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Sun Pharma, Celgene to resolve patent litigation for Generic Revlimid in US

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As a result of the settlement, all Hatch-Waxman litigation between Sun Pharma and Celgene, regarding the Revlimid patents, will be dismissed



Sun Pharmaceutical Industries along with one of its wholly-owned subsidiaries announced that they have reached an agreement with Celgene Corporation (Celgene), a wholly-owned subsidiary of Bristol Myers Squibb, to resolve the patent litigation regarding submission of an Abbreviated New Drug Application (ANDA) for a generic version of Revlimid (lenalidomide capsules) in the US.

According to the terms of the settlement, Celgene will grant Sun Pharma a license to Celgene's patents required to manufacture and sell (subject to US FDA approval) certain limited quantity of generic lenalidomide capsules in the US beginning on a confidential date that is sometime after March 2022. In addition, the license will also allow Sun Pharma to manufacture and sell an unlimited quantity of generic lenalidomide capsules in the US beginning January 31, 2026.

As a result of the settlement, all Hatch-Waxman litigation between Sun Pharma and Celgene, regarding the Revlimid patents, will be dismissed. Additional details regarding the settlement are confidential. The agreement is subject to customary regulatory approvals.