 (1991) (Scalia, J., in chambers). The same standard applies whether or not the lower court has issued its mandate; it makes no difference that the Circuit Justice must order the mandate recalled before staying it. *See, e.g.*, *Wise v. Lipscomb*, 434 U.S. 1329, 1333-34 (1977) (Powell, J., in chambers) (applying stay standard).

In this case the Court has already granted certiorari, eliminating any dispute on the first point. The grant largely answers the second point as well: the Court would not have granted review in a patent case if it did not see at least a "fair prospect" that it would reverse the Federal Circuit. The widespread criticism of the

Federal Circuit's rule, including from the United States and a sizeable minority of the circuit's judges, confirms that there is *more* than a fair prospect of reversal here. And the Federal Circuit's insistence on putting its mandate into effect and prematurely lifting the District Court's injunction is threatening irreparable injury to Teva because it would allow respondents to launch infringing products and irreversibly reshape the relevant market before this Court can review the Federal Circuit's decision on the merits. The mandate should be recalled and the District Court's injunction restored.

I. Respondents' previous arguments opposing a stay are largely mooted by the grant of certiorari.

Respondents devoted the lion's share of their previous brief opposing a stay to arguments that this Court should not and would not grant certiorari. So long as the Federal Circuit was considering the same issue in *Lighting Ballast*, they contended, the question presented could not be certworthy. 13A458 Resps.' Stay Opp. 1-2, 10-11. And they argued that this case would be an unsuitable or inferior vehicle to decide the question presented. *Id.* at 11-13, 14-16.

This Court has now granted certiorari. Accordingly, most of respondents' arguments have been mooted. The only remaining questions are whether there is fair prospect that this Court will reverse, and whether reinstating the District Court's injunction while this Court considers the merits would prevent irreparable injury to Teva. The answer to both questions is yes.

II. There is a fair prospect that this Court will rule that factual findings made by district courts in claim construction should be reviewed for clear error.

This Court does not generally grant review in patent cases from the Federal Circuit—where there are no circuit splits to resolve—without perceiving at least a "fair prospect" of reversal. This case is no exception. Perhaps the clearest sign that the Court is likely to reverse is the unwillingness of the litigants who have benefited from the Federal Circuit's current rule, either in this case or in *Lighting Ballast*, to defend that rule on its merits. In their 30-page brief in opposition to certiorari, respondents did not offer *a single word* in defense of the Federal Circuit's current standard. And in *Lighting Ballast*, even the appellant that had prevailed before the panel under a *de novo* standard of review declined to stand squarely behind the no-deference rule; in its en banc brief it "support[ed] modifying [the Federal Circuit's longstanding approach] to apply a clearly erroneous standard of review when, as part of claim construction, the district court resolves a disputed issue of historical fact." Reh'g En Banc Brief of Def.-Appellant at 13, *Lighting Ballast*, *supra* (Fed. Cir. filed May 20, 2013) (No. 2012-1014). Many *amici* in *Lighting Ballast* likewise conceded that factual issues can arise during claim construction, even while they supported retaining the no-deference rule in large part. *See Lighting Ballast*, 2014 WL 667499, at *31 (O'Malley, J., dissenting) (citing amicus briefs). And many other *amici* expressly opposed the no-deference rule, including the United States. *See* U.S. Amicus Br. at 4-18, *Lighting Ballast*, *supra* (Fed. Cir. filed June 11, 2013) (No. 2012-1014). The no-deference rule has drawn

consistent criticism from district judges, practitioners, and academics as well. *See Lighting Ballast*, 2014 WL 667499, at *24-25 (O'Malley, J., dissenting).

Yet the Federal Circuit retained its no-deference rule *unmodified*, solely as a matter of *stare decisis*, and with the votes of judges who had previously expressed willingness—or even eagerness—to reconsider it. *Compare Lighting Ballast*, 2014 WL 667499 (6-4 majority opinion joined by Dyk and Moore, JJ.), *with Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 659 F.3d 1369, 1373 (Fed. Cir. 2011) (Moore, J., dissenting from denial of rehearing en banc) (describing the no-deference rule as resting on the "fallacy that the entire process is one of law," and opining that claim construction "is *clearly* a mixed question of law and fact and deference should be given to the factual parts") (emphasis added), *and Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 469 F.3d 1039, 1045 (Fed. Cir. 2006) (Gajarsa, J., joined by Linn and Dyk, JJ., concurring in denial of rehearing en banc) (expressing willingness to reconsider the no-deference rule where resort to expert evidence is needed "to interpret particular claim terms in the field of the art"). Indeed, only Judge Lourie defended the *de novo* standard of review on the merits, in a solo concurrence. 2014 WL 667499, at *17-21.

But this Court is certainly not bound by *stare decisis* to follow Federal Circuit precedent. And on the merits, the Federal Circuit's no-deference rule is wrong. *See Lighting Ballast*, 2014 WL 667499, at *29 (O'Malley, J., dissenting) ("*Cybor* was not compelled by the Supreme Court's guidance; . . . it is actually a wide departure from it."). Rule 52(a)(6) and the decisions of this Court require courts of appeals, in all

cases and without exception, to review a district court's findings of fact only for clear error. *See Anderson v. City of Bessemer City*, 470 U.S. 564, 573-74 (1985); *Pullman-Standard v. Swint*, 456 U.S. 273, 287 (1982) (Rule 52(a) "does not make exceptions"). 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. After considering the expert evidence—which on the key points was unrebutted—the district court made findings to resolve that factual question. That is a "clear example" of a claim-construction issue whose "'evidentiary underpinnings'" are properly the subject of factual findings. U.S. Amicus Br. at 15, *Lighting Ballast, supra* (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996)). There is at least a "fair prospect" that this Court will apply Rule 52(a)(6) and hold that finding entitled to deference.

III. Teva will likely face irreparable harm if the mandate is not recalled.

Absent a recall of the mandate, respondents will be free to launch products that infringe the '808 patent fifteen months before that patent expires. In analyzing whether that premature launch will cause Teva irreparable harm, the Court assumes that Teva's legal position is correct, *Barnes*, 501 U.S. at 1302—an assumption that carries greater weight now that the Court has chosen to grant the petition. Applying that standard, the Federal Circuit's insistence on lifting the District Court's injunction while this Court's review proceeds will leave Teva unprotected and likely cause Teva serious, irreparable harm.

As a threshold matter, it is too late for respondents to dispute the risk of irreparable harm. The District Court necessarily found such a risk by predicating its permanent injunction on 35 U.S.C. § 283, which authorizes injunctions "in accordance with the principles of equity." Final Judgment ¶ 11. Those principles that include the requirements of irreparable harm and inadequacy of legal remedies. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).[2] Respondents did not challenge the propriety of this injunction before the District Court (where a factual record could have been made) or on appeal. They should not be heard to challenge the propriety of such relief now.

Nor would such a challenge have any merit. The launch of a generic competitor to a patented drug often results in a severe, and usually irreversible, decline in the price of the patented drug, among other forms of irreparable harm. Such launches therefore are routinely enjoined when they would infringe a patent. *See*, *e.g.*, *Aria Diagnostics, Inc . v. Sequenom, Inc.*, 726 F.3d 1296, 1304-05 (Fed. Cir. 2013); *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382-83 (Fed. Cir. 2006); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001).

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[2] The '808 patent is not the type of patent for which Congress specifically authorized limited injunctive relief as an infringement remedy because the '808 patent claims a method of manufacturing a drug, not the drug itself or the use of the drug. 35 U.S.C. § 271(e)(2), (e)(4). Because the '808 patent is the only patent-in-suit that will still be in force between May 2014 and September 2015, respondents had the right—and every incentive—to raise in the District Court the same arguments about the supposed lack of irreparable harm during that period that they now advance in their opposition. They did not do so.

Teva faces these harms and more. As the declaration of John Hassler submitted as Appendix 2 to this application makes clear,[3] in the market for prescription drugs the entry of lower-cost generic competitors typically results in the reassignment of the innovative drug to a less favorable tier on drug formularies, *i.e.*, lists of drugs compiled by third-party payors such as HMOs that are covered by insurance programs. Such reassignment usually triggers a higher co-payment by insured patients, or, in some instances, makes the innovative product ineligible for reimbursement by the patient's insurer. The innovator must then either significantly reduce its prices or watch most of the demand for its product evaporate. Even if Teva ultimately prevails, the price concessions it would be forced to make are for all practical purposes irreversible. Appendix 2, ¶¶ 13-16. Moreover, the decimation of the market for Copaxone® will severely impair Teva's ability to sustain programs in which Teva pays for nursing assistance for MS patients using Copaxone®. *Id.* ¶¶ 17-25.

The arguments that respondents advanced in opposing Teva's earlier application to recall the mandate have by now lost whatever limited force they had several months ago. Respondents argued that Teva faced no *imminent* irreparable harm in November 2013 when the earlier application was filed, because other patents protect Copaxone® until May 24, 2014, and certiorari might be denied by then. 13A458 Resps.' Stay Opp. 17-19. But that date is now near at hand; the case

[3] As noted above, respondents failed to make a record on the supposed lack of irreparable harm in the District Court, but in their previous opposition, they included two cursory paragraphs attempting to dispute the irreparable harm to Teva—without evidence. Teva has accordingly been compelled to take the unusual step of submitting a declaration to this Court.

is still pending (now on the merits) and will not be resolved until next Term; and unless the mandate is recalled Teva's patents will stop offering protection against a generic launch in a matter of weeks.[4] Respondents have planned on such a launch since the Federal Circuit's decision, *see* p. 7, *supra* (quoting an executive's statement in March that Mylan plans a May launch), and they have recently indicated that those plans may proceed despite the grant of certiorari.[5] The imminence of the harm is now beyond dispute.

Respondents also faulted Teva for supposedly delaying its request to recall the mandate, even while respondents argued that Teva's request was premature because any harm was not imminent. 13A458 Resps.' Stay Opp. 19-20. Teva has now renewed its application literally days after the grant of certiorari, and with the

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[4] While respondents may state that they do not yet have FDA approval to market their generic formulations of copolymer-1, that is no reason to withhold relief. The only remaining *patent-related* impediment to FDA approval will be lifted on May 24, 2014, when the other patents expire. See 35 U.S.C. § 271(e)(4)(A). Once that date passes, if the FDA decides to approve a generic product, it typically does so without providing any advance public notice. Upon receiving FDA approval, the generic company can, and often does, begin selling immediately. Respondents' own track records prove this point. *See*, *e.g.*, Sandoz Int'l, Press Release, *Sandoz leads the way with first generic version of 'gold standard' anti-thrombotic Lovenox®* (July 23, 2010) (Sandoz began product shipment "immediately following approval by [FDA]"; FDA did not give tentative approval beforehand); Mylan Inc., Press Release, *Mylan Launches Generic Myfortic® Delayed-Release Tablets* (Jan. 9, 2014) (similar).

Respondents have not offered any assurance that if that happens, they will refrain from marketing while Teva seeks an emergency stay at that time. And this Court need not be detained by the possibility that respondents will not obtain FDA approval or will choose for business reasons of their own not to launch: under either of those scenarios, recalling and staying the Federal Circuit's mandate obviously will do respondents no harm.

[5] For instance, respondent Natco has "indicated it could go ahead with plans to sell the generic version of multiple-sclerosis drug Copaxone in the United States, despite the Supreme Court there agreeing to hear an appeal by Israel's Teva Pharmaceutical . . . ." CR Sukumar, *Natco set for US launch of generic copy of Teva's drug*, Economic Times, Apr. 2, 2014, http://articles.economictimes.indiatimes.com/2014-04-02/news/48801353_1_copaxone-natco-shares-natco-pharma. Respondent Sandoz's parent has said through a spokesperson: "Together with our collaboration partner Momenta, we look forward to marketing an affordable, high-quality generic version of Copaxone at the earliest possible opportunity." Greg Stohr & Susan Decker, *Teva Gets Supreme Court Hearing on Generic Copaxone Delay*, Bloomberg News, Mar. 31, 2014, http://www.bloomberg.com/news/2014-03-31/teva-gets-supreme-court-hearing-on-generic-copaxone-delay.html.

benefit of statements by respondents about their plans to launch infringing generic products despite the grant of certiorari. *See* note 5, *supra.* As respondents' primary submission was that a stay should be denied because certiorari would never be granted, respondents can hardly suggest that Teva was dilatory by waiting to renew its application until certiorari was in fact granted.

In addition, respondents previously argued cursorily—for the first time in this litigation—that the harm to Teva from launching an infringing product would not be irreparable. 13A458 Resps.' Stay Opp. 19. They did not dispute that the launch of a generic drug can and often does cause irreparable injury by permanently eroding the price of a patented product. Rather, they asserted without citation that the loss of revenue for "only" fifteen months—from May 2014 to September 2015—would not be irreparable. They cited no support for their arbitrary line-drawing, and their attempt to minimize the harm to Teva rings hollow where Copaxone® generates nearly $3 billion in annual sales. Indeed, even if the effect on Teva's product were reversible, any substantial reduction in sales in such a market, even for fifteen months, would raise serious questions about respondents' ability to pay money damages if the District Court's ruling is ultimately upheld.[6] Additionally, as the Hassler Declaration makes clear, the harms that will result from respondents' launching generic versions of Copaxone® are not limited to Teva's lost revenues. *See* Appendix 2, ¶¶ 17-26.

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[6] It is well-settled that damages are an inadequate remedy and a plaintiff faces irreparable harm if the defendant's ability to satisfy a money judgment is uncertain. *E.g.*, *Deckert v. Independence Shares Corp.*, 311 U.S. 282, 290 (1940); *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1154-55 (Fed. Cir. 2011).

Finally, respondents argued that even if the Federal Circuit's decision is erroneous and the '808 patent should have been upheld, a stay of the erroneous decision should be denied because the public interest is served by making available a less expensive generic drug, albeit an infringing one. 13A458 Resps.' Stay Opp. 20-21. But it is simply not correct that whatever makes patented inventions available more cheaply will serve the public interest. To be sure, Congress enacted the Hatch-Waxman Act to facilitate the launch of generic products. But Congress also recognized that without the full economic benefits of pharmaceutical patents, drug companies would be unable to sustain the staggeringly expensive process of developing new medicines. That is why Congress extended the terms of certain pharmaceutical patents, recognizing that the lengthy regulatory process required before patented drugs could be sold would otherwise deprive patentees of the full economic benefit of those patents. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-70 (1990). The public interest at stake thus turns on whether the '808 patent is valid, as this Court must assume for purposes of this motion—and as the District Court found based on factual findings to which the Federal Circuit gave no deference whatsoever. If the patent is valid, then the public interest is best served by recalling the mandate and preserving the status quo.

IV. Relief likely can come only from this Court or the Circuit Justice.

Teva has returned to this Court because it appears that only this Court can grant relief now that certiorari has been granted. Although the usual practice *before* certiorari is granted is to request relief from the lower court before making an application to the Circuit Justice, once the Court has granted a writ of certiorari "it

[is] doubtful that [the lower courts] ha[ve] the authority" to grant Teva relief. *Heckler v. Turner*, 468 U.S. 1305, 1308 (1984) (Rehnquist, J., in chambers).

Indeed, it appears that the Federal Circuit likely shares the view that it lacks power to act. In a note accompanying its Rules of Practice, the Federal Circuit states that a typical reason for staying a mandate pending certiorari is "to forestall action in the trial court or agency that would necessitate a remedial order *of the Supreme Court* if the writ of certiorari were granted." Fed. Cir. R. 41 Practice Note (emphasis added). That is just what has happened here: the Federal Circuit's issuance of its mandate caused the trial court to provide that its injunction would terminate at a time while the case is before this Court on the merits. And the Federal Circuit apparently contemplates that in this posture, any "remedial order" must come from this Court.

That view is consistent with the Federal Rules of Appellate Procedure, which authorize courts of appeals to stay or recall their mandate "pending the filing of a petition for a writ of certiorari," Fed. R. App. P. 41(d)(2)(A), but do not mention recalling a mandate after this Court grants certiorari. The Rules of this Court, by contrast, do not distinguish between stay requests filed before or after certiorari is granted. *See* this Court's Rule 23.3.

In addition, Teva's likelihood of success now turns on whether there is a "fair prospect" that this Court will reverse. *King*, 133 S. Ct. at 2 (citations omitted). In this posture—only a few days after the Members of this Court discussed Teva's

petition and decided to grant certiorari—that predictive judgment is best made by the Circuit Justice or by the Court itself.

Proceeding in the first instance before the Federal Circuit—when that court's jurisdiction to take any action is in serious doubt at best—threatens to consume a considerable portion of the limited time remaining before the other patents expire on May 24, 2014. And the most likely outcome, based on the Federal Circuit's own rulebook and the cautionary language in *Turner*, is that the Federal Circuit would decline to take action while the matter is pending on the merits before this Court. That would return the matter to this Court some weeks from now, *see* Fed. R. App. P. 27(a)(3) (general briefing schedule for motions), with much of the time until a potential generic launch consumed.

If this Court directs Teva to proceed in the first instance before the Federal Circuit, it should do so expressly, in a way that will quiet the Federal Circuit's doubts about its power to act. Teva has returned directly to this Court because, following the grant of certiorari, this Court is the proper forum and there is a strong likelihood that no other forum can provide Teva relief. But if this Court were to conclude that notwithstanding the grant of certiorari Teva should still pursue relief in the court of appeals first, and communicate that direction to Teva and the court of appeals, Teva will follow this Court's direction expeditiously.

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The District Court found after a trial that respondents' products would infringe the '808 patent and would thereby cause Teva irreparable harm. It

therefore enjoined respondents from launching their products until after the '808 patent expires on September 1, 2015. Respondents' sole remaining ground for challenging the District Court's judgment and injunction is their contention that the patent is invalid because it is indefinite. And the only reason why the Federal Circuit agreed with that argument is that it reviewed the question *de novo* rather than with deference to the District Court's well-supported findings. This Court has now taken up the very basis of the Federal Circuit's decision. Under the settled standard for stays of mandate, the District Court's original injunction should have remained in effect until this Court could consider the matter. The Federal Circuit issued its mandate nonetheless, perhaps considering Teva's petition insubstantial. But this Court has now granted the petition, and there is a fair prospect of reversal. The District Court's original injunction should remain in effect, and continue protecting Teva against irreparable injury, until this Court decides whether the Federal Circuit was right or wrong.

CONCLUSION

The mandate of the Federal Circuit should be recalled and stayed until the sending down of this Court's judgment in No. 13-854, thus requiring the District Court to restore the original injunction in force before the mandate issued.

Respectfully submitted.

Elizabeth J. Holland
KENYON & KENYON LLP
One Broadway
New York, NY 10004-1050

William G. James, II
KENYON & KENYON LLP
1500 K St., N.W.
Washington, DC 20005

Alan M. Dershowitz
1575 Massachusetts Ave.
Cambridge, MA 02138

Jay P. Lefkowitz, P.C.
John C. O'Quinn
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005

Henry C. Dinger
John C. Englander
Daryl L. Wiesen
Nicholas K. Mitrokostas
GOODWIN PROCTER LLP
Exchange Place
Boston, MA 02109

William M. Jay
Counsel of Record
GOODWIN PROCTER LLP
901 New York Ave., N.W.
Washington, DC 20001
(202) 346-4000
wjay@goodwinprocter.com

David M. Hashmall
GOODWIN PROCTER LLP
620 Eighth Ave.
New York, NY 10018

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