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Teva Launches Generic Prevacid After Patent Win

By **Jocelyn Allison**

Law360, New York (November 10, 2009) -- Teva Pharmaceutical Industries Ltd. plans to begin marketing a generic version of the acid reflux drug Prevacid now that a federal judge has ruled in its favor in a patent battle with Takeda Pharmaceutical Co. Ltd.

Judge Sue L. Robinson of the U.S. District Court for the District of Delaware issued final judgment for Teva on Tuesday after concluding that Takeda had failed to prove infringement on the final patent-at-issue in the case.

Teva said in a statement that the U.S. Food and Drug Administration has approved its product and customers will begin receiving the drug in 15 mg and 30 mg delayed-release capsules starting Wednesday.

U.S. Patent Number 5,464,632 was the final hurdle in Teva's efforts to bring a generic version of Prevacid to market after the compound patent for the drug, which the company had been found liable of infringing, expired Tuesday.

Takeda and Ethylpharm SA, which owns the patent, had asserted four patents against Teva in response to its abbreviated new drug application with the FDA to make generic Prevacid: U.S. Patent Numbers 5,464,632 ; 4,628,098; 5,045,321 ; and 6,328,994.

While Teva was found liable for infringing the '098 patent, which covers the drug compound, the court previously found Takeda had failed to show Teva infringed the '321 patent. The parties later dropped claims related to the '994 patent, the ruling said.

The only unresolved claims revolved around the '632 patent, which covers a pharmaceutical formulation known as the orally disintegrating tablet, a tablet that dissolves on contact with a patient's saliva rather than with water, the ruling said.

The issue of infringement in Teva's ANDA product centered on the operation of StarLac, the substance in the drug that the parties agreed was responsible for the rapid disintegration of the generic product, according to the ruling.

StarLac is made by co-processing lactose monohydrate and maize starch. Judge Robinson said in her ruling that although StarLac causes the disintegration of the ANDA product, it is questionable exactly which component induces the disintegration.

“While plaintiffs have shown that lactose has some disintegrative properties, the record as a whole indicates that the prior art did not characterize lactose as a disintegrating agent,” Judge Robinson wrote.

“It is insufficient that an excipient merely possess a tendency to disintegrate; the excipient must actually cause the disintegration of the formulation in order to read upon this limitation of the '632 patent,” she wrote.

The judge said it was just as likely that starch caused the disintegration, and that even if Takeda could prove it was lactose, the patentee's disavowal of lactose in order to distinguish its invention from prior art showed lactose could not be a disintegrating agent within the meaning of the '632 patent.

“Finally, because the starch in StarLac cannot meet both the disintegrating agent and the swelling agent limitations of the '632 patent, a finding of noninfringement is proper in this case,” Judge Robinson wrote.

Takeda is represented by Ashby & Geddes PA, DLA Piper LLP, Hogan & Hartson LLP, Patterson Belknap Webb & Tyler LLP. Ethylpharm SA is represented by Ashby & Geddes PA, Baker Botts LLP and Hogan & Hartson LLP.

Teva is represented by Young Conaway Stargatt & Taylor LLP and Sutherland Asbill & Brennan LLP.

The patents-in-suit are U.S. Patent Number 5,464,632; 4,628,098; 5,045,321; and 6,328,994.

The case is Takeda Pharmaceutical Co. Ltd. et al. v. Teva Pharmaceuticals USA Inc. et al., case number 07-cv-00331, in the U.S. District Court for the District of Delaware.