William J. O'Shaughnessy
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry St.
Newark, New Jersey 07102
Phone: (973) 622-4444
Facsimile: (973) 624-7070

Of Counsel:
Dominick A. Conde
Nina Shreve
Josh Calabro
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104
Tel. 212.218.2100
Fax 212.218.2200

Attorneys for Plaintiffs
DAIICHI SANKYO COMPANY, LIMITED
and DAIICHI SANKYO, INC.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DAIICHI SANKYO COMPANY, LIMITED and DAIICHI SANKYO, INC., Plaintiffs and Counterclaim Defendants, v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES INC., MATRIX LABORATORIES LTD., and MYLAN INC. Defendants and Counterclaim Plaintiffs.	Civil Action Nos. 2:06-3462, 07-3039, and 08-2752 (WJM)(MF) (Consolidated) **PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR FED. R. CIV. P. 60(a) MOTION FOR CLARIFICATION OF FINAL JUDGMENT OF AUGUST 6, 2009**

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I. Introduction

Plaintiffs ("Daiichi Sankyo") ask this Court to resolve a dispute between them and Defendants ("Mylan") over when, consistent with the Judgment entered herein on August 6, 2009 (D.I. 143), Mylan can begin marketing its generic versions of Daiichi Sankyo's patented olmesartan medoxomil blood pressure medicines BENICAR®, BENICAR HCT® and AZOR® (collectively, "the olmesartan medoxomil products"). The dispute is over one day—October 25, 2016, as Mylan contends, or October 26, as Daiichi Sankyo contends. But it is significant, as North American sales of Daiichi Sankyo's olmesartan medoxomil products average over $2.2 million per day. *See* Calabro Decl. Ex. A at 2 of 2.

The Judgment enjoins Mylan from making, using, and selling its generic olmesartan medoxomil products until the expiration date of Daiichi Sankyo's U.S. Patent No. 5,616,599 ("the '599 patent") and "all extensions" thereof. The Judgment does not include the precise date when Mylan would be free of restraints on its generic olmesartan medoxomil products. In fact, in light of the pediatric exclusivity extension granted by the FDA, that date is October 26, 2016, *i.e.*, the day **after** expiration of Daiichi Sankyo's pediatric exclusivity period for the '599 patent. That extension of exclusivity had not yet been granted when this Court's Judgment was entered. Mylan asserts it can launch one day earlier (on October 25) and contends that "all extensions" of the '599 patent does not include pediatric exclusivity, and that Mylan has thus been free of the injunction restraints since April 25, 2016, when the '599 patent originally would have expired without the pediatric exclusivity extension.

Mylan is wrong. Courts have ruled that a generic drug manufacturer is only free to launch after pediatric exclusivity has ended, *i.e.*, after all extensions have expired. *Takeda Pharm. Co. v. Teva Pharms. USA, Inc.*, No. 06-33-SLR, 2009 WL 3738738, at *3 (D. Del. Nov. 9, 2009) (the patent owner "should continue to get the benefit of its exclusive rights until the day

after the patent and its related period of exclusivity expires.") (emphasis added). Thus, if it launches on October 25, Mylan will violate the Judgment.

In support of its recently-stated position, Mylan mistakenly relies on *AstraZeneca AB v. Apotex Corp*., 782 F.3d 1324 (Fed. Cir. 2015), which does not address the issue presented here and, if anything, supports Daiichi Sankyo's position. There, the Federal Circuit cited with approval a district court's "order resetting [the generic's] ANDA effective date" to the end of the pediatric exclusivity period. *Id.* at 1341.

Accordingly, by this application, Daiichi Sankyo respectfully seeks a revised Judgment pursuant to Fed. R. Civ. P. 60(a) that expressly sets forth October 26, 2016 as the earliest date that Mylan can market its generic olmesartan medoxomil products.

II. Background

Daiichi Sankyo holds approved New Drug Applications Nos. 21-286 (BENICAR®), 21-532 (BENICAR HCT®) and 22-100 (AZOR®). Mylan filed three Abbreviated New Drug Applications ("ANDAs") seeking Food and Drug Administration ("FDA") approval to manufacture and sell generic copies of these products before expiration of the '599 patent-in-suit. With each ANDA, Mylan filed a Paragraph IV certification that the '599 patent was invalid and not infringed by Mylan's generic olmesartan medoxomil product. *See* 21 U.S.C § 355(j)(2)(A)(vii)(IV).

In response, Daiichi Sankyo filed the three listed actions against Mylan, which this Court consolidated. Because Mylan stipulated to infringement, the only issue at trial was validity. After a ten-day bench trial, this Court upheld the validity of the '599 patent (D.I. 139) and entered Judgment on August 6, 2009. The Judgment states:

> [P]ursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval by the United States Food and Drug Administration of Mylan's Abbreviated New Drug Applications ("ANDA") Nos. 78-276, 78-827, and 90-398 shall be a date which is

> not earlier than the expiration date of the '599 patent, including all extensions thereof . . . .
>
> [P]ursuant to 35 U.S.C. § 271(e)(4)(B), Mylan, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, are 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 ANDA Nos. 78-276, 78-827, and 90-398 . . . .

D.I. 143 at 2-3.[1]

At the time the Court entered its Judgment, Daiichi Sankyo's submission to the FDA concerning pediatric exclusivity for its olmesartan medoxomil products was still pending.[2] Subsequent to entry of Judgment, in October 2009, the FDA granted pediatric exclusivity, thereby extending Daiichi Sankyo's market exclusivity for an additional six months beyond the date the '599 patent would otherwise expire, from April 25, 2016 to October 25, 2016. Calabro Decl. Ex. B at 7 of 11 (no. 141); Ex. C (FDA Orange Book entry for olmesartan medoxomil tablets showing October 25, 2016 under "Patent Expiration" for Patent No. "5616599*PED").

On September 8, 2016, Daiichi Sankyo requested that Mylan "confirm the parties' understanding of when Mylan will be free of the restraints imposed in Judge Martini's August 6, 2009 judgment," namely, on October 26, 2016. *See* Calabro Decl. Ex. D. Mylan responded a week later and disagreed with Daiichi Sankyo's interpretation of the Judgment. Mylan stated its opposition to the present motion based on two grounds. First, according to Mylan, the Federal Circuit's 2015 *AstraZeneca* decision held that pediatric exclusivity does not extend the patent term, and therefore the language in the 2009 Judgment concerning "the expiration date of the

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[1] Mylan appealed the Court's Judgment, and the Federal Circuit affirmed. *See* D.I. 149.

[2] If the FDA requests that a patent owner conduct studies of a drug in the pediatric population, and the patent owner completes the studies, the patent owner is eligible for an additional six-month period of market exclusivity that begins on the day after the patent would otherwise expire. *See* 21 U.S.C. § 355a.

'599 patent, including all extensions thereof," does not include Daiichi Sankyo's pediatric exclusivity period. Mylan therefore believes that the restraints in the Judgment lapsed on April 25, 2016 when the '599 patent otherwise expired except for pediatric exclusivity. Second, Mylan claimed Daiichi Sankyo's motion was untimely.

Mylan is wrong on both counts.

III. Argument

A. The Court should confirm that the restraints in the Judgment extend up to and including October 26.

Daiichi Sankyo respectfully asks the Court to confirm in a revised Judgment that the earliest date Mylan may obtain FDA approval and commercially release its generic olmesartan medoxomil products is October 26, 2016.

An October 25, 2016 Mylan launch date violates the Federal Food, Drug, and Cosmetic Act ("FDCA"), which states that "the period during which an [ANDA] application may not be approved . . . shall be extended [based on pediatric exclusivity] by a period of six months after the date the patent expires (including any patent extensions)." 21 U.S.C. § 355a(b)(1)(B)(i)(II). The FDCA is phrased as a negative and bars the FDA from approving Mylan's ANDAs during Daiichi Sankyo's exclusivity period, a period which extends six months after the '599 patent would otherwise expire on April 25, 2016, *i.e.*, **up to and including** October 25, 2016. *See also* Calabro Decl. Ex. E, at 1; Ex. F, at 1; Ex. G, at 1, 3 (U.S. Patent and Trademark Office decisions indicating that a patent expires at midnight on the date of expiration). October 26, 2016 therefore is the earliest date that FDA may approve Mylan's ANDAs for generic olmesartan medoxomil products.

Courts that have addressed this issue have reached the same conclusion: "(1) there should be no overlap between the expiration of a patent's exclusivity period and the commencement of a

generic's period of marketing exclusivity; and (2) [the patent owner] should continue to get the benefit of its exclusive rights until the day **after** the patent and its related period of exclusivity expires." *Takeda Pharm. Co. v. Teva Pharms. USA, Inc.*, No. 06-33-SLR, 2009 WL 3738738, at *3 (D. Del. Nov. 9, 2009) (emphasis added); *see, e.g., Wyeth v. Teva Pharms. USA Inc.*, No. 04-2355 (JLL), 2010 WL 3211126, at *3-*4 (D.N.J. Aug. 13, 2010) (ordering that the effective date for FDA approval of an ANDA shall not be earlier than the day **after** expiration of pediatric exclusivity); *Alcon, Inc. v. Teva Pharms. USA, Inc.*, No. 06-234, 2010 WL 3081327, at * 1 (D. Del. Aug. 5, 2010) (same). The Court in *Takeda* grounded its holding in "common sense" as well as lack of prejudice to the generic manufacturer, whose 180-day exclusivity period would not be shortened if it commenced one day later. *Id.* at *2. The Court also noted that the patent owner would suffer significant harm if the generic manufacturer launched its product a day early. *Id.* at *2 n.3. The same would be true here, as North American sales of Daiichi Sankyo's olmesartan medoxomil products average over $2.2 million per day. *See* Calabro Decl. Ex. A at 2 of 2.

Accordingly, to ensure that Mylan complies with the Court's Judgment, Daiichi Sankyo respectfully requests a revision of paragraphs five and six from:

> [P]ursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval by the United States Food and Drug Administration of Mylan's Abbreviated New Drug Applications ("ANDA") Nos. 78-276, 78-827, and 90-398 shall be a date which is not earlier than the expiration date of the '599 patent, including all extensions thereof . . . .
>
> [P]ursuant to 35 U.S.C. § 271(e)(4)(B), Mylan, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, are 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 ANDA Nos. 78-276, 78-827, and 90-398 . . . .
>
> to:

> [P]ursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval by the United States Food and Drug Administration of Mylan's Abbreviated New Drug Applications ("ANDA") Nos. 78-276, 78-827, and 90-398 shall be no earlier than October 26, 2016, the day after expiration of the '599 patent, including all extensions thereof . . . .
>
> [P]ursuant to 35 U.S.C. § 271 (e)(4)(B), Mylan, its officers agents, servants and employees, and those persons in active concert or participation with any of them, are enjoined until October 26, 2016, the day after expiration 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 ANDA Nos. 78-276, 78-827, and 90-398.

See Plaintiffs' Proposed Revised Judgment, attached hereto as Exhibit 1.

Resolution of this issue in advance of October 25, 2016 will promote judicial economy by obviating the need for what could be a complex hearing on damages. And confirming the duration of the restraints in the Judgment will benefit all parties.

B. The Judgment presumptively extends the restraints through any pediatric exclusivity period.

During the parties' recent discussion of the issues raised by this motion, Mylan did not assert the *Takeda* case was incorrectly decided.[3] Instead, Mylan alleged the restraints in the Judgment lapsed on April 25, 2016 because those restraints do not extend through Daiichi Sankyo's pediatric exclusivity period. Not so. It is well-settled that, in cases brought under the Hatch Waxman Act, Courts order that FDA approval of an ANDA not become effective until after expiration of any pediatric exclusivity that attaches to a valid and infringed patent. *See, e.g.*, *Wyeth*, 2010 WL 3211126, at *3-*4 (ordering "the effective date of any final approval of [Defendant's] ANDA 78-281 shall be a date which is not earlier than January 20, 2011, the first

[3] Plaintiffs are not aware of another case besides *Takeda* that squarely addressed the issue of whether a manufacturer is free to launch its generic drug on the day **of** patentee's exclusivity expiration or the day **after** patentee's exclusivity expiration.

day after the date on which Plaintiffs' pediatric exclusivity period ends," citing "ample case law supporting this Court's power to enforce grants of pediatric exclusivity."); *Alcon*, 2010 WL 3081327, at * 1 ("[T]he court must order that the FDA not approve Teva's ANDA prior to the September 29, 2019 expiration date of the '830 patent. In addition, Alcon was granted a pediatric exclusivity period for six months following expiration of the '830 patent. . . . Accordingly, it is appropriate for the court to order that the FDA not approve ANDA No. 78-073 until March 30, 2020."); *Janssen Prods., L.P. v. Lupin Ltd.*, 109 F.Supp.3d 650, 708-09 (D.N.J. 2014) ("Because Lupin's ANDA products infringe claim 4 of the '645 Patent, and that claim is valid, this Court will enter an order under 35 U.S.C. § 271(e)(4)(A) directing the FDA not to approve Lupin's ANDA until after the expiration of the '645 Patent and any associated period of pediatric exclusivity."), modified, 2016 WL 1029269 (D.N.J. Mar. 15, 2016); *see* 35 U.S.C. § 271(e)(4)(A) ("[T]he 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 the expiration of the patent which has been infringed.") (emphasis added).

Courts likewise routinely enjoin generic manufacturers from launching their proposed ANDA products during a patent owner's pediatric exclusivity period. *See, e.g.*, *Takeda*, 2009 WL 3738738, at *1, *3 ("[T]he FDA[] granted an additional six months of pediatric exclusivity, extending Takeda's market exclusivity through November 10, 2009 . . . . Accordingly, the court clarifies that, by its Final Judgment Order (D.I. 186), November 11, 2009 is the earliest effective date upon which Teva may launch its commercial generic product."); *see Takeda*, No. 06-33-SLR, Order (D.I. 193) (D.N.J. Nov. 10, 2009) (attached as Calabro Decl. Ex. H) ("Teva is enjoined from launching its commercial generic product until November 11, 2009. . . .").

The Judgment here both (1) sets the effective date for any approvals of Mylan's ANDAs after the expiration of the '599 patent, **including any extensions thereof**, and (2) enjoins Mylan from launching its generic olmesartan medoxomil products until after the expiration of the '599 patent, **including any extensions thereof**. D.I. 143 at 2-3. Consistent with the cases above, "extensions" includes the pediatric exclusivity that was granted by the FDA shortly after the Court entered Judgment. Otherwise, both restraints would have lapsed at a time (April 2016) when it is undisputed that (1) FDA could not approve Mylan's ANDAs for generic olmesartan medoxomil products and (2) Mylan could not launch those products.[4] Such interpretation makes no sense and would deprive Daiichi Sankyo of a significant portion of the relief requested in its complaint, *e.g.*, an Order that the "effective date of any approval of . . . Mylan's ANDA . . . be a date which is not earlier than the expiration of the right of exclusivity under the '599 patent, **or any later date of exclusivity to which Plaintiffs become entitled**[.]") D.I. 1 (No. 2:06-3462), at 8 (emphasis added); *see, e.g.*, *McNickle v. Bankers Life and Cas. Co*., 888 F.2d 678, 681-82 (10th Cir. 1989) (ordering correction of judgment under Fed. R. Civ. P. 60(a) to award prejudgment interest where plaintiff requested interest in its complaint and "put the court and the defendant on notice of th[at] specific claim").

During the parties' discussion of the issues raised by this motion, Mylan offered no reason why the Court in this case would have departed from the standard practice of enjoining generic entry through the expiration of pediatric exclusivity. Nor did Mylan explain why Daiichi Sankyo would not have been entitled to the relief it sought in its complaint and earned by prevailing at trial. And Mylan did not cite any precedent where an injunction lapsed at the outset

[4] Mylan does not dispute that the FDA cannot approve Mylan's ANDAs until at least October 25, 2016, and that Mylan must obtain such approval prior to launching its generic olmesartan medoxomil products.

of a pediatric exclusivity period, as Mylan asserts occurred here. *See Wyeth*, 2010 WL 3211126, at *1, *4 (emphasizing defendant's "fail[ure] to cite a case declining to enter the requested relief," *i.e.*, an order "mandating that the effective dates of [ANDAs] . . . be set for a date after" expiration of pediatric exclusivity).

Rather than identify authority or a reasoned basis for the outcome it urges, Mylan relies instead on a tortured, semantic argument regarding the meaning of patent "extensions."

C. The 2015 *AstraZeneca* decision did not and could not change the intent behind the 2009 Judgment.

Mylan relies on the Federal Circuit's 2015 *AstraZeneca* decision in support of its flawed theory that "the expiration date of the '599 patent, including all extensions thereof," excludes the pediatric exclusivity period for the '599 patent. The argument fails for at least four reasons.

First, a 2015 decision cannot change the intentions behind the Judgment that was entered in 2009, which are the only factual matters properly before the Court now.[5] *See Garamendi v. Henin*, 683 F.3d 1069, 1079 (9th Cir. 2012) ("Rule 60(a) allows for clarification and explanation, **consistent with the intent of the original judgment**, even in the absence of ambiguity, if necessary for enforcement."); *Agro Dutch Indus. Ltd. v. United States*, 589 F.3d 1187, 1192 (Fed. Cir. 2009) ("Courts enjoy broad discretion to correct clerical errors ['or a mistake arising from oversight or omission'] in previously issued orders in order to conform the record to **the intentions of the court and the parties**."); *In re Walter*, 282 F. 3d 434, 440-41 (6th Cir. 2002) ("[A] court properly acts under Rule 60(a) when it is necessary to 'correct mistakes or oversights that cause the judgment to fail to reflect **what was intended at the time of trial** [and] . . . make

[5] In their proposed form of judgments, both Daiichi Sankyo and Mylan used the identical language at-issue—"the expiration date of the '599 patent, including all extensions thereof." *See* D.I. 141-1; D.I. 142-2.

the judgment or record speak the truth.'" (quoting *Vaughter v. Eastern Air Lines, Inc.*, 817 F.2d 685, 689 (11th Cir. 1987)) (emphases added). In 2009, the parties and the Court were well aware of the possibility of additional exclusivities, which were expressly contemplated by the relief sought in Daiichi Sankyo's 2006 complaint (D.I. 1, at 8), and the Judgment was intended to account for those exclusivities. Indeed, the absence of a precise date in the original judgment implies that the Judgment would encompass after-arising extensions such as pediatric exclusivity that had not yet been granted by the FDA.

Second, *AstraZeneca* is inapposite because the Federal Circuit only addressed whether 35 U.S.C. § 284 allowed a patentee to recover royalties based on generic sales during the pediatric exclusivity period, which is not at issue here. *See AstraZeneca*, 782 F. 3d at 1341-45. The Federal Circuit did not, as Mylan contends, foreclose injunctive relief during the pediatric exclusivity period. In fact, it did the opposite. The Federal Circuit in *AstraZeneca* cited with approval the Federal Circuit's prior decision in the same case "affirming the district court's order resetting Apotex's ANDA effective date" to the end of the pediatric exclusivity period. *Id.* at 1341 ("[A]lthough the asserted patents expired on April 20, 2007, the district court ordered that the effective date of Apotex's ANDA approval be set six months later, on October 20, 2007."), citing *In re Omeprazole Patent Litig.*, 536 F.3d 1361 (Fed. Cir. 2008). Thus, to the extent it is relevant, the *AstraZeneca* decision supports Daiichi Sankyo's position.

Third, the Court in *AstraZeneca* could not exclude pediatric exclusivity from the general meaning of patent extensions because earlier Federal Circuit decisions included pediatric exclusivity within the patent term. *Alza Corp. v. Mylan Labs., Inc.*, 391 F.3d 1365, 1368 and n.3 (Fed. Cir. 2004) (case not moot despite fact that patent would have expired but for pediatric exclusivity: "following the Food and Drug Administration's approval of pediatric use of [the

drug], the patent will now expire on January 23, 2005."); *see, e.g.*, *Teva Pharma. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1329 and n.4 (Fed. Cir. 2005) (stating Pfizer's patent "expires on June 30, 2006," and noting "the FDA granted Pfizer a six-month pediatric exclusivity extension for the drug, pursuant to 21 U.S.C. § 355a, making June 30, 2006 the effective expiration date of the patent"), abrogated on other grounds by *MedImmune, Inc. v. Genentech, Inc*., 549 U.S. 118 (2007). And the earlier decisions would control over *AstraZeneca*. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) ("[W]e note that decisions of a three-judge panel of this court cannot overturn prior precedential decisions."); *Kimberly-Clark Corp. v. Ft. Howard Paper Co*., 772 F.2d 860, 863 (Fed. Cir. 1985) ("Counsel is apparently unaware that a panel of this court is bound by prior precedential decisions unless and until overturned *en banc*.").

Fourth, Mylan admitted in a recent case in this District—**after** the Federal Circuit's 2015 *AstraZeneca* decision—that it understood pediatric exclusivity extends the patent term, in accordance with the Federal Circuit's earlier cases. On July 21, 2015, Mylan (through the same counsel involved here) filed a brief opposing a motion for a preliminary injunction in *AstraZeneca AB v. Mylan Labs. Ltd*., No. 12-CV-01378-MLC-TJB, D.I. 222 (D.N.J.) (attached as Calabro Decl. Ex. I). Mylan's brief discusses the Federal Circuit's 2015 *AstraZeneca* decision at length. *Id.* at 22-28. Despite Mylan's awareness of the *AstraZeneca* case at that time, Mylan stated in its brief that "[Plaintiff] currently alleges that Mylan infringes claims of only two [patents]: the '085 patent . . . and '070 patent . . . . These two leftover **patents expire on November 25, 2018, following a period of pediatric exclusivity**." *Id.* at 3 (emphasis added). Therefore, Mylan knew then, as it did before, that pediatric exclusivity extended the term of those patents (which otherwise would have expired on May 25, 2018; *see* Calabro Decl. Ex. J),

just as Mylan understood in 2009 that "the expiration date of the '599 patent, including all extensions thereof," encompassed any pediatric exclusivity period. The Federal Circuit's *AstraZeneca* decision did not change Mylan's understanding of pediatric exclusivity or patent extensions. Mylan's own statements thus undermine its current position and confirm Mylan contrived a theory here solely to wrestle one undeserved day from the exclusivity period that Daiichi Sankyo earned for performing pediatric studies.

D. Daiichi Sankyo timely moved for clarification of the Judgment.

Finally, Daiichi Sankyo's motion is timely because Fed. R. Civ. P. 60(a) allows the Court 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." (emphasis added). Significantly,

> Rule 60(a) is not confined just to fixing typographical and other clerical errors. The Rule's text also authorizes a court to correct "a mistake arising from oversight or omission." Fed.R.Civ.P. 60(a). Such a mistake occurs when there is an inconsistency between the text of an order or judgment and the district court's intent when it entered the order or judgment. **A "mistake arising from oversight or omission" also includes an unintended ambiguity that obfuscates the court's original intent**. Rule 60(a) authorizes a district court to correct either such mistake to conform the text with its original intent.

Sartin v. McNair Law Firm PA, 756 F.3d 259, 265-66 (4th Cir. 2014) (emphasis added); *see Agro*, 589 F. 3d at 1192 ("The trial court's discretion is not limited to the correction of clerical or typographical errors but encompasses the correction of errors needed to comport the order with the original understandings and intent of the court and the parties."). For example, more than one year after the Court in *Takeda* entered its original Judgment, the Court clarified that Judgment to preclude defendant from launching its generic product until the day after pediatric exclusivity expired. *Takeda*, 2009 WL 3738738, at *1; *see Calabro* Decl. Ex. H (entering an Order revising the original Judgment on the same day the defendant had planned to launch its generic product); *see also Alcon*, 2010 WL 3081327, at *1 (clarifying, pursuant to Fed. R. Civ.

P. 60(a), that FDA may not approve an ANDA prior to the day after expiration of pediatric exclusivity); *see, e.g., Klingman v. Levinson*, 877 F.2d 1357, 1359, 1363 (7th Cir. 1989) (finding Fed. R. Civ. P. 60(a) permitted the bankruptcy court to change a "judgment more than a year and a half old which had been affirmed by the district court and court of appeals.")

In September 2016, as Mylan's anticipated launch date approached, Daiichi Sankyo sought Mylan's confirmation that the Judgment barred Mylan from launching prior to October 26. After being informed that Mylan contends it is free to launch one day earlier, based on Mylan's strained interpretation of the Judgment, Daiichi Sankyo promptly filed the present motion. Daiichi Sankyo thus properly and timely invoked Fed. R. Civ. P. 60(a) to clarify the Judgment so that it conforms to the Court's and parties' intent.

IV. Conclusion

For the reasons discussed above, Daiichi Sankyo respectfully requests the Court to issue an Order (in the form attached as Exhibit 1) revising the Judgment (D.I. 143) to expressly set forth October 26, 2016 as the earliest date that Mylan may (1) obtain FDA approval of its ANDAs for generic olmesartan medoxomil products and (2) begin marketing those products.

Respectfully Submitted,

Dated: September 23, 2016

By: /s William J. O'Shaughnessy

William J. O'Shaughnessy
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry St.
Newark, New Jersey 07102
Phone: (973) 622-4444
Facsimile: (973) 624-7070

Of Counsel:
Dominick A. Conde

Nina Shreve
Josh Calabro
FITZPATRICK, CELLA,
HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104
Tel. 212.218.2100
Fax 212.218.2200

Attorneys for Plaintiffs
DAIICHI SANKYO COMPANY, LIMITED
and DAIICHI SANKYO, INC.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR FED. R. CIV. P. 60(a) MOTION FOR CLARIFICATION OF FINAL JUDGMENT OF AUGUST 6, 2009 was caused to be served on September 23, 2016, via ECF and email upon the following:

Arnold B. Calmann
Jeffrey Soos
Katherine A. Escanlar
SAIBER LLC
One Gateway Center, 13th Floor
Newark, New Jersey 07102-5311

David J. Harth
Melody K. Glazer
Autumn N. Nero
David Pekarek Krohn
PERKINS COIE LLP
One East Main Street, Suite 201
Madison, Wisconsin 53703

Shannon M. Bloodworth
PERKINS COIE LLP
607 Fourteenth Street, NW, Suite 800
Washington, D.C. 20005

/s William J. O'Shaughnessy
William J. O'Shaughnessy