UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DAIICHI SANKYO COMPANY, LIMITED and DAIICHI SANKYO, INC., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES INC., MATRIX LABORATORIES, LTD., and MYLAN INC. Defendants.	Civil Action Nos. 2:06-3462, 07-3039 and 08-2752 (WJM) (MF) (Consolidated) Motion Date: To Be Determined Oral Argument Requested ***DOCUMENT ELECTRONICALLY FILED***

DEFENDANTS' BRIEF IN OPPOSITION TO PLAINTIFFS' FED. R. CIV. P. 60(a) MOTION

Arnold B. Calmann (abc@saiber.com)
Jeffrey Soos, Esq. (js@saiber.com)
Katherine A. Escanlar (kae@saiber.com)
SAIBER LLC
One Gateway Center, 10th Floor
Newark, NJ 07102-5311
Tel: (973) 622-3333
Fax: (973) 622-3349

Shannon M. Bloodworth
(sbloodworth@perkinscoie.com)
PERKINS COIE LLP
700 13th Street, N.W., Suite 600
Washington, DC 20005-3960
(202) 654-6200 (telephone)
(202) 654-6211 (facsimile)

Autumn N. Nero (anero@perkinscoie.com)
Melody K. Glazer (mglazer@perkinscoie.com)
PERKINS COIE LLP
One East Main Street, Suite 201
Madison, WI 53703
(608) 663-7460 (telephone)
(608) 663-7499 (facsimile)

Attorneys for Defendants

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

INTRODUCTION

Although Daiichi's motion purports to seek "clarification" about just "one day," the motion is really an improper effort to resurrect an injunction on a patent that *expired almost six months ago* and extend its statutory monopoly far beyond what the law allows. Daiichi's Motion is substantively groundless as a matter of law, procedurally infirm, and contrary to the purposes of Rule 60(a).

This Court entered final judgment in this case back in August 2009, enjoining Mylan from practicing the '599 patent during the term of that patent (including any extensions) and ordering that Mylan's approval from FDA to launch its generic version of Mylan's olmesartan medoxomil ANDA products would take effect no earlier than that expiration date. The '599 patent expired on April 25, 2016. Now, five months later, and just a month before Mylan is eligible for final FDA approval allowing it to begin selling its generic olmesartan ANDA products, Daiichi inexplicably asks the Court to retroactively rewrite its seven-year-old final judgment and enjoin Mylan through October 26.

Daiichi's motion has no basis in law. This case was brought under the Patent Act, and the Court entered its injunction pursuant to the Patent Act. Daiichi argues that the Federal Food, Drug and Cosmetic Act (FFDCA) mandates extending the injunction through October 26, but the FFDCA does not even address patent terms. In October 2009, shortly after this Court entered the August 2009 final judgment, FDA awarded Daiichi a six-month "pediatric exclusivity" period as a reward for investigating olmesartan's effects on children ("Pediatric Exclusivity"). But although that award delays the date on which FDA may approve Mylan's ANDA application, FDA could not and did not change the patent's expiration date under the Patent Act. Nor could it

or did it extend the life of the Court's injunction under the Patent Act. That injunction, like the '599 patent, ended almost six months ago on April 25th.

The distinction between extension of a patent term under the Patent Act and an award of Pediatric Exclusivity under the FFDCA is important. Injunctions under the Patent Act broadly prohibit making, using, selling, offering for sale, or importing a patented product while that product is still under patent. FDA's grant of a six-month Pediatric Exclusivity period may delay FDA's approval of generic ANDAs (without which of course generics cannot sell their products), but it does not bar ANDA filers from, e.g., engaging in pre-launch activities such as manufacturing those products to the extent authorized by FDA. In this case, the '599 patent expired on April 25 of this year and this Court's injunction expired by its terms on that date. Mylan is thus free to make the product and prepare for launch even though it will not receive final FDA approval until Daiichi's six-month Pediatric Exclusivity ends on October 25.

In seeking a supposedly urgent "clarification," Daiichi pulls a bait and switch. Daiichi's memorandum pretends that this dispute is merely over "one day"—whether Mylan may launch on October 25 or October 26. In fact, Daiichi's "Revised Proposed Judgment" actually seeks six months plus a day. *See* ECF No. 154-1. Indeed, Daiichi's revised proposed judgment would not only postpone Mylan's *launch date* to October 26, but would have the Court retroactively extend the already-expired patent *injunction* to bar Mylan from "engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States" until October 26. Thus, *after waiting seven years to file its motion,* Daiichi's request is riddled with gross distortions of law and misleading statements designed to misguide the Court into awarding relief that Daiichi is not entitled to as a matter of law. Stripped of these distortions, Daiichi's motion amounts to nothing more than a disguised, belated, and

anticompetitive attempt to extend its expired Patent Act monopoly and prevent Mylan from competing until well after October 26.

What is more, Daiichi is wrong about the "one day." Because patents are in effect from midnight on the day they issue, they expire at the stroke of midnight on the day of expiration—i.e., at the very start of the day. Because Daiichi's patent expired at the stroke of midnight on April 25, Daiichi's Pediatric Exclusivity period will expire at the stroke of midnight on October 25. *See* Decl. of Shannon M. Bloodworth ("Bloodworth Decl.") Ex. 1 (timeline of '599 patent). In other words, FDA's approval becomes effective at that moment the calendar rolls over from October 24 to October 25, and marketing can commence immediately at that time. Daiichi may not double count the issuance day of its patent by adding it on to the end of the term to extend its statutory monopoly, even by a single day.

Finally, Daiichi's motion is not only substantively groundless, but procedurally improper. Daiichi moves under Rule 60(a), but that rule is designed to correct clerical errors and ambiguities. It is not a proper vehicle to make substantive changes to a more than seven-year old injunction and final judgment. Moreover, even if Rule 60(a) applied and even if the motion had any substantive merit, the motion should be denied on grounds of laches. Daiichi was awarded Pediatric Exclusivity in October 2009, and the '599 patent expired in April 2016. Yet Daiichi sat on its hands for seven years, waiting until a month before Mylan's launch to seek to resurrect and extend the injunction. That delay has greatly prejudiced Mylan.

For all these reasons, the Court should deny Daiichi's motion.

BACKGROUND

I. PATENT TERMS, PATENT TERM EXTENSIONS, AND PEDIATRIC EXCLUSIVITY PERIODS

Patent terms specify the periods during which patentees have the exclusive right to make, use, sell, offer for sale, or import a patented invention. They accordingly specify the periods for which courts may award injunctions and damages to enforce those rights. Patent terms also establish the first date on which FDA may approve an Abbreviated New Drug Application (ANDA) to produce a generic version of a patented drug. FDA's award of Pediatric Exclusivity may postpone FDA's approval date, but it does not affect the term of the patent itself.

A. Patent terms and patent extensions under the Patent Act

Patent terms are governed by 35 U.S.C. §§ 154 and 156. Because the patent in this case dates back to January 1995, it had a basic term of 17 years from its issuance on April 1, 1997. *See* 35 U.S.C. § 154(c)(1) (terms for patents issued on applications filed before June 8, 1995 are the greater of 20 years from application or 17 years from issuance). Base patent terms may be reduced by terminal disclaimers, *see id.*, and they may be extended under either 35 U.S.C. § 154(b) due to delay by the Patent Office in reviewing the application or 35 U.S.C. § 156 for certain reasons, including delays in FDA regulatory review. But pediatric research efforts are *not* a ground for extending a patent's term under either Section 154 or Section 156. Indeed, the Patent Act nowhere mentions Pediatric Exclusivity.

B. FDA pediatric marketing exclusivity under the Food, Drug and Cosmetic Act

Unlike patent extensions, which are governed by Title 35 ("Patents"), Pediatric Exclusivity is a regulatory privilege authorized under Title 21 ("Food and Drugs"). Under Section 505A of the FFDCA, 21 U.S.C. § 355a(c)(1), FDA may ask a supplier of an FDA-approved drug to perform studies on use of the drug in children. If the drug manufacturer

complies, FDA may grant it a Pediatric Exclusivity period that delays the date on which FDA will approve competitors' ANDAs until six months after the patent expires. 21 U.S.C. § 355a(c)(1)(B)(ii). But that is all a Pediatric Exclusivity period does. Pediatric Exclusivity is awarded by FDA, not by the courts or the Patent Office, and although delays in regulatory approval of generic competition may effectively extend a branded drug maker's commercial monopoly, they do not extend the patent term itself and thus do not entitle the recipient to injunctive relief, damages, or attorneys' fees under the Patent Act. In fact, both FDA and the courts have made clear that FDA lacks the expertise to determine matters of substantive patent law.[1]

The distinction is important because patent protection and regulatory protection are not co-extensive. While a patent is in force, the patentee has the exclusive right to make, use, sell, offer for sale, and import the patented product—and in appropriate circumstances may obtain an injunction to enforce that exclusive right. 35 U.S.C. § 271. Regulatory protection (status as the only company with FDA approval to market a drug) is much more limited in scope, as FDA approval is necessary only to "introduce [a new drug] or deliver [it] for introduction into interstate commerce." 21 U.S.C. § 355(a); *see also In re Schering Plough Corp. Intron/Temodar*

[1] *See, e.*g., *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012) ("According to [FDA], it lacks 'both [the] expertise and [the] authority' to review patent claims; although it will forward questions about the accuracy of a use code to the brand, its own 'role with respect to patent listing is ministerial.'" (quoting 68 Fed. Reg. 36682-36683, 36683 (June 18, 2003)); *see also* 68 Fed. Reg. 36683 ("A fundamental assumption of the Hatch-Waxman Amendments is that the courts are appropriate mechanism for the resolution of disputes about the scope and validity of patents."); *AaiPharma Inc. v. Thompson*, 296 F.3d 227, 241 (4th Cir. 2002) ("FDA has no expertise in making patent law judgments."); *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1080 (D.C. Cir. 2001) ("The FDA, pursuant to longstanding practice and its own regulations, and based on its acknowledged lack of expertise and resources, has refused to become involved in patent listing disputes …."); *Watson Pharm., Inc. v. Henney*, 194 F. Supp. 2d 442, 445-46 (D. Md. 2001) ("[FDA] has no expertise—much less any statutory franchise—to determine matters of substantive patent law.").

Consumer Class Action, 678 F.3d 235, 239 (3d Cir. 2012) ("The FDCA ... provides that a drug cannot be *sold in interstate commerce* unless it is approved by the FDA ….") (emphasis added).

Accordingly, once a patent on a compound has expired, a generic competitor is free to manufacture that compound, package it, label it, and prepare to sell it in this country before receiving FDA approval. *See Altana Pharma AG v. Teva Pharm. USA, Inc*., No. CIV. A. 04-2355 JLL, 2012 WL 2068611, at *2 (D.N.J. June 7, 2012) ("During the instant pediatric exclusivity period, others were free to make, sell, offer to sell, import and use the compounds claimed in the '579 patent. Pediatric Exclusivity is a regulatory privilege; a patent term extension is a patent privilege.").

C. Patent infringement and injunctions under 35 U.S.C. § 271

Section 271 of the Patent Act, 35 U.S.C. § 271, specifies what acts constitute infringement of a U.S. patent. In general, one who (without a license) makes, uses, sells, offers to sell, or imports a patented invention in the United States "during the term of the patent therefor" commits patent infringement, 35 U.S.C. § 271(a), and courts may award remedies for infringement including injunctions, damages, and attorneys' fees under 35 U.S.C. §§ 283, 284, and 285. Section 271(e)(2), however, contains a special provision establishing a "highly artificial" act of infringement when a drug company submits an ANDA seeking FDA approval to market a generic version of an approved patented drug, even if it has not yet made or sold the drug. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). If a court finds that the proposed ANDA product would infringe a valid patent, the court may award remedies as set forth in Section 271(e)(4), including:

- an order making the effective date of FDA approval of the generic drug "not earlier than the date of the expiration of the patent which has been infringed," 35 U.S.C. § 271(e)(4)(A);

- injunctive relief preventing the generic competitor from making, using, selling, offering for sale, or importing the drug, 35 U.S.C. § 271(e)(4)(B); and
- damages for past manufacture, use, sale, offer for sale, or importation, 35 U.S.C. § 271(e)(4)(C).

The Section 271(e)(4)(A) remedy regarding the effective date of FDA approval is unique to the artificial infringement scenario in an ANDA case, but the injunctive and damages remedies are essentially the same as the remedies in typical patent cases. *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1342 (Fed. Cir. 2015). By statute, the remedies in Section 271(e)(4) are the "only remedies," apart from attorneys' fees, that may be awarded for the artificial act of infringement established in Section 271(e)(2). 35 U.S.C. § 271(e)(4).

II. DAIICHI'S LAWSUIT AND THIS COURT'S AUGUST 2009 INJUNCTION AND SECTION 271(e)(4)(A) ORDER

This case involves the popular high-blood-pressure drugs olmesartan medoxomil (also known as "olmesartan") and olmesartan medoxomil hydrochlorothiazide (also known as "olmesartan HCT"). Daiichi makes and sells these drugs under the brand names Benicar® and Benicar HCT®, respectively. In obtaining FDA approval to sell these drugs, Daiichi asserted that they were covered by the '599 patent. Daiichi also agreed to perform pediatric studies on Benicar, and on October 7, 2009, the FDA awarded it six months of Pediatric Exclusivity. *See* Bloodworth Decl. Ex. 2 at 7.

The original term of the '599 patent began on April 1, 1997, the date it issued. *See* 35 U.S.C. § 154(a)(2) (Each patent grant "shall be for a term beginning on the date on which the patent issues."). The base term of the '599 patent ran for 17 years, expiring on April 1, 2014. *See* 35 U.S.C. § 154(c)(1). Due to regulatory delay in receiving FDA approval for Benicar®, Daiichi received an extension of 755 days under the Patent Act, 35 U.S.C. § 156, extending the expiration date to April 25, 2016. Bloodworth Decl. Ex. 3 (Nov. 29, 2004 Patent Term

Extension Certificate); *see also* Bloodworth Decl. Ex. 1 (timeline). FDA maintains an "Orange Book" of approved drugs, related patents, and exclusivity periods. The Orange Book accordingly listed April 25, 2016, as the expiration date of the '599 patent, and October 25, 2016, as the expiration date of Daiichi's Pediatric Exclusivity—i.e., the first date on which competitors could be authorized to sell competing generic versions. ECF No. 154-5.

In 2006, Mylan became the first generic drug manufacturer to file a substantially complete ANDA seeking approval of its generic olmesartan and olmesartan HCT products. Mylan made "paragraph IV" certifications regarding the '599 patent, contending that Daiichi's patent claims were invalid, and Daiichi promptly sued Mylan for infringement under 35 U.S.C. § 271(e)(2). At trial, Mylan conceded that its generic product would infringe the '599 patent if the patent was valid, and this Court rejected Mylan's invalidity challenge. ECF No. 139. The parties submitted competing forms of judgment, ECF Nos. 141, 142, and the Court entered final judgment on August 6, 2009. ECF No. 143. The Federal Circuit later affirmed that judgment. *Daiichi Sankyo Co. v. Matrix Labs., Ltd*., 619 F.3d 1346, 1351 (Fed. Cir. 2010).

The Court's August 2009 final judgment included provisions under both Section 271(e)(4)(A) and Section 271(e)(4)(B). "[P]ursuant to 35 U.S.C. § 271(e)(4)(A)," the Court declared that "the effective date of any approval by [FDA] of Mylan's [ANDAs] shall be a date which is *not earlier than the expiration date of the '599 patent, including all extensions thereof*." ECF No. 143 (emphasis added). "[P]ursuant to 35 U.S.C. § 271(e)(4)(B)," the Court further ordered that Mylan, its officers, agents, servants and employees were "enjoined, *until the expiration date of the '599 patent, including all extensions thereof*, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the products which are subject of [Mylan's ANDAs.]" *Id*. (emphasis

added). The August 2009 final judgment did not mention Daiichi's then-pending application for Pediatric Exclusivity, which made sense and was entirely appropriate because Pediatric Exclusivity periods are a matter for the FDA to address under the FFDCA, not a matter for courts to address under the Patent Act.

Daiichi never contended—either in 2009 or at any time over the next seven years—that FDA's grant of Pediatric Exclusivity in October 2009 extended the expiration date of the '599 patent beyond April 25, 2016, that the Court's Section 271(e)(4)(B) injunction extended until the end of that Pediatric Exclusivity period, or that the Pediatric Exclusivity period expired on October 26, 2016, rather than October 25, 2016.

On April 25, 2016, the '599 patent expired. This had two effects. First, this Court's injunction expired by its terms. Second, Daiichi's six-month Pediatric Exclusivity period began and postponed the earliest date of FDA approval of Mylan's ANDA until October 25, 2016. Because Daiichi's patent and this Court's injunction have expired, however, Mylan has been free to manufacture the drugs so that it can begin selling and marketing as soon as FDA approval takes effect.

The first Mylan heard about any purported ambiguities in the Court's August 2009 final judgment was on September 8, 2016, when Daiichi asked Mylan to stipulate to a "revised final judgment" that (a) deemed the expiration date of the '599 patent to be October 25, 2016, rather than April 25, 2016 (which is incorrect), and (b) deemed the effective date of FDA approval of Mylan's ANDAs to be October 26, 2016, rather than October 25, 2016 (also incorrect). ECF No. 154-6; *see also* ECF No. 154-2. That request came out of the blue. Daiichi and Mylan have been co-defendants in separate litigations involving these same products against separate ANDA

filers since 2012. Mylan repeatedly asserted in these litigations that it was entitled to FDA approval on October 25, 2016, and Daiichi never disagreed.

Mylan refused to stipulate, and Daiichi filed its motion seeking "clarification" of the original August 2009 final judgment and requesting the Court enter a rewritten judgment. ECF No. 154-6; *see also* ECF No. 154-2. Although Daiichi's motion purports merely to seek clarification of when Mylan's FDA approval will be effective, Daiichi's proposed amended final judgment would extend the terms of the original order to enjoin Mylan from manufacture, use and importation—not just sale and offer for sale—of its proposed ANDA products until October 26. ECF No. 154-2. At least because Daiichi's demand is unfounded in law and an improper belated attempt to expand the August 2009 final judgment, Mylan opposes the motion.

LEGAL STANDARDS

Federal Rule of Civil Procedure 60(a) authorizes courts to "correct a clerical mistake or a mistake arising from oversight or omission whenever one is found in a judgment, order, or other part of the record." Rule 60(a) "encompasses only errors mechanical in nature, apparent on the record, and not involving an error of substantive judgment." *Pfizer Inc. v. Uprichard*, 422 F.3d 124, 129-30 (3d Cir. 2005) (quotation omitted). Indeed, "[i]t is only mindless and mechanistic mistakes, minor shifting of facts, and no new additional legal perambulations which are reachable through Rule 60(a)." *Id.* at 129-30 (citation omitted). Courts' power under Rule 60(a) "to correct inadvertent ministerial errors may not be used as a guise for changing previous decisions." *Slate v. Am. Broad. Co.*, 12 F. Supp. 3d 30, 36 (D.D.C. 2013), *aff'd.*, 584 F. App'x 2 (D.C. Cir. 2014).

"[T]he relevant test for the applicability of Rule 60(a) is whether the change affects substantive rights of the parties and is therefore beyond the scope of Rule 60(a) or is instead a

clerical error, a copying or computational mistake, which is correctable under the Rule." *Pfizer*, 422 F.3d at 130; *see also Gutierrez v. Johnson & Johnson*, 743 F. Supp. 2d 418, 422-23 (D.N.J. 2010). When the proposed change is substantive in nature, Rule 60(a) cannot be used as a vehicle for amending the judgment; instead, the movant must rely on Rules 59(e) or 60(b), which have stricter time limits. *See Pfizer*, 422 F.3d at 130 n.9 ("Pfizer's request to substantively amend the judgment should have been made through a Fed. R. Civ. P. 59(e) motion."); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, 200 F. App'x 95, 105 (3d Cir. 2006) ("[T]he Trust should have moved the District Court, perhaps under Fed. R. Civ. P. 60(b), to correct the District Court's prior judgment."). Daiichi has not moved to amend the judgment under Rules 59(e) and 60(b), apparently recognizing that such motions would be untimely.[2]

ARGUMENT

I. MYLAN IS NO LONGER SUBJECT TO THE SECTION 271(e)(4)(B) INJUNCTION BECAUSE THE '599 PATENT EXPIRED ON APRIL 25, 2016

Although Daiichi pretends otherwise, the main dispute here is whether Daiichi's Pediatric *Exclusivity* period extended the '599 patent's life beyond April 25, 2016, and thereby extended the Court's *injunction* entered pursuant to 35 U.S.C. § 271(e)(4)(B). Daiichi's motion invites the Court to commit legal error because, as a matter of settled law, the Pediatric Exclusivity did not extend that injunction.

[2] A motion under Rule 59(e) must be brought within 28 days of the judgment. Fed. R. Civ. P. 59(e). A motion under Rule 60(b) "must be made within a reasonable time," and in many situations within a year of the judgment. Fed. R. Civ. P. 60(c)(1).

A. The '599 patent is unenforceable beyond its expiration date, and Daiichi's Pediatric Exclusivity period did not alter that date

This Court's August 2009 injunction enjoined Mylan from commercially manufacturing, using, offering for sale or importing Mylan's ANDA products "*until the expiration date of the '599 patent, including all extensions thereof*." ECF No. 143 (emphasis added). As the parties previously agreed and the Orange Book makes clear, the '599 patent expired on April 25, 2016. ECF No. 154-5. In a recent case involving olmesartan medoxomil, the Federal Circuit confirmed that the '599 patent "expires on April 25, 2016," even though Daiichi's Pediatric Exclusivity period means that FDA must wait "until October 25, 2016" before approving a generic version of the drug. *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1358 (Fed. Cir. 2015), *cert. denied sub nom.*, *Daiichi Sankyo, Inc. v. Apotex, Inc.*, 136 S. Ct. 481 (2015), *cert. denied sub nom.*, *Mylan Pharm., Inc. v. Apotex, Inc.* 136 S. Ct. 485 (2015).

Daiichi nonetheless contends that the injunction runs six more months (and an extra day) past April 25, 2016, due to FDA's grant of Pediatric Exclusivity. According to Daiichi, the six-month exclusivity period constitutes an "extension" of the patent term, and the Court should therefore enjoin Mylan from engaging in manufacturing and other pre-marketing activities that do not require FDA approval until October 26, 2016. Daiichi confuses and conflates Pediatric Exclusivity periods with patent term extensions, which are different concepts addressing different matters under different statutes.

As discussed above, a *patent term extension* lengthens the term of a patent for specific reasons specified in Sections 154(b) and 156 of the Patent Act. By contrast, a *Pediatric Exclusivity period* is a regulatory privilege that FDA may award under Section 505A of the Food, Drug and Cosmetic Act for a different reason: as an incentive and reward for studying the effects of a drug on children. The Pediatric Exclusivity period runs *from the expiration* of the

patent (i.e., the end of the patent term)—which includes any extensions under Sections 154(b) and 156—and has the effect of delaying FDA approval of a competing generic ANDA by six months. Section 505A expressly distinguishes between *patent term* extensions and the six-month extension of the period during which an ANDA cannot be approved, making clear that the six-month exclusivity runs "after the date the patent expires (including any patent extensions)":

> [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 of this title, 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) of this title or section 355(j)(5)b) of this title *shall be extended by a period of six months after the date the patent expires (including any patent extensions).*

21 U.S.C. § 355a(b)(1)(B)(ii) (emphasis added). A Pediatric Exclusivity period thus does not extend the term of the patent itself and it does not entitle the Pediatric Exclusivity holder to damages or injunctive relief during the six-month period. In cases where a court has issued a Section 271(e)(4)(A) order, the Pediatric Exclusivity period simply postpones the earliest possible date of FDA approval of the generic company's ANDA until six months after the patent's expiration date, which remains the same.

The Federal Circuit has expressly held that the FDA's grant of *exclusivity* does *not* constitute an *extension* of the patent term. *AstraZeneca v. Apotex*, 782 F.3d at 1342. In *AstraZeneca*, while district court litigation was proceeding, Apotex received FDA approval to market a generic version of AstraZeneca's branded omeprazole product and entered the market. *Id.* at 1329. After the patent expired, but during AstraZeneca's period of Pediatric Exclusivity, the district court found that Apotex's formulation infringed AstraZeneca's patents while they were in force. *Id.* FDA then revoked Apotex's ANDA approval because AstraZeneca was entitled to its period of Pediatric Exclusivity, and Apotex stopped distributing its generic

product. *Id.* at 1341. AstraZeneca then sought damages for Apotex's infringement, including damages based on sales that Apotex made during and through the end of the Pediatric Exclusivity period. The Federal Circuit rejected AstraZeneca's argument and held that AstraZeneca was only entitled to damages for the term of its patent, not for the Pediatric Exclusivity period, because, as a matter of law, the Pediatric Exclusivity period was not an extension of the patent and instead ran during a period when the patent was already *expired*. *Id.* at 1342.

In so ruling, the Federal Circuit stressed the fundamental principles that "'there can be no infringement once the patent expires,'" and that "'the rights flowing from a patent exist only for the term of the patent.'" *Id.* at 1343 (quoting *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1550 (Fed. Cir. 1994)). Because "[t]he pediatric exclusivity period [wa]s not an extension of the term of the patent," *id.* (citations omitted), it was "clear that Apotex did not infringe Astra's patents during the exclusivity period, since those patents had expired." *Id.* To be sure, the FDA had properly revoked Apotex's previous approval to launch, but AstraZeneca was not entitled to typical patent remedies, such as injunctive relief and monetary damages, during the Pediatric Exclusivity period. *See id.* (Unlike the remedy, under 35 U.S.C. § 271(e)(4)(A), regarding the effective date of FDA approval of an ANDA, § 271(e)(4)(B) and § 271(e)(4)(C) "provide the 'typical remedies' for patent infringement: injunctive relief and money damages.").

AstraZeneca did not establish new law—it accorded with both previous Federal Circuit precedent and FDA's own interpretation of the statute it is charged with enforcing. In *In re Omeprazole Patent Litigation*, 536 F.3d 1361, 1368 (Fed. Cir. 2008), decided before this Court's August 2009 final judgment, the Federal Circuit also distinguished between patent extensions and Pediatric Exclusivity period. It recognized that "[i]n most circumstances, the effective date

in a district court's order under section 271(e)(4)(A) [regarding FDA approval] will be the date of patent expiration, including any patent extensions." *Id.* In that case, however, the patentee (again AstraZeneca) was "entitled to an additional six-month period of market exclusivity (sometimes known as a period of 'pediatric exclusivity') under the Food and Drug Administration Modernization Act of 1997." *Id.* The Federal Circuit thus recognized that Pediatric Exclusivity is an *additional* period that begins *after* patent extensions and does not constitute a patent extension itself. *Id.* Courts in this district have similarly recognized that a patent term extension is distinct from an exclusivity period. In *Altana v. Teva*, the court recognized that "[d]uring [a] pediatric exclusivity period, others [a]re free to make, sell, offer to sell, import and use the compounds claimed in the [patent in suit]" and that "[p]ediatric exclusivity is a regulatory privilege" whereas "a patent term extension is a patent privilege." 2012 WL 2068611, at *2. For its part, FDA has maintained the same view in official guidance *since 1999*, unequivocally stating that "[p]ediatric exclusivity attaching to the end of a patent term is *not a patent term extension under 35 U.S.C. 156*" but instead "extends the period during which the approval of an abbreviated new drug application (ANDA) or 505(b)(2) application may not be made effective." FDA, *Guidance for Industry Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act* (Sept. 1999) ("FDA Guidance") at 13 (attached as Bloodworth Decl. Ex. 4) (emphasis added).

B. Daiichi's contrary arguments are wrong

Daiichi's theory that pediatric exclusivity is itself a patent extension is nonsensical because by the terms of the pediatric exclusivity statute itself, pediatric exclusivity periods run from the end of the patent term. 21 U.S.C. § 355a(b)(1)(B)(ii). If Daiichi were right that

the '599 patent has not expired, then its pediatric exclusivity period would not have begun yet. Yet even Daiichi concedes that the pediatric exclusivity period is currently running.

Daiichi's efforts to avoid the Federal Circuit's decision in *AstraZeneca* fall flat. Daiichi first argues (at 9) that *AstraZeneca* does not apply because, as a 2015 decision, it says nothing about this Court's intention in 2009. That is doubly wrong. The Court's intention and the August 2009 final judgment were clear: Mylan was enjoined from making, using, selling, offering for sale, and importing only "until the expiration date of the '599 patent, including all extensions thereof." ECF No. 143. The issue before the Court is therefore whether or not a Pediatric Exclusivity period constitutes an "extension" of the patent term. As *AstraZeneca* held, a grant of Pediatric Exclusivity does *not* extend the patent term; it just delays the earliest date of FDA approval. Furthermore, contrary to Daiichi's suggestion, *AstraZeneca* did not announce a new rule of law: as shown above, it was consistent with previous Federal Circuit precedent (*In re Omeprazole*), previous precedent of this Court (*Altana*), and FDA's Guidance since 1999.

Nothing in the August 2009 final judgment or case history suggests that this Court intended to stray from the definition of patent "extension" under the Patent Act. Indeed, even if the Court had wanted to do so, it would have had no power to enjoin anyone from practicing an expired patent because injunctions under Section 271 are designed to prevent patent infringement and "there can be no infringement once the patent expires." *AstraZeneca*, 782 F.3d at 1343.

Daiichi also tries (at 10) to distinguish *AstraZeneca* on the ground that the Federal Circuit merely addressed whether *damages* could be recovered during Pediatric Exclusivity periods. *AstraZeneca* did involve a damages claim, but the Federal Circuit's holding turned on whether the patent term had expired or had been extended by FDA's award of Pediatric Exclusivity. *Id.* at 1342-43. Moreover, the Federal Circuit addressed injunctive and damages relief in tandem. It

observed that injunctions against ANDA applicants are a "typical remed[y]" for patent infringement and thus, like damages, are available only for the patent term and not during a Pediatric Exclusivity period. *Id.* at 1344. In any event, Daiichi's interpretation of the August 2009 judgment in this case turns on the premise that Pediatric Exclusivity is an extension of the patent term, and the Federal Circuit unequivocally rejected that premise, saying in no uncertain terms that "[t]he pediatric exclusivity period is not an extension of the term of the patent." *Id.* at 1343.

Daiichi is correct that "[t]he Federal Circuit in *AstraZeneca* cited with approval the Federal Circuit's prior decision [in *Omeprazole*] … affirming the district court's order resetting Apotex's ANDA effective date to the end of the pediatric exclusivity period," but that discussion related to the Section 271(e)(4)*(A)* order regarding the effective date of FDA authorization. *In re Omeprazole*, 536 F.3d at 1381. The *AstraZeneca* court did not approve any extension of a Section 271(e)(4)(*B*) injunction, which is what Daiichi seeks here. To the contrary, the Federal Circuit specifically distinguished between 271(e)(4)(A) orders and typical injunction and damage remedies: "While the remedy under subparagraph (A) is unique to section 271(e)(2) infringement, subparagraphs (B) and (C) provide the 'typical remedies' for patent infringement: injunctive relief and money damages." *AstraZeneca*, 782 F.3d at 1342.

Daiichi stretches *Alza Corp. v. Mylan Laboratories, Inc.*, 391 F.3d 1365 (Fed. Cir. 2004), and *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005), *abrogated on other grounds by MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), beyond the breaking point in claiming (at 10-11) those cases held that Pediatric Exclusivity extends a patent's term. Because a Pediatric Exclusivity period can, as a practical matter, extend the patentee's monopoly, courts and litigants sometimes loosely (but mistakenly) characterize exclusivity periods as equivalent to patent term extensions in cases where the distinction makes

no difference. But such loose *dicta* are not binding precedent, and loose *dictum* is all that Daiichi cites. In *Alza*, the court merely mentioned the patent's expiration date and Pediatric Exclusivity period as background in an opinion affirming the district court's construction of "skin permeable form" and its determination that the patent was not invalid. 391 F.3d at 1369, 1374. The brief mention of the patent's term was unimportant and far from necessary to the judgment. For its part, *Teva* involved an appeal from a district court's determination that there was no actual controversy between the parties under the Declaratory Judgment Act, 395 F.3d at 1327, and the decision mentioned the expiration date and pediatric exclusivity only in a footnote, *id.* at 1329 n.4. As in *Alza*, the distinction between patent terms and Pediatric Exclusivity was irrelevant to and had no effect on the result. In contrast, *AstraZeneca*'s statement "[t]he pediatric exclusivity period is not an extension of the term of the patent" was a binding *holding* because it was essential to the court's analysis. 782 F.3d at 1343.

Daiichi also relies (at 11) on a passing reference from Mylan's briefing in an unrelated case where the distinction between Pediatric Exclusivity and patent term again was not at issue. Far more illuminating are the positions that both Mylan and Daiichi have taken about the expiration of the '599 patent at issue here: both parties have repeatedly affirmed that the '599 patent would expire or already had expired on April 25, 2016. *See, e.g.*, Memo. in Supp. of Mylan's Mot. to Dismiss, *Apotex, Inc. v. Daiichi Sankyo Co.*, No. 12-cv-9295, ECF No. 32, at 6 (N.D. Ill. Apr. 9, 2013) (attached as Bloodworth Decl. Ex. 5); Memo in Supp. of Mylan's Mot. for Judg. on Pleadings, *Alembic Pharm. Ltd. v. Daiichi Sankyo Co.*, No. 16-cv-3956, Mylan's Mem. in Supp. of Mots. for J. on the Pleadings at 7, ECF No. 40 (N.D. Ill. May 18, 2016) ("The '599 patent expired on April 25, 2016, but remains under a period of marketing exclusivity until October 25, 2016") (attached as Bloodworth Decl. Ex. 6); Answer to Am. Compl., *Sandoz,*

Inc. v. Daiichi Sankyo Co., No. 16-cv-0081, ECF No. 22, at 7 (E.D. Va. Apr. 21, 2016) ("Daiichi Sankyo admits that the '599 patent expires on April 25, 2016 …."), (attached as Bloodworth Decl. Ex. 7).

Daiichi also ignores that the Federal Circuit issued an opinion in one of those cases in which it carefully recognized the distinction between exclusivity periods and patent term extensions and correctly stated that the '599 patent "expires on April 25, 2016, but because Daiichi provided the FDA certain data concerning the drug's effects on children, the FDA must wait six months longer—i.e., until October 25, 2016—before approving a generic version of the drug." *Apotex v. Daiichi Sankyo*, 781 F.3d at 1358.

As a matter of law, Daiichi is simply wrong in contending that the expiration date of the '599 patent is October 25, 2016, and that Mylan remains enjoined through that date. Because the Pediatric Exclusivity period is not an extension of the term of the patent, Mylan is now free to manufacture the formerly patented drugs and conduct pre-marketing activity to the extent consistent with FDA regulations even though Mylan does not yet have FDA permission to launch its generic products. The Court's original injunction expired when the patent expired on April 25, 2016, and this Court cannot amend its patent-law injunction under Section 271(e)(4)(B) to prohibit infringement of a patent that has already expired. Although Daiichi's Pediatric Exclusivity period remains in effect until October 25, 2016, its patent monopoly is over.

II. THE PEDIATRIC EXCLUSIVITY PERIOD UNDER SECTION 271(E)(4)(A) EXPIRES ON OCTOBER 25, 2016—NOT ON OCTOBER 26, 2016, AS DAIICHI CLAIMS

Daiichi is also wrong in asserting that Mylan cannot receive FDA approval, and thus cannot launch its generic product until October 26, 2016. As a matter of law, the Pediatric Exclusivity period expires at midnight on October 25, 2016, and Mylan may launch on that day.

A. Patents become unenforceable on their expiration dates, not a day later, and Pediatric Exclusivity periods delay launch by exactly six months, not six months and one day

To understand when the Pediatric Exclusivity period expires and when Mylan's approval from FDA will take effect, it helps to go back to the beginning, when the '599 patent issued on April 1, 1997. *See* Bloodworth Decl. Ex. 1 (illustrating the days of the '599 patent's term, the extensions of the '599 patent's term, and the period of Pediatric Exclusivity that followed the '599 patent's expiration). Daiichi's patent was in effect all day on April 1, 1997, from the first stroke of midnight, and Daiichi was entitled to enforce that patent by suing on that day and seeking both an injunction and damages for that day. Under Section 154(a)(2), patents are in effect "for a term beginning on the date on which the patent issues." As courts have long recognized, "the monopoly of a patent arises on the day it is granted and … it is enforceable on that date against any infringers." *Archer Daniels Midland Co. v. Ralston Purina Co.*, 321 F. Supp. 262, 264 (S.D. Ill. 1971). Consistent with that principle, patentees often file suit shortly after midnight on the date of issuance.[3]

Without any extensions, Daiichi's patent term would have lasted for 17 years and expired at midnight on April 1, 2014. Daiichi could not have obtained damages or an injunction for April 1, 2014, itself, as that would have given it a term of 17 years and a day. In actuality, Daiichi received a 755-day extension for regulatory delay under Section 156, so the term of the '599 patent expired on April 25, 2016, but the analysis is the same. Because Daiichi was free

[3] *See, e.g.*, *Abbott Labs. v. Johnson & Johnson, Inc.*, 524 F. Supp. 2d 553, 556 (D. Del. 2007) (suit filed at 12:02 a.m. of day of issuance), *aff'd*, 297 F. App'x 966 (Fed. Cir. 2008); *D2L Ltd. v. Blackboard, Inc.*, 671 F. Supp. 2d 768, 774 n.3 (D. Md. 2009) (complaint filed at 12:01 a.m. of day of issuance); *Hertz Corp. v. Enterprise Rent-a-Car Co.*, 557 F. Supp. 2d 185, 188 & n.2 (D. Mass. 2008) (complaint filed at "the stroke of midnight" of day of issuance); *Encore Wire Corp. v. Southwire Co.*, No. 10-cv-86-BMGL, 2011 WL 833220, at *1 (N.D. Ga. Mar. 4, 2011) (complaints filed at 12:07 a.m. EDT and 12:10 a.m. CDT of day of issuance).

to enforce its patent on the day of issuance (April 1, 1997), it could not also enforce the patent on the day of expiration, as that would effectively give it an extra day of patent protection. The '599 patent thus expired at the stroke of midnight, as the calendar rolled over from April 24, 2016 to April 25, 2016. *See* Bloodworth Decl. Ex. 1.

Daiichi cites (at 4) three PTO decisions for the proposition that "a patent expires at midnight on the date of expiration." That is correct, but Daiichi forgets that midnight (12:00 a.m.) on April 25, 2016, marked the *beginning* of that day, not the end. *See Justice v. Town of Cicero, Ill.*, 682 F.3d 662, 664 (7th Cir. 2012) ("Yet it does not take a reference to *Cinderella* to show that midnight marks the end of one day and the start of another."). Simply put, a patent expires at the first moment of the day of expiration—i.e., at the stroke of midnight—and is no longer enforceable after that. *See Ranbaxy Labs. Ltd. v. FDA*, 307 F. Supp. 2d 15, 19, 21 (D.D.C.) (recognizing that a patent expired at the "magic moment" of midnight on the day of expiration), *aff'd*, 96 F. App'x 1 (D.C. Cir. 2004).

Consistent with this analysis, the FFDCA recognizes that FDA approval may take effect on the same day that the patent term expires, and need not wait until the following day. Under 21 U.S.C. § 355(j)(5)(B)(ii), FDA approval "may be made effective on the date certified under subclause (III) [21 U.S.C. § 355(j)(2)(A)(vii)(III)]," which is "the date on which such patent will expire." *See also Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1131 (Fed. Cir. 1995) ("If the ANDA contains a paragraph III certification, and all applicable scientific and regulatory requirements have been met, approval is effective on the patent expiration date stated in the certification.").[4]

[4] *See also aaiPharma Inc. v. Thompson*, 296 F.3d 227, 232 (4th Cir. 2002) ("An ANDA that contains a paragraph III certification becomes effective on the patent's expiration date, assuming that other FDA requirements have been satisfied."); *In re Metoprolol Succinate Direct Purchaser*

In short, a Pediatric Exclusivity period delays the effective date of FDA approval until six months after patent expiration, but no more:

> [T]he period during which an application may not be approved under section 355(c)(3) of this title or section 355(j)(5)(b) of this title shall be extended by a period of six months after the date the patent expires (including any patent extensions).

21 U.S.C. § 355a(b)(1)(B)(II); *see also Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1284 (D.C. Cir. 2004). Here, Daiichi's patent expired at midnight at the beginning of April 25, 2016, so Daiichi's Pediatric Exclusivity period will expire at midnight (12:00 a.m.) on October 25, 2016, and Mylan will be able to launch at any time on October 25.

The Court should therefore recognize that FDA is entitled to approve Mylan's ANDAs effective October 25, 2016, and that Mylan will free to launch on that day with such approval.

B. *Takeda* does not change the analysis

Daiichi's contrary argument is based on an unreported District of Delaware case, *Takeda Pharmaceutical Co. v. Teva Pharmaceuticals. USA, Inc*., No. CIV. 06-33-SLR, 2009 WL 3738738, at *1 (D. Del. Nov. 9, 2009). *Takeda* does not warrant the weight that Daiichi places on it. *Takeda* addressed whether there is overlap between Pediatric Exclusivity and "first-filer exclusivity" (a separate exclusivity period awarded pursuant to the FFDCA, which rewards the first ANDA filer to file an ANDA and challenge the patent(s) listed in the Orange Book), but *Takeda* did not analyze in depth the critical issue here: proper calculation of a patent term under the Patent Act. 2009 WL 3738738, at *2.[5] Instead, the *Takeda* court briefly analogized to other

---

Antitrust Litig., No. CIV. A. 06-52 (GMS), 2010 WL 1485328, at *2 (D. Del. Apr. 13, 2010) ("A certification under Paragraph III indicates that the ANDA may be approved on the patent expiration date.") (emphasis added).

[5] The other unreported district court cases cited by Daiichi also provided little analysis. *See Wyeth v. Teva Pharm. USA Inc*., No. CIV. A. 04-2355 JLL, 2010 WL 3211126, at *1 (D.N.J. Aug. 13, 2010); *Alcon, Inc. v. Teva Pharm. USA, Inc*., No. CIV. 06-234-SLR, 2010 WL 3081327, at *1 (D. Del. Aug. 5, 2010).

scenarios: deadlines under the Federal Rules of Procedure, stale groceries, and dates for renewing a driver's license. *Id.* If anything, the *Takeda* court's analogies highlight the error in its conclusion.[6]

Responsive deadlines under the Federal Rules of Civil Procedure are calculated at the date level of granularity, but electronic filings may occur at any time during the day. To ensure that the responding party has full time to respond, the Rules count the passage of time from the end of the filing day (11:59 p.m.), not the beginning (12:00 a.m.). For example, if a filing occurs at any time on May 1 and the response period is 14 days, the responding party may file its response on May 15. The Patent Act is different. Patents are in effect starting at midnight on the day of issuance, and that day is not double-counted. For example, if a patent issued on May 1, 2000 with a 17-year term, it expires at the end of April 30, 2017—not at the end of May 1, 2017. The difference between the Federal Rules and patent terms was recognized in *Archer Daniels*, which observed that "[w]hile it is common in the law to exclude the first day of a time period and to include the last in computing [such as in Fed. R. Civ. P. 6(a)], it would indeed be an anomaly to hold that the rights under a patent did not arise on the day that it was issued." 321 F. Supp. at 264.

The other scenarios discussed in *Takeda* also are inapt analogies to a patent term that starts on a date certain and lasts for a specified term. Yes, "sell by" dates for milk normally allow the milk to be sold until the end of the stated day, and drivers' licenses typically extend through the end of the stated date. But patents do not work that way. Patents have issuance

[6] Notably, the order issued in *Takeda* stated that "although Teva is enjoined from launching its commercial generic product until November 11, 2009, the FDA may grant its Final Approval for said product today, November 10, 2009 [the final day of pediatric exclusivity]." Bloodworth Decl., Ex. 8 (*Takeda Pharm. Co. v. Teva Pharm. USA, Inc.*, No. CIV. 06-33-SLR, ECF No. 193 (D. Del. Nov. 10, 2009)),

dates, and the terms of patents of the vintage relevant here run for 17 years from that date, absent any disclaimer or extension. Because the issuance date is part of the patent term, the public is free to practice them starting at the beginning of the same day 17 years later.[7]

Similarly here, Daiichi's patent term expired at midnight on April 25, 2016, and its Pediatric Exclusivity period will expire exactly six months later, at midnight on October 25, 2016. As the Federal Circuit has recognized, "Mylan's earliest date of market entry—the earliest effective date of any FDA approval for Mylan—is October 25, 2016, six months after the expiration date of the '599 patent." *Apotex v. Daiichi Sankyo*, 781 F.3d at 1359.

III. DAIICHI'S MOTION IS IMPROPER UNDER RULE 60(a) AND BARRED BY LACHES

Even if Daiichi had a valid legal argument (it does not), this Court should deny the motion because Rule 60(a) is not a proper vehicle to make a substantive change to a judgment and because Daiichi unduly delayed in filing the motion, causing great prejudice to Mylan.

A. Rule 60(a) is not a proper vehicle to alter the substance of a judgment

Rule 60(a) authorizes courts to "correct a clerical mistake or a mistake arising from oversight or omission" in a judgment. As the Third Circuit has recognized, Rule 60(a) does not afford "a perpetual right to apply different legal rules or different factual analyses to a case. It is only mindless and mechanistic mistakes, minor shifting of facts, and no new additional legal perambulations which are reachable through Rule 60(a)." *Pfizer*, 422 F.3d at 130. Accordingly, courts in this district routinely reject Rule 60(a) motions when they seek to alter the substantive relationship between the parties. *See, e.g.*, *Malik v. Hannah*, No. CIV. 05-3901 JBS/JS, 2012 WL 359747, at *6 (D.N.J. Feb. 2, 2012) (Rule 60(a) motion improper because it was "clearly

[7] Birthdays provide a better analogy. If a child was born on November 1, 1996 and the state drinking age is 21, she is free to order a beer and celebrate at midnight on November 1, 2016. She need not wait until the day after her birthday because her date of birth counts toward the 21 years.

seeking to substantively alter" an order and not simply seeking to correct a mere clerical error); *Days Inn Worldwide, Inc. v. JPM, Inc.*, No. 13-3017 KM, 2015 WL 5474882, at *5 (D.N.J. Sept. 15, 2015) (purported errors in liquidated damages and interest calculations were "not the kind of clerical mistake that can be corrected without reopening the merits" as Rule 60(a) was "not intended to reach claims of this kind"); *see also Oriakhi v. Wood*, 250 F. App'x 480, 481 (3d Cir. 2007) (affirming district court's denial of Rule 60(a) motion as merely an attempt to "re-open a final judgment").

Daiichi claims that Rule 60(a) is a proper vehicle here because it merely seeks to "clarify" the date on which Mylan is "free to launch." But Daiichi does not merely seek to clarify Mylan's launch date; it improperly requests a *substantive change* to the August 2009 final judgment, extending the injunction and barring Mylan from doing things that it is currently entitled to do, including manufacturing its generic product and engaging in pre-launch activities that FDA permits. That is not a proper use of Rule 60(a).

Daiichi contends (at 12) that Rule 60(a) applies because the August 2009 judgment supposedly contains an alleged "unintended ambiguity that obfuscates the court's original intent." Not so. As detailed above, the August 2009 final judgment unambiguously stated that Mylan was enjoined from making, using, selling, offering for sale, and importing the patented compound only "until the expiration date of the '599 patent, including all extensions thereof." ECF No. 143. Daiichi now tries to repackage FDA Pediatric Exclusivity as a patent term extension, but that ruse cannot mask the fact that it is trying to make a substantive change to the term of the injunction. The various out-of-circuit cases relied on by Daiichi are thus inapposite.[8]

[8] *See Sartin v. McNair Law Firm PA*, 756 F.3d 259, 265-66 (4th Cir. 2014) (district court properly amended judgment under Rule 60(a) to specify that sanctions were against an attorney personally, rather than the plaintiff generally, where the transcripts confirmed that the court

B. Laches bars the relief requested by Daiichi because it unduly delayed in filing its motion and Mylan would be highly prejudiced

Finally, even if Daiichi's motion had arguable merit and even if Rule 60(a) were a proper vehicle, the Court should deny the motion on grounds of laches. Laches bars relief where the plaintiff has unduly delayed and that delay has substantially prejudiced the defendant. *See EEOC v. Great Atl. & Pac. Tea Co.*, 735 F.2d 69, 80 (3d Cir. 1984); *see also Kaufhold v. Caiafa*, 872 F. Supp. 2d 374, 379 (D.N.J. 2012). Here, Daiichi waited far too long to file this motion, and granting relief now would be highly prejudicial to Mylan.

This Court issued its final judgment in August 2009, and FDA granted Daiichi Pediatric Exclusivity in October 2009. If Daiichi had wanted to assert that FDA's grant of Pediatric Exclusivity extended the term of the '599 patent and thereby extended the term of the patent-law

---

intended to sanction the attorney himself and not the party); *Argo Dutch Indus. Ltd. v. United States*, 589 F.3d 1187, 1192 (Fed. Cir. 2009) (district court properly amended an injunction to correct the timing of liquidation of imported goods where both parties and the court agreed the amendment comported with the original intent of the order); *Klingman v. Levinson*, 877 F.2d 1357 (7th Cir. 1989) (where judgment against debtor was nondischargeable, Rule 60(a) was the appropriate avenue to amend it to specify that interest on that judgment was also non-dischargeable); *McNickle v. Bankers Life & Cas. Co.*, 888 F.2d 678, 681-82 (10th Cir. 1989) (allowing amendment of judgment to address prejudgment interest); *Garamendi v. Henin*, 683 F.3d 1069 (9th Cir. 2012) (allowing amendment of judgment to clarify terms so that judgment could be enforced in France where amendments did not alter substantive terms and merely clarified the original intent of original judgment); *In re Walter*, 282 F.3d 434, 440-41 (6th Cir. 2002) (allowing amendment of judgment to remove debtor's ex-husband from a bankruptcy order where a clerical error had rendered the judgment unclear and the court's intent was to remove ex-husband); *see also Alcon*, 2010 WL 3081327, at *1 (Rule 60(a) was a proper vehicle to clarify an original judgment that was silent regarding ANDA approval by including the date FDA could approve defendants' ANDA and not otherwise altering the rights of the parties).

Even *Takeda* does not support the broad relief that Daiichi seeks. In that case, the original judgment delayed approval of defendants' ANDA until "no earlier than the date of [patent] expiration … and any pediatric exclusivity," and the district court clarified the dates on which FDA could approve an ANDA and the defendant could launch its generic product. But the court did *not* alter any provisions related to the defendants' right to, for example, manufacture and import its product after patent expiration, as permitted under the original final order. *See* 2009 WL 3738738, at *1.

injunction against Mylan to October 25 or 26, 2016, Daiichi should have taken action at that time. Instead, Daiichi sat and waited for almost seven years.

Daiichi certainly should have moved for relief before April 25, 2016, the date on which all parties and FDA had previously agreed that the patent would expire. And it was completely inexcusable for Daiichi to delay filing its motion until just a month before the disputed October 25, 2016 date. Daiichi cannot blame any change in law because its primary authority, *Takeda*, was decided in November 2009. If Daiichi thought that the Federal Circuit's April 2015 decision in *AstraZeneca v. Apotex* created doubt rather than resolving the issue, it at least could and should have moved at that time.

Daiichi's dilatory behavior is highly prejudicial to Mylan. Mylan understood that the patent and the injunction against it expired on April 25, 2016, leaving it free to engage in manufacture and other pre-marketing activities that are prohibited during the term of a patent but are allowed when an ANDA holder is merely waiting for FDA launch approval. Daiichi never disputed Mylan's ability to engage in pre-launch activities starting on April 25, 2016, or that Mylan could receive FDA approval and launch on October 25, 2016. To the contrary, Daiichi told both the Supreme Court and the district court presiding over the lawsuit by Apotex against both Mylan and Daiichi that "the date [Mylan] first markets its ANDA product can be no earlier than *October 25, 2016*." Pet. for Writ of Cert., *Daiichi Sankyo Co. v. Apotex Inc.*, No. 15-281, at 6 (U.S. Sept. 8, 2015) (attached as Bloodworth Decl. Ex. 9); Memo in Opp. to Apotex's Mots.for Summ. J., *Apotex Inc. v. Daiichi Sankyo Co.*, No. 12-cv-9295, ECF No. 116, at 6 (N.D. Ill. Oct. 16, 2015) (attached as Bloodworth Decl. Ex. 10).

Again, the stakes here are not simply "one day"—October 25 versus October 26. Daiichi seeks to retroactively enjoin Mylan from manufacturing and other pre-launch activities during

the entire six-month Pediatric Exclusivity period. Through delay in bringing this motion, Daiichi is seeking to harm Mylan to Mylan's prejudice. To allow Daiichi to lie in wait until shortly before October 25 and then spring into action to block Mylan from exercising rights that Mylan had every reason to think it has had since April 25 would be highly inequitable.

CONCLUSION

Daiichi's motion is both unfounded and improper. In view of Daiichi's efforts to cloud Mylan's rights, Mylan asks the Court to deny the motion immediately and issue any explanatory opinion in due course.

Respectfully submitted,

SAIBER LLC

Attorneys for Defendants,
Mylan Pharmaceuticals Inc.,
Mylan Laboratories Inc.,
Matrix Laboratories, Ltd. and
Mylan Inc.

By: /s/ Arnold B. Calmann

Arnold B. Calmann (abc@saiber.com)
Jeffrey Soos (js@saiber.com)
Katherine A. Escanlar (kae@saiber.com)
One Gateway Center, 10th Floor
Newark, New Jersey 07102-5311
(973) 622-3333 (telephone)
(973) 286-2465 (facsimile)

Shannon M. Bloodworth
(sbloodworth@perkinscoie.com)
PERKINS COIE LLP
700 13th Street, N.W., Suite 600
Washington, DC 20005-3960
(202) 654-6200 (telephone)
(202) 654-6211 (facsimile)

Autumn N. Nero (anero@perkinscoie.com)
Melody K. Glazer
(mglazer@perkinscoie.com)
PERKINS COIE LLP
One East Main Street, Suite 201
Madison, WI 53703
(608) 663-7460 (telephone)
(608) 663-7499 (facsimile)

Dated: October 7, 2016