EXHIBIT 1

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' SUR-REPLY IN OPPOSITION TO PLAINTIFFS' FED. R. CIV. P. 60(a) MOTION

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DAIICHI CONCEDES IT IS NOT ENTITLED TO AN AMENDED INJUNCTION

Daiichi now admits that it is foregoing relief that it included in its proposed revised final judgment. Therefore, entering that form of judgment would be improper, even if this Court sides with Daiichi on the merits of its motion.

On October 14, 2016, Daiichi submitted its reply in support of its motion under Fed. R. Civ. P. 60(a) for "clarification" of this Court's August 6, 2009 final judgment. ECF No. 158. Daiichi's reply brief makes clear that it is no longer seeing to enjoin Mylan from pre-marketing activities, as had been requested in Daiichi's proposed revised final judgment. ECF No. 158 at 12 ("[An] … Order here enjoining Mylan from *launching* its products … [would] eliminate Mylan's concern about retroactive relief regarding its manufacturing or other *preparations* for launch"). Because Daiichi's arguments no longer support its requested relief, Mylan submits this sur-reply and counter proposed revised judgment, filed herewith.

In its reply, Daiichi concedes that it is not attempting to alter (or even clarify) the injunction under 35 U.S.C. § 271(e)(4)(B) against Mylan.[1] Instead, Daiichi stated that it is seeking "only prospective relief" "to clarify a dispute over one day." ECF No. 158 at 2. Daiichi's concession means that it recognizes that the second provision of its proposed revised final judgment, reproduced below, does not apply:

> **ORDERED** that, pursuant 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,

[1] For context, 35 U.S.C. § 271(e)(4)***(A)*** relates to the effective date of FDA approval, while 35 U.S.C. § 271(e)(4)***(B)*** relates to injunctive relief against the generic competitor. *See* ECF No. 157 at 6-7.

> 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.

ECF No. 154-02.

Instead, Daiichi states that it wants only a "similar Order" to that entered in *Takeda Pharm. Co. v. Teva Pharms. USA, Inc.*, No. 06-33-SLR, 2009 WL 3738738 (D. Del. Nov. 9, 2009). That order, filed in this case as ECF No. 157-9, includes no § 271(e)(4)(B) injunction against the generic manufacturer in that case.

For all of the reasons stated in its opposition brief, ECF No. 157, Mylan continues to assert that it is free to launch on October ***25***, 2016, pending FDA approval, and disputes Daiichi's assertion that Mylan cannot launch until October ***26***, 2016. *See also* ECF No. 157-2 (chart 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). But at the very least, Daiichi's reply makes clear that its revised proposed judgment goes beyond the relief it argued for in its papers. As discussed in Mylan's opposition, that proposed judgment improperly attempts to revive the § 271(e)(4)(B) injunction, an injunction that—along with the '599 patent—expired in April of this year. ECF No. 157 at 11-15.

Daiichi has now conceded that it is only seeking *prospective* relief regarding Mylan's launch, and is not attempting to curtail any pre-launch activities by Mylan. Even if Daiichi is right on the merits of the "one day"—and it is not—its proposed judgment cannot be entered. Therefore, Mylan submits a counter revised proposed judgment, filed herewith, which properly

notes that because of Daiichi's pediatric exclusivity under 21 U.S.C. § 355a, the effective date of any FDA approval of Mylan's ANDA's shall be no earlier than October 25, 2016.[2]

Respectfully submitted,

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Dated: October 18, 2016

[2] To the extent this Court finds in Daiichi's favor on the "one day" issue, Mylan asserts its form of proposed revised judgment should still be used, with "October 25" struck out and replaced with "October 26."