No. 13A1003
(13-854)

IN THE SUPREME COURT OF THE UNITED STATES

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Applicants,

v.

SANDOZ, INC., *et al.*,

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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REPLY IN SUPPORT OF APPLICATION TO RECALL AND STAY THE FEDERAL CIRCUIT'S MANDATE

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RULE 29.6 STATEMENT

The Rule 29.6 statement included in Teva's application remains accurate.

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INTRODUCTION

The District Court in this case entered an injunction barring respondents from infringing Teva's '808 patent until it expires September 1, 2015. Respondents never disputed that their launch of an infringing product, anytime during that period, would cause Teva irreparable injury. They never sought a stay of that injunction. And the only reason why that injunction will now expire May 24, 2014, is that the Federal Circuit prematurely issued a mandate declaring the '808 patent invalid. The court of appeals did so only because it reviewed *de novo* and second-guessed the District Court's factual findings. This Court will now decide whether the Federal Circuit erred, and should instead have reviewed the factual findings deferentially as Fed. R. Civ. P. 52(a)(6) requires. But respondents conspicuously do not deny that during the window before this Court's decision, they intend to launch their infringing products immediately if they secure FDA approval, inflicting the very irreparable harm the District Court originally enjoined. This Court should recall and stay the Federal Circuit's mandate, "thereby effectively reviving" the District Court's judgment and injunction as they stood before the Federal Circuit issued its reversal. *Norman v. Reed*, 502 U.S. 279, 287 (1992).

Respondents latch onto the District Court's purely ministerial order conforming its injunction to the terms of the Federal Circuit's mandate. The District Court's original permanent injunction is gone, they say, and Teva must satisfy the standard to get a new injunction from scratch—as if Teva were in the

same position as a litigant who has *failed* to obtain an injunction at every level of the federal judicial system and finally seeks an injunction from the Circuit Justice. That is nonsense. Teva *secured* an injunction, and the only thing that affected that injunction is the Federal Circuit's mandate—the same mandate that is under this Court's review and will likely be reversed.

What Teva needs is a stay of that mandate, and it amply meets the relevant standard. There plainly is at least a "fair probability" that this Court will reverse. The grant of certiorari is powerful evidence by itself; the point is confirmed by the extensive criticism the Federal Circuit's no-deference rule has drawn from the United States, scholars, practitioners, and even many Federal Circuit judges. Indeed, while the stay standard looks only to success *in this Court*, Teva is likely to succeed *fully*: under the correct standard of review, respondents cannot overcome the District Court's findings and their indefiniteness defense cannot prevail.

The irreparable-harm calculus has not changed since the District Court entered the permanent injunction: both then and now, the launch of an infringing generic during the term of the '808 patent would cause Teva irreparable injury. Respondents' harm arguments are premised entirely on the Federal Circuit's flawed finding that Teva's patent is invalid, but the law is clear: in assessing irreparable harm, this Court presumes that *Teva* is correct on the merits. With the proper understanding—that the Federal Circuit erred in invalidating the '808 patent—the balance of hardships and the public interest overwhelmingly support restoring the injunction until this Court decides the merits.

ARGUMENT

I. This is an application for a stay of mandate, not an injunction.

The relief Teva seeks is simple: the Federal Circuit's decision should not remain in effect, and disrupt the District Court's permanent injunction, while this Court reviews whether the Federal Circuit's decision rests on a fundamentally wrong foundation—*de novo* review rather than deference. The stay Teva seeks is identical in every material way to the stays of mandate pending certiorari review that courts of appeals routinely grant, dozens of times a year, under Fed. R. App. P. 41(d)(2). The fact that in this case the court of appeals issued the mandate, minutes after denying a stay and before this Court could consider the matter, does not change the standard, *see* Stay Appl. 8, a point that respondents have conceded. *See* 13A458 Stay Opp. 9 (reciting the stay standard).

Yet respondents now contend that what Teva is really seeking is an injunction, not a stay, and that Teva must therefore meet a higher standard.[1] That contention misunderstands the difference between a stay and an injunction. "A stay simply suspends judicial alteration of the status quo, while injunctive relief grants judicial intervention that has been withheld by lower courts." *Nken v. Holder*, 556 U.S. 418, 429 (2009) (citations and brackets omitted). Teva is not seeking something "that has been withheld by lower courts" at all; it is seeking to

[1] Respondents also offer a cursory assertion (Stay Opp. 15) that Teva's burden should be higher because it did not proceed first in the court of appeals. But respondents offer no response at all to Teva's discussion of why the Federal Circuit very likely lacks authority to grant any such relief. Stay Appl. 17-19. Respondents thus miss the point: Teva should not be held to a higher standard merely because it has proceeded in *the one court with clear authority to grant relief* following the grant of certiorari. Teva reiterates (*see id.* at 19) that it will proceed expeditiously in the Federal Circuit if this Court or the Circuit Justice directs Teva to do so after clarifying that the Federal Circuit may grant Teva relief notwithstanding this Court's having taken the case on certiorari.

reinstate the original injunction that the District Court issued, by asking this Court to "suspend[]" the Federal Circuit's "alteration of the status quo." *Id.* Even under the Federal Circuit's mandate, a permanent injunction is in force today. That injunction can and should remain in force past May 24, 2014, as the District Court originally specified—so long as the Federal Circuit's mandate is stayed.

Put another way, Teva is not asking *this* Court to enjoin respondents from infringing the '808 patent, any more than Maryland was asking this Court to convict Alonzo King. *See Maryland v. King*, 133 S. Ct. 1 (2012) (Roberts, C.J., in chambers) (staying mandate of appellate court that reversed King's criminal conviction). The District Court in this case enjoined respondents from such infringement, and the requested stay would prevent the Federal Circuit's incorrect decision from disrupting that injunction while this Court decides whether (as is likely) the Federal Circuit must be reversed. *See, e.g.*, *U.S. Postal Serv. v. Nat'l Ass'n of Letter Carriers*, 481 U.S. 1301, 1301-02 (1987) (Rehnquist, C.J., in chambers). In *Letter Carriers*, the Postal Service had sued in district court and won an order precluding reinstatement of a letter carrier who had been convicted of delaying the mail (as an arbitrator had ordered). The D.C. Circuit reversed, but the Circuit Justice—applying the stay standard, not the injunction standard—stayed that mandate to permit "[c]ontinuation of the status quo," *i.e.*, the District Court's order granting the Postal Service relief. *Id.* at 1302-03. Although the effect of this Court's order was to continue the restraint precluding the felonious postal worker from being reinstated, this Court's order was a stay, not an injunction.

Respondents cite a host of cases applying the injunction standard. But in those cases, unlike this one, injunctive relief had been "withheld by lower courts." *Nken*, 556 U.S. at 429.[2] Respondents contend that this case moved into that category the moment the District Court undertook the routine act of conforming its injunction to the Federal Circuit's mandate. That argument ignores the sole reason *why* the District Court modified the injunction: the Federal Circuit had issued its mandate and required the District Court to treat the '808 patent as invalid. And the '808 patent was the only patent protected by the injunction beyond May 24, 2014. Accordingly, when the mandate issued, the District Court had no choice: it had to modify the injunction so that it no longer protected the '808 patent. *See, e.g.*, *Briggs v. Pa. R.R. Co.*, 334 U.S. 304, 306 (1948).[3] For that reason, the parties agreed upon a modification "in light of the Federal Circuit mandate." Unopposed Mot. to Enter J. Pursuant to L. Civ. R. 58.1, at 2, ECF No. 270, No. 1:09-cv-08824-WHP (S.D.N.Y. filed Dec. 16, 2013). Teva did not oppose and, indeed, *could not* have opposed the modification because "the form of judgment accurately reflect[ed] the mandate from the Federal Circuit." *Id.*

A ministerial, nondiscretionary act by the District Court, obeying the court of

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[2] *See Hobby Lobby Stores, Inc. v. Sebelius*, 133 S. Ct. 641, 642 (2012) (Sotomayor, J., in chambers); *Lux v. Rodrigues*, 131 S. Ct. 5, 6 (2010) (Roberts, C.J., in chambers); *Turner Broad. Sys., Inc. v. FCC*, 507 U.S. 1301, 1301 (1993) (Rehnquist, C.J., in chambers); *Ohio Citizens for Responsible Energy, Inc. v. NRC*, 479 U.S. 1312, 1312 (1986) (Scalia, J., in chambers).

[3] Although the Federal Circuit dropped a footnote suggesting that the District Court should consider whether modification of the injunction was necessary, that was because the Federal Circuit evidently did not realize that the '808 patent (which is not listed in the "Orange Book") expired later than the other patents. Pet. App. 24a n.5 ("We note that, according to the Orange Book, all of Teva's Copaxone® patents expire on the same date: May 24, 2014. We remand for the district court to determine whether there exists any need to modify its injunction."). The mandate to implement the decision invalidating the '808 patent left the District Court with no choice.

appeals, cannot fundamentally alter the standard that Teva must meet *in this Court*. The combined actions of the Federal Circuit (issuing its mandate) and the District Court (obeying it) do not wipe the slate clean and require Teva to submit new proofs to this Court as if Teva had never had an injunction—any more than the modification moots the appeal from the original order, *see United States v. Villamonte-Marquez,* 462 U.S. 579, 581 n.2 (1983); *Aetna Cas. & Surety Co. v. Flowers*, 330 U.S. 464, 467 (1947). If this Court stays the Federal Circuit's mandate while considering the merits, the relief the court of appeals awarded respondents will be put on hold, the '808 patent will no longer be treated as invalid, and the modification of the injunction will no longer be appropriate. In short, a stay should be sufficient to "reviv[e]" the District Court's original injunction. *Norman*, 502 U.S. at 287.[4] Even if it were not, the stay certainly would "remove the . . . barrier" to the District Court's undoing the ministerial act it undertook to comply with the mandate, and reinstating its original injunction. *Graddick v. Newman*, 453 U.S. 928, 944 (1981) (opinion of Rehnquist, J.).

That is particularly true where the status quo has not yet changed. The District Court's modification of the injunction has no effect until May 24, 2014, and respondents do not claim that anyone has taken any action in supposed reliance on the modification. This case is therefore completely different from *Graddick*, in which the disagreement between Justice Powell (whose solo opinion respondents

[4] In *Norman*, the lower courts had reversed the decision of an administrative agency. The Circuit Justice ordered the mandate "stayed or, if necessary, recalled," and this Court continued the stay pending certiorari. 502 U.S. at 287. As this Court later described, its order staying the mandate "thereby effectively reviv[ed] the [agency's] decision." *Id.*

cite) and then-Justice Rehnquist was over whether a writ of habeas corpus could still be stayed weeks after it had been executed and more than 200 prisoners released. *Compare id.* at 936 (opinion of Powell, J.) (suggesting "that an order, once executed, cannot be 'stayed'"), *with id.* at 943-44 (opinion of Rehnquist, J.) (opining that the habeas writ could still be stayed because it had continuing effects). Whatever the correct answer to that question of habeas practice, it is clear that *this* order has not been "executed" and has had no effect on the parties' conduct. "Affirmative action" is not "necessary to restore the status quo," *id.* at 936 (opinion of Powell, J.), precisely because the disruption to the status quo comes only from the Federal Circuit's mandate, which has not yet had any real-world effect. All that is necessary is to recall that mandate and permit the reinstatement of the District Court's permanent injunction.

II. Teva has amply demonstrated a fair prospect that this Court will reverse the Federal Circuit.

Respondents accuse Teva of "simply assum[ing]" or perhaps "assert[ing]" that the grant of certiorari establishes the likelihood of success. Stay Opp. 15-16. In fact, Teva discussed its likelihood of success at length, Stay Appl. 10-12, and demonstrated more than the requisite "fair prospect that the Court will . . . reverse the decision below," *King*, 133 S. Ct. at 2 (Roberts, C.J., in chambers) (citation omitted). Respondents suggest that Teva must show that it will *also* succeed in some other forum, *e.g.*, on remand. This Court has never required any such showing of future success, but in any event Teva has amply demonstrated that reversing the Federal Circuit's error will also reverse the outcome.

A. The no-deference rule is ripe for reversal.

Respondents contend that they "may well" win on the merits. Stay Opp. 17. That bears no resemblance to the actual stay standard, which is whether there is a "fair prospect" that this Court will reverse. *King,* 133 S. Ct. at 2.

The grant of certiorari in a patent case from the Federal Circuit is itself powerful evidence that there is a "fair prospect" that this Court will set aside the Federal Circuit's ruling. This Court is not likely to invest its time reviewing a Federal Circuit patent case between private parties if there were not even a reasonable prospect that the Court would reverse.

But in this case there is far more: for instance, the briefs of the United States and a host of other *amici*, the closely divided *en banc* court (6–4), and two decades of vigorous dissents from Federal Circuit judges seeking to overturn the no-deference rule all demonstrate not just a fair prospect, but a probability of reversal. Stay Appl. 10-11. Indeed, the outcome in *Lighting Ballast* rests on the vote of a judge who, *as respondents emphasized at the certiorari stage*, was one "of the most vocal judges calling for a deferential standard of review of claim-construction rulings." Br. in Opp. 26; *see* Stay Appl. 11. Judge Moore set aside her conviction that the Federal Circuit's no-deference rule is wrong, based on *stare decisis*. But *stare decisis* does not require this Court to follow Federal Circuit precedent, and respondents do not rely on it.

Rather, respondents offer two halfhearted paragraphs on the merits. Stay Opp. 16-17. These paragraphs represent the first time respondents have actually joined issue on the merits of the Federal Circuit's no-deference rule. *See* Cert. Reply

1 (noting that respondents had written a 30-page opposition to certiorari without a word on the merits). If respondents really thought this Court had already squarely answered the question presented here, in a decision as recent as *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), they certainly would have said so in their brief in opposition. They did not. And *Markman* reserved the question presented here; it did not decide it.[5] Ultimately, the most that respondents can say is that the Court "may well" answer the question presented their way. Stay Opp. 17. That is not the standard for opposing a stay. Rather, to prevail on likelihood-of-success grounds, respondents would have to show that this Court *almost certainly* will answer the question presented their way (*i.e.*, that there is not even a reasonable possibility that Teva will prevail). They cannot make any such showing.

Nor do respondents gain any ground by recycling, almost word for word, the section of their brief in opposition in which they contended that this case was a poor vehicle to decide the question presented. *Compare* Br. in Opp. 19-21 *with* Stay Opp. 18-19. This Court has already rejected such considerations by granting certiorari. And even if it had not, respondents' repeated emphasis on Figure 1 of the patent (Stay Opp. 7-8, 19) is telling. Both Teva's expert and the District Court explained why a skilled artisan would understand that figure not to support respondents' position. Those are matters of historical scientific fact—how is a graph like that depicted in the figure generated, and what is the expected effect of the data

[5] This Court held in *Markman* that the Seventh Amendment did not require submission of claim construction to the jury, but stated that it was *not* deciding whether its conclusion "crystallized a law/fact distinction." 517 U.S. at 384 n.10. The application of Rule 52(a)(6) turns on precisely that distinction. This case presents the question that this Court expressly declined to reach in *Markman*.

conversion necessary to generate the figure?—and thus are properly the subject of factual findings. Respondents offered no contrary evidence; they simply convinced the Federal Circuit to interpret the graph in exactly the way the District Court found would be scientifically incorrect, without ever impeaching the District Court's findings. Teva explained as much at the certiorari stage. Cert. Reply 3-4. It is telling that instead of responding to this point, respondents just deny once again that any scientific facts bore on the interpretation of this patent.

B. The analysis ends with a "fair prospect that [this] Court will . . . reverse the decision below."

Respondents devote much of their discussion of the merits to asserting that the Federal Circuit will eventually reinstate its "invalidity judgment" *even if* this Court reverses the Federal Circuit's decision. That prediction is flawed on its merits, as discussed below. *See* Section II.C, *infra*. But as a threshold matter, *future* proceedings are irrelevant: a stay lasts only while the case is pending in this Court, and so a stay applicant need establish only a fair prospect of success *in this Court*, as decades of opinions confirm.

This Court has consistently described likelihood of success as "'a fair prospect' that the Court will . . . *reverse the decision below*." *King*, 133 S. Ct. at 2 (emphasis added) (quoting *Conkright v. Frommert*, 556 U.S. 1401, 1402 (2009) (Ginsburg, J., in chambers)). The analysis stops with the fair prospect of reversal. *Accord, e.g.*, *John Doe Agency v. John Doe Corp.*, 488 U.S. 1306, 1308 (1989) (Marshall, J., in chambers) (stating that a Circuit Justice must attempt to predict "the final outcome of the case *in this Court*") (emphasis added). That is why this Court has from time

to time described the test as whether "at least five Justices" will ultimately decide the question presented to this Court in favor of the stay applicant. *Araneta v. United States*, 478 U.S. 1301, 1304 (1986) (Burger, C.J., in chambers); *accord, e.g.*, *Conkright*, 556 U.S. at 1401 (requiring "a fair prospect that a majority of th[is] Court will conclude that the decision below was erroneous"); *Rostker v. Goldberg*, 448 U.S. 1306, 1308 (1980) (Brennan, J., in chambers) (same).[6] The Circuit Justice need not *also* predict how a panel of circuit judges, or a district judge, or a jury might later decide the case once the case is remanded—particularly where, as here, that future decision may turn on issues outside the question presented to this Court. *See, e.g.*, *Nat'l Farmers Union Ins. Co. v. Crow Tribe of Indians*, 468 U.S. 1315, 1315-16, 1321 (1984) (Rehnquist, J., in chambers) (granting a stay based in part on the "reasonable probability for at least partial success on the merits" of a justiciability issue, while expressing "no opinion" about whether, if this Court reversed the court of appeals' holding of nonjusticiability, "applicants would necessarily prevail" on the merits).

The question presented here is whether the Federal Circuit erred by reviewing factual findings *de novo*. Pet. i. In ruling on the stay application, the Court need "express no opinion" about the ultimate merits of respondents' patent-invalidity argument. *Nat'l Farmers*, 468 U.S. at 1321. What matters is that Teva has shown a "sufficient likelihood that the court below erred in one or more important respects." *NCAA v. Board of Regents*, 463 U.S. 1311, 1313-14 (1983)

[6] The same is true when a court of appeals stays a district court's ruling. The question is not whether the appellant will ultimately prevail—*e.g.*, at trial; the question is the "likelihood of success *on appeal*." *Hilton v. Braunskill*, 481 U.S. 770, 778 (1987) (emphasis added).

(White, J., in chambers).

Respondents also make the equally unpersuasive suggestion (Stay Opp. 23 n.3) that the Court might affirm on the ground that the patent is indefinite anyway, under any change to the indefiniteness standard that the Court might announce in *Nautilus, Inc. v. Biosig Instruments, Inc.*, No. 13-369. But as respondents themselves have emphasized, any revision of the substantive indefiniteness standard is "not relevant to the question presented" here.[7]

C. Teva has far more than a "fair prospect" of ultimately prevailing on clear-error review

Even if the stay analysis, or the question presented, encompassed whether the District Court's factual findings would survive clear-error review, respondents still could not show that those findings were so deficient that Teva has no "fair prospect" of prevailing. As Teva has explained throughout these proceedings, the standard of review was outcome-determinative. Pet. 24-27; Cert. Reply 2-5. Respondents' invalidity defense required them to convince the court, by clear and convincing evidence, that the '808 patent was so ambiguous that even a highly trained chemist familiar with peptide synthesis could not decipher the meaning of "average molecular weight." The District Court found that such a highly skilled artisan *would* know the meaning of the disputed term. The court's findings are not clearly erroneous, and they defeat the invalidity claim.

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[7] Br. in Opp. 27-28 (asserting that "the underlying substantive issue of what standard of indefiniteness should be applied . . . is not relevant to the question presented as framed by Teva"). Teva urged the Court to hold for *Nautilus* because that case may shed light on a different point, *i.e.*, whether claim construction for indefiniteness purposes entails factual issues. Pet. 32-35; Cert. Reply 8-11. This Court's decision on *that* point could only help Teva, since the Federal Circuit holds that there are no factual issues in claim construction. Pet. 4-6.

Respondents simply mischaracterize Dr. Grant's testimony in asserting that he "opined that Figure 1 [of the patent specification] was erroneous." Stay Opp. 22. Rather, Dr. Grant explained how to *read* Figure 1, from the perspective of a scientist familiar with interpreting chromatography results. And he explained why the inference respondents sought, and that the court of appeals later drew—that Figure 1 is inconsistent with the use of peak average molecular weight—was simply wrong. Respondents put in no contrary evidence and have never given any reason why the District Court's findings crediting Dr. Grant were incorrect, much less clearly erroneous. And if the District Court's findings were right, the Federal Circuit's own lay reading of the patent was wrong, and the patent is not indefinite.[8]

III. As the District Court's injunction reflected, respondents' contemplated launch of infringing products threatens irreparable harm, which justifies recalling the mandate and reinstating the injunction.

A. Respondents never disputed below that the District Court's permanent injunction protects Teva against irreparable harm.

Respondents never argued below that Teva would face no irreparable harm if they are permitted to launch their generic copolymer-1 products before the expiration of the '808 patent. They made no effort, and certainly made no record, to support such a contention in the District Court, and the District Court entered a permanent injunction. Respondents then made no attempt whatever to persuade

[8] Respondents' reference to Teva's pursuit of a reissue patent (Stay Opp. 10-11) is altogether irrelevant here. In unsuccessfully *seeking* a reissue patent—which the patent examiner has since denied—Teva stated after the Federal Circuit's mandate issued that the patent was invalid for indefiniteness. That statement was and is legally correct, because the Federal Circuit has put its decision into effect; however, recalling the mandate (or reversing the Federal Circuit) would change the patent's status, and Teva would update the oath as appropriate. Any innuendo that Teva misled the Patent Office is unfounded: Teva has kept the Patent Office fully informed of the filing and content of its previous stay application and certiorari papers.

the Federal Circuit that the District Court erred in granting injunctive relief. Teva now seeks a stay to restore that very injunction and to prevent the very same irreparable harm—the launch of an infringing product.

Respondents now insist that before issuing a stay to restore the injunction, the Circuit Justice should assume the mantle of a trial judge and consider evidence about the effect of a generic launch on the market for copolymer-1 treatments for multiple sclerosis, without the benefit of any discussion or analysis by the lower courts.[9] There is no warrant for such a demand. Respondents acknowledge that the only thing that has changed since they accepted injunctive relief without complaint is that the Federal Circuit ruled on their appeal. Stay Opp. 24-25. But that ruling carries no weight in the stay analysis, because this Court assesses irreparable harm "assuming [Teva's] position on the merits is correct." *E.g.*, *Philip Morris USA Inc. v. Scott*, 131 S. Ct. 1, 3 (2010) (Scalia, J., in chambers); *see* Stay Appl. 8, 12.

Nor does the fact that the District Court was compelled by the Federal Circuit's mandate to modify its permanent injunction reopen that court's earlier finding of irreparable harm. *Contra* Stay Opp. 25. On remand from the Federal Circuit, the District Court certainly did not conclude that irreparable harm exists only until May 24, 2014, and not thereafter. It did not weigh irreparable harm on

[9] Respondents suggest that Teva "implicitly acknowledged" that this Court should revisit irreparable harm in connection with its application to recall the mandate by submitting the Declaration of John Hassler. But Teva stated clearly in its application that irreparable harm was established below without objection from respondents and that it was too late for them to raise an objection in this Court. Stay Appl. 13. The Hassler Declaration was submitted because, in their previous stay opposition, respondents asserted for the first time (and cursorily) that Teva would face no irreparable harm. *Id.* at 14 n.3. Teva accordingly submitted the declaration to confirm that this case is similar to many other cases, cited in Teva's application, that found irreparable harm sufficient to support an injunction against generic launch before patent expiration.

remand *at all*. It simply did what was required by the Federal Circuit's mandate.

B. Respondents' arguments do not undermine the District Court's determination of irreparable harm

Respondents do not dispute that courts routinely conclude that pharmaceutical company patentees face irreparable harm from the launch of infringing generic drug products. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008); Stay Appl. 13 (citing cases). *See generally eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 395 (2006) (Roberts, C.J., concurring) ("[C]ourts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases."). Nor do respondents deny that the intangible harms that will result from reduced patient services and the layoff of experienced personnel who support such services, *see* Stay Appl. 14, are commonly found irreparable as well. *See, e.g.*, *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382-83 (Fed. Cir. 2006). The only contrary case respondents cite is *Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1578-79 (Fed. Cir. 1996). That decision merely considered whether a district court committed clear error in denying a preliminary injunction because, "under the specific circumstances of this case," the patentee would not face irreparable harm during the pendency of the litigation. *Id.* at 1578. The Federal Circuit reviewed that finding deferentially and found no "clear error." *Id.* Here, of course, the District Court found irreparable harm and entered a permanent injunction.

Respondents seek to score rhetorical points by pointing out that as a defendant, Teva has attempted to "refute" similar claims of irreparable harm. The argument that "Teva was right then" (Stay Opp. 26) is curious coming from

respondents, who have *successfully* argued that they would suffer irreparable harm if their competitors are not enjoined from launching generic products prior to the expiry of respondents' patents.[10] In that case, the district court credited Momenta's and Sandoz's assertions and found irreparable harm based on their arguments that such "harm would likely involve price erosion, lost market share, loss of market capitalization, reputational injury and threats to both the funding of ongoing research development and the hiring and retention of critical scientific talent." *Momenta Pharms., Inc. v. AmphaStar Pharms, Inc.*, 882 F. Supp. 2d 184, 197 (D. Mass. 2011), *rev'd on other grounds*, 686 F.3d 1348, 1361 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 2854 (2013). By contrast, Teva's argument was *unsuccessful* in the case respondents cite; the district court concluded (in line with the decisions cited above) that Teva's launch of a generic drug *would* cause irreparable injury. *Eisai Co. Ltd. v. Teva Pharms. USA, Inc.*, No. 05-cv-5727, 2008 U.S. Dist. LEXIS 33747 (D.N.J. Mar. 28, 2008). That past litigation in no way refutes the irreparable injury to Teva in *this* case.

Respondents' suggestion that Teva's "delay" in filing its cert petition undermines its allegations of irreparable harm similarly makes no sense, especially coming from respondents. Teva sought a stay at the earliest opportunity following denial of rehearing and issuance of the mandate. No. 13A458. Respondents

[10] *See* Momenta & Sandoz Mem. in Supp. of Mot. for Expedited Discovery at 3, *Momenta Pharms., Inc. v. AmphaStar Pharms, Inc.*, ECF No. 20, No. 11-cv-11681-NMG (D. Mass. filed Sept. 30, 2011) ("If Defendants are allowed to launch their infringing product, ... it will have an immediate and permanent impact on the enoxaparin market, resulting in substantial price erosion and loss of market share. Even if Defendants were subsequently removed from the market, it is uncertain whether Sandoz could ever recover the lost pricing power and there is no way to calculate the impact of customer goodwill of Sandoz attempts to raise prices.").

opposed both the stay request and certiorari as premature, arguing that the issue was unripe until the Federal Circuit decided the *Lighting Ballast* case. And they filed their opposition to certiorari weeks early, hoping that the petition would be considered—and denied—before the Federal Circuit decided *Lighting Ballast* and made the issue undeniably ripe. Their gambit nearly worked, but not quite: *Lighting Ballast* was decided on February 21, 2014, only two weeks before the Court first considered the petition at conference. Teva can hardly be said to have filed its petition too *late*; it narrowly avoided filing too *early* to obtain review. And once this Court granted review, Teva renewed its application within days.

C. Neither the countervailing harms posited by respondents nor the public interest warrants denial of the application.

Respondents complain that recalling and staying the mandate would deprive them of the opportunity to compete with Teva during part of the '808 patent's remaining term. But if the Federal Circuit had not improperly substituted its judgment for the District Court's, respondents would still be permanently enjoined from launching until September 2015. If this Court hears argument early next Term, it will be in a position to decide this case in late 2014 or early 2015.

Respondents' argument seems to be that if they could launch before this Court decides the case, they could lock up more customers who have not yet tried Teva's new three-times-per-week Copaxone® product. That product is now FDA-approved, is as efficacious as the daily injection, and allows patients to substantially reduce the number of injections they must undergo. Respondents hope that insurance companies will decide to reimburse patients only for the less expensive

(but still expensive) generic daily injection product. Respondents' desire to lock up customers before they try Teva's three-times-a-week product rests on speculation about voluntary choices between products that patients and doctors will make.[11] Such speculative fear of competition is not cognizable harm in any event.

If anything, the existence of three-times-a-week Copaxone® undermines *respondents'* position. Respondents oppose reinstating the District Court's injunction precisely so that they can undermine Teva's ability to sell the new product—one that offers real advantages to patients—and permanently erode the price of that product as well. What respondents seek to preserve is their chance to *increase* the irreparable harm that the launch of their generic products before the expiration of the '808 patent would cause Teva. Such changes in the market would make the damages from the launch of an infringing generic product even *more* difficult to calculate here than in other cases in which courts have routinely found that launching a generic product would create irreparable harm.

Respondents also repeat their bald assertion that the introduction of cheaper generic drugs inevitably serves the public interest. As Teva demonstrated in the application, Congress placed equal emphasis on giving pharmaceutical patentees the full economic benefit of their patents, recognizing that truncating that benefit would result in the development of fewer life and health saving drugs. Stay Appl.

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[11] The various newspaper and internet articles cited by Respondents are no more than the speculation of analysts and others about what percentage of patients will switch to this new formulation. Respondents fail to note that these discussions in the popular press all assume that generic entry will be possible as of May 24, 2014. In other words, contrary to the point Respondents are attempting to make, these articles merely demonstrate that the advantages of the three times per week formulation will encourage patients to switch *even if the generics are able to launch on May 24, 2014*. They do not establish any harm to respondents if the District Court's original injunction, through September 1, 2015, is restored by recalling the Federal Circuit's mandate.

17. Respondents do not dispute this, but say only that the '808 patent is invalid and invalid patents should not delay generic launch.

But this response, like respondents' entire opposition, begs the question. The District Court found that respondents had *not* proved the '808 patent to be invalid. The Federal Circuit erroneously substituted its findings for those of the District Court. And under a clear-error standard, that decision cannot stand.

D. Respondents do not substantiate any need for a bond, much less one of the magnitude they demand.

Respondents' new request for the imposition of a bond, if the Federal Circuit's mandate is stayed or recalled, is misguided. Bonds are sometimes required for preliminary injunctions, and for orders granting or staying injunctions pending appeal. But as discussed above, that is not what Teva seeks. Teva seeks an order from this Court directing the recall of the Federal Circuit's mandate and *reinstatement* of the District Court's *permanent* injunction. Had the Federal Circuit not erroneously substituted its judgment for that of the District Court, that permanent injunction—which respondents never sought to stay, and against which they never sought a bond—would still restrain respondents from launching their infringing products even after May 24, 2014. Teva has demonstrated that this Court is likely to reject the Federal Circuit's approach. Under these circumstances, no bond should be required simply to reinstate a permanent injunction that itself had no bond attached.

If the Court determines that some sort of bond is necessary, Teva is prepared to post one, as discussed further below. But this Court need not waste time

analyzing in detail the declarations submitted under seal by respondents. Rather than undertake a complex fact-finding process itself, if this Court requires a bond it can and should authorize the District Court to determine what amount would suffice. *See, e.g.*, *California v. Am. Stores Co.*, 492 U.S. 1301 (1989) (O'Connor, J., in chambers) ("This order is conditioned upon the posting of a good and sufficient bond with the Clerk of the United States District Court for the Central District of California, the adequacy of such bond to be determined by that Court."); *Becker v. United States*, 451 U.S. 1306 (1981) (Rehnquist, J., in chambers) (similar).[12]

This course is particularly warranted because the record before this Court provides no basis for determining what amount would fairly compensate respondents if this Court affirms the Federal Circuit's decision.[13] Respondents' declarations contain no more than speculative assertions, with little explanation and no supporting facts—plainly insufficient to carry respondents' burden to establish the appropriate size of any bond. *See, e.g.*, *Int'l Equity Investments, Inc. v. Opportunity Equity Partners Ltd.*, 441 F. Supp. 2d 552, 566 (S.D.N.Y. 2006) ("In fixing the amount of security required, a court is not required to order security in respect of claimed economic damages that are no more than speculative."). Trial courts exercising their discretion under Fed. R. Civ. P. 65 in imposing bonds in

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[12] *See also Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, No. 06A179 (Aug. 22, 2006) (Scalia, J., in chambers) (order recalling and staying the Fifth Circuit's mandate "conditioned upon the posting of a good and sufficient bond with the Clerk of the … Fifth Circuit, the adequacy of such bond to be determined by that Court").

[13] Because the purpose of the bond would be to secure respondents against the (unlikely) possibility that Teva will not in fact prevail in this Court on the question presented, a payment obligation under the bond would be triggered only by this Court's affirming the judgment of the Federal Circuit and respondents' proving damages attributable to the delay between the date of FDA approval and the date of this Court's judgment.

connection with preliminary injunctions are certainly not required to accept the enjoined party's unsupported word as to the appropriate amount of the bond. *See, e.g.*, *Sanofi-Synthelabo*, 470 F.3d at 1384-85; *Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 931 (Fed. Cir. 2012). Nor should this Court.

In a full evidentiary hearing before the District Court, Teva would demonstrate that the bond amount respondents seek is unjustifiably high. For example, Mylan, in the Tighe Declaration, includes unsupported assumptions concerning the size of the market, the percentage of the market that will shift to Mylan's product, and future harm extending many years past patent expiration. But Mr. Tighe presents no basis for any *ipse dixit* in his declaration. And Mylan's "evidence" in this regard is substantially more detailed than that provided by either Sandoz or Momenta, which offer nothing more than bald assertions of what profits they would lose over a lengthy period.

Significantly, each respondent's speculation contradicts the other's. Each respondent makes at least one key assumption that, if true, would mean the other respondent's assumption is not true. They cannot both be correct. *Compare, e.g.*, Butera Decl. ¶¶ 6 (second sentence), 11 (third sentence) *with* Tighe Decl. ¶ 6(1). Respondents' suggestion to combine their bond figures (Stay Opp. 34 n.7) therefore would entail significant double-counting even if their figures were reliable, which they are not. The conclusions reached by each respondent as to the profits that a generic product will generate between May 24, 2014 and September 1, 2015—products assumed to be equivalent, over the identical time period—are staggeringly

different. *Compare* Butera Decl. ¶ 6 *with* Tighe Decl. ¶ 8. Their numbers simply cannot be reconciled. Unsubstantiated speculation, submitted in sealed newly filed in this Court, cannot establish the appropriate size of any bond now.

Moreover, both sets of numbers rest on the assumption that respondents will have received FDA approval by May 24, 2014. That may not occur. And the longer the FDA withholds approval after May 24, the smaller the "harm" that would be attributable to the reinstatement of the injunction—and thus the smaller an adequate bond could be.

Respondents have demonstrated neither the need for a bond nor the appropriate amount of any bond, and the latter is inherently speculative because neither the timing of FDA approval nor the number of generic products that will launch can be known at this juncture. But if this Court concludes both that it must condition an order recalling the Federal Circuit's mandate on Teva's posting a bond *and* that this Court must itself set a figure (rather than leave it to the District Court), Teva is prepared to comply. If a bond is ordered, Teva is prepared to post a bond of up to $500 million at the earliest practicable time, but in no event later than May 24, 2014. The District Court should be authorized to consider whether any additional security is required or whether a lower amount could adequately secure respondents. Until the District Court rules, Teva's proposed bond would fully protect both respondents for many months of sales even under their most wildly optimistic projections. *See* Stay Opp. 35 (claiming harm in the "hundreds of millions of dollars").

CONCLUSION

For the foregoing reasons and those stated in the application, 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.

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