Taisho's Commercial Molecule Luseogliflozin Has Been Granted Patent in India After Dismissal of 4-pre-grant Oppositions

Thought Leadership • November 20, 2020

The patent application (6000/DELNP/2007) for the commercial compound Luseogliflozin was subject to four pre-grant opposition. The hearing u/s 25(1) held and The patent application (6000/DELNP/2007) is directed to the compound ((1S)-1,5-anhydro-1-[3-(4-ethoxybenzyl)-6-methoxy-4-methylphenyl]-1-thio-D-glucitol), i.e., Luseogliflozin , which is an SGLT2 inhibitor. Series of four pre-grant oppositions has been filed to delay the grant of the patent. The hearing u/s 25(1) was held and the Controller has rejected the pre-grant opposition and granted the patent for the compound, Luseogliflozin. Luseogliflozin is a unique and novel "1-Thio-C-Glucoside" compound having a "thiol-glucosyl" ring, C-Glucosidic bond to attach "phenylene ring" with 'thio-glucosyl" moiety; and phenylene ring is substituted at four positions, as "1-thioglucosyl", "6-methoxy", "4-methyl", and "3-(4-ethoxybenzyl)" group. The Applicant also submitted evidence of four experts, including, Dr. Koji Yamamoto, Ms. Fusayo IO, Dr. Hiroyuki Kakinuma and Dr. Hideya Yuasa. The Controller has rejected the arguments of Opponents relying on 9 documents, WO 2004014931, US 6414126, Link and Sorensen, US 6515117, WO 2004080990, Yao et al, Kajimoto et al, Hirayama et al., WO 2004063209, in order to challenge the patentability of the Luseogliflozin on the ground of lack of inventive step. Further, the Controller has also rejected the Opponent's ground of Section 3(d) and Section 8. The Controller held that "the cited documents do not explicitly disclose the compound of the claimed invention. And it is not easy for a person skilled in the art to conceive of modifying the prior art O-glucoside compound to arrive at Luseogliflozin, the C-glucoside compound. The cited documents do not ascertain clear and definite directions to make the compound in the claimed invention." The order also acknowledged that a compound's chemical and pharmacological properties do not result solely from its core or from individual substituents, but rather from the entirety of the molecule and how all its component atoms interact. Thus, the biological activity of a compound is based on the structure of the molecule as a whole. (**Merck vs Glenmark 2015**). With regard to Section 3(d), the Controller held that the claims of the present application relate to a new chemical entity, **Luseogliflozin** and is not a mere discovery of a known substance and cannot be derived from any of the prior art compounds.