No. 2007-1362

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

MERCK & CO, INC.,
Plaintiff-Appellee,

v.

APOTEX CORP.,
Defendant-Appellant.

Appeal from the United States District Court
for the District of Delaware, Civil Case No. 06-230
Judge Gregory M. Sleet

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF-APPELLEE SUPPORTING AFFIRMANCE

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Dated: September 20, 2007

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Washington Legal Foundation certifies the following:

1. The full name of every party / *amicus curiae* represented by me is:

Washington Legal Foundation

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the parties / *amicus curiae* represented by me are:

None

4. x - There is no such corporation as listed in paragraph 3.

5. The names of all law firms and the parties and associates that appeared for the party represented by me in the trial court or are expected to appear in this case:

Daniel J. Popeo
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Dated: September 20, 2007

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INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation (WLF) is a public interest law and policy center that devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. WLF believes strongly that maintenance of a limited government requires courts to respect limitations on their jurisdiction and to avoid reaching out to adjudicate matters not involving a justiciable case or controversy. WLF regularly participates in federal court proceedings in which the scope of the judicial power is at issue. *See, e.g., Friends of Earth v. Laidlaw Environmental Services (TOC),* 528 U.S. 167 (2000); *Steel Co. v. Citizens for a Better Env't,* 523 U.S. 83 (1998); *Lujan v. Defenders of Wildlife,* 504 U.S. 555 (1992); *Lujan v. National Wildlife Fed'n,* 497 U.S. 871 (1990).

In particular, WLF has filed *amicus curiae* briefs in this Court in a number of cases raising important jurisdictional issues in drug patent disputes. *See, e.g., Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), *cert. denied*, 537 U.S. 941 (2002).

WLF is concerned that the position of Appellant Apotex, Inc., if upheld by this Court, would expand federal court jurisdiction well beyond the limitations imposed by Article III of the Constitution, which limits jurisdiction to "Cases" or "Controversies." WLF does not believe that federal courts should be in the

business of rendering advisory opinions of the sort Apotex is seeking in this case. In the absence of any case or controversy, Apotex's appropriate recourse is to take its case to Congress and to request revision of the rules governing the grant of a 180-day exclusivity period for the first filer of an ANDA – not to complain to a court about the unfairness of those rules.

WLF's brief only addresses whether the Court has jurisdiction over Apotex's appeal from the dismissal of Apotex's noninfringement/invalidity counterclaim. It takes no position on whether the district court abused its discretion in denying Apotex's motion for leave to amend in order to add an antitrust counterclaim. WLF is filing its brief with the consent of both parties.

STATEMENT OF THE CASE

Appellee Merck & Co., Inc. (Merck) developed (and for a number of years has been marketing) Fosamax, a drug approved by the Food and Drug Administration (FDA) for the treatment and prevention of osteoporosis. Merck owns ten patents that cover Fosamax or its use, and has listed those patents in FDA's Orange Book.

Because of Fosamax's commercial success, numerous generic drug companies are interested in marketing a generic form of Fosamax. But federal law prohibits a generic drug company from doing so until such time as FDA

approves the company's Abbreviated New Drug Application (ANDA) for its generic version of the drug. It is the absence of an approved ANDA, not Merck's patents, that ultimately is preventing Apotex from marketing a generic version of Fosamax.

In seeking to promote the Nation's health care delivery system, Congress has recognized two important goals that are in considerable tension with one another. On the one hand, Congress seeks to provide an economic incentive for new product development by providing pharmaceutical companies that gamble the substantial sums necessary for the development of new therapies the opportunity to reap substantial rewards in those few instances in which their research and development bear fruit. It does so by affording pioneer drug manufacturers a substantial period of exclusivity, during which potential competitors are not permitted to market the same product. On the other hand, once that appropriate period of exclusivity has expired, Congress has determined that consumers are well served by government policies that encourage other companies to market generic versions of the new drug, thereby ensuring the competition necessary to produce lower prices.

There is an inherent tension between these two goals – rewarding research and development while lowering the cost of drugs through competition.

Congress attempted to strike a balance between those competing interests when, in 1984, it adopted the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* Pub. L. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e). The Act benefitted generic manufacturers by creating the ANDA procedure, which greatly streamlined the process by which generic manufacturers can receive FDA approval to market generic copies of pioneer drugs. 21 U.S.C. § 355(j). The Act benefitted pioneer manufacturers by granting patent-term extensions under certain circumstances. 35 U.S.C. §§ 156 & 21 U.S.C § 355a(c)(2).[1]

The Act also included a provision designed to encourage challenges to potentially invalid drug patents – it provided rewards to the first generic drug manufacturer to take on the burden of challenging a drug patent. The Act provided that, subject to certain limitations, the first ANDA filer was entitled to a 180-day exclusivity period following the launch of its product pursuant to an approved ANDA, during which no other generic company's ANDA would be

1 For example, pursuant to the FDCA, Merck received a six-month extension on the '077 patent, its patent covering alendronate sodium, the active ingredient of Fosamax. The patent was initially scheduled to expire in August 2007 but was extended to February 6, 2008 pursuant to the pediatric exclusivity provision of the FDCA, in return for Merck having undertaken studies of Fosamax's safety and effectiveness among pediatric patients.

approved. 21 U.S.C. § 355(j)(5)(B)(iv).

The Act also set forth procedures for resolving patent disputes between pioneer and generic manufacturers. Those procedures are set forth in § 505(j) of the Federal Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 355(j). The FDCA provides that FDA is to maintain a list of FDA-approved drugs and to include on that list (known as the "Orange Book") any patent information respecting those drugs. 21 U.S.C. § 355(j)(7)(A). If a generic manufacturer seeks to market a generic version of an approved drug for which a patent is claimed in the Orange Book, the manufacturer must include in its ANDA a certification "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).[2] Congress has decreed that the filing of a Paragraph IV certification injures a patent holder by infringing his property rights in the patent, and has authorized patent holders to file an infringement suit against the Paragraph IV filer. 35 U.S.C. §§ 271(e)(2)(A) & 281. The Act also permits the filer of a Paragraph IV certification, under certain circumstances, to file a civil action for a declaratory judgment of noninfringement and/or invalidity. 21 U.S.C. § 355(j)(5)(C).

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2 Such a certification is often referred to as a "Paragraph IV certification."

Apotex notified Merck of its ANDA filing in February 2006, many years after the first ANDAs were filed by Teva Pharmaceuticals and Zenith Goldline Pharmaceuticals (collectively, "Teva"). Teva's ANDA included Paragraph IV certifications with respect to the '077 patent and many of the other Fosamax patents listed in the Orange Book. In subsequent patent infringement litigation initiated by Merck, a federal district court upheld the '077 patent and held that it was infringed by Teva's filing. *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 228 F. Supp. 2d 480 (D. Del. 2002), *aff'd*, 347 F.3d 1367 (Fed. Cir. 2003). The claims and counterclaims regarding the other Fosamax patents were voluntarily dismissed in advance of trial. Because the '077 patent does not expire until February 6, 2008, FDA will not approve the sale of a generic version of Fosamax until after that date.

As noted above, by virtue of its status as the first ANDA filer, Teva is entitled to a 180-day exclusivity period during which the numerous ANDAs filed by other generic drug companies will not be approved. 21 U.S.C. § 355(j)(5)(B)(iv).[3] In all likelihood, the 180-day period will be deemed to commence on the day that Teva begins selling its generic drug (presumably in

[3] The parties' briefs indicate that Barr Laboratories also may be deemed a first Paragraph IV certification filer with respect to some of the patents at issue.

February 2008). Apotex is filing this appeal in hopes that it can trigger an earlier start to the 180-day exclusivity period and thereby accelerate the launch of its own generic version of the drug.

Following its February 2006 receipt of notification that Apotex had filed an ANDA, Merck sought clarification from Apotex regarding the details of its proposed generic drug.[4] After failing to receive such clarification, Merck filed a patent infringement action against Apotex; Apotex countersued, seeking a declaratory judgment of invalidity and noninfringement of the nine patents. After conducting discovery, Merck determined that Apotex's Paragraph IV certifications did not infringe the nine listed patents; accordingly, it sought dismissal of its infringement action and provided Apotex an unconditional covenant not to sue with respect to any of those patents. In May 2007, the district court granted Merck's motion to dismiss, finding that no case or controversy existed with respect to Apotex's invalidity/noninfringement counterclaim.

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[4] Apotex's ANDA included Paragraph IV certifications for nine of the ten patents listed in the Orange Book. But no certification was included for the '077 patent. With respect to that patent, Apotex made a Paragraph III certification, *i.e.,* it would not seek to market a generic version of Fosamax until after the '077 patent expired in February 2008.

SUMMARY OF ARGUMENT

Apotex seeks a declaratory judgment that it has not infringed the nine Fosamax patents at issue and/or that those patents are invalid. However, no case or controversy exists between the parties with respect to those patents, and thus the district court properly held that it lacked subject matter jurisdiction over Apotex's declaratory judgment claims. Merck has provided Apotex with an unconditional covenant not to sue with respect to those patents. Moreover, unlike the plaintiff in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007), Apotex is not being required to forbear from any desired activity in order to avoid being sued for patent infringement – its freedom from such a suit is *unconditional*. Under those circumstances, it cannot be said that the minimum prerequisites for a "case" or "controversy" exist in this case: "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality." *Id.* at 771. Apotex is asking the federal courts to reach a legal determination that Merck does not dispute: that Apotex's Paragraph IV certifications did not violate any patent rights belonging to Merck. The federal courts lack Article III jurisdiction to issue such advisory opinions.

In order to establish its Article III standing to sue in federal court, a party must at a minimum establish that it has suffered injury-in-fact that is directly

traceable to the opposing party's conduct. *See, e.g.*, *Steel Co.*, 523 U.S. at 103. Apotex has failed to establish any such injury. Its only conceivable injury in this case is its inability to market its generic version of Fosamax, an inability occasioned by FDA's refusal to approve its ANDA as quickly as Apotex would like. That injury cannot be deemed directly traceable to Merck. Rather, approval of Apotex's ANDA is a multi-step process involving numerous variables. Apotex contends that a federal court judgment declaring the nine Fosamax patents invalid or not infringed would be an important step in the process of obtaining such approval. But the Supreme Court has held repeatedly that litigants may not use a declaratory judgment action to obtain piecemeal adjudication of issues that would not finally and conclusively resolve the underlying litigation. *See, e.g.*, *MedImmune*, 127 S. Ct. at 771 n.7. Because a declaratory judgment in this proceeding would not finally and conclusively resolve Apotex's injury (its failure to obtain an ANDA on an accelerated basis), the federal courts lack jurisdiction to consider Apotex's patent-related claims. Congress has not created the private right of action that Apotex seeks to invoke; moreover, if it had wanted to do so, Congress lacks the power to authorize suits in excess of federal courts' Article III jurisdiction.

Apotex's claims are based on a fundamental misunderstanding of patent

law. Patent invalidity is an affirmative defense to patent infringement, not a freestanding cause of action. *See* 35 U.S.C. §§ 282(2)-(3). One does not suffer injury in the abstract based on the existence of patents that infringe upon one's otherwise unlimited range of commercial activity in one's area of interest. Rather, to challenge a patent, one must establish an injury consisting of either: (1) a reasonable apprehension that one will be sued for violating the patent; or (2) forbearance from activity that one would engage in but for the likelihood that doing so would lead to a potentially ruinous patent infringement suit. Because Apotex cannot make either showing, the district court properly dismissed Apotex's noninfringement and invalidity claims.

ARGUMENT

I. SUBJECT MATTER JURISDICTION IS LACKING BECAUSE, IN LIGHT OF MERCK'S UNCONDITIONAL COVENANT NOT TO SUE, THERE EXISTS NO CONTROVERSY BETWEEN PARTIES HAVING ADVERSE LEGAL INTERESTS

Apotex seeks a declaratory judgment that is has not infringed the nine Fosamax patents at issue and/or that those patents are invalid. Although the Declaratory Judgment Act, 28 U.S.C. § 2201, permits parties to file federal court suits in which (as here) the only relief sought is declaratory in nature, it did not (and could not) relax Article III's command that an actual case or controversy

exist before federal courts may adjudicate a question. U.S. Const., Art. III, § 2. *See Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 272-73 (1941). The Act merely provides a different procedure for bringing an actual case or controversy before a federal court; it does not purport to expand federal court jurisdiction. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937) ("[T]he operation of the Declaratory Judgment Act is procedural only.").[5]

In *MedImmune*, the Supreme Court recently reiterated the traditional formulation regarding the minimum prerequisites necessary to meet the case-or-controversy requirement:

> Basically, the question in each case is whether the facts alleged, under all the circumstances, show 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, 127 S. Ct. at 771 (quoting *Maryland Casualty*, 312 U.S. at 273).

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[5] The Act provides in relevant part:

> In a case of *actual controversy within its jurisdiction* . . . any Court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201(a) (emphasis added). As this Court recently explained, § 2201(a)'s "actual controversy within its jurisdiction" language refers to the types of "Cases" and "Controversies" that are justiciable under Article III. *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1336 (Fed. Cir. 2007).

Apotex cannot begin to meet those prerequisites: there is *no* controversy (and certainly not a "substantial" one) between the parties, they do not have adverse legal interests, and any alleged controversy lacks immediacy – given the absence of an ongoing relationship between Merck and Apotex. As noted above, Merck has provided Apotex with an unconditional covenant not to sue with respect to the nine Fosamax patents. That covenant eliminated any controversy between the parties and rendered moot all claims related to those patents.

Prior to the *MedImmune* decision, this Court adhered to the "reasonable apprehension of suit" test, pursuant to which the case-or-controversy requirement barred suits by a party seeking a declaratory judgment that a patent was invalid or not infringed, unless the party had a reasonable apprehension that the patent holder would sue him for infringement. *See, e.g.*, *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005). *MedImmune* disapproved of the reasonable apprehension test, finding it inconsistent with Supreme Court precedent and an overly narrow interpretation of the case-or-controversy requirement. *MedImmune*, 127 S. Ct. at 774 n.11. But while *MedImmune* expanded this Court's prior understanding of Article III jurisdiction, it did so in a manner wholly unrelated to the facts of this case.

MedImmune addressed a situation in which the party seeking declaratory

relief is himself preventing the complained-of injury from occurring. That is, only by complying with a demand from the defendant, a demand to which he objects, is the declaratory judgment plaintiff forestalling injury. The Supreme Court noted that under well-established case law, where the demand for compliance comes from the *government*, such a plaintiff need not refuse to comply with the demand – thereby exposing himself to government sanction – before being permitted to seek declaratory relief. *Id.* at 772.[6] The Court determined that the same rule should apply where the demand for compliance comes not from the government but from a private party, at least where the threatened sanction for noncompliance is quite severe: "The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80% of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III." *Id.* at 775. Thus, the *MedImmune* plaintiff was permitted to seek a declaratory judgment that it was not infringing a patent at the same time that it was forestalling a potentially devastating infringement action by paying royalties to the patent holder. *Id.* at

[6] Thus, in *Steffel v. Thompson*, 415 U.S. 452 (1974), the Supreme Court "did not require the plaintiff to proceed to distribute handbills and risk actual prosecution before he could seek a declaratory judgment regarding the constitutionality of a state statute prohibiting such distribution." *Id.*

777. The issue was no less a "substantial controversy" between the parties simply because the plaintiff was paying tribute to the patent holder under protest. *Id.*

Apotex's situation does not even remotely resemble the facts in *MedImmune*. Apotex is not making any payments to Merck or taking any other actions at Merck's behest. Apotex is refraining from marketing a generic form of Fosamax not because of any actions by Merck but because FDA has not approved its ANDA. Nor has Merck threatened to sue Apotex for infringement of any of the Fosamax patents; to the contrary, Merck has provided Apotex with an unconditional covenant *not* to sue. In short, despite Apotex's reliance on *MedImmune*, Apotex Br. 20-21, nothing in that case provides support for Apotex's claim that it meets the case-or-controversy requirement.

Similarly unavailing is Apotex's reliance on *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993). Apotex Br. 22-23. In that case, the Supreme Court overturned this Court's prior rule that if – on an appeal from a district court judgment that a patent was either valid or invalid – this Court found that the patent was not infringed, it would automatically vacate the validity/ invalidity judgment as moot based on lack of jurisdiction. While recognizing that there might be sound policy reasons for vacating a declaratory judgment

regarding patent validity in an individual case, the Supreme Court held that an appellate decision that a patent is not infringed does not *automatically* divest the appellate court of jurisdiction over a patent validity issue *that was properly before the district court.* *Id*. at 96. Thus, *Cardinal Chemical* assumed for purposes of decision the very issue raised in this case: whether the district court possessed jurisdiction over the alleged infringer's invalidity counterclaim. Moreover, the Supreme Court arrived at its decision for reasons wholly unrelated to Apotex's claims. For example, the Supreme Court noted that all Federal Circuit noninfringement decisions are subject to reversal in the Supreme Court, and that that possibility serves to keep alive in the lower federal courts any controversy regarding whether a patent is valid, even after this Court has determined that a patent is not infringed. *Id.* at 97. In contrast, because in this case Merck has provided Apotex with an unconditional covenant not to sue, there is *no* possibility that the issue of patent infringement will ever arise again and thus nothing to keep alive any "controversy" regarding the validity of the Fosamax patents.

Apotex, as the party claiming declaratory judgment jurisdiction, bears the burden of establishing that such jurisdiction existed at the time it filed its counterclaim *and at all times thereafter*. *Benitec Australia, Ltd v. Nucleonics,*

Inc., ___ F.3d ___, 2007 U.S. App. LEXIS 17299 at *9 (Fed. Cir. July 20, 2007). Once Merck provided its unconditional covenant not to sue, Apotex could no longer meet that burden. *See Benitec*, *id.* at *15- *16 (once patent holder promised not to sue defendant for patent infringement arising from activities and/or products occurring on or before the date of the district court's dismissal of the defendant's invalidity and noninfringement counterclaim, counterclaim was rendered moot; possibility of renewed suit years hence, if and when the defendant filed a NDA with FDA, did not create a controversy of sufficient "immediacy and reality" to justify continued exercise of jurisdiction). Apotex is asking the federal courts to reach a legal determination that Merck does not dispute: that Apotex's Paragraph IV certifications did not violate any patent rights belonging to Merck. The federal courts lack Article III jurisdiction to issue such advisory opinions.

II. APOTEX LACKS STANDING BECAUSE IT HAS NOT SUFFERED ANY INJURY AT THE HANDS OF MERCK

In order to establish its Article III standing to sue in federal court, a party must at a minimum establish that it has suffered injury-in-fact that is directly traceable to the opposing party's conduct. *See, e.g.*, *Steel Co.*, 523 U.S. at 103.[7]

[7] A party asserting standing must also establish that the remedy it seeks will redress its alleged injury. *Id.*

Apotex has failed to establish any such injury.

Apotex contends that it has been injured by the denial of its "right" to bring a suit for the purpose of establishing "the invalidity and noninfringement of a challenged Orange Book patent." Apotex Br. 16. In support of its claim to such a right, Apotex points to 21 U.S.C. § 355(j)(5)(C)(i), which provides that the filer of a Paragraph IV certification may file an action seeking a declaration of patent invalidity/noninfringement, but *only* if the patent owner (or the holder of an approved NDA) does not file a patent infringement action within 45 days of notification of the Paragraph IV certification. That statutory provision is inapplicable to this case because Merck *did* file suit within 45 days and thus the statutory provision never kicked in; *i.e.*, it provides no rights to Apotex. Apotex also points to 35 U.S.C. § 271(e)(5), which purports to grant federal district courts subject matter jurisdiction over a Declaratory Judgment Act suit filed pursuant to 21 U.S.C. § 355(j)(5)(C)(i) by the filer of a Paragraph IV certification. But that provision is unhelpful to Apotex for the same reason: it too includes a provision limiting its applicability to cases (unlike this case) in which the patent holder does not file a patent infringement suit within 45 days of notification of the Paragraph IV certification.

Apotex's only conceivable injury in this case is its inability to market its

generic version of Fosamax, an inability occasioned by FDA's refusal to approve its ANDA as quickly as Apotex would like. That injury cannot be deemed directly traceable to Merck. Rather, FDA approval of Apotex's ANDA is a multi-step process involving numerous variables.

Apotex contends that a federal court judgment declaring the nine Fosamax patents invalid or not infringed would be an important step in the process of obtaining such approval. But even if the district court were to enter such a judgment, it is far from certain that Apotex would obtain FDA approval of its ANDA any more quickly than if no judgment were issued. It is totally up to FDA to determine whether such a judgment should be deemed a triggering event that would start the clock on Teva's 180-day exclusivity period. And of course, unless the clock starts to run before February 2008 – when Teva is projected to begin marketing of its generic version of Fosamax, thereby marking the beginning of its exclusivity period, *see* 21 U.S.C. § 355(j)(5)(B)(iv)(I) – it would have absolutely no effect on the date on which Apotex would be eligible for approval of its ANDA. Moreover, there is no guarantee that FDA will ever approve Apotex's ANDA; FDA may yet determine, for example, that the ANDA is deficient for failing to meet the application requirements imposed by 21 U.S.C. § 355(j)(2)(A). Under those circumstances, there is no reasonable basis

for attributing to Merck responsibility for possible delays in approval of Apotex's ANDA. *See Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976) ("The 'case or controversy' limitation of Article III . . . requires that a federal court act only to redress injury that fairly can be traced to the challenged action of the defendant, and not injury that results from the individual action of some third party not before the court.").

Moreover, the Supreme Court has held repeatedly that litigants may not use a declaratory judgment action to obtain piecemeal adjudication of issues that would not finally and conclusively resolve the underlying litigation. For example, in *Calderon v. Ashmus*, 523 U.S. 740 (1998), the Supreme Court held that a group of prisoners on California's death row lacked standing to bring a declaratory judgment action against state officials, seeking a declaration that California failed to qualify for expedited federal habeas corpus proceedings.[8] The Court held that no case or controversy existed, because the prisoners could not show that they had been injured by California's assertion that it *did* qualify

[8] A 1996 federal statute permits States to qualify for expedited federal habeas corpus proceedings for capital prisoners (thereby eliminating often substantial delays in carrying out death sentences), but only if the States can demonstrate that they have implemented a system designed to ensure that murder defendants are adequately represented in state court by competent counsel. *See id.* at 742-43.

for expedited federal proceedings. The Court explained that the real controversy between the parties was whether the prisoners were entitled to federal habeas relief, *i.e.*, an order setting aside their state court convictions. *Id*. at 746. The prisoners were simply "attempt[ing] to gain a litigation advantage by obtaining an advance ruling on an affirmative defense." *Id.* at 747. The declaratory judgment action did not present a case or controversy because it "would not completely resolve" whether the prisoners were entitled to habeas relief but rather "would simply carve out one issue in a dispute for separate adjudication." *Id.* at 749. The Court explained that "the traditional scope of declaratory judgment actions" encompasses only those suits whose resolution "completely resolve[] a concrete controversy susceptible to conclusive determination." *Id*. (citing *Steffel v. Thompson*, 415 U.S. 452 (1974)).

MedImmune cited *Calderon* with approval and reaffirmed the principle that the Declaratory Judgment Act does not authorize suits designed to resolve a single issue within a larger controversy. *MedImmune* cited *Calderon* for the proposition that "a litigant may not use a declaratory-judgment action to obtain piecemeal adjudication of defenses that *would not finally and conclusively resolve* the underlying controversy." *MedImmune*, 127 S. Ct. at 771 n.7. *MedImmune* and *Calderon* make clear that Apotex may not use a declaratory judgment action

against Merck as a means of gaining an advantage in its underlying controversy with FDA.

As noted above, the only "injury" that Apotex claims to have suffered at the hands of Merck itself is denial of its statutory right to file a declaratory judgment action against Merck. Of course, that "right" never actually existed in this case, because it only exists in those instances in which the patent holder does not file a patent infringement action. 21 U.S.C. § 355(j)(5)(C)(i). Perhaps more importantly, procedural rights of this sort are not the sort of statutory rights whose violation can give rise to the injury-in-fact necessary to establish standing.

Thus, for example, the Supreme Court held in *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), that the plaintiffs lacked standing to challenge the Department of Interior's alleged violations of § 7(a)(2) of the Endangered Species Act (ESA), 16 U.S.C. § 1536(a)(2), even though the ESA contains a citizen-suit provision that authorizes private citizens to sue to enjoin violations of the ESA.[9] The Court explained that even when Congress creates a right of

[9] § 7(a)(2) of the ESA requires each federal agency to consult with the Department of Interior (DOI) to ensure that its actions are unlikely to jeopardize the continued existence of any endangered or threatened species. When DOI issued regulations limiting § 7(2)(a) to actions taken within the United States, various environmental groups sued DOI under the ESA's citizen suit provision.

action authorizing private individuals to file suit, the plaintiffs nonetheless may not invoke federal court jurisdiction unless they can establish standing – which requires, among other things, a showing of injury-in-fact. *Id.* at 576. The Court held that where, as in that case, the plaintiffs could not demonstrate injury-in-fact, the federal courts lack Article III jurisdiction to hear the case; Congress's creation of a private right of action does not supply the necessary injury. *Id.* The Court explained:

> Whether the courts were to act on their own, or at the invitation of Congress, in ignoring the concrete injury requirement described in our cases, they would be discarding a principle fundamental to the separate and distinct constitutional role of the Third Branch – one of the essential elements that identifies those "Cases" and "Controversies" that are the business of the courts rather than the political branches.

Id. Congress is, of course, entitled to adopt statutes creating new substantive rights. When it does so, actions infringing those rights can give rise to injury-in-fact that can form the basis for a plaintiffs' standing.[10] But as *Lujan* explained, "Statutory broadening of the categories of injury that may be alleged in support of standing is a different matter from abandoning" traditional standing requirements, including the requirement that the plaintiff has suffered some

[10] An example of a congressional statute that creates a new substantive right is 35 U.S.C. § 271(e)(2)(A). Adopted as part of the Hatch-Waxman Act in 1984, that statute declares that the filing of a Paragraph IV certification injures the patent holder by infringing her property rights in the patent.

actual injury – whether an injury to rights created by statute or created by some other source. *Id.* at 578.

WLF does not understand Congress to have intended to permit filers of Paragraph IV certifications to bring declaratory judgment actions even when the filer has not suffered any injury-in-fact. *See* 35 U.S.C. § 271(e)(5) (limiting federal court subject matter jurisdiction over such declaratory judgment actions to those cases in which an assertion of jurisdiction is "consistent with the Constitution."). But as *Lujan* makes clear, even if Congress had intended to create federal court jurisdiction over declaratory judgment actions brought by filers of Paragraph IV certifications who have not suffered injury at the hands of the patent holder, it lacks authority to do so. In the absence of any evidence that Apotex has suffered injury-in-fact, it lacks standing to sue.

III. THE COURTS HAVE NEVER RECOGNIZED A FREESTANDING CAUSE OF ACTION FOR PATENT INVALIDITY

Apotex does not claim that its actions are being affected in any way by Merck. It is not living in dread of a patent infringement suit by Merck, nor is it altering its behavior to avoid such a suit. It nonetheless insists that, because from Apotex's perspective the world would be a better place in which to live if the Fosamax patents were invalidated, it has standing to maintain a declaratory

judgment action against Merck, a party that denies that there exists any sort of controversy between it and Apotex.

Apotex's claims are based on a fundamental misunderstanding of patent law. Patent invalidity is an affirmative defense to patent infringement, not a freestanding cause of action. *See* 35 U.S.C. §§ 282(2)-(3). One does not suffer injury in the abstract based on the existence of patents that infringe upon one's otherwise unlimited range of commercial activity in one's area of interest. Rather, to challenge a patent, one must establish an injury consisting of either: (1) a reasonable apprehension that one will be sued for violating the patent; or (2) forbearance from activity that one would engage in but for the likelihood that doing so would lead to a potentially ruinous patent infringement suit.

Take, as an example, an inventor of mousetraps. It would be in the interests of such an inventor if all mousetrap patents were invalidated. That action would allow the inventor freer rein to go about designing a better mousetrap without having to worry that others might claim that the new design infringes one or more existing patents. But that generalized interest in invalidating patents does not provide the inventor with standing to challenge all mousetrap patents, if there is neither reasonable apprehension of suit nor forbearance from activity that would result in potentially ruinous litigation.

Similarly, Apotex lacks standing to challenge the Fosamax patents based simply on a belief that invalidation of those patents *might* speed up FDA approval of Apotex's ANDA.

As this Court recently explained, the point of the Declaratory Judgment Act is to relieve a party from legal uncertainty when another party with whom one has a substantial controversy and adverse legal interests nonetheless declines to file suit:

> [T]he Declaratory Judgment Act was intended to fix the problem that arises when the other side does not sue. *See Minn. Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 673 (Fed. Cir. 1991) ("In promulgating the Declaratory Judgment Act, Congress intended to prevent avoidable damages from being incurred by a person uncertain of his rights and threatened with damages by delayed adjudication."); *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987) ("[T]he purpose of the Declaratory Judgment Act . . . in patent cases is to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights."). Before the Declaratory Judgment Act, a patent owner engaging in "extra-judicial patent enforcement" tactics rendered its competitors
>
> > helpless and immobile so long as patent owners refused to grasp the nettle and sue. After the Act, those competitors were no longer restricted to an *in terrorem* choice between the incurrence of a growing potential liability and abandonment of their enterprises; they could clear the air by suing for a judgment that would settle the conflict of interests.
>
> *Arrowhead* [*Indus. Water, Inc. v. Ecolochem, Inc.*], 846 [F.2d 731,] 735 [(1988)].

Sony Electronics, Inc. v. Mitsubishi Digital Electronics America, Inc., ___ F.3d ___, 2007 U.S. App. LEXIS 18465 (Fed. Cir., Aug. 3, 2007).

Apotex faces no legal uncertainty. It knows that it will not be sued by Merck for patent infringement. Instead, the sole purpose of its suit is to undercut Teva's position as the first ANDA filer by cutting short Teva's 180-day exclusivity period and thereby, it hopes, speeding up FDA approval of its ANDA. The Declaratory Judgment Act was not adopted to serve such purposes, and such freestanding patent challenges fall outside the federal courts' Article III jurisdiction.

"A useful question to ask in determining whether an actual controversy exists is what, if any, cause of action the declaratory judgment defendant may have against the declaratory judgment plaintiff." *Benitec*, 2007 U.S. App. LEXIS 17299, at *8-*9. The answer here: Merck has no cause of action, having granted Apotex an unconditional covenant not to sue. It follows that subject matter jurisdiction is absent in this case: "'Without an underlying legal cause of action, any adverse economic interest that the declaratory plaintiff may have against the declaratory defendant is not a legally cognizably interest sufficient to confer declaratory judgment jurisdiction.'" *Id.* at *9 (quoting *Microchip Tech. Inc. v. Chamberlain Group, Inc.*, 441 F.3d 936, 943 (Fed. Cir. 2006))

CONCLUSION

Amici curiae respectfully request that the Court affirm the judgment of the district court.

Respectfully submitted,

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Dated: September 20, 2007

CERTIFICATE OF COMPLIANCE

I am an attorney for *amicus curiae* Washington Legal Foundation (WLF). Pursuant to Fed.R.App.P. 32(a)(7)(C), I hereby certify that the foregoing brief of WLF is in 14-point, proportionately spaced CG Times type. According to the word processing system used to prepare this brief (WordPerfect 12.0), the word count of the brief is 6,064, not including the certificate of interest, table of contents, table of authorities, certificate of service, and this certificate of compliance.

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Richard A. Samp

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of September, 2007, two copies of the foregoing brief of *amici curiae* WLF, *et al.*, in support of Plaintiff-Appellee were deposited in the U.S. mail, with first-class postage affixed, addressed as follows:

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