IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 04-1186

TEVA PHARMACEUTICALS USA, INC,

Plaintiff-Appellant,

v.

PFIZER INC,

Defendant-Appellee

BRIEF OF UNITED STATES SENATORS EDWARD M. KENNEDY, JOHN S. McCAIN, AND CHARLES E. SCHUMER AS *AMICI CURIAE* IN SUPPORT OF PETITION OF TEVA PHARMACEUTICALS USA, INC. FOR REHEARING OR REHEARING *EN BANC*

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25 February 2005

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Teva Pharmaceuticals USA. Inc. v. Pfizer Inc.

No. 04-1186

CERTIFICATE OF INTEREST

Counsel for the amicus Kennedy and Schumer certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

United States Senator Edward M. Kennedy
United States Senator John S. McCain
United States Senator Charles E. Schumer

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:

N/A

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

N/A

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

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

Theodore Case Whitehouse, Willkie Farr & Gallagher LLP

25 February 2005
Date


Signature of counsel

Theodore Case Whitehouse
Printed name of counsel

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Preliminary Statement of *Amici Curiae*

Amicus Edward M. Kennedy is the senior United States Senator from Massachusetts and the ranking minority member on the Senate Committee on Health, Education, Labor and Pensions and a member of the Senate Judiciary Committee. *Amicus* John S. McCain is the senior United States Senator from Arizona. *Amicus* Charles E. Schumer is the senior United States Senator from New York and a member of the Senate Judiciary Committee. *Amici* Kennedy, McCain, and Schumer played central roles in the legislative process leading to the enactment of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, §§ 1101-1123 ("MMA"), certain provisions of which were construed in this Court's January 21, 2005 opinion in this case. *Amicus* Kennedy negotiated these provisions in committee and in the conference committee on the MMA.

Amicus McCain and Schumer were the original co-sponsors of legislation to address abuses of the Hatch-Waxman Act, and they were among the principal co-sponsors of the bill containing the provisions to amend the Hatch-Waxman Act that were ultimately enacted, in amended form, in the MMA.

Amici submit this *amicus* brief in their legislative leadership capacities because the panel opinion in this case misapprehended the legislative history of the provisions of the MMA that created a declaratory judgment remedy for generic drug companies seeking to challenge patents listed in the so-called "Orange Book." Based in part on this misapprehension, the Court ruled in a manner that effectively thwarts the goals that Congress sought to achieve in enacting this remedy and re-

duces dramatically the effectiveness of the MMA in reducing the staggering cost of prescription drugs in this country. *Amici* offer this brief to provide a context for this legislation in the hope that the Court will grant rehearing or rehearing *en banc* and overturn the panel's erroneous decision.

Argument

I. CONGRESS INTENDED TO EXPAND SUBJECT MATTER JURISDICTION OVER DECLARATORY JUDGMENT ACTIONS BY GENERIC DRUG COMPANIES TO THE CONSTITUTIONAL LIMIT.

Generic drugs play a vital role in moderating the rapidly increasing prices of prescription drugs in the United States. These costs affect patients, employers who provide health coverage for their employees, and state and federal governments that provide health benefits for their citizens through Medicare, Medicaid, and other programs. One of the main goals of the MMA was to reduce these costs.

When Congress in 1984 enacted the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly referred to as the "Hatch-Waxman Act," it sought to reduce those costs by encouraging the introduction of less expensive generic drugs as rapidly as possible consistently with the legitimate rights of holders of pharmaceutical patents. *See generally Eli Lilly & Co. v. Medtronic, Inc.,* 496 U.S. 661 (1990). One of the ways by which Congress sought to accelerate the introduction of generic drugs was to encourage the prompt resolution of patent disputes. Congress recognized that the uncertainties concerning the application of patents owned by innovator drug companies, coupled with the prospect of massive and potentially disastrous liability for the infringement of pat-

ents on "blockbuster" drugs such as Pfizer's Zoloft®, resulted in a *de facto* "extension" of many pharmaceutical patent terms. *See id.* at 676. To avoid this, Congress provided that the filing of an Abbreviated New Drug Application (or "ANDA"), coupled with a challenge to a patent listed in the "Orange Book," would constitute an act of infringement sufficient to permit immediate judicial resolution of patent disputes. Congress anticipated that, by providing for a 30-month stay of FDA approval of an ANDA if the innovator company brought an infringement suit within 45 days of receiving the ANDA applicant's challenge, the Hatch-Waxman Act would encourage the resolution of such patent disputes early enough to avoid any *de facto* patent extension.

In many instances, this worked. However, Congress learned that, in a number of cases, innovator companies delayed bringing suit to advance their own economic interests in delaying competition from generic companies. As *amicus* Senator Kennedy explained on the Senate floor in support of the MMA:

> For example, the brand drug company might have several patents listed in the Food and Drug Administration's Orange Book with respect to a particular drug. It could be in the company's interest to bring suit within 45 days on one patent and to hold the others in reserve. The suit on one patent would automatically stay approval of the generic application until the lawsuit is resolved or the 30 months elapses. Holding the other patents in reserve would introduce uncertainty that could discourage generic companies from devoting resources to bring the generic drug to market and that would give the brand drug company a second opportunity to delay generic competition by suing the generic company for infringement of the reserved patents after the resolution of the initial infringement suit.

> Or for patents on which no 30-month stay is available, the brand drug company could sit back to create uncertainty and similarly delay generic entry by delaying resolution of those patents. Or when generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the "failure to market" provision and force the first generic to market.

149 Cong. Rec. S15885 (Nov. 25, 2003) (statements of Sen. Kennedy).

Congress sought to amend the Hatch-Waxman Act to make sure that generic companies in the situations described by Senator Kennedy could bring a declaratory judgment action against the innovator company to seek a judicial determination of invalidity or non-infringement. This was an effort to balance the scales by extending to generic companies the same ability to seek a judicial resolution of disputes concerning Orange Book patents that the innovator companies enjoyed.

As this Court pointed out at page 21 of its opinion, an early version of the bill would have deemed the failure of the innovator company to commence an infringement action within 45 days to "establish an actual controversy between the [ANDA] applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States." However, the Justice Department's Office of Legal Counsel submitted a statement to the Senate Judiciary Committee, in connection with hearings on the bill, that raised questions concerning the constitutionality of that approach. The Justice Department advised the Committee that Congress lacks the power to declare that any particular case presents an "actual controversy" under Article III because determining the scope of Article III is a judicial function.

Recognizing the primary role of the judiciary in defining the scope of Article III's case or controversy requirement, Congress took a different approach to accomplish the same goal. In the version of the bill that was signed into law on December 8, 2003, Congress passed a new 21 U.S.C. § 355(j)(5)(C)(i)(II) that specifically permits an ANDA applicant to bring a declaratory judgment action "against the owner [of a patent listed in the Orange Book] or holder [of an NDA with respect to the drug associated with such listed patent] ... for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval." The bill also amended 35 U.S.C. § 271 to provide that district courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any [declaratory judgment] action brought by [such an ANDA applicant] for a declaration" of invalidity or non-infringement. This recognized the power and obligation of federal courts to limit their actions to "actual controversies" while making it clear that such declaratory judgment actions were to be entertained unless it would be a violation of Article III to do so.

The creation of this declaratory judgment remedy was politically controversial. Representatives of innovator drug companies insisted Article III required generic companies seeking declaratory relief to demonstrate a "reasonable apprehension of suit," and representatives of generic drug companies argued that there was no such constitutional requirement. Both sides urged the inclusion of language in the legislative history to reflect their views in this regard.

In the end, the senators and representatives who made up the Conference Committee formed to reconcile the House and Senate versions of the bill approved a compromise formulation in their report that essentially left this question to the courts. The report stated: "The conferees expect courts to apply the 'reasonable apprehension' test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III." In other words, the conferees anticipated that this Court would apply the reasonable apprehension test, if, *but only if*, the Constitution required it. The conferees took no position whether the reasonable apprehension test was, in fact, constitutionally required, but rather recognized that to be a question for the courts to decide, not Congress. But wherever the constitutional line were drawn, Congress provided in the statute itself that the courts should go right up to that line.

The conferees also expressed the view that the courts would "examine as part of their analysis the particular policies served by the Hatch-Waxman Act." That purpose, expressed in the report, was to prevent "an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies." Whatever the precise contours of Article III might be, Congress expected its bill to expand the opportunities to seek declaratory relief where the innovator company delayed filing suit.

II. THE PANEL OPINION UNDERMINES THE GOALS OF THE 2003 AMENDMENTS.

This expectation that the amendment would expand the opportunities for declaratory relief was critical to the enactment of the bill. These amendments to the Hatch-Waxman Act were part of legislation that created a new prescription drug benefit for older Americans. This benefit and other aspects of the bill required significant new public expenditures and it was vitally important to include provisions that resulted in cost savings for the federal government. Budgetary analyses that we reviewed suggested that there would be very significant savings associated with the more rapid introduction of generic drugs. Congress included the declaratory judgment provisions to speed introduction of generic drugs and achieve these savings.

From this perspective, the panel majority's decision can only be viewed as frustrating the purpose of the amendments. First, the panel majority not only concluded that the reasonable apprehension of suit is required in these ANDA cases, but also that the ANDA applicant must face an apprehension of *imminent* suit. Since Congress' goal was to authorize declaratory judgment actions precisely in those cases where the innovator company seeks to delay, often for months or years, the commencement of infringement litigation, the panel's decision effectively negates the amendment and eliminates any possibility of achieving the accelerated introduction of generic drugs (and the concomitant cost savings) that Congress expected to achieve.

Second, the panel majority grounded its decision — including the imminence requirement — in Article III. As a result, Congress is unable to achieve its goals simply by making its intentions clearer. If the panel majority's decision stands, Congress would have to take other steps to realize the cost savings on which the Medicare Amendments were predicated, steps such as requiring innovator companies to commence litigation within 45 days or lose any right thereafter to recover damages for patent infringement.

Finally, the panel majority's decision frustrates the original purpose of the Hatch-Waxman Act by providing constitutional protection for strategies by innovator companies that effectively extend the term of pharmaceutical patents. As noted above, uncertainties concerning the application of Orange Book patents, coupled with exposure to ruinous liability for infringement, can lead to *de facto* patent term extensions, particularly where, as here, an unchallenged patent covering the active ingredient eliminates any incentive to initiate litigation with respect to related patents covering polymorphs, methods of use, or formulations. Unless litigation concerning the latter patents can be initiated well before the expiration of the unchallenged patents, few generic products will launch upon such expiration. These delays will cost the public billions of dollars without protecting any legitimate patent rights of innovator drug companies.

Conclusion

For the foregoing reasons, rehearing or rehearing *en banc* should be granted.

Dated: Washington, DC
25 February 2005

Respectfully submitted,

UNITED STATES SENATORS
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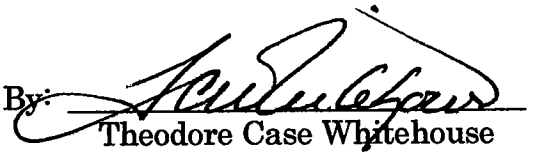
JOHN S. McCAIN, AND
CHARLES E. SCHUMER,
AS *AMICI CURIAE*

By: 
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No. 04-1186

Teva Pharmaceuticals USA, Inc. v. Pfizer Inc

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TEVA PHARMACEUTICALS USA, INC.,

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ORDER GRANTING MOTION OF UNITED STATES SENATORS EDWARD M. KENNEDY, JOHN S. McCAIN, AND CHARLES E. SCHUMER FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* IN SUPPORT OF PETITION OF TEVA PHARMACEUTICALS USA, INC. FOR REHEARING OR REHEARING *EN BANC*

This matter is before the Court on the motion of United States Senators Edward M. Kennedy, John S. McCain, and Charles E. Schumer for leave to file a brief as *amici curiae* in support of the pending petition of Teva Pharmaceuticals USA, Inc., for rehearing or rehearing *en banc*. Upon consideration of the motion, any response thereto, and the record herein, it is this 4th day of March, 2005, hereby

ORDERED that the motion for leave to file be GRANTED.

FOR THE COURT

Jan Horbaly

Jan Horbaly
Clerk