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Axinn Protects Client Endo Pharmaceuticals Inc.'s Approval for Generic Valcyte[®]

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March 11, 2015

Axinn, on behalf of client Endo Pharmaceuticals Inc., successfully defended the U.S. Food and Drug Administration's final approval of Endo's generic Valcyte by securing summary judgment in favor of Endo and FDA. Plaintiff Ranbaxy Laboratories, Ltd. had sought an order reversing FDA's approval of Endo's generic Valcyte product after FDA recently decided to revoke tentative approval of Ranbaxy's generic Valcyte ANDA and determined that Ranbaxy had forfeited its generic marketing exclusivity rights. Judge Beryl Howell of the United Stated District Court for the District of Columbia determined that FDA had acted within its authority.

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