

Sheppard Mullin Obtains Complete Non-Infringement Victory For Alembic Pharmaceuticals

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On September 30, 2021, the United States District Court for the District of Delaware issued an opinion finding that our client, Alembic Pharmaceuticals (Alembic), does not infringe any of Takeda's and Lundbeck's patents covering the antidepressant drug, Trintellix®. This decision may clear the way for Alembic and other generic pharmaceutical companies to launch generic versions of Trintellix® prior to the expiration of the patents.

Alembic and other generic pharmaceutical companies filed Abbreviated New Drug Applications (ANDAs) to market generic versions of Trintellix®, and they filed paragraph IV certifications asserting that the Trintellix® patents were invalid and/or would not be infringed by the generic products. Plaintiffs, including H. Lundbeck A/S and Takeda Pharmaceutical Company, Ltd., "allege[d] that Alembic's ANDA Product contains an infringing form of vortioxetine hydrobromide, which, according to the asserted claims, must have XRPD peaks at 6.89, 9.73, 13.78 and $14.62 \pm 0.10^\circ$ 2 and/or must be characterized by the XRPD pattern of FIG. 3 [in the patents]." The Court determined that "Alembic's ANDA Product has a non-infringing form as its API – which is not claimed by either of the Crystalline Form Patents." The Court held that "Plaintiffs have not proven by a preponderance of evidence that Alembic's form will convert to a crystalline infringing form." The Court noted that Plaintiffs failed to test samples of Alembic's ANDA product, and Alembic's internal testing, including testing conducted beyond the shelf life, showed no conversion to the infringing form. In addition, the Court held that Alembic's ANDA product will not infringe method of treatment patents, because Alembic carved out claimed indications from its label.

The trial took place over the course of nearly three weeks in January, 2021, and it was fully remote in light of the COVID-19 pandemic.

Sheppard Mullin Chicago partner Brad Graveline and associate Jesse Salen led the Alembic trial team, with assistance from Rebecca Mackin, Tom Carr and Ann Castro.

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