NO. 15-307

In the
Supreme Court of the United States

MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

APOTEX INC.,

Respondent.

On Petition for Writ of Certiorari to the U.S. Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

There is plainly a lively dispute among the parties as to whether this case presents a justiciable controversy. But there is no dispute about the only issue that Apotex's lawsuit purports to address—whether Apotex's proposed generic drug will infringe Daiichi's already disclaimed patent. Indeed, Apotex itself has made the absence of a dispute on the merits crystal clear in both this Court and in the District Court. In its brief in opposition, Apotex unequivocally recognizes that "because Daiichi has disclaimed the '703 patent, there is no realistic possibility that it will sue Apotex for infringement of that patent." Opp.8. That statement should be the end of the case. And, if anything, Apotex made the absence of a justiciable controversy even more transparent in the motion for summary judgment it filed recently in the District Court, which is reproduced in full as an appendix to this reply. Apotex needed only three pages to make its case, because there can be no dispute in light of the disclaimer. As Apotex explained, the '703 patent "is not, will not, and cannot be infringed" by Apotex's generic product "because every claim of the patent was disclaimed under 35 U.S.C. §253." Reply.App.2-3 (Doc. 104 at 2-3).

While the Federal Circuit appreciated the obvious point that Apotex cannot infringe Daiichi's disclaimed patent, it missed something equally evident: that undisputed fact means there is no Article III case or controversy here. The disclaimer of the '703 patent eliminates the possibility of an infringement of the patent, and Apotex's desire for a judicial declaration of something no one disputes is no substitute for a case

or controversy. The Federal Circuit's decision to the contrary opens up district courts across the Nation to non-disputes over patents that no longer exist.

The prospect of the proliferation of litigation antithetical to Article III fully justifies plenary review. But the Court also has on its merits docket two cases that throw the Federal Circuit's errors into sharp relief. To the extent that Apotex relies on the statutory benefits it could derive from a judicial declaration of non-infringement as a substitute for Article III injury, *Spokeo v. Robins*, No. 13-1339, is directly on point. To the extent the disclaimer gives Apotex all the relief it could obtain from its lawsuit but Apotex demands a judgment reflecting what no one disputes, Apotex stands in the shoes of the plaintiff in *Campbell-Ewald v. Gomez*, No. 14-857. If the Court finds that the lower courts in either *Spokeo* or *Campbell-Ewald* lacked jurisdiction, then *a fortiori* the Federal Circuit exceeded its constitutional limitations. *Spokeo* and *Campbell-Ewald* thus highlight both that plenary review is appropriate in this case and that, at a minimum, this petition should be held until those cases have been decided.

I. This Court Should Grant Review To Determine Whether Article III Courts Can Be Used As A Vehicle For Plaintiffs To Obtain Judgments Of Non-Infringement Regarding Disclaimed Patents.

"Article III of the Constitution grants the Judicial Branch authority to adjudicate 'Cases' and 'Controversies.'" *Already, LLC v. Nike, Inc.*, 133 S. Ct. 721, 726 (2013). "In our system of government, courts have 'no business' deciding legal disputes or

expounding on law in the absence of such a case or controversy." *Id.* (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 341 (2006)). "No principle is more fundamental to the judiciary's proper role in our system of government than th[is] constitutional limitation" on federal court power. *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 37 (1976); *see Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1146 (2013) (same).

For the reasons explained in Mylan's petition, Apotex's effort to secure a declaratory judgment of non-infringement of the disclaimed '703 patent is exactly the sort of non-dispute that has "no business" in a federal court. This Court recognized more than 80 years ago in *Altoona Publix Theatres v. American Tri-Ergon Corp.*, 294 U.S. 477 (1935), that once a patent has been disclaimed it is as if the patent never existed. That means that, in light of Daiichi's disclaimer, if this suit is allowed to go forward there will be no meaningful litigation on the merits. *See* Reply.App.2-4. As Apotex itself has repeatedly argued, Daiichi's disclaimer makes infringement of the '703 patent legally impossible.

Apotex's efforts to insist that Article III jurisdiction exists in the absence of a dispute concerning infringement of the '703 patent are unavailing. Apotex's attempt to recast Article III's "fundamental" case or controversy requirement as a mere "prudential" concern is squarely foreclosed by a host of this Court's precedents, including *Already, LLC*, *DaimlerChrysler*, *Simon*, and *Clapper*.

Apotex fares no better with its repeated attempts to rely on the '703 patent's continued listing in the

FDA Orange Book. *See, e.g.*, Opp.4, 8, 13 ("Apotex faces concrete injury, fairly traceable to Daiichi's listing of th[e '703] patent in the Orange Book"). Apotex concedes, as it must, that it filed this suit to obtain "a declaratory judgment that Apotex will not infringe" the '703 patent. Opp.1. If Apotex's real goal was to force FDA to remove the '703 patent from FDA's Orange Book, then it plainly sued the wrong party for the wrong thing. This suit is clearly a suit against Daiichi for non-infringement of a patent that has been disclaimed, and the disclaimer just as clearly eliminates any case or controversy here. If Apotex suffers an injury from FDA's continued listing of the disclaimed patent in the Orange Book, then Apotex should sue FDA and seek an order forcing FDA to delist. But even assuming there would be a case or controversy over *that suit* against FDA, it would not create a case or controversy in *this suit* against Daiichi, which still involves only an effort to obtain a declaration of non-infringement of a disclaimed patent. There may be a very understandable, merits-based reason Apotex has not sued FDA, namely the D.C. Circuit's decision in *Teva Pharmaceuticals USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010). But Apotex's problem on the merits of its justiciable claim against FDA is no excuse for filing a different non-justiciable claim against Daiichi.[1]

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[1] As Apotex points out, in *Teva* the D.C. Circuit "held that a patent owner's request to remove a patent from the Orange Book is not a sufficient basis to permit the FDA to do so." Opp.2; *see* Opp.9. That holding may or may not be extended to a suit by a non-patent owner, like Apotex, but whatever the strength of Apotex's claim on the merits, there would at least be a justiciable controversy.

While Apotex fails to cite or discuss this Court's decision in *Altoona Publix Theatres*, which makes plain that there can be no case or controversy over whether a disclaimed patent is infringed, Apotex does invoke this Court's decisions in *INS v. Chadha*, 462 U.S. 919 (1983), and *United States v. Windsor*, 133 S. Ct. 2675 (2013), in opposing this Court's review. Opp.11-13. Apotex's reliance on *Chadha* and *Windsor* is misplaced. First and foremost, in both cases, there was unquestionably a case or controversy at the outset. Windsor sought a tax refund from the federal government, and Chadha sought to avoid his deportation. If six years before the respective suits, the federal government had refunded Windsor's taxes or repealed the statute permitting the House to effectively force Chadha's deportation, there would have been no case or controversy. Indeed, *Windsor* suggested that there might not have been a case or controversy if the federal government paid the refund after the litigation was initiated. *See* 133 S. Ct. at 2686 (suggesting it would be "a different case if the Executive had taken the further step of paying Windsor the refund to which she was entitled under the District Court's ruling"). Here, of course, the '703 patent was disclaimed six years before Apotex sought a declaration that it did not infringe the long-disclaimed patent. *Chadha* and *Windsor* provide no assistance in Apotex's efforts to create a live controversy over a long-dead patent.

While *Chadha* and *Windsor* both began with an actual case or controversy, the federal government in both cases eventually agreed with the bottom line of the legal positions of both plaintiffs. That agreement raised concerns about the existence of the adverseness

required by Article III. In both cases, unique separation of powers concerns, and the participation of the House and/or Senate to defend the constitutionality of the federal statute, permitted this Court to exercise jurisdiction. Here, by contrast, there was no case or controversy at the outset, there are no special separation of powers concerns implicated by the legal issues, and there is no one to defend the vitality of Daiichi's long-disclaimed patent. The vast differences between this case and *Chadha* and *Windsor* underscore that this case is completely unprecedented. But while this case is unprecedented now, it will not stay that way if this Court denies review. Given the Federal Circuit's nationwide jurisdiction, district courts throughout the country would have to open their doors to non-disputes over disclaimed patents. This Court should intervene to avoid that unacceptable and *ultra vires* prospect.

II. This Court Should Grant Review To Decide Whether The Statutory Consequences Of A Judgment Can Serve As A Substitute For An Actual Case Or Controversy.

Because the '703 patent is a nullity, Apotex's injury is not traceable to the '703 patent, and a judicial judgment of non-infringement cannot redress Apotex's alleged injuries. Apotex cannot infringe a disclaimed patent with or without a judgment of non-infringement. And the fact that Apotex *may* derive a *statutory* benefit from a judicial declaration of something no one does or can dispute may explain why Apotex filed suit, but it is no substitute for an actual controversy concerning the '703 patent. The Federal Circuit's contrary view provides an additional reason

for this Court's review; it is contrary to the plain text of the Hatch-Waxman Act, Congress' intent in adopting that text, and this Court's precedent. *See* Pet.25-28.

At a minimum, however, this Court should hold this petition pending the disposition of *Spokeo* and *Campbell-Ewald*. The question in *Spokeo* is whether Congress can create an Article III injury where there would otherwise be none. Apotex concedes that if it sought this declaration of non-infringement of a disclaimed patent outside the Hatch-Waxman context, its case would have been a constitutional non-starter. *See* Opp.8. Thus, if there is an actual case or controversy here, it is only because Congress created one. The Court's decision in *Spokeo* will shed light on whether Congress has the power to do that.

The relationship between *Spokeo* and this case would be undeniable if the decision below were based on the application of a law giving a bounty to anyone who could secure a judgment of invalidity or non-infringement over any patent including a disclaimed one. The bounty would provide an incentive to sue, but it would not ensure that there was a case or controversy over the subject matter of the suit, and the disclaimer would ensure that there was no case or controversy. The only material difference between Apotex's suit and that one is that the bounty here is not a straightforward cash payment but a more complicated regulatory benefit. That difference, however, is immaterial to the Article III issue and in no way renders a hold inappropriate. Indeed, to the extent there is any material difference between this case and *Spokeo* it is only that Daiichi's disclaimer

eliminates the possibility of a case or controversy over the '703 patent in a way that has no analog in *Spokeo*. That suggests that plenary review is appropriate, but in no way makes a hold for *Spokeo* inappropriate.

Apotex contends that *Spokeo* is inapposite because while the defendant there alleges that there is no "concrete harm," Apotex is suffering the concrete harm of being barred from the market, which can only be removed if a declaratory judgment acknowledging that Apotex's generic does not infringe the '703 patent is entered. Opp.19. Thus, while Daiichi's disclaimer of the '703 patent forecloses the possibility of Apotex infringing the '703 patent, Apotex still claims a right to a judgment declaring what no one can or does dispute. This precise issue—"whether there's an Article III case or controversy when the defendant is no longer fighting over the result as to the thing at issue" but the plaintiff still wants a judgment—was argued before the Court just days ago in *Campbell-Ewald*. Tr. of Oral Argument at 12:1-4, *Campbell-Ewald*, No. 14-857 (Oct. 14, 2015).

In that case, the defendant offered the plaintiff arguably complete relief on his claim after the litigation was initiated, but the plaintiff insisted that a controversy remained because, *inter alia*, the plaintiff desired a judicial finding of liability. Numerous Justices probed whether there was Article III jurisdiction, and some expressed skepticism that a litigant who has received all the relief to which he is entitled has an independent interest in obtaining a judicial declaration embracing its views. *See, e.g., id.* at 35:23-36:5 (questioning why plaintiff was "entitled to get a legal ruling, even though … there's nothing

more that [the court] can give you;" "you won't take 'yes' for an answer."). Another Justice questioned plaintiff's position on the ground that in addition to the other requirements of Article III "there's an additional requirement of adverseness." *Id.* at 58: 21-22.

The Court's decision in *Campbell-Ewald* will clearly shed light on the answers to those questions and will in turn inform whether there is jurisdiction here. Apotex's case is an *a fortiori* example of some of the Justices' hypotheticals, as Apotex received all it was entitled to in the litigation years *before* it filed suit as a result of Daiichi's disclaimer. And Apotex claims it is "entitled to get a legal ruling" concerning something no one disputes. *Id.* at 35:25. Thus, even if this Court does not grant plenary review, at a minimum it should hold this petition pending the disposition of *Spokeo* and *Campbell-Ewald*.

In its efforts to resist further review, Apotex complains that if this matter is not resolved "by the summer of 2016, this case will become moot" because "Mylan is eligible to enter the market on October 25, 2016." Opp.17; *see* Opp.5, 20. Putting to one side whether a case that lacked a controversy from day one can really "become moot," Apotex should not be heard to complain about timing issues in this case. Mylan filed its ANDA regarding the generic drug at issue in April 2006. Apotex waited more than six years—until June 2012—to file its ANDA and this related litigation. Accordingly, the timing of this case is a result of Apotex's actions and Apotex's actions alone. It could have submitted its ANDA and filed its suit seeking a judgment that its generic product will not

infringe a disclaimed patent that cannot be infringed years ago. In fact, it could have done exactly what Mylan did: filed its ANDA before Daiichi's disclaimer.

In all events, if this Court grants review this case can easily be resolved in advance of October 2016. *Spokeo* is set for argument on November 2, 2015, *Campbell-Ewald* has already been argued, and a decision in those cases is likely "by the summer of 2016." Moreover, if review is granted now, this case will be briefed and argued this Term, which would likewise result in a decision no later than June 2016. With that decision in hand, the case will be all but resolved. As explained at the outset, while there is plainly a lively dispute among the parties as to whether this case presents a justiciable case or controversy, there is no dispute about whether Apotex can infringe the '703 patent. It cannot. A decision from this Court will thus be dispositive. If the absence of a controversy defeats Article III jurisdiction, then this lawsuit will be over. And if not, there will still be no dispute on the merits. While it is understandable that Apotex would not want to subject the Federal Circuit's decision to this Court's review, Apotex's concerns about timing are misplaced.

CONCLUSION

The Court should grant the petition or, at a bare minimum, hold the petition pending the Court's resolution of *Spokeo v. Robins*, No. 13-1339, or *Campbell-Ewald v. Gomez*, No. 14-857.

Respectfully submitted,

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October 20, 2015

APPENDIX

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Appendix A

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

No. 12-cv-09295

APOTEX, INC.,
Plaintiffs,
v.
DAIICHI SANKYO, INC.,
and
DAIICHI SANKYO CO., LTD.,
Defendants,
and
MYLAN PHARMACEUTICALS INC.,
Intervenor-Defendant.

Filed: September 15, 2015

APOTEX MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

Declaratory Judgment Plaintiff Apotex, Inc. respectfully moves for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure.

A. Facts as to Which There is No Genuine Dispute.

U.S. Patent No. 6,878,703 issued on 12 April 2005, and it was assigned to Sankyo Company, Limited at that time. Ex. A (front page). Sankyo Company, Limited disclaimed every claim of US 6,878,703 on 11 July 2006. Ex. B.

Apotex has submitted an Abbreviated New Drug Application ("ANDA") 204089, seeking FDA approval for the commercial manufacture, use, importation, offer for sale and sale of a proposed generic drug product containing 5 mg, 20 mg, or 40 mg olmesartan medoximil.

B. No Infringement of US 6,878,703.

US 6,878,703 will not be infringed by a generic drug product proposed by Apotex's ANDA because every claim of the patent was disclaimed under 35 U.S.C. §253, by submitting the disclaimer to the patent office in writing with the required fee. Ex. B. In the captioned action, the Federal Circuit stated, "[a]s is undisputed here, non-infringement of the '703 patent follows as a matter of law from the fact that Daiichi has formally disclaimed it." *Apotex Inc. v. Daiichi Sankyo, Inc. et al.* 781 F.3d 1356, 1359 (Fed. Cir. 2015); Dkt. 61.

Therefore, Apotex's Abbreviated New Drug Application ("ANDA") No. 204089 does not, and the manufacture, marketing, use, offer for sale, sale or importation of products that are the subject of Apotex's ANDA No. 204089 will not, directly infringe or induce or contribute to the infringement by others of any claim of US 6,878,703.

C. The Federal Circuit Decided There Is Jurisdiction.

Defendants previously challenged subject matter jurisdiction in this action. On appeal, subject matter jurisdiction was confirmed. *Apotex Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356 (Fed. Cir. 2015).[1] The Federal Circuit stated, "we hold that Apotex has alleged facts supporting the conclusion 'that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.' *MedImmune*, 549 U.S. at 127, 127 S.Ct. 764 (internal quotation marks and citation omitted)." *Apotex*, 781 F.3d at 1371.

There is Personal jurisdiction over the defendants and proper venue in this District. The defendants waived any possible lack of personal jurisdiction or improper venue defense by omitting it from their previous Rule 12 motion, Fed.R.Civ.P. 12(h)(1).

D. Conclusion.

For at least the foregoing reasons, Apotex respectfully requests that summary judgment be granted for Apotex, declaring that U.S. Patent No. 6,878,703 is not, will not, and cannot be infringed by

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[1] On September 4, 2015, Daiichi filed its Petition for a Writ of Certiorari to the U.S. Supreme Court. *Daiichi Sankyo, Inc., et al. v. Apotex, Inc.*, Case No. 15-281. For the reasons previously stated in open court in support of Apotex's Motion to Lift Stay and as stated in *Apotex's Response To Daiichi's Supplemental Statement Regarding Apotex's Motion to Lift Stay* (Dkt. 87), which stay the Court lifted pursuant to its Order dated August 4, 2015 (Case No.12-CV-09295, Dkt. 94), this petition should in no way delay these proceedings and the issuance of the requested judgment

the filing of Apotex's ANDA No. 204089, or by the manufacture, marketing, use, offer for sale, sale or importation of products that are the subject of Apotex's ANDA No. 204089.

Respectfully submitted,

HAHN LOESER & PARKS LLP