

## **US District Court approves sanofi-aventis, Sun Pharma patent settlement on Eloxatin**

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Despite the hesitation of sanofi-aventis to stay put with a settlement it has finalised with the Mumbai-based Sun Pharmaceutical Industries Ltd, earlier this year, over marketing a generic version of the formers colon cancer drug Eloxatin (oxaliplatin), the US District Court for the District of New Jersey approved the settlement agreement as valid.

The District Court has now ruled that since the terms of the agreement were explained in both the letter of intent and the term sheets, the agreement is enforceable without considering whether all the required signatures are obtained or not. Sanofi-aventis has failed to submit all the relevant signature pages to the court, according to patent experts.

Even as the talks for the settlement were in final stage and the copy of agreement was signed earlier, sanofi-aventis later refused to continue the efforts as the District Court, on June 17, ruled against its plea to stop Sandoz, a generic major, from selling generic Eloxatin equivalent. An appeal filed by sanofi-aventis against this decision has been cleared by the higher court asking the lower court to re-evaluate the decision, evidently as an advantage to the innovator company.

Approving the agreement, the Court also commented that sanofi-aventis is bound to act according to the settlement and that both parties, prior to the Court's ruling on June 17, had considered the settlement complete and no further revisions are required on this.

Sanofi-aventis has filed a law suit against Sandoz, Mayne Pharma, Teva Pharmaceutical Industries, and Hospira, Inc, other than Sun Pharma to avoid marketing of generic equivalent of Eloxatin. Sanofi holds US patent No 5,338,874 for Eloxatin till 2013. Following the District Court order, Teva and Hospira have already initiated process to launch the generic version of the US\$ 2.3 billion Eloxatin (in US). Oxaliplatin is used for treating colon and rectal cancer.

Sun Pharma had in August 2009 received approval from US Food & Drug Administration (US FDA) for abbreviated new drug applications (ANDAs) for oxaliplatin, a generic version of Eloxatin. However, the company officials refused to reveal the terms of settlement. Sanofi-aventis has already settled a patent row with the Austrian pharmaceutical company Ebewe Pharma, earlier this year as the latter agreed that its ANDA infringed the formers patent claims.