2007-1194

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PFIZER INC.,

Plaintiff-Appellee,

v.

MYLAN LABORATORIES INC. and MYLAN PHARMACEUTICALS INC.,

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA IN CASE NO. 2:02-CV-1628, JUDGE TERRENCE F. McVERRY

RESPONSE OF DEFENDANTS-APPELLANTS, MYLAN LABORATORIES INC. AND MYLAN PHARMACEUTICALS INC., TO THE COURT'S ORDER OF MARCH 23, 2007 REQUESTING FURTHER BRIEFING

E. Anthony Figg
Steven Lieberman
Minaksi Bhatt
ROTHWELL, FIGG, ERNST & MANBECK
1425 K Street, N.W.; Suite 800
Washington, DC 20005
(202) 783-6040

David J. Harth
HELLER EHRMAN LLP
One Madison Street,
Madison, Wisconsin 53703
(608) 663-7460

Shannon M. Bloodworth
HELLER EHRMAN LLP
1717 Rhode Island Ave., N.W.
Washington, D.C. 20036
(202) 912-2165

Attorneys for Defendants-Appellants

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Pfizer Inc. v. Mylan Laboratories, No, 2007-1194

Certificate of Interest

Counsel for Defendants-Appellants Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. certifies the following:

1. The full name of every party or *amicus* represented by me is Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc.

2. The parties named in the caption that I represent are the real parties in interest.

3. There is no parent corporation or publicly held company that owns 10 percent or more of the stock of the parties represented by me.

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

FROM HELLER EHRMAN LLP: David J. Harth, E. Josh Rosenkranz, Shannon M. Bloodworth, and Joseph Whitlock.

FROM ROTHWELL, FIGG, ERNST & MANBECK:
Edward Anthony Figg, Steven Lieberman, Minaksi Bhatt, Martha Cassidy, Joo Mee Kim, and Randy Elizabeth Brenner-Leifer.

FROM KEEVICAN, WEISS, BAUERLE & HIRSCH: Brian P. Fagan.

FROM KEPNER, KEPNER & CORBA: Ray C. Stoner.

FROM ECKERT, SEAMANS, CHERIN & MELLOTT, LLC:
Robert V. Campedel.

FROM BUCHANAN INGERSOLL: Roberta R. Wilson.

FROM DKW LAW GROUP: Bradley A. Plotner and Terry L. Schnell.

FROM PLUMMER & FINNERTY, LLP: Kathryn C. Finnerty.

FROM MYLAN LABORATORIES INC. AND MYLAN PHARMACEUTICALS INC.: Stuart A. Williams, Brian S. Roman, and Jill M. Ondos.

March 26, 2007
Date

Signature of Counsel

E. Anthony Figg
Printed Name of Counsel

I. INTRODUCTION

Defendants-Appellants, Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan"), respectfully submit this brief in connection with their emergency motion to stay the injunction of the United States District Court for the Western District of Pennsylvania in response to the Court's March 23, 2007 Order.

This Court ordered that,

> (1) Pfizer and Mylan [] each are directed to respond, no later than 10 a.m. on Monday, March 26, 2007, concerning how the invalidity determination affects the pediatric exclusivity period and the ANDA approval. Inter alia, the parties should address when and how the FDA will likely respond to the court's decision in no. 2006-1261. Each response should not exceed 15 pages.

The Court also held Mylan's motion to stay pending appeal in abeyance, and temporarily stayed the district court's order until this Court has an opportunity to consider the parties' submissions. This submission is Mylan's response to paragraph (1) of the Court's order.

Mylan responds by emphasizing three points: *First*, this Court's decision that Pfizer's U.S. patent 4,879,303 (the "'303 patent") is invalid is dispositive of this appeal and confirms that Pfizer is not entitled to so-called "pediatric exclusivity" with respect to Mylan. *Second*, this Court's temporary stay through patent expiration provided Mylan with the relief it sought, and the expiration of Pfizer's patent now renders Mylan's stay motion moot. However, if Mylan's stay

motion is not dismissed as moot, Mylan requests that a stay be granted pending final resolution of this appeal. *Third*, Pfizer's entitlement to pediatric exclusivity *vel non* is not an issue before this Court.

II. THE INVALIDITY OF PFIZER'S PATENT IS DISPOSITIVE AND DEPRIVES PFIZER OF PEDIATRIC EXCLUSIVITY AS AGAINST MYLAN

A. This Court's Determination in *Apotex* is Dispositive of This Case

This Court's decision in *Pfizer v. Apotex*, Docket No. 2006-1261, holding that all of the claims of Pfizer's '303 patent that have been asserted against Mylan are invalid under 35 U.S.C. § 103 is dispositive of all issues of this appeal. (At trial, Pfizer alleged that Mylan infringed only claims 1-3.) That holding collaterally estops Pfizer from obtaining any relief in this case and compels reversal of the district court's judgment and vacatur of its injunctions against Mylan. *Blonder-Tongue Lab. v. Univ. of Ill. Found.*, 402 U.S. 313, 332-34 (1971); *Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc.*, 170 F.3d 1373, 1379-80 (Fed. Cir. 1999).

B. Pfizer is Not Entitled to Pediatric Exclusivity With Respect to Mylan

The invalidity of Pfizer's '303 patent also confirms that Pfizer is not entitled to so-called "pediatric exclusivity" with respect to Mylan – a determination that the FDA has already made. That result follows both because the applicable provision of the pediatric exclusivity statute can only extend a thirty-month stay of FDA

approval, which does not exist here, because Pfizer failed to sue Mylan within the required forty-five day period and because that provision expressly requires that the involved patent be valid and infringed. Neither of those conditions is met here.

"Pediatric exclusivity" arises from amendments to the Federal Food, Drug & Cosmetic Act ("FDCA") implemented in 1997. Congress amended the FDCA to encourage drug manufacturers to study the effects of their products on children. *See* 21 U.S.C. 355a. Under certain well-defined circumstances, this "pediatric exclusivity" provision rewards drug manufacturers who complete such studies at FDA's request with an additional six-month period of market exclusivity beyond regulatory or patent exclusivity already in place for the drug in question. 21 U.S.C. § 355a(b) and § 355a(c)(2)(A) and (B). Specifically, § 355a(c)(2)(A) of the pediatric exclusivity statute applies to ANDAs that contain patent certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(II) (a "Paragraph II certification") or (III) (a "Paragraph III certification").[1] *See Ranbaxy Laboratories Ltd. v. FDA*, 307 F. Supp. 2d 15 (D.D.C 2004), *summ. aff'd*, No. 04-5079, 2004 U.S. App. LEXIS 8311 (D.C. Cir. Apr. 26, 2004) (per curiam); *Mylan v. Thompson*, 389 F.3d 1272, 1278 (D.C. Cir. 2004). Subsection 355a(c)(2)(B) applies to ANDAs that contain certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV

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[1] Under Paragraph II, an applicant certifies that a listed patent has expired. Under Paragraph III an applicant seeks approval upon patent expiration and certifies the date of patent expiration.

certification").[2]

At all times during the pendency of Mylan's ANDA, including when Pfizer's '303 patent expired at midnight on March 25, 2007, Mylan's abbreviated new drug application ("ANDA") contained a Paragraph IV certification. Accordingly, the provision of the pediatric exclusivity statute that is applicable to this case is 21 U.S.C. § 355a(c)(2)(B).[3] That subsection provides in relevant part:

> [I]f the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section [355](b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) [i.e., a Paragraph IV certification], and *in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed*, the period during which an application may not be approved under section [355](c)(3) or section [355](j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

21 U.S.C. § 355a(c)(2)(B) (emphasis added).

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[2] In an ANDA with a Paragraph IV certification, the applicant seeks FDA approval prior to expiration of the listed patent and certifies that it believes "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."

[3] The situation in this case is distinguishable from that which exists when the ANDA applicant has tentative approval at the time of patent expiration. In *Mylan v. Thompson*, 389 F.3d at 1282-83, the D.C. Circuit held that when an ANDA applicant holds a tentative approval at the time of patent expiration, the Paragraph IV certification is no longer accurate and it converts to a Paragraph II certification as a matter of law. That court further held that 21 U.S.C. § 355a(c)(2)(A) applies pediatric exclusivity to ANDAs containing Paragraph II certifications by extending the period by which the ANDA cannot be approved by six months beyond patent expiration.

Section 355a(c)(2)(B) would only extend "the period during which the application may not be approved under . . . section [355](j)(5)(B)" by a period of six months after the date the patent expires. Section 355(j)(5)(B) relates to the approval of ANDAs by FDA and subsection (iii) is the part of that section that deals with the approval of ANDAs containing Paragraph IV certifications. It provides, in pertinent part:

> The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:
>
> . . .
>
> (iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. *If such an action is brought before the expiration of such days, the approval shall be made effective on the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i)* or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action . . ..

21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added).

Thus, the period during which an application containing a Paragraph IV certification (like Mylan's) may not be approved is the thirty-month stay period that arises only when the patent holder brings an action for infringement within forty-five days of notice of a Paragraph IV certification. Pfizer failed to bring suit within the forty-five-day period, therefore, there was no thirty-month stay, and the

FDA granted final approval of Mylan's ANDA in October 2005 when substantive review had been concluded.

Moreover, the portion of the statute italicized in the above quotation expressly requires that the court determine that the asserted patent is valid and infringed. Thus, an extension under that subsection is not available to Pfizer in any event, in view of this Court's determination that the '303 patent is invalid. *See Ranbaxy*, 307 F. Supp. 2d at 20, n.3 (summarizing FDA's position that because the court hearing the infringement case had not entered a finding of validity or infringement, § 355a(c)(2)(B) did not apply).

For at least the foregoing reasons, Pfizer is not entitled to extension of the period during which the FDA is prohibited from approving Mylan's ANDA under the pediatric exclusivity statute.

C. The FDA Has Recognized that Mylan's Final Approval Was Not Blocked by Pfizer's Pediatric Exclusivity

With regard to the Court's inquiry about what the FDA is likely to do as a result of the invalidity holding, the parties need not speculate. Before this Court issued its order on March 23, 2007, the FDA had informed counsel for Mylan that, in the absence of a stay of the district court's injunction under 35 U.S.C. § 271(e)(4)(A) prior to expiration of the '303 patent, it would convert Mylan's final approval to a tentative approval. Bloodworth Decl. ¶4. That conversion

would have prevented Mylan from commercially launching its generic amlodipine besylate product. However, upon learning of this Court's stay of the district court's injunction, the FDA assured Mylan that it would not convert its final approval to tentative approval.[4] Thus, this Court's holding that the '303 patent is invalid and its temporary stay of the district court's injunction order resulted in the FDA's determination that Mylan's final approval should remain in effect through patent expiration. The Agency necessarily determined that pediatric exclusivity does not apply to Mylan, otherwise it would have revoked Mylan's final approval or converted it to a tentative approval.

III. MYLAN'S MOTION TO STAY IS MOOT

The injunctive relief contained in the district court's order ended with patent expiration on March 25, 2007. Specifically, the District Court:

> **ORDERED, ADJUDGED AND DECREED** that, pursuant to the provisions of 35 U.S.C. §271(e)(4)(A), the effective date of any approval of Mylan's Abbreviated New Drug Application No. 76-418, seeking FDA approval of amlodipine besylate tablets, 2.5, 5 and 10 mg dosage strengths, shall be a date which is not earlier than the date of expiration of the '303 patent (March 25, 2007); and it is further,
>
> **ORDERED, ADJUDGED AND DECREED** that, pursuant to the

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[4] Early on Friday, March 23, 2007, Mylan filed an action against the FDA in the United States District Court for the District of Columbia and an application for a temporary restraining order to enjoin the FDA from converting Mylan's final approval to tentative pending this Court's ruling on Mylan's motion to stay. When the FDA learned that this Court had temporarily stayed the Pennsylvania district court's order, its counsel assured Mylan and the D.C. District Court that the FDA would not alter Mylan's final approval. *See* Bhatt Decl. ¶2.

> provisions of 35 U.S.C. §271(e)(4)(B), Mylan, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with Mylan are enjoined until the date of expiration of the '303 patent (March 25, 2007), from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any product comprising the chemical compound amlodipine besylate covered by, or the sale or use of which is covered by claims 1-3 of the '303 patent.

Bhatt Decl. Exh. 1, March 16, 2007 Order of Court. Because the District Court's injunction was properly limited to activities occurring before patent expiration and the '303 patent has now expired, Mylan's motion to stay the injunction is now moot. This Court stayed the district court's order up to and beyond the expiration of the '303 patent; therefore, it provided the relief that Mylan sought. The district court's order therefore no longer has any force or effect, and Mylan's motion for emergency stay became moot when the '303 patent and the district court's order expired. Accordingly, Mylan requests that its motion now be dismissed as moot. Alternatively, in the event that the motion is not dismissed, Mylan requests that it be granted and the district court's order be stayed pending appeal, because Pfizer is not entitled to injunctive relief based on an invalid patent.

IV. THE PEDIATRIC EXCLUSIVITY ISSUE IS NOT THE SUBJECT OF MYLAN'S APPEAL

Mylan respectfully submits that the questions regarding ANDA approval and whether or not Pfizer is entitled to pediatric exclusivity are not before this Court. Those issues were not before the District Court. Pediatric exclusivity and ANDA

approval are both determinations that are made in the first instance by the FDA and are subject to judicial review under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq.* As such, this Court does not have subject matter jurisdiction over this issue in connection with Mylan's appeal from the district court's judgment.

The district court made no findings regarding pediatric exclusivity[5] nor did it enter any conclusion of law that Pfizer was entitled to pediatric exclusivity applicable to Mylan. The district court's original order enjoined Mylan from "making, using, selling, offering to sell, or importing into the United States the Mylan Amlodipine Tablets described in ANDA No. 76-418 until after the expiration of Pfizer's '303 patent term, *as extended by the pediatric exclusivity period.*" Bhatt Decl. Exh. 2, February 27, 2007 Order of Court (emphasis added). Mylan moved the district court to amend its judgment, pointing out that the court had no basis for issuing post-patent expiration relief. In response, the district court amended its judgment and order, deleting the reference to the pediatric exclusivity period. In its accompanying order, the district court acknowledged that "the issue of pediatric exclusivity *per se* was not before the Court in this infringement

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[5] Finding of Fact No. 11 in the district court's Findings of Fact and Conclusions of Law merely states that "the six-month period of pediatric exclusivity of the '303 patent, *to the extent applicable*, expires on September 25, 2007." (emphasis added.) That Court made no determination of the extent, if any, to which pediatric exclusivity was applicable to Mylan.

action." Bhatt Decl. Exh. 1, March 16, 2007 Order of Court.

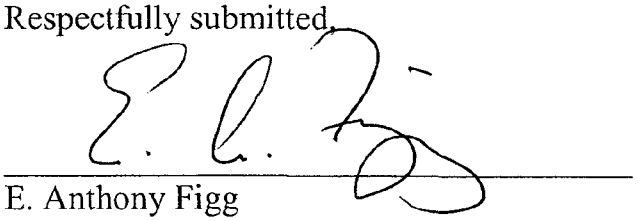
Because that issue was not before the district court, it is not part of this appeal and is not before this Court.

V. CONCLUSION

For the foregoing reasons, Mylan respectfully requests that the Court enter no ruling on the issue of Pfizer's entitlement *vel non* to pediatric exclusivity.

Date: March 26, 2007

Respectfully submitted,



E. Anthony Figg
Steven Lieberman
Minaksi Bhatt
ROTHWELL, FIGG, ERNST & MANBECK
1425 K Street, N.W.; Suite 800
Washington, DC 20005
(202) 783-6040

Shannon M. Bloodworth
HELLER EHRMAN LLP
1717 Rhode Island Avenue, NW
Washington DC 20036
(202) 912-2000

David J. Harth
HELLER EHRMAN LLP
1 East Main Street
Madison Wisconsin 53703
(608) 663-7470

Attorneys for Defendants-Appellants
Mylan Laboratories Inc. and
Mylan Pharmaceuticals Inc.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing **1) RESPONSE OF DEFENDANTS-APPELLANTS, MYLAN ABORATORIES INC. AND MYLAN PHARMACEUTICALS INC., TO THE COURT'S ORDER OF MARCH 23, 2007 REQUESTING FURTHER BRIEFING, 2) DECLARTION OF MINAKSI BHATT IN SUPPORT OF MYLAN'S RESPONSE TO THE COURT'S ORDER OF MARCH 23, 2007 REQUESTING FURTHER BRIEFING, AND 3) DECLARATION OF SHANNON M. BLOODWORTH IN SUPPORT OF MYLAN'S RESPONSE TO THE COURT'S ORDER OF MARCH 23, 2007 REQUESTING FURTHER BRIEFING** were served electronically and by Federal Express, overnight delivery, this 26Thday of March, 2007 on the following counsel for Plaintiffs:

Richard Greco, Esq.
Donald B. Cameron
Milton Sherman
David O. Bickart
Daniel Boglioli
Kaye Scholer LLP
425 Park Avenue
New York, New York 10022

Patrick Collares