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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)

Motion Date: To Be Determined

Oral Argument Requested

PLAINTIFFS' REPLY 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

Daiichi Sankyo's motion only requires resolution of a straightforward dispute over whether pediatric exclusivity earned by Daiichi Sankyo prevents Mylan from launching its generic olmesartan medoxomil products until October 25 or October 26. Mylan cannot (and does not try to) distinguish the *Takeda* case that resolved this dispute in Daiichi Sankyo's favor. Instead, Mylan avoids unequivocal and dispositive statutory text with a debate concerning the precise moment a patent issues and the meaning of "midnight." The Court need not engage with Mylan's academic exercise. The pediatric exclusivity statute bars FDA from approving Mylan's ANDAs for six months "**after the date**" that Daiichi Sankyo's '599 patent-in-suit originally expired. The '599 patent undisputedly expired on April 25, 2016, so FDA cannot approve Mylan's ANDAs for another six months after that date, *i.e.*, from April 26 *through and including* October 25. Mylan's theory that Daiichi Sankyo's pediatric exclusivity period commenced on April 25 contradicts the pediatric exclusivity statute, which plainly states that pediatric exclusivity periods begin the day **after** patent expiration.

Mylan's remaining two arguments misconstrue Daiichi Sankyo's motion. First, Mylan argues that Daiichi Sankyo's motion improperly invokes Rule 60(a) because the motion requests a substantive change to the Judgment. Second, Mylan argues that laches bars Daiichi Sankyo's motion. Both arguments turn on Mylan's

mistaken belief that Daiichi Sankyo "seeks to retroactively enjoin Mylan from manufacturing and other pre-launch activities during the entire six-month Pediatric Exclusivity period," which began on April 26, 2016. Daiichi Sankyo seeks no such relief. Daiichi Sankyo seeks only prospective relief, namely, an order barring Mylan from launching its generic olmesartan medoxomil products before October 26. Thus, Daiichi Sankyo properly requested relief under Rule 60(a) to clarify a dispute over one day. And Mylan's laches argument fails because Mylan does not and cannot allege any prejudice from that one-day difference in Mylan's launch date, which will not curtail Mylan's 180-day exclusivity period.

II. The '599 patent originally expired at the end of April 25, 2016, and the pediatric exclusivity period runs through the end of October 25, 2016.

Mylan makes four flawed arguments in support of its theory that FDA can approve Mylan's ANDAs on the day of, rather than the day after, pediatric exclusivity expiration.

First, Mylan asserts that "FFDCA recognizes that FDA approval may take effect on the same day that the patent term expires." Opp. at 21. But Mylan quotes the wrong statute and relies on irrelevant cases (*Bristol Myers*, *aaiPharma*, *Metoprolol*) applying that statute. 21 U.S.C. § 355(j)(5)(B)(ii) does not govern when FDA can approve Mylan's ANDAs because it does not address pediatric exclusivity. 21 U.S.C. § 355a (not 21 U.S.C. § 355) governs ANDA approval where, as here, FDA awarded pediatric exclusivity to a patentee. That provision

states "[t]he 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." 21 U.S.C. § 355a(b)(1)(B)(i)(II) (emphasis added). Mylan does not dispute that the '599 patent expired on April 25, 2016 (aside from pediatric exclusivity). *See* Opp. at 2 ("[T]he '599 patent expired on April 25.") Regardless of when on April 25 the '599 patent expired, pediatric exclusivity extends the period during which FDA cannot approve Mylan's ANDA by an additional six months "after th[at] date"—from April 26 through and including October 25. Mylan's position that FDA can approve Mylan's ANDAs on October 25 violates the plain language of § 355a, which prohibits FDA from approving Mylan's ANDAs during the six month period that began the day **after**—not the day of—patent expiration.

Second, Mylan alleges that because courts have subject matter jurisdiction over patent cases from the beginning of the day on which a patent issues, the patent term must end at the beginning of the expiration date. According to Mylan, that means Daiichi Sanyo's pediatric exclusivity period also expires at the beginning of the day, and FDA thus can approve Mylan's ANDAs anytime on October 25. Mylan then disparages the *Takeda* decision for failing to "analyze in depth th[is] critical issue here: proper calculation of a patent term." Opp. at 22. But the Court in *Takeda* correctly ignored Mylan's diversion about patent issuance because

patent **expiration** triggers the pediatric exclusivity period. The Court therefore applied its "common sense," and determined FDA could not approve an ANDA until the day after patentee's pediatric exclusivity ended. *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."). The Court did not need to re-calculate a patent term based on the alleged minute or second a patent issues, as Mylan tries to do here. Indeed, one of Mylan's cited cases expressly disavows extrapolating a patent term based on the Court's mere recognition that a case or controversy existed at 12:07 am on the date of patent issuance: "how the law measures the length of a patent's protection is not the same question as whether a patent was in existence at the time a complaint was filed" for purposes of subject matter jurisdiction. *Encore Wire Corp. v. Southwire Co*., No. 10-cv-86-BMGL, 2011 WL 833220, at *2 (N.D. Ga. Mar. 4, 2011).

Mylan thus lacks authority for its interpretation of patent terms that would compel a different result here than in *Takeda*. In fact, one court has expressly rejected Mylan's position that patents expire at the start of a day. *Abbott Labs. v. Sandoz, Inc*., 486 F. Supp.2d 767 (N.D. Ill. 2007), involved the same dispute at-issue here: "Plaintiffs and Defendants . . . agree that the '334 Patent expires on May 6, 2007. The question is: When on May 6th? Plaintiffs assert that the term

runs through the end of May 6th (i.e., midnight May 6, 2007). [Defendant] contends it expires at the start of May 6th, providing, in essence, no patent protection on May 6th." (Calabro Decl. Ex. A, at 4 of 11.) The court agreed with plaintiffs and held that "the '334 patent expires on May 6, 2007 at 11:59 p.m., EDT." *Abbott*, 486 F. Supp.2d at 768.

Third, Mylan dismisses the *Takeda* decision, which granted the precise relief Daiichi Sankyo seeks, because the Court allegedly relied on "inapt analogies." Opp. at 23 (stating the "Patent Act is different," and "patents do not work that way."). Rather than look to the patent statutes, as Mylan asserts the Court in *Takeda* should have done, Mylan makes its own inapt analogy to birthdays, and the legality of alcohol consumption at the beginning of one's twenty-first birthday. Opp. at 24 n.7. But Mylan does not even try to explain why an irrelevant cultural custom should override uniform judicial and PTO precedent recognizing that time periods in patent statutes extend through and include their expiration date.

For example, a non-provisional patent application filed "not later than 12 months **after the date** on which the provisional application was filed," benefits from the earlier application filing date. 35 U.S.C. § 119(e)(1). Although section 119 contains the same "after the date" language used in the pediatric exclusivity statute, Courts do not parse whether an application was filed at the beginning or end of a day, as Mylan does here. Nor do Courts exclude the one-year anniversary

date from the time to file a non-provisional application. To the contrary, twelve months "after the [filing] date" of a provisional application includes the full day that is exactly one year after the provisional application filing date—irrespective of the precise filing time of either application. *See, e.g., UCB, Inc. v. Accord Health., Inc.*, No. 13-1206-LPS, 2016 WL 4376346, at *26, *47-*48 (D. Del. Aug. 15, 2016) (non-provisional application timely filed Monday, March 17, 1997 because applicant filed a provisional application on March 15, 1996 and March 15, 1997 fell on a Saturday). Applicants rely on that well-settled law and routinely file non-provisional applications one year after filing a provisional application. *Bayer Schering Pharma AG v. Barr Labs., Inc.*, No. 05-2308, 2008 WL 628592, at *12 (D.N.J. Mar. 3, 2008) ("On August 31, 1999, Bayer filed a provisional application for a patent for the oral contraceptive, and exactly one year later [on August 31, 2000, *see* Calabro Decl. Ex. C, at (22)], the final application for the '531 Patent was filed."); *see also Switzer v. Sockman*, 333 F.2d 935, 940 (C.C.P.A. 1964) (holding "that the Switzer et al. application serial No. 484,319, filed on January 26, 1955 . . . was filed prior to one year from the January 26, 1954 date on which the Sockman et al. patent was granted within the meaning of 35 U.S.C. § 135" for presenting claims to provoke an interference); Calabro Decl. Ex. B, at 5 of 8 [MPEP § 2304.02(c)] ("[T]he expression 'prior to one year from the date on which the patent was granted' in 35 U.S.C. 135(b) includes the one-year anniversary date

of the issuance of a patent."). Adopting Mylan's theory would upset established interpretations of patent laws and cast doubt on whether time periods extend through their expiration date and permit action on the day of a deadline. *See Immersion Corp. v. HTC Corp*., 826 F.3d 1357, 1365 (Fed. Cir. 2016) ("[R]epeated, consistent . . . judicial and agency interpretations . . . provide a powerful reason to read [a patent statute] to preserve, not upset, the established position.")

Fourth, Mylan admits Daiichi Sankyo's authority—PTO decisions on maintenance fees—"is correct" that patents expire at midnight on the date of expiration (Opp. at 21), but Mylan contends that the PTO considers "midnight" the beginning of the day. Here too, Mylan is wrong. Pursuant to 37 C.F.R. 1.362(g), a "patent which expires for the failure to pay the maintenance fee will expire **at the end** of the same date (anniversary date) the patent was granted in the 4th, 8th, or 12th year after grant." (emphasis added) (Calabro Decl. Ex. D). Moreover, the PTO stated in connection with patent term legislation that patents remain "in force" on their expiration date:

> Q. What is the critical date on which a patent must be in force in order to be entitled to the longer of the 17 or 20-year patent term?
> A. June 8, 1995. . . .
> Q. If a patent expires on June 8, 1995, is it "in force" for the purpose of the 17/20 provision?
> A. Yes, the patent expires at midnight on June 8, 1995.

Calabro Decl. Ex. E, at 14, 16. Those statements and regulations are "consistent with ordinary English usage of the word 'midnight' on a given day as being the end rather than the beginning of that day." *S. New Jersey Rail Grp., LLC v. Lumbermens Mut. Cas. Co*., No. 06-4946, 2007 WL 2296506, at *11 (S.D.N.Y. Aug. 13, 2007) (citation omitted). For example, the IRS website explains that "[i]f April 15 falls on a weekend or legal holiday, you have until midnight the next business day following April 15 to timely file . . . your tax return." Calabro Decl. Ex. F. The IRS did not need to specify that midnight is the end of the day because that is the common knowledge; taxpayers understand they can file returns anytime on the due date. Indeed, Mylan's opposition was due at midnight on October 7, and would have been untimely under Mylan's theory that midnight is the beginning of a day because Mylan did not file its brief until after 4 pm on October 7. L. Civ. R. 5.2(5).

Mylan misplaces reliance on two cases for its definition of midnight. Opp. at 21. The Court in *Ranbaxy Labs. Ltd. v. FDA*, 307 F. Supp. 2d 15, 19, 21 (D.D.C. 2004), merely recognized that patents expire at midnight, but did not, as Mylan urges, redefine "midnight" to mean the beginning rather than the end of the day. And *Justice v. Town of Cicero, Ill.*, 682 F.3d 662, 664 (7th Cir. 2012), undermines Mylan's theory, holding that "litigants have until 11:59 PM" for filings due "at midnight."

Accordingly, Mylan's timeline (D.I. 157-2) is irrelevant and incorrect. The '599 patent originally expired at the end of April 25, 2016, and Daiichi Sankyo's pediatric exclusivity period expired at the end of October 25, 2016. October 26, 2016 is the first day that: (1) FDA can approve Mylan's ANDA, and (2) Mylan can launch its generic products.

III. Daiichi Sankyo properly and timely moved under Rule 60(a).

Mylan characterizes Daiichi Sanyo's motion as a "belated" "ruse" that improperly invokes Rule 60(a) because Daiichi Sankyo does not seek correction of a "clerical error, [or] a copying or computational mistake." Opp. at 10, 24-25, quoting *Pfizer Inc. v. Uprichard*, 422 F.3d 124 (3d Cir. 2005). But Rule 60(a) permits correction of "mistake[s] arising from oversight or omission"—not just clerical errors—which can be corrected "whenever one is found in a judgment." The Third Circuit in *Pfizer* did not excise that language from Rule 60(a), as Mylan would have this Court believe. *See* Opp. at 25 (dismissing "out-of-circuit cases relied on by Daiichi [Sankyo]" as "inapposite.") Mylan misplaces reliance on *Pfizer* and ignores decisions from courts in this Circuit that granted, pursuant to Rule 60(a), the precise relief Daiichi Sankyo seeks.

In *Takeda*, a court in this Circuit granted a motion to clarify a judgment filed more than one year after judgment was entered and less than two weeks before a disputed launch date. 2009 WL 3738738, at *1, *3. Daiichi Sankyo's similar

motion here was filed more than one month before the disputed launch date. While Mylan repeatedly refers to the "seven years" between the judgment and Daiichi Sankyo's motion, Mylan fails to cite a single case rejecting a motion as untimely under Rule 60(a). Indeed, Mylan's cited cases expressly state that a "Rule 60(a) motion . . . may be filed at any time." *Days Inn Worldwide, Inc. v. JPM, Inc.*, No. 13-3017 KM, 2015 WL 5474882, at *3 (D.N.J. Sept. 15, 2015). Nor does Mylan attempt to reconcile its timeliness argument with the timeline in *Takeda* or the language of Rule 60(a) that permits correction of an error "whenever one is found." Moreover, in *Alcon, Inc. v. Teva Pharms. USA, Inc*., No. 06-234, 2010 WL 3081327, at * 1 (D. Del. Aug. 5, 2010), a court in this Circuit ordered, pursuant to Rule 60(a), that the effective date for FDA approval of an ANDA not be earlier than the day after expiration of pediatric exclusivity. Notably, the original judgment in *Alcon* "did not order [any] injunctive relief or [set] an FDA approval date for [defendant's] ANDA." *Id.* The original judgment here did both, and Daiichi Sankyo seeks only to clarify when those provisions in the original judgment lapse. Thus, Daiichi Sankyo's motion is proper and timely under Rule 60(a). *See United States v. Stuart*, 392 F.2d 60, 62 (3d Cir. 1968) (Rule 60(a) "permits the correction of irregularities which becloud" a judgment).

Mylan glosses over *Takeda* and *Alcon*, and relies instead on inapposite cases that did not involve an ambiguity analogous to the one-day dispute here. In *Pfizer*,

the court exceeded its authority under Rule 60(a) by requiring that defendant sign a settlement agreement as a condition for receiving an arbitration award because neither the arbitration award nor the court's original order required that the defendant sign any agreement. 422 F.3d at 130. *Malik v. Hannah*, No. 05-3901 JBS/JS, 2012 WL 359747, at *5-*6 (D.N.J. Feb. 2, 2012) involved a challenge to the court's substantive determination that equitable tolling of a statute of limitations allowed plaintiff to amend its complaint to add new defendants. In *Oriakhi v. Wood*, 250 F. App'x 480, 481 (3d Cir. 2007), movant "claim[ed] that he did not receive notification of the court's order [and] attempt[ed] to use Rule 60(a) to re-open a final judgment in order to restart the clock for Fed. R. App. P. 4(a) purposes." In *Days Inn*, 2015 WL 5474882, at *4-*5, movant attempted to add liquidated damages to a judgment after movant's claim for such damages had been considered and expressly rejected by the court.

Mylan also mischaracterizes Daiichi Sankyo's motion by assuming that it seeks substantive relief. To the contrary, Daiichi Sankyo seeks no relief with respect to Mylan's manufacture of generic olmesartan medoxomil products. Daiichi Sankyo seeks only an injunction barring Mylan from launching one day too early, and an order setting October 26 as the earliest date for FDA approval of Mylan's ANDAs. Mylan's confusion perhaps stems from Daiichi Sankyo's proposed judgment, which tracks the language in the original judgment here as

well as the clarified judgment proposed by patentee in the *Takeda* case. The Court in *Takeda*, however, did not enter patentee's proposed judgment, and instead issued an order that simply "enjoined [defendant] from launching its generic product" until one day after pediatric exclusivity expiration. D.I. 157-9. That is all we ask of this Court. A similar Order here enjoining Mylan from *launching* its products until October 26 would provide Daiichi Sankyo with all the relief it seeks, and eliminate Mylan's concern about retroactive relief regarding its manufacturing or other *preparations* for launch.

Finally, Mylan correctly states that Courts cannot consider "new additional legal perambulations" under Rule 60(a). Opp. at 24, quoting *Pfizer*, 422 F.3d at 130. But Mylan, not Daiichi Sankyo, needlessly injects new legal perambulations. Mylan does not dispute that the Court properly (1) enjoined Mylan from launching until after the expiration of the '599 patent and any extensions of that date, and (2) ordered FDA approval of Mylan's ANDA not become effective until after the expiration of the '599 patent and any extensions of that date. Mylan also agrees it cannot launch until at least October 25 because FDA cannot approve Mylan's ANDA before that date. Daiichi Sankyo's motion thus raises a straightforward Rule 60(a) dispute over one day: whether Mylan can obtain FDA approval and launch on October 25 or October 26.

Because Mylan could not distinguish the three decisions (D.I. 154-1, at 4-5,

citing *Takeda*, *Wyeth*, and *Alcon*) that resolved the one-day dispute in Daiichi Sankyo's favor, Mylan developed a nonsensical theory that the restraints in the judgment lapsed six months before the enjoined activity (Mylan's launch) could occur. Not surprisingly, Mylan found no case where a Court ordered that FDA approval could become effective and a generic manufacturer could launch at the start of pediatric exclusivity. Mylan therefore cobbled together a new improper legal argument. First, Mylan relies on the 2015 *AstraZeneca* case that refused to award damages during the pediatric exclusivity period, which is neither at-issue here nor probative of intentions behind a 2009 judgment. *See* D.I. 154-1, at 9-12. Second, Mylan relies on FDA Guidance stating that pediatric exclusivity "is not a patent term extension under 35 U.S.C. § 156." Opp. at 15. But 35 U.S.C. § 156 addresses patent extensions due to FDA delay. The Judgment here does not cite 35 U.S.C. § 156 (or 35 U.S.C. § 154) and is not limited to those types of patent extensions. Third, Mylan relies on *Altana Pharma AG v. Teva Pharm. USA, Inc*., No. 04-2355 JLL, 2012 WL 2068611, at *2 (D.N.J. June 7, 2012), which analyzed whether royalties collected during the pediatric exclusivity period could give rise to patent misuse. But this case does not involve royalties or patent misuse. Mylan's attempt to retroactively define words in the 2009 Judgment to make it inconsistent with cases uniformly setting FDA approval and/or launch dates at the

end of pediatric exclusivity periods, should be rejected.[1]

IV. Mylan suffered no prejudice that could give rise to laches.

Mylan's laches argument fails because Mylan alleges prejudice based solely on Mylan's mistaken belief that Daiichi Sankyo seeks retroactive relief. Mylan does not contend that it would suffer prejudice if its launch was pushed back from October 25 to October 26. Nor could it. As explained in *Takeda*, defendant "suffers no prejudice if [the Court] resolve[s] th[is] question in favor of" the patentee because that decision would not curtail defendant's 180-day marketing exclusivity. 2009 WL 3738738, at *3.

Mylan claims prejudice based on Daiichi Sankyo's statements from different cases brought by different ANDA applicants involving a different patent and a different issue, namely, the court's subject matter jurisdiction to adjudicate a dispute over a disclaimed patent. Opp. at 18, 27. And Mylan sloughs off its own concession in another case that patent terms include pediatric exclusivity as "a

[1] Notwithstanding Mylan's argument to the contrary, the Federal Circuit's statement that pediatric exclusivity is part of the patent term was "necessary to the judgment" in *Alza Corp. v. Mylan Labs., Inc*., 391 F.3d 1365 (Fed. Cir. 2004). Opp. at 18. That statement explained why the case was not moot despite the fact that the patent had expired. *Id.* at 1368, n.3 ("[T]his case will be moot after" pediatric exclusivity ends). Mootness is an issue of subject matter jurisdiction that the Court must resolve in every case "before it assumes jurisdiction." *North Carolina v. Rice*, 404 U.S. 244, 246 (1971) (court must resolve mootness; *Powell v. McCormack*, 395 U.S. 486, 496-97 (1969) (court lacks jurisdiction "when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome."); *Hall v. Beals*, 396 U.S. 45, 48 (1969) (decision on the merits of a moot claim would constitute an impermissible advisory opinion.).

passing reference from Mylan's briefing in an unrelated case." Opp. at 18. Yet Mylan never attempts to explain why Daiichi Sankyo's passing references in briefs from unrelated cases are any more relevant. *See Generally Fidelity & Deposit Co. of Maryland v. Hudson United Bank*, 493 F. Supp. 434, 443 (D.N.J. 1980) ("Pleadings may be judicial admissions but only in the cause in which they are made."), *rev'd on other grounds*, 653 F.2d 766, 776 n.12 (3d Cir. 1981) (noting "the district court was correct in not relying on" statements in pleadings from another action). Neither Mylan's launch date, the '599 patent's expiration date, nor the pediatric exclusivity expiration date was at-issue in the *Apotex* or *Sandoz* actions. And, in any event, Daiichi Sankyo's statements, *e.g.*, "the '599 patent expired on April 25, 2016, but remains under a period of marketing exclusivity until October 25, 2016," are not inconsistent with its current position that Mylan cannot launch until October 26.

Mylan also quotes dicta from the Federal Circuit's decision in the unrelated *Apotex* case but ignores that the Federal Circuit also stated "Mylan is presumptively entitled to a period of 180 days of exclusivity—starting whenever, **after October 25, 2016**, it enters the market." *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1360 (Fed. Cir. 2015) (emphasis added).

V. Conclusion

The Court should grant Daiichi Sankyo's motion.

Respectfully Submitted,

Dated: October 14, 2016

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of PLAINTIFFS' REPLY 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 October 14, 2016, via ECF and email upon the following:

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