IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

PFIZER INC.,	:	
Plaintiff and Counterclaim-Defendant,	:	
v.	:	**Civ. Action No. 02-CV-1628**
MYLAN LABORATORIES, INC. and MYLAN PHARMACEUTICALS, INC.,	:	**Hon. Terrence F. McVerry**
Defendants and Counterclaim-Plaintiffs.	:	

PFIZER'S RESPONSE TO MYLAN'S MOTION TO DISMISS THE CLAIM OF INFRINGEMENT OF THE '909 PATENT FOR LACK OF SUBJECT MATTER JURISDICTION

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issue presented by this motion will not arise again.

Respectfully submitted,

By: /s/ C. James Zeszutek

Dated: September 29, 2006

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PRELIMINARY STATEMENT

Pfizer submits this brief in opposition to Mylan's motion to dismiss as moot Pfizer's claim to enforce U.S. Patent No. 4,572,909 (the "'909 patent"). Under the Federal Circuit decision in *Alza Corp. v. Mylan Laboratories, Inc.*, 391 F.3d 1365 (Fed. Cir. 2004), a decision that is directly on point but neither cited nor addressed in Mylan's brief,[1] the court retains jurisdiction after patent expiration to resolve the contested patent issues on which Pfizer's right to pediatric exclusivity depends. A trial of this action is necessary and appropriate to vindicate Pfizer's statutory right to pediatric exclusivity which it rightfully earned by performing pediatric clinical studies of Norvasc® requested by the FDA.

Mylan's arguments on this motion directly contradict the express holding of the Federal Circuit and the D.C. Circuit, both of which have rejected Mylan's efforts in the past to undercut the right to pediatric exclusivity with the same arguments it raises here. Just as a trial before expiration of the '909 patent would have insured that the full six-month pediatric period would have begun at the expiration of the patent on July 31, 2006, a decision before the pediatric period expires will ensure preservation of the remainder of the pediatric exclusivity right.

The '909 patent is one of two patents that protect the Pfizer drug Norvasc®, the other being U.S. Patent No. 4,879,303 (the "'303 patent") which expires in March 2007. After two separate trials, two different Federal district judges sitting in different districts held that the '303 patent is valid and infringed. While the '303 patent case will be a re-run of the *Apotex* trial, the '909 patent has not been tried. Should this Court disagree with the prior judgments entered on the '303 patent, the '909 patent rights, and its associated pediatric exclusivity right, will

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[1] Mylan was a party to that case and was represented by the same counsel as this case.

remain important property rights that cannot be cast aside without Mylan demonstrating by clear and convincing evidence that the patent is invalid or unenforceable.[2]

Mylan's motion to dismiss the '909 patent claims should be denied because:

(1) The Federal Circuit in *Alza Corp. v. Mylan Laboratories, Inc.*, 391 F.3d 1365 (Fed. Cir. 2004), held that expiration of a patent does not deprive a court of jurisdiction to decide the issues of patent validity and infringement when, as in this case, the right of pediatric exclusivity depends on that decision. This Court therefore retains jurisdiction to decide a disputed issue of patent validity and enter judgment under 35 U.S.C. § 271(e)(4), as the decision of the validity of the '909 patent determines Pfizer's right to the period of pediatric exclusivity.

(2) Pfizer is entitled to the period of pediatric exclusivity, which does not expire until January 31, 2007, under 21 U.S.C. § 355a. As the D.C. Circuit ruled in upholding the FDA interpretation of the pediatric exclusivity statute, a court judgment upholding patent validity and infringement, entered after the FDA has given final approval to an ANDA, modifies the approval status by operation of 35 U.S.C. § 271(e)(4)(A), and converts the final approval to a tentative approval. The pediatric exclusivity statute, 21 U.S.C. § 355a, requires the enforcement of the period of pediatric exclusivity in such a situation so long as the judgment is entered before the six-month pediatric period expires.

(3) The pediatric exclusivity right will have two months to run on the '909 patent at the time of the trial, and that protection has a value to Pfizer exceeding $300 million if the later expiring '303 patent were held invalid by this Court.

A Procedural Approach That Could Avoid The Need For A Trial On The '909 Patent

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[2] Infringement of the '909 patent has been admitted.

In recognition of the fact that the '909 patent trial would not be necessary as a practical matter if the '303 patent is once again found valid, infringed, and enforceable, the order of the trial could be structured so that the '909 patent is tried only if the pediatric exclusivity period for that patent becomes material. The order of the trial can be structured so that '303 patent can be tried first. If the Court is able to rule at the conclusion of the trial[3] (as Judge Rosenbaum did in the Apotex trial), the '909 trial could proceed only if the '303 patent is found invalid, unenforceable or not infringed, or if the Court concludes that it cannot decide the '303 case at that point.

If such an approach was taken, this motion itself could be decided only if it is necessary to proceed with the '909 patent trial following the '303 patent trial. This procedure would preserve Pfizer's right to the pediatric exclusivity period for the '909 patent, but would also avoid the need for a '909 patent trial if the right to predict exclusivity is redundant by reason of the protection afforded by the '303 patent.

Of course, the '909 trial could also be avoided if Mylan would acknowledge that it will not launch its ANDA product before January 31, 2007, but Mylan has not agreed to make such a commitment. Accordingly, the pediatric exclusivity period may become critically important.

This motion emphasizes the need for a decision on the '303 patent before the March 25, 2007 expiration date, or this same issue will arise again in the context of that patent.

STATEMENT OF FACTS

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[3] Written findings and Conclusions can follow at a later date.

Pfizer's cardiovascular drug Norvasc® is protected by two patents, the '909 and '303 patents. The '909 patent protects the biologically active molecule amlodipine and pharmaceutically acceptable salts thereof. The '303 patent protects a particular superior salt form of amlodipine, amlodipine besylate.

Under 21 U.S.C. § 355(b) and FDA regulations thereunder, Pfizer listed the '909 and '303 patents in the FDA publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly called the "Orange Book") as patents which cover Norvasc®, and the patent expiration dates and pediatric exclusivity dates are set out there. Mylan asserted in its ANDA that the '303 and the '909 patents were invalid (a paragraph IV certification), 21 U.S.C. § 355(j)(2)(vii)(IV). Pfizer sued Mylan for infringement of both patents pursuant to 35 U.S.C. § 271(e)(2)(A).

Pfizer's Right To A Period of Pediatric Exclusivity

In accordance with 21 U.S.C. § 355a, Pfizer, as the owner of the New Drug Application ("NDA") for Norvasc®, was requested by the FDA to, and did, perform clinical trials in pediatric populations, and the studies were accepted as satisfactory by the FDA. Accordingly, the FDA awarded Pfizer a six-month period of pediatric exclusivity pursuant to 21 U.S.C. § 355a, and that exclusivity period is listed in the Orange Book with both the '909 and '303 patents covering Norvasc®. Pfizer received its award of pediatric exclusivity for Norvasc® in November 2001, well before Mylan filed the Abbreviated New Drug Application ("ANDA") that precipitated this litigation. The pediatric exclusivity period for the '909 patent expires on January 31, 2007, six months after the '909 patent expired on July 31, 2006.[4]

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[4] Pursuant to the Patent Term Restoration Act, 35 U.S.C. § 156, the term of the '909 patent was extended by the U.S. Patent and Trademark Office to July 31, 2006, to restore the (continued...)

The pediatric exclusivity period provides a six-month period of exclusivity, in addition to other periods of exclusivity that the NDA holder is entitled to by reason of a patent and the Hatch-Waxman statute. The purpose of the additional exclusivity period is to provide an economic incentive to pharmaceutical companies to conduct expensive and risky clinical trials in pediatric populations. The FDA described the purpose and explained the importance of the statute in its brief to the United States District Court for the District of Columbia in *Mylan v. Thompson* (Mylan Ex. 2, pp. 11-12):

> "Congress amended the FDCA [Food, Drug and Cosmetic Act] in 1997 to provide an economic incentive for drug manufacturers to invest the resources necessary to conduct and submit pediatric studies of drugs. At that time, 'less than 20 percent of the prescription medications on the United States market [were] approved for use in the pediatric population and labeled for pediatric use,' often forcing physicians to prescribe drugs that were developed for and tested on adults for use in children. S. Rep. No.105-43, at 51 (1997). . . .
>
> "Despite the need, drug manufacturers have had little incentive to conduct such studies for several reasons. Drugs approved for use in children do not ordinarily generate significant revenue. Further, '[p]ediatric studies pose ethical and moral issues' not present in adult studies, raise 'substantial product liability and medical malpractice issues,' have difficulty attracting subjects, and present special problems of 'drug administration and patient compliance. . . . Congress determined that drug manufacturers needed a greater economic incentive to conduct pediatric studies. It therefore enacted 21 U.S.C. § 355a, granting pediatric exclusivity – an additional six months of marketing exclusivity beyond the term of applicable patents and other marketing exclusivities – to drug manufacturers that conduct such pediatric studies at FDA's request. S. Rep. No. 105-43, at 52."

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[4] (...continued)
time lost from the patent term during the more than five years that the drug was undergoing clinical trials, and FDA review and approval.

The six-month pediatric exclusivity period has succeeded in advancing a vital public interest – making clinical trial data for children on important drugs available to practicing physicians. In 2001, the FDA advised Congress that the "pediatric exclusivity provision has done more to generate clinical studies and useful prescribing information for the pediatric population than any other regulatory or legislative process to date." *See* S. Rep. No. 107-79 on Best Pharmaceuticals for Children Act at 5.

The six-month exclusivity period is also a valuable economic right to the NDA holder. Its value provides compensation for investing in the drug and conducting the pediatric studies that otherwise probably would not be carried out. Norvasc® is the world's leading cardiovascular drug, and its sales in the United States are over $2 billion per year. The loss of six months' exclusivity in the United States has a value to Pfizer of approximately $1 billion.[5] The two months of pediatric exclusivity that will remain at the time of trial of this action are worth over $300 million to Pfizer should the '909 patent become the sole obstacle to copying Norvasc®.

The History of This Action

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[5] A loss of exclusivity results in the great bulk of patients rapidly switching to the generic products. It has been reported that: "Once drug patents and other forms of market exclusivity expire, generic companies are free to develop and market generic forms of previously patented drugs. Pioneer drugs can lose up to 70% of their market share over-night with the entry of generic drugs." *See e.g.*, www.dnapatent.com/Patentexpiration.php.

Mylan's effort in its brief to blame Pfizer for the absence of a decision on the '909 patent is baseless. The record plainly shows that Pfizer repeatedly sought to obtain a trial of this case in sufficient time for entry of a judgment before the '909 patent expired.

Pfizer commenced this action on September 20, 2002. All fact and expert discovery has been completed and the parties completed pretrial order submissions on November 12, 2004. Summary judgment motions were filed by both Pfizer and Mylan and fully briefed by October 28, 2004 and denied on November 2, 2005.

By joint letter dated January 27, 2005, both Pfizer and Mylan requested a conference to set a trial date in June 2005. By joint motion dated February 28, 2005, both parties requested a conference with the Court to discuss a trial date. Pfizer again requested a conference by letter dated July 1, 2005. After Mylan received final approval from the FDA for its ANDA, Pfizer separately moved on October 5, 2005 for a conference with the Court to set a trial date.

The Court held a pretrial conference on December 9, 2005. At the conference, Pfizer requested a trial on the '909 patent in time for a decision to be rendered before July 31, 2006. Pfizer proposed a trial between two other trials relating to the '303 patent: (1) the *Pfizer v. Apotex* trial, which was scheduled for trial in Chicago in January 2006; and (2) the *Pfizer v. Synthon* trial, which was scheduled for trial in North Carolina in April 2006. Mylan, switching its position from earlier in the year, vigorously opposed setting any trial date.

Another pretrial conference was held on May 12, 2006. Again, Pfizer sought a trial date and Mylan opposed it. When a trial date was set for October 31, 2006, Mylan moved for an adjournment because of a trial scheduled for its counsel in another federal district court.

<u>The Continued Importance of The '909 Pediatric Exclusivity Period</u>

The pediatric period is potentially of great importance to Pfizer. While the pediatric period will expire on January 31, 2007, the United States sales of Norvasc® averaging over $150 million per month still leaves a very substantial amount at issue.

The Norvasc® drug is protected by both the '303 and the '909 patents and a separate six-months' pediatric period applies to each of the patents. Pfizer has tried the '303 patent twice, in January and April, 2006. Based on the trials, two different federal district courts have entered judgments for Pfizer, ruling that the patent is valid and was infringed.[6] In the *Apotex* trial where a claim of inequitable conduct virtually the same as that raised by Mylan here was tried, the Court flatly rejected the argument ruling from the bench that there had been neither material misrepresentations nor intent to deceive by Pfizer during patent prosecution. The '303 patent will be tried for a third time in this Court, and a decision on infringement and validity of that patent is required before March 25, 2007 in order to avoid a repetition of this motion respecting the '303 patent. If this Court does not agree with the results reached in the two prior trials respecting the '303 patent, the '909 patent pediatric period could become Pfizer's only remaining patent protection for Norvasc®.

If the '909 patent pediatric exclusivity period were truly irrelevant, Mylan could avoid a trial on the '909 patent simply by acknowledging that it does not intend to market its generic product before January 31, 2007, when the period of pediatric exclusivity expires. It will not do so, indicating that Mylan holds open the option, if the opportunity presents itself, to exploit the potential windfall arising from the failure to obtain a decision on the '909 patent case.

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[6] A Canadian appellate court also has held that the Canadian patent which is the counterpart of the '303 patent in that country is valid and was infringed, reversing a lower court finding to the contrary. We acknowledge that the Canadian decision has no precedential effect on the outcome of this case, but in prior arguments Mylan's counsel cited as relevant the now reversed finding of invalidity by the trial court in Canada.

ARGUMENT

I. THE FEDERAL CIRCUIT HAS HELD THAT SUBJECT MATTER JURISDICTION EXISTS OVER A SECTION 271(e)(2)(A) INFRINGEMENT SUIT AFTER THE PATENT HAS EXPIRED IF PEDIATRIC EXCLUSIVITY REMAINS AT ISSUE

The issue presented by Mylan's motion – whether the Court retains jurisdiction over a patent infringement case when the patent has expired but the period of pediatric exclusivity remains at issue – has been squarely resolved by the Federal Circuit against Mylan.

In *Alza v. Mylan Laboratories, Inc.*, 391 F.3d 1365 (Fed. Cir 2004), the district court in a § 271(e)(2)(A) ANDA case held that the patent in suit was valid and infringed, and an appeal was taken. The appeal remained pending after the patent expired. The Federal Circuit held that it had jurisdiction to hear the appeal notwithstanding the patent's expiration because the right to a period of pediatric exclusivity depended on a decision of whether the expired patent was valid and infringed. 391 F.3d at 1368.

In *Alza*, Mylan filed an ANDA with a paragraph IV certification challenging the patent protecting the pain-relieving drug fentanyl. The patent owner, Alza, did not sue Mylan until the forty-*sixth* day after it received the notice letter, and therefore no thirty-month stay of final FDA approval of Mylan's ANDA was available in that case. Prior to the decision in the patent infringement litigation, the FDA granted final approval to Mylan's ANDA. The district court thereafter entered judgment in March 2004, holding the patent valid and infringed, and the patent expired on July 23, 2004. In response to the judgment, the FDA withdrew its final approval of Mylan's ANDA, and ruled that the court's judgment that the patent was valid and infringed converted the final approval into a tentative approval. The FDA thereafter applied

pediatric exclusivity, and held that Mylan ANDA's could not be approved before the pediatric exclusivity period expired.

Mylan appealed the judgment of infringement and validity, and two days before the expiration of the patent moved for an expedited appellate argument. (Exhibit A to this brief).[7] The Federal Circuit denied the motion for expedited consideration, heard the appeal after the patent had expired, and affirmed the judgment on December 10, 2004, over four months after the patent expired, but before the pediatric exclusivity period expired.

The Federal Circuit found that it had jurisdiction to hear the appeal on the expired patent. In fact, the Federal Circuit treated the pediatric period as the equivalent of an extension of the patent, stating:

> "It [the patent] was due to expire in July of 2004; however, following the Food and Drug Administration's approval of the pediatric use of Duragesic®, the patent will now expire on January 23, 2005."
> 391 F.3d at 1368.

The Federal Circuit concluded that the case would be moot after the expiration of the pediatric period, not upon the expiration of the patent six months earlier. *Id.* 1368 n.3.

While Mylan and Alza agreed that the case was not moot by reason of the expiration of the patent, the Federal Circuit itself must also have agreed that it had jurisdiction. Mootness would have defeated subject matter jurisdiction, a defeat the parties cannot waive. *U.S. v. Newport News Shipbuilding & Dry Dock Co.*, 933 F.2d 996, 998n.1 (Fed. Cir. 1991).

Accordingly, the holding of *Alza v. Mylan* is that when a decision on the validity of the expired patent will impact the right to pediatric exclusivity, jurisdiction and a justiciable dispute remain after patent expiration. That is exactly the situation here.

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[7] Obviously, Mylan did not believe that the expiration of the patent would deprive the court of jurisdiction.

That the '909 patent has expired in this case no more moots this case than the fact that the patent in *Alza v. Mylan* had expired before the Federal Circuit decision. Both cases involve actual controversies because this Court's decision, changing the approval status of the ANDA (from final to tentative approval), controls attachment of Pfizer's right to pediatric exclusivity.

In an analogous context, the Federal Circuit has held that it retained jurisdiction to decide the validity of an expired patent when another right, in that case the right to attorneys' fees for willful infringement, was dependent in part on the issue of the patent's validity. In *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 1346 (Fed. Cir. (Ill.) 2004), also an ANDA action, the district court found that the patent was valid and infringed, and further found willful infringement for which it awarded attorneys' fees. The generic manufacturer appealed and the patent expired before the appeal was decided. While a dissenting judge argued that the question of validity was moot since there was no past damage award and the patent had expired, the majority of the Federal Circuit panel disagreed. The court held that it was necessary to decide validity of the expired patent, because the question of willful infringement in part depended on whether the patent was valid.

Here, the issues of patent infringement and validity are still justiciable because Pfizer's right of pediatric exclusivity turns on them.

II. A DECISION UPHOLDING THE VALIDITY OF THE '909 PATENT WILL RESULT IN THE APPLICATION OF THE PEDIATRIC EXCLUSIVITY PERIOD

In an action under 35 U.S.C. § 271(e)(4)(A) if infringement of a valid patent is found, "the court shall order the effective date of any approval of the drug . . . involved in the

infringement to be a date which is not earlier than the date of expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A). In *Mylan v. Thompson* – the case Mylan unsuccessfully brought against the FDA to challenge the FDA's decision to apply the pediatric exclusivity period with respect to fentanyl – the FDA has acknowledged in its brief (Exhibit 2 to Mylan's motion) that a judgment issued under section 271(e)(4)(A) does not only reset the date of final approval to a date not earlier than the expiration of the patent, but it also converts any final approval that the FDA previously had given to an ANDA into a tentative approval, which is not made final again until the FDA affirmatively determines that final approval is appropriate. The Court of Appeals for the D.C. Circuit upheld the FDA's interpretation of the statute in *Mylan Laboratories, Inc. v. Thompson*, 389 F.3d 1272 (D.C. Cir. 2004).

Based on the decision in *Mylan Labs.*, entry of a judgment here that the '909 patent is valid and infringed would necessarily convert the FDA's final approval of Mylan's ANDA to a tentative approval under the terms of 35 U.S.C. § 271(e)(4)(A), and the tentative approval could not be made final by the FDA until after the period of pediatric exclusivity has expired on January 31, 2007. 21 U.S.C. §355a(c)(2)(B).

Mylan argues that an injunction cannot be issued on the '909 patent, because it has expired. But an injunction is not necessary in this case. All that is needed is a judicial determination that the patent challenged is valid. The mandatory relief that the court must then award pursuant to section 271(e)(4)(A) automatically converts the FDA's final approval of Mylan's ANDA to a tentative approval, as the D.C. Circuit held in *Mylan Laboratories, Inc. v. Thompson, supra*.

Moreover, Mylan seeks a declaratory judgment that the '909 patent is invalid, and that claim remains pending. Because Pfizer's entitlement to pediatric exclusivity depends on

whether the patent is held valid, substantial rights depend on the resolution of the claim and it cannot be moot. "Mootness of an action relates to the basic dispute between the parties, not merely the relief requested. Thus, although subsequent acts may moot a request for particular relief or a count, the constitutional requirement of a case or controversy may be supplied by the availability of other relief."' *Jazz Photo Corp. v. United States*, 439 F.3d 1344, 1349 (Fed. Cir. 2006)(quoting *Intrepid v. Pollock*, 907 F.2d 1125, 1131 (Fed. Cir. 1990).

When an ANDA applicant does not challenge the patents protecting the NDA drug (a paragraph III certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) of the Hatch-Waxman Act) or where the patent has expired (a paragraph II certification under 21 U.S.C. § 355(j)(2)(A)(vii)(II) before final approval, the six-month period of pediatric exclusivity automatically applies. Where the patent has been challenged (a paragraph IV certification under 21 U.S.C. § 335(j)(2)(A)(vii)(IV)), the statute, 21 U.S.C. 355a(c)(2)(B) provides:

> "if 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 505 [21 U.S.C. § 355(b)(A)(2)(A) or (j)(2)(A)(vii)(IV)], 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 505(c)(3) or 505(j)(4)(B) [21 U.S.C. § 355(c)(3) or (j)(4)(B)] shall be extended by a period of six months after the date the patent expires (including any patent extensions)(emphasis added)."

One condition recited in the statute for pediatric exclusivity to apply in a paragraph IV (contested patent) ANDA is that the outcome of the litigation be in favor of the patentee. No time limit is placed on when the judgment of patent validity must occur in relationship to the patent's expiration date. Rather, the FDA must honor the pediatric exclusivity period in any case where the judgment in the patent action determines that the patent is valid and infringed. The pediatric exclusivity statute, 21 U.S.C. § 355a, using the mandatory term "shall,"

requires that the approval for an ANDA application may not be final until six months after the patent expiration.

Recognizing that the statute does not expressly address the situation where the patent expires before a decision in the patent infringement case is reached, both the FDA and the courts have concluded that the pediatric exclusivity period still can apply. In *Ranbaxy Laboratories Ltd. v. U.S. Food & Drug Admin.*, 307 F.Supp.2d 15 (D.D.C. 2004), *aff'd*, 96 Fed. Appx 1, 2004 WL 886333 (D.C. Cir. 2004), the FDA explained that pediatric exclusivity was not lost when a patent expires in a paragraph IV ANDA case without the court having rendered its decision on patent validity:

> "Assuming its duty to fill gaps left in the statute by Congress, the FDA concluded that the absence of a provision addressing unresolved patent litigations in the Paragraph IV certification context did not mean that Congress intended to exclude such circumstances from the pediatric exclusivity provision."

Both the district court and the D.C. Circuit agreed with the FDA and applied the period of pediatric exclusivity. *Id.*

Congress also took care to protect the innovator's right to pediatric exclusivity even when the award of pediatric exclusivity by the FDA is not made until after the patent expires. Under 21 U.S.C. § 355a(e), the FDA must delay a generic approval for 90 days after the patent has expired to permit the FDA to evaluate pediatric studies submitted before the patent expires. If pediatric exclusivity is found appropriate, the six-month pediatric exclusivity period is deemed to have been running during the period of delay.

A judgment of validity and infringement by this Court, even if it is entered after the patent has expired, establishes that Pfizer was fully entitled to six-months' exclusivity in addition to its valid patent term. There is no reason Pfizer should be deprived of that right for

the balance of the period remaining, if Mylan's challenge to patent validity is resolved against it during the pediatric exclusivity period rather than before the start of that period. Indeed, in view of the policy of the pediatric exclusivity, and the bargain it strikes with NDA holders to induce them to make the expenditures and take the risks of pediatric studies, it would make no sense if the consideration for undertaking such studies – the six-month period of pediatric exclusivity – could be lost even when the patent is held valid and infringed.

If Mylan had not challenged the '909 patent, its approval could not have become final until the pediatric extension period ends on January 31, 2007. Mylan's argument that it is entitled to market its Norvasc® copy before that date, based on a patent challenge that a court rejects as baseless, has no support in the language or policy of the pediatric exclusivity extension statute.

III. MYLAN'S ARGUMENT THAT PFIZER TOOK AN INCONSISTENT POSITION IN THE *RANBAXY* CASE OR IN THE RELATED NORVASC® CASES IS BASELESS

Contrary to Mylan's argument, Pfizer consistently has maintained its entitlement to pediatric exclusivity based on a judgment of patent validity entered after the '909 patent expires.

Pfizer, in the face of strong opposition from Mylan to setting a trial date, urged this Court to try the case before July 31, 2006, if possible, because that would have precluded the need to address this motion, and Pfizer's right to the pediatric period would have been beyond dispute. In addition, Pfizer wanted a trial before the expiration date of the '909 patent so that the pediatric period of the '909 patent would take effect immediately on expiration of the patent, leaving no argument that a gap occurred in the protection for Norvasc® in the event that the '303 patent were not available, or in case Mylan attempted to launch its ANDA product

notwithstanding the pendency of Pfizer's patent infringement case. Pfizer did not take the position that it would irretrievably lose the right to the pediatric exclusivity if the judgment of patent validity came after patent expiration, but during the pediatric period itself.

Referring to *Ranbaxy Laboratories Ltd. v. U.S. Food & Drug Admin.*, 307 F.Supp.2d 15 (D.D.C. 2004), *aff'd*, 96 Fed. Appx.1, 2004 WL 886333 (D.C. Cir. 2004), Mylan asserts that in "a factually similar case" Pfizer agreed to dismiss a patent infringement action as moot when the patent expired notwithstanding the pediatric exclusivity period. Mylan asserts that this is an admission that the Court no longer has jurisdiction to render a judgment that would make the pediatric period apply. Mylan has both the facts and the law of that case completely wrong.

In that case, Ranbaxy had filed a paragraph IV certification ANDA, but the court's trial schedule did not permit a trial before patent expiration. Because the 30-month stay was in effect, and would not expire before the patent expiration, the parties stipulated to dismiss the case as moot on the date that the patent expired. At the time of the stipulation, the FDA had not granted pediatric exclusivity to Pfizer. After the stipulation was entered, the FDA awarded Pfizer pediatric exclusivity.

Ranbaxy did *not* have final approval before the patent in that case expired, and it could not obtain final approval by the expiration date because the 30-month stay was still in effect and remained in effect throughout the entire patent term. As the FDA, the district court and the D.C. Circuit all agreed, *Ranbaxy Laboratories Ltd. v. U.S. Food & Drug Admin.*, 307 F.Supp.2d 15 (D.D.C. 2004), *aff'd*, 96 Fed. Appx.1, 2004 WL 886333 (D.C. Cir. 2004), the pediatric exclusivity period automatically applied to Ranbaxy in those circumstances. When the patent expired, Ranbaxy's application was still pending and subject to the requirement to amend

the patent information as it changed. The expiration of the patent required the ANDA application to be amended from one challenging the patent (paragraph IV) to one where the patent has expired (paragraph II). In the case of a paragraph II ANDA, pediatric exclusivity automatically attaches to the patent immediately on patent expiration. *See* 21 U.S.C. § 355a(c)(2)(A); *Mylan Laboratories, Inc. v. Thompson, supra.*

Accordingly, the stipulation in *Ranbaxy* was not an admission of anything concerning jurisdiction to adjudicate patent validity after expiration when the pediatric exclusivity period depends on patent validity. First, there was no pediatric exclusivity to protect when the stipulation to dismiss was entered. Second, no trial was needed in the *Ranbaxy* case to trigger pediatric exclusivity. Pediatric exclusivity attached as soon as the patent expired, because Ranbaxy did not have (and could not obtain) a final approval before the patent expired. It was therefore required to amend its ANDA certification to a paragraph II (the patent has expired), to which pediatric exclusivity applies without any decision upholding the patent. 21 U.S.C. §355a(c)(2)(A).

Here, because Mylan already has a *final* approval of its ANDA, the issues of infringement and validity of the '909 patent remain as live controversies. The expiration of the '909 patent did not require Mylan to amend its ANDA certification to paragraph II (the patent has expired), because the final approval had issued. Accordingly, unlike in *Ranbaxy* where, based on the necessary amendment to a paragraph II certification, pediatric exclusivity attached under section 355a(c)(2)(A) without a trial and judgment, a court decision the '909 patent invalidity is necessary here. That decision would convert the FDA final approval into a tentative one, and Pfizer's pediatric exclusivity necessarily would follow from the Court's order under section 271(e)(4)(A) that no final approval of Mylan's ANDA shall be granted to Mylan's

ANDA until a date which is after patent expiration. *Mylan v. Thompson,* 389 F. 3d 1272 (D.C. Cir. 2004).[8]

IV. THE THIRTY-MONTH STAY UNDER THE HATCH-WAXMAN ACT IS NOT RELEVANT TO PFIZER'S RIGHT OF PEDIATRIC EXCLUSIVITY

Mylan, as it has on previous occasions, suggests that the absence of a 30-month stay in this case precludes application of the pediatric exclusivity period. (Mylan Brief, pp. 1, 4). Mylan's assertion that denying Pfizer's pediatric exclusivity right results from a problem of Pfizer's "own making," because the suit was not filed within 45 days, has no basis at all. Mylan makes this bald assertion without even attempting to show how the absence of a 30-month stay – which would long ago have expired anyway – has any bearing on pediatric exclusivity, and without addressing the D.C. Circuit's holding, the FDA's ruling, and the Federal Circuit's holdings in *Mylan v. Thompson*, 389 F.3d 1272 (D.C. Cir. 2004), and *Alza Corp. v. Mylan Laboratories, Inc.*, 391 F.3d 1365 (Fed. Cir. 2004), that completely rejected Mylan's argument.

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[8] There was a much more plausible argument in the *Alza* case than there is in this case that the court's decision would not affect pediatric exclusivity. In the *Alza* case, Mylan did not have final approval when the patent expired, so that, under 21 U.S.C. § 355a(c)(2)(A)(i) the required patent certification – a "paragraph II certification" that the patent "has expired" – precluded FDA from approving its ANDA until the six-month pediatric exclusivity had also ended. It was by no means clear that a Federal Circuit decision in Mylan's favor, ruling that the patent in suit was invalid or had not been infringed would have allowed Mylan to withdraw paragraph II certification. That certification – that the "patent has expired"– arguably continued to be correct, regardless of the outcome of any infringement action. In contrast, in this case Mylan's ANDA will retain its approval *unless* the district court enters a judgment under 35 U.S.C. § 271(e)(4)(A). In the absence of such a judgment, there is no statutory basis for changing the ANDA's approval status. The FDA's discussion, at n.20 of its brief in *Mylan v. Thompson*, that Mylan cites, is based on the text of § 355a(c)(2)(A)(i); it does not consider the effect of § 355a(c)(2)(B), which provides a pediatric exclusivity where the ANDA maintains a paragraph IV certification and a judgment of infringement has been entered.

In the related cases of *Mylan v. Thompson*, 389 F.3d 1272 (D.C. Cir. 2004) and *Alza Corp. v. Mylan Laboratories, Inc.*, 391 F.3d 1365 (Fed. Cir. 2004), Mylan filed an ANDA with a paragraph IV certification, but the patentee did not sue for infringement until the forty-*sixth* day after it received notice of the filing. *Id.* at 1277. No 30-month stay attached as a result. Mylan argued, as it does here, that a failure to sue within the 45-day period in order to trigger the 30-month stay precluded the application of pediatric exclusivity. Nonetheless, the FDA held that pediatric exclusivity applied and the courts agreed with its determination.

The FDA, in its letter to Mylan's counsel, Mr. Figg (Exhibit B, p.13, fn. 11), rejected Mylan's argument that the 30-month stay was a prerequisite to pediatric exclusivity, stating: "This outcome makes little sense, and would substantially diminish the incentives for innovator firms to undertake the studies requested by the FDA to earn pediatric exclusivity which was so tenuous and easily evaded." The D.C. Circuit held in *Mylan Laboratories, Inc. v. Thompson, supra*, that the FDA was correct and that pediatric exclusivity applied. The Federal Circuit, in *Alza Corp. v. Mylan Laboratories, Inc., supra*, the appeal from the finding of infringement and validity of Alza's patent, agreed that pediatric exclusivity applied and the pediatric exclusivity issue gave the court jurisdiction to adjudicate the expired patent's validity. It is difficult to understand how Mylan can ignore this case in presenting its argument.

The 30-month stay is not a condition for application of the pediatric period. Moreover, even if a 30-month stay had attached in this case, it would no longer be relevant as it would have expired in early 2005 and could have no effect.

V. COMPLEXITY IS NO GROUND FOR AVOIDING THE DECISION

Mylan contends that the law on pediatric exclusivity is complex and uncertain. The fact that Pfizer acknowledged that the law is complex and with few precedents is, however,

not a reason to avoid decision and deprive Pfizer of its valuable right. Federal courts address complex legal issues in unclear areas all the time, and several courts have already analyzed the pediatric exclusivity provisions, notwithstanding their acknowledgments of its complexity. The courts that have done so have all rejected Mylan's arguments repeated here.

Pfizer has acknowledged that the law of pediatric exclusivity is complex in the case against Dr. Reddy's quoted by Mylan, but Pfizer also made clear that the correct interpretation of the law is that its right to pediatric exclusivity is not lost by the lack of a decision in the infringement case before patent expiration. In the brief cited by Mylan (Mylan Ex. 4), Pfizer stated:

> "There is little case law addressing pediatric exclusivity and no case explicitly interpreting this provision under these circumstances. Pfizer contends that it would be contrary to the policy of the pediatric exclusivity statute and an incorrect construction to allow the exclusivity rights to be lost if no decision is reached for each ANDA filer before the patent expires, particularly when, as in this case, the patent has been sustained in a decision against at least one other ANDA filer. In the absence of clear case law, however, Pfizer should not be forced to put its rights at risk unnecessarily."

Pfizer is entitled to the pediatric period if the patent is held to be valid and infringed. While the analysis is complex, Pfizer's right conclusively follows from both the language and the policy of the statute.

VI. THERE IS NO PROCEEDING IN THE FDA AVAILABLE TO RESOLVE THE ISSUE

Mylan suggests that the issue before the Court should be litigated in the FDA, but that is also a baseless position. Because Mylan has obtained final approval, it is necessary under the terms of the statute for this Court to decide whether the patent is valid and infringed, and to issue judgment under 35 U.S.C. § 271(e)(4)(A) to convert Mylan's final approval to a tentative

one. The pediatric exclusivity period will then apply. That decision can be made only by this Court and not by the FDA.

CONCLUSION

Mylan's motion to dismiss the '909 patent litigation should be rejected. Since a very valuable right remains at stake and turns on the issue of patent validity and infringement, the Court plainly has jurisdiction over the '909 patent claim. Moreover, in view of Mylan's admitted infringement of the '909 patent, Pfizer should not be deprived of the pediatric exclusivity period it earned by responding to the FDA request for pediatric clinical testing of Norvasc® unless Mylan succeeds in proving by clear and convincing evidence that the '909 patent is invalid.

The proposed procedure of having the '303 trial first, with the '909 patent trial to follow only if the '303 patent is held invalid, unenforceable or not infringed would preserve the parties' rights, but still avoid a trial of the '909 patent if the protection of the '303 patent makes that right academic. The decision on the '303 patent before March 25, 2007 will ensure that the

CERTIFICATE OF SERVICE

I hereby certify that on September 29, 2006, the foregoing Response to Mylan's Motion to Dismiss the Claim of Infringement of the '909 Patent for Lack of Subject Matter Jurisdiction was filed electronically. Notice of filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ C. James Zeszutek