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The Honorable Sue L. Robinson
United States District Court
844 King Street
Wilmington, DE 19801

Re: *Takeda Pharmaceutical Co. Ltd. and TAP Pharmaceutical Products Inc. v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.*, Civil Action No. 06-33-SLR

Pursuant to the Court's order during the September 20, 2006 Discovery Status Conference (see D.I. 59 at 39-40), Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Teva") respectfully submit this letter concerning the date restrictions imposed by the Plaintiffs in connection with documents produced in the referenced matter.

A. Teva's Requests Nos. 10, 11, 15-19 and 38-39

These requests seek documents relating to the research, development and testing of lansoprazole, the drug at issue in this matter, and related compounds ("R&D Documents"). Plaintiffs produced only documents dated on or before July 18, 1995, the date of issuance of the last of the patents-in-suit. There are two components to this dispute.

(1) Regarding R&D Documents as a whole, Teva respectfully submits that Plaintiffs should be required to produce such Documents dated on or before January 6, 1997, the date on which Takeda was granted a patent term extension on United States Patent No. 4,628,098 ("the '098 patent"), which Takeda asserts in this action.

Takeda was subject to a duty to disclose "material information adverse to a determination of entitlement to the extension sought . . . ." 37 C.F.R. § 1.765(a); see also Pfizer Inc. v. Ranbaxy Labs. Ltd., 405 F. Supp. 2d 495, 511 (D. Del. 2005). But for that extension, the '098 patent would have expired on July 29, 2005, before this action was filed. If Takeda had information that called into question the validity of the '098 Patent, that patent would not have been eligible for the extension: "No patent will be determined eligible for extension and no extension will be issued if it is determined that fraud on the [Patent and Trademark] Office or the Secretary [of Health and Human Services] was practiced or attempted or the duty of disclosure was violated through bad faith or gross negligence in connection with the patent term extension proceeding." 37 C.F.R. § 1.765(c).

Takeda argued during prosecution of the '098 patent that lansoprazole possessed "surprising" efficacy that demonstrated that the compound was novel and non-obvious. After the patents were issued but before Takeda obtained the extension of the '098 patent term, however, Plaintiffs continued to test the compounds described in the '098 patent and obtained data that was inconsistent with those representations. For example, Takeda published at least two articles in 1996 indicating that the relative efficacy of lansoprazole was much smaller than Plaintiffs represented to the PTO in connection with prosecution of the '098 patent.[1]

Teva respectfully submits that Takeda produce all such Testing Documents, as well as any documents that contradict or fail to support its assertions, without date restriction.

(2) Teva believes Plaintiffs are likely to rely on research, development, or testing documents, or underlying data or analysis, that demonstrate the efficacy of lansoprazole ("Testing Documents") as purported evidence of secondary indicia of non-obviousness. Testing Documents may include testing that compares lansoprazole to other Substituted Benzimidazoles.

Teva submits that Takeda should produce all Testing Documents, even those dated after July 18, 1995. Moreover, to the extent Plaintiffs are in possession of documents – such as the two 1996 publications discussed above – that contradict any assertions of secondary indicia, Teva submits that Takeda should produce such Testing Documents regardless of date.

B. Teva's Request Nos. 26, 28 and 43

These requests seek documents concerning TAP's New Drug Application ("NDA") No. 20-406, including the application file for the NDA and for package labeling, and any communications with the FDA concerning the foregoing (collectively, "NDA Documents"). Plaintiffs refused to produce documents dated after May 10, 1995, the date of approval of TAP's NDA by the FDA.

The NDA was approved months before the last patent issued, and two years before Takeda sought the patent term extension. As pointed out above, representations to the FDA concerning efficacy of lansoprazole, whenever made, are relevant to the validity of the patents in suit. Further, the FDA website contains copies of letters indicating that TAP submitted multiple amendments and supplements to its NDA and package labeling between 1999-2002. Such documents are relevant, at least, to the question the issue of secondary indicia of non-obviousness, such as Plaintiffs' claims regarding unexpected efficacy of lansoprazole products.

Respectfully Submitted,

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[1] *Effects of lansoprazole on indomethacin-induced gastric bleeding and mucosal lesions in rats*, Murakami I. et al., Nippon Yakurigaku Zasshi , 1996, vol. 108, no. 6, pp. 323-332; *Effects of intravenous lansoprazole on acute gastric mucosal lesions and acid secretion*, Murakami I. et al., Japanese Pharmacology & Therapeutics, 1996, vol. 24, no. 8, pp. 129-144.

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