United States Court of Appeals for the Federal Circuit

04-1186

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff-Appellant,

v.

PFIZER INC.,

Defendant-Appellee.

Henry C. Dinger, Goodwin Procter LLP, of Boston, Massachusetts, filed a combined petition for panel rehearing and rehearing en banc for plaintiff-appellant. Of counsel on the petition was Thomas J. Meloro, Jr., Kenyon & Kenyon, of New York, New York.

Dimitrios T. Drivas, White & Case LLP, of New York, New York, filed an opposition to the petition for defendant-appellee. With him on the opposition were Jeffrey J. Oelke and Adam Gahtan.

Brian T. Moriarty, filed an amicus curiae brief for the Generic Pharmaceutical Association.

William L. Mentlik, Lerner, David, Littenberg, Krumholz & Mentlik, LLP, of Westfield, New Jersey, filed an amicus curiae brief for IVAX Pharmaceuticals, Inc. With him on the brief was Roy H. Wepner.

Lawrence DeMille-Wagman, Attorney, Federal Trade Commission, of Washington, DC, filed an amicus curiae brief for the Federal Trade Commission. With him on the brief were John D. Graubert, Acting General Counsel; Susan A. Creighton, Director, Bureau of Competition; John F. Daly, Deputy General Counsel for Litigation; and Lore A. Unt, Counsel for Intellectual Property.

Theodore Case Whitehouse, Willkie Farr & Gallagher LLP, of Washington, DC, filed an amici curiae brief for United States Senators Edward M. Kennedy, John S. McCain, and Charles E. Schumer.

Appealed from: United States District Court for the District of Massachusetts

Judge Richard G. Stearns

United States Court of Appeals for the Federal Circuit

04-1186

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff-Appellant,

v.

PFIZER INC.,

Defendant-Appellee.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, CLEVENGER, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, and PROST, Circuit Judges.

O R D E R

A combined petition for panel rehearing and rehearing en banc was filed by the Appellant, and a response thereto was invited by the court and filed by the Appellee.[1] The petition for rehearing was referred first to the merits panel that heard the appeal. Thereafter, the petition for rehearing en banc, response, and the amici curiae briefs were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition for panel rehearing is denied.

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[1] Amicus curiae briefs were filed by:
1- The Federal Trade Commission.
2- The Generic Pharmaceutical Association.
3- Ivax Pharmaceuticals, Inc.
4- United States Senators Edward M. Kennedy, John S. McCain, and Charles E. Schumer.

(2) The petition for rehearing en banc is denied.

(3) The mandate of the court will issue on April 11, 2005.

MAYER, GAJARSA, and DYK, Circuit Judges, would rehear the appeal en banc.

GAJARSA, Circuit Judge, with whom DYK, Circuit Judge, joins, dissents in a separate opinion.

DYK, Circuit Judge, with whom GAJARSA, Circuit Judge, joins, dissents in a separate opinion.

FOR THE COURT

April 4, 2005
Date

s/ Jan Horbaly
Jan Horbaly
Clerk

cc: Henry C. Dinger, Esq.
Dimitrios T. Drivas, Esq.
William L. Mentlik, Esq.
Sarah Lenz Lock, Esq.
Lawrence DeMille-Wagman, Esq.
Brian T. Moriarty, Esq.
Theodore Case Whitehouse, Esq.

United States Court of Appeals for the Federal Circuit

04-1186

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff-Appellant,

v.

PFIZER, INC.,

Defendant-Appellee.

GAJARSA, Circuit Judge, with whom DYK, Circuit Judge, joins, dissenting from the order declining rehearing en banc.

The Court has denied the petition to review this case en banc. I must respectfully dissent from that denial. This is a critical issue under the Hatch-Waxman Act.[1] The failure of this court by en banc action to correct the Teva court's decision, 395 F.3d 1324 (Fed. Cir. 2005), allows the statutory procedures to be manipulated by the patent holders to the clear and foreseeable detriment of the generic drug industry.

The Teva court's reasonable apprehension analysis is the wrong test for a concrete, actual, or imminent injury in fact when considering the problem of a generic

[1] The Patent Laws and Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271 and 282 (2000)), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)).

with a second-filed ANDA certification.[2] Article III does not compel it, and the Supreme Court has rejected the doctrinal rigidity that Teva introduces. Our cases recognize reasonable apprehension, in the typical patent infringement case, as but a pragmatic attempt to give operational guidance against which patentees can structure their conduct, and control their litigation costs, in a fact-specific area of law. The ANDA facts correspond to the typical infringement case in name only, and it is this court's constitutional duty to look at those facts in their proper context. The Teva court's misguided Article III analysis further thwarts Congress's clear intent to foster, through the detailed provisions of Hatch-Waxman, greater competition in generic pharmaceuticals.

I.

The question is whether Teva has shown a justiciable case or controversy within Article III. Congress unambiguously swept aside any additional limitation on jurisdiction potentially introduced by the Declaratory Judgment Act, 28 U.S.C. § 2201.

> [T]he courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

35 U.S.C.A. § 271(e)(5) (West Supp. 2004), as added by Pub. L. 108-173, 117 Stat. 2457 (Dec. 8, 2003). The law is clear that this justiciability issue has three elements: (1) a concrete, actual or imminent injury in fact; (2) fairly traceable causation between the injury and defendant's conduct; and (3) redressability. See Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 103-04 (1998); Valley Forge Christian Coll. v. Ams. United

[2] The overall scheme of the Hatch-Waxman Act is described in detail in our decisions in Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323 (Fed. Cir. 2001) and Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368 (Fed. Cir. 2002).

for Separation of Church and State, Inc., 454 U.S. 464, 472 (1982). Only the concrete injury in fact is disputed.

The cases treat the controversy requirements of Article III and § 2201 together and their approach is instructive here. Jurisdiction under § 2201 can be no broader than jurisdiction under Article III, yet the cases show that § 2201 is very broad indeed. Article III is no narrower. See Aetna Life Ins. Co. of Hartford, Conn. v. Haworth, 300 U.S. 227, 240 (1937) (§ 2201 "has regard to the constitutional provision and is operative only in respect to controversies which are such in the constitutional sense[.]"). As the Supreme Court recognizes, the § 2201 controversy requirement is highly fact specific.

> The difference between an abstract question and a 'controversy' contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy. 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.

Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941). The Supreme Court,[3] this court,[4] and our sister circuits[5] consistently apply this holding by looking to all the circumstances surrounding a controversy.

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[3] See Steel Co., 523 U.S. at 103-04; Duke Power Co. v. Carolina Envtl. Study Group, Inc., 438 U.S. 59, 81 (1978) (finding actual case and controversy where plaintiffs would sustain injury from operation of planned nuclear power plant, and injury was redressable by constitutionality challenge to Price-Anderson Act).

[4] See EMC Corp. v. Norand Corp., 89 F.3d 807, 810 (Fed. Cir. 1996) (quoting Md. Cas.); BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993) ("There is no simple rule that addresses all shades of relationships between disputants."); Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 735-36 (Fed. Cir. 1988) (observing "there is no specific, all-purpose test" for an actual controversy).

A.

The Teva majority opinion does not, and its reasons for failing to do so are not convincing. In far more difficult factual contexts the courts have nonetheless found "a concrete, actual or imminent injury in fact" satisfying Article III. In Duke Power Co. v. Carolina Envtl. Study Group, Inc., 438 U.S. 59 (1978), for example, the appellees challenged the constitutionality of the Price-Anderson Act. By that Act, Congress limited the aggregate tort liability of nuclear power plant operators for a single nuclear "incident." The appellant was a utility that was constructing nuclear power plants. The appellees, including persons "who live within close proximity of the planned facilities," challenged the statute under the Fifth Amendment. Id. at 67 (emphasis added). Their theory was that "in the event of a nuclear accident their property would be 'taken' without any assurance of just compensation." Id. at 69 (emphasis added). The court concluded that this theory stated a justiciable Article III controversy. See id. at 81 ("[A]ppellees will sustain immediate injury from the operation of the disputed power plants.").

The breadth of Article III standing in environmental cases sharply contrasts with the Teva court's narrow construction in this ANDA context. The Supreme Court has held that a concrete injury in fact, for Article III, is shown where a non-profit's members allege that a polluter's discharges, "and the affiant members' reasonable concerns about the effects of those discharges, directly affected those affiants' recreational, aesthetic, and economic interests." Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.

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[5] See, e.g., Riva v. Mass., 61 F.3d 1003, 1009-10 (1st Cir. 1995); Kidder, Peabody & Co., Inc. v. Maxus Energy Corp., 925 F.2d 556, 562-63 (2d. Cir. 1991); Oneida Tribe of Indians of Wis. v. State of Wis., 951 F.2d 757, 760 (7th Cir. 1991).

(TOC), Inc., 528 U.S. 167, 183-84 (2000) (emphasis added). The Court expressly ruled that conditional statements – that members would use a river for recreation if Laidlaw stopped discharging pollutants into it – sufficed to show concrete injury in fact under Article III. Id. at 184. Teva's injury in this case, by comparison, is far more immediate.

The facts showing Teva's "concrete, actual or imminent injury" are far easier to identify. Ivax filed the first ANDA on the active ingredient for Zoloft; Teva filed a subsequent or second ANDA. Teva certified that its proposed formulation would not infringe Pfizer's U.S. Patent No. 5,248,699, or that the patent was invalid. Pfizer had 45 days to sue Teva for this patent infringement, 35 U.S.C. § 271(e)(2)(A), and did not. Although Pfizer had sued Ivax, they settled out of court. Pfizer granted Ivax a royalty bearing license for the '699 patent, preserved Ivax's 180 day statutory exclusivity, and designed a comfortable duopoly set to begin on June 30, 2006 and potentially last 180 days past the '699 patent expiration in 2010. The FDA therefore could not approve Teva's generic drug until 180 days after Ivax's exclusivity expired – when either the '699 patent expired or was invalidated – and without FDA approval Teva could not market its product.

By settling with Ivax, Pfizer leveraged the Hatch-Waxman exclusivity to insulate the '699 patent from any validity challenge. Pfizer also insulated itself from any judicial determination of the metes and bounds of its '699 patent claim scope in relation to a design-around, a determination central to the proper function of our patent system. Because of this insular effect, Pfizer effectively extended – as against all but Ivax – the

term of its underlying U.S. Patent No. 4,356,518, which expires on June 30, 2006, to coincide with the '699 patent's later expiration in 2010.[6]

This ties up Teva's investment in its proposed generic until at least 2010, precludes it from testing a potentially weak patent, precludes it from triggering the statutory exclusivity period with a successful validity challenge, and precludes it from introducing an effective design-around, as is its right and as the patent law encourages. The live controversy is found on the face of this bottleneck under the statute.[7] Any of this defines a concrete, actual or imminent injury in fact within the meaning of Article III, and on that basis Teva states a justiciable controversy under § 2201.

B.

None of these problems can be found in the typical patent infringement context, in which this court has regularly tested immediate injury in fact by the reasonable apprehension test. Consistent with Maryland Casualty, this court has never held that Article III required that analysis. Quite to the contrary, this court has repeatedly observed that reasonable apprehension was simply a functional approach to typical patent infringement problems under § 2201. See EMC Corp. v. Norand Corp., 89 F.3d

[6] That is, the '518 patent claims the active ingredient in Zoloft. The '699 patent is an improvement. A generic, like Teva, that could design around the '699 but not the '518 – or that thought it had found invalidating art for the '699 patent – would need a license to the '518 patent to enter the market, or face an infringement action. Once the '518 patent expired, Teva could confidently enter the market with a compound that did not infringe the '699 patent. But because of the Hatch-Waxman exclusivity, Pfizer insulated the '699 patent from any test in litigation. In practice this extends the '518 patent term until the '699 patent expires.

[7] Cf. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1073 n.18 (D.C. Cir. 1998) ("It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a 'case or controversy' without demonstrating an immediate risk of being sued.").

807, 810 (Fed. Cir. 1996) (quoting Md. Cas.); BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993) ("There is no simple rule that addresses all shades of relationships between disputants."); Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 735-36 (Fed. Cir. 1988) (observing "there is no specific, all-purpose test" for an actual controversy). The purpose of the reasonable apprehension analysis "is to determine whether the need for judicial attention is real and immediate." BP Chems., 4 F.3d at 978. The Teva court ignores this precedent and reads general infringement policy considerations into Article III, where they do not belong.

The contextual differences between the second ANDA filer and the typical patent infringement case make the reasonable apprehension test inappropriate for this action. By guiding the patentee's conduct in the typical case, the reasonable apprehension analysis allows the patentee to avoid litigation. Identifying a justiciable controversy in terms of a threat of infringement litigation, the doctrine establishes the circumstances in which the uncertainty of legal rights materially harm a potential infringer in the marketplace. The injury facing Teva in this case is different in kind, but no less actionable.

Teva's injury does not depend on threats from the incumbent. In view of the statute, the injury exists independent of any threat, and the policy motivation for applying the reasonable apprehension test is completely lacking. There is no sense in the court demanding the incumbent to brandish the threat of infringement actions, even beyond the act of listing a patent in the Orange Book, given a statutory system that encourages the incumbent to do everything possible to prevent its patents from being put in play. No incumbent will ever make the threat, if it can simply ride out the term in

the listed patent.[8] From first principles, a fact specific analysis shows that the reasonable apprehension test is not designed for this case.

II.

The language of § 271(e)(5) grants Article III jurisdiction to the maximum extent possible. The statute provides that the courts shall have subject matter jurisdiction. The majority's analysis in Teva of the legislative history to the 2003 Act[9] seems addressed to this point, but its reasoning is unconvincing.

The statute specifically provides that the courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action." The court, therefore, has a Congressional directive to refrain from applying any jurisdictional limitation crafted by the courts or found in § 2201. The Teva court overlooks this basic point.

The Teva court further focuses on the language originally introduced for § 271(e)(5), which provided that an incumbent's failure to sue within 45 days "shall establish an actual controversy between the applicant and the patent owner." Teva, 395 F.3d at 1336. In conference the language was changed to a provision that the courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" over these actions. Id. The court concludes that § 271(e)(5) was "not meant to automatically bestow district court jurisdiction over actions such as Teva's." Id. This conclusion is contrary to the plain language of § 271(e)(5). The change in

[8] See Minn. Mining and Mfg. Co. v. Barr Labs., Inc., 289 F.3d 775 (Fed. Cir. 2002).

[9] Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)) [hereinafter "2003 Act"].

language bestowed full Article III jurisdiction and simply recognizes the court's role in declaring when the judicial powers under Article III extend to this action. It does not bear on the proper scope of Article III.

The Teva court also focuses on a Committee Report accompanying the modified 2003 Act. The language in the Report cannot contradict the plain language of § 271(e)(5). A legislative enactment cannot limit the judicial power under Article III, and, a fortiori, language in a Committee Report that misstates our Article III jurisprudence cannot bind this court.

Ultimately, the idea that § 271(e)(5) suggests a limitation on standing is misplaced, given the plain language of Hatch-Waxman. The statute provides an express mechanism for generics to challenge, with declaratory actions, the claim scope or validity of listed patents. Under this statutory scheme, it is court challenges by generic drug companies that limit incumbent overreaching by submitting over-inclusive lists of patents applicable to any given branded formulation. Congress's intent to foster early generic market entry precludes any real argument for any limitation. Certainly under the circumstances of this case, Teva's declaratory action is the ideal method to police Pfizer's strategic manipulation of the Hatch-Waxman exclusivity provisions. Delayed resolution of the bottleneck facing Teva serves no purpose, as by then the patents at issue will have expired. There is no basis for precluding this suit on Article III grounds.

III.

The Teva court's Article III analysis distorts longstanding Supreme Court jurisprudence and misapplies the decisions of this court. Teva has presented a

justiciable controversy, and the courts should decide it. Worst of all, the Teva court's Article III analysis forestalls legislative correction. The court should have corrected this error en banc. I respectfully dissent from the refusal to do so.

United States Court of Appeals for the Federal Circuit

04-1186

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff-Appellant,

v.

PFIZER, INC.,

Defendant-Appellee.

DYK, Circuit Judge, with whom GAJARSA, Circuit Judge, joins, dissenting from the order denying rehearing en banc.

This case presents an important question under the Hatch-Waxman Amendments, which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc (2000) and 35 U.S.C. §§ 156, 271, 282 (2000))—whether a patent holder can delay Food and Drug Administration ("FDA") approval of an application for a competing generic drug by the simple expedient of refusing to sue for infringement. Here there is a present controversy over Teva's right to secure approval of its Abbreviated New Drug Application ("ANDA"), plainly adequate to satisfy the requirements of Article III.

The Declaratory Judgment Act, 28 U.S.C. § 2201 (2000), and the 2003 Medicare Amendments, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, Pub. L. No. 108-173, 117 Stat.

2066, 2448-69 (codified in pertinent part at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)), were designed to create a declaratory judgment remedy in circumstances permitted by Article III. The panel's holding, relying on earlier decisions of our court, that Article III bars such a remedy unless "a reasonable apprehension of imminent suit" exists is incorrect. Teva Pharm. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1333 (Fed. Cir. 2005). I dissent from the denial of rehearing en banc.

I

The plain language of the 2003 Medicare Amendments requires that in the Hatch-Waxman context the federal courts allow declaratory judgment actions to the full extent allowed by Article III. 35 U.S.C.A. § 271(e)(5) ("[C]ourts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought . . . under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed."). Even if the legislative history could be read as approving our reasonable apprehension test, that history cannot overcome the plain language of the statute. So we must decide whether Article III is satisfied.

There are relatively few Supreme Court cases dealing with Article III and declaratory judgments, but the few cases that do exist provide no support for a reasonable apprehension of imminent suit requirement. The declaratory judgment statute was designed to deal with a situation in which the declaratory judgment defendant declined to bring suit, i.e., in which there was no reasonable apprehension of imminent suit. The Supreme Court case upholding the statute involved just such a situation—one in which there was no imminent risk of suit because the potential plaintiff

declined to sue. Aetna Life Ins. Co v. Haworth, 300 U.S. 227 (1937). In that case, the insured on several policies stopped making premium payments and made repeated claims for benefits on account of total and permanent disability. Id. at 237-38. Aetna refused to pay benefits because it contended that the insured was not disabled and that the policies had lapsed due to nonpayment. Id. at 238. The insured failed to bring suit, so Aetna filed for a declaratory judgment that the insured was not disabled and that the policies had lapsed. Id. at 239. The Court found that these facts gave rise to a controversy within the meaning of Article III, stating "[t]here is here a dispute between parties who face each other in an adversary proceeding. . . . The dispute is defined and concrete, not hypothetical or abstract. . . . It calls, not for an advisory opinion upon a hypothetical basis, but for an adjudication of present right upon established facts." Id. at 242.

Likewise, the Ninth Circuit, in a case in which the plaintiff faced a risk of liability rather than suit, has held that "[a]n action for a declaratory judgment . . . is a case or controversy if the plaintiff has a real and reasonable apprehension that he will be subject to liability," not suit. Societe de Conditionnement en Aluminium v. Hunter Eng'g Co., Inc., 655 F.2d 938, 944 (9th Cir. 1981) (emphasis added).[1] The First Circuit has even more directly addressed the issue in Sallen v. Corinthians Licenciamentos LTDA, 273 F.3d 14 (1st Cir. 2001), and adopted a view that conflicts with the panel decision in this case. There, a World Intellectual Property Organization ("WIPO") panel found

[1] That case involved a manufacturer that filed for declaratory judgment of invalidity of the defendant's patent after a potentially unauthorized person working for the defendant threatened a third party with suit if the third party purchased the plaintiff's equipment. Id. at 941, 944-45. The third party purchased the equipment. Id. at 941. A

Sallen to be a cybersquatter and ordered his domain name transferred to Corinthians Licenciamentos LTDA ("CL"). Id. at 21-22. Sallen filed suit in federal district court seeking a declaration that under United States law (which allowed a challenge to the WIPO decision) he was entitled to the domain name. Id. at 22. The district court dismissed the case because CL had no intent to sue Sallen under United States law. Id. On appeal, the First Circuit rejected CL's argument that a reasonable apprehension of suit is required to satisfy Article III:

> CL claims that a reasonable apprehension of suit is required to meet Article III's case or controversy requirement. But this is not the only way to establish the existence of a case for purposes of Article III. The reasonable apprehension of suit doctrine exists to cabin declaratory judgment actions where the only controversy surrounds a potential, future lawsuit. That is not this case.

Id. at 25 (internal citations omitted and emphasis added). The court found that United States law "provides a registrant who has lost a domain name . . . with a cause of action for an injunction returning the domain name if the registrant can show that she is in compliance with" United States law. Id. at 26. Thus, the court found that the controversy in issue was certain and that "a certain controversy renders the 'reasonable apprehension' question irrelevant." Id.

In my view, the First Circuit is correct: the proper test under Article III is whether there is a present concrete controversy, and the panel here applied an incorrect test. The panel here also reached the wrong result in this case by relying on that erroneous test.

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hold harmless provision in the contract between the third party and the plaintiff placed the plaintiff in reasonable apprehension of liability. Id. at 945.

II

Here it seems to me that there are three potential controversies:

1. There is a potential controversy over whether the ANDA filing itself was an infringement. I doubt whether this, standing alone, satisfies Article III because Pfizer seems not to care whether such an infringement occurred. Textron Lycoming Reciprocating Engine Div., AVCO Corp. v. UAW, 523 U.S. 653, 661 (1998) (finding no constitutional controversy where the declaratory judgment defendant had no "interest in defending the binding nature of the contract").

2. There is also a potential controversy over whether Teva should be allowed to manufacture and market the drug without incurring damages for infringement. The problem here is that Teva has not alleged that it intends to market or sell the drug at any time in the near future or that it is being prevented from doing so by the risk of infringement damages. Instead, Teva alleges only that the filing of its ANDA constituted technical infringement; that Pfizer did not file suit within the 45-day period; that Pfizer included the '699 patent in the Orange Book; and that Pfizer tends to enforce its patents through litigation. (J.A. at 52.) Unless Teva actually is about to manufacture or sell the drug, there would seem to be no case or controversy under this theory. Societe de Conditionnement, 655 F.2d at 944.

3. The third potential controversy is over whether Teva's ANDA should be approved earlier than 180 days after Ivax commences marketing. In my view, there is a present and concrete controversy over Teva's right to such an approval, which satisfies the requirements of Article III. The Hatch-Waxman Amendments provide for the right to secure resolution of the controversy through a declaratory judgment.

Ivax earlier filed a paragraph IV certification regarding the '699 patent and then settled with Pfizer. Thus, Ivax will enjoy a 180-day exclusivity period beginning with the earlier of (1) the first day it markets its generic drug (which cannot be earlier than June 30, 2006) or (2) the date that the '699 patent is held invalid or not infringed in the decision of a court.[2] Because of the paragraph IV certification, Teva's application cannot be approved by the FDA until after Ivax's 180-day exclusivity period ends. Teva, 395 F.3d at 1328, 1330. In other words, the running of the exclusivity period could be triggered before Ivax's first marketing date if Teva could secure a declaratory judgment of non-infringement or invalidity. Approval of Teva's ANDA would follow 180 days thereafter.

Normally, one would expect that the approval issue would be litigated between Teva and the FDA, but, as we recognized in Minnesota Mining and Manufacturing Co. v. Barr Laboratories, Inc., 289 F.3d 775, 778 (Fed. Cir. 2002), Congress provided that approval would depend on the outcome of litigation between private parties (the patent owner and the potential infringer) over the questions of infringement and validity.[3] There is certainly a concrete controversy between Pfizer (and Ivax) and Teva over when Teva's ANDA should be approved. Both Pfizer and Ivax want the approval of Teva's application delayed. Teva wants to avoid delay. The question of delay turns on

[2] To be sure, Pfizer's failure to bring suit within the 45-day period specified in section 21 U.S.C. § 355(j)(5)(B)(iii) means that the approval of the ANDA will not be delayed under that section, but despite Pfizer's failure to sue, 21 U.S.C. § 355(j)(5)(B)(iv) will bar approval until 180 days after Ivax markets the drug unless there is an earlier holding of non-infringement or invalidity.

[3] See also Apotex, Inc. v. Thompson, 347 F.3d 1335 (Fed. Cir. 2003); Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323 (Fed. Cir. 2001).

infringement and validity.[4] Under these circumstances, I think there is a case or controversy within the meaning of Article III, and that the questions of infringement and validity should be addressed. The panel appears to recognize the existence of a controversy, but holds that the controversy is insufficient for purposes of Article III.[5] I respectfully disagree. Under the panel's decision Teva lacks any remedy to contest the delay in its ANDA approval. I agree with Judge Mayer and Judge Gajarsa that Article III does not require such unfairness.

[4] While the '518 patent imposes an additional limitation on the approval of Teva's ANDA such that it could not be approved until the '518 patent expires (June 30, 2006), it is hardly premature to litigate the approval date since litigation over infringement and invalidity of the '699 patent could itself consume a significant time.

[5] The panel states that "[t]he fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer." Teva, 395 F.3d at 1338.