

In May 2018, Amarin announced a settlement agreement with Teva as part of its ANDA litigation, noting that Teva could enter the market prior to the August 9, 2029 settlement date “under the customary circumstances”. Now that Amarin lost its patent trial judgment, when can Teva enter the market if Teva obtains FDA approval of its ANDA for a generic version of VASCEPA®?

In May 2018, Amarin announced a settlement agreement with Teva Pharmaceuticals USA, Inc. in connection with its ANDA patent litigation in the United States District Court for the District of Nevada that allows for Teva to begin to sell its generic version of VASCEPA® in the United States subject to FDA approval on August 9, 2029, or earlier under certain customary circumstances. As currently relevant here, in light of the March 30, 2020 district court ruling, such customary circumstances include the following, each of which are subject to FDA approval of the Teva ANDA:

1. If another generic company obtains FDA approval and launches at risk to them pending the planned appeal of the March 2020 United States District Court for the District of Nevada ruling, only if Amarin does not obtain an injunction removing such product from the market within 60 days. In such case, Teva could also launch at risk to them but would be required to withdraw its product from the market if the other entities that launched at risk withdraw their products.
2. If Amarin loses its substantive appeal of the March 2020 district court decision (i.e., after issuance of the Federal Circuit mandate after any Federal Circuit rehearing or *en banc* review).

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