

NATCO, Dismissal of Litigation over “Gad Patents” is Positive, Potential Launch Timing Still Contingent on Federal Circuit Outcome

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Abstracts

US district court (NY Southern) granted a motion by Mylan and Sandoz to dismiss the litigation over 4 non OB patents ('938, '802, '359 – expiring in Sept, 2019 and '580 – expiring in Feb – 2020). Together these patents are referred to as Gad Patents. The patents in suit claim polypeptide “markers” and methods of using such markers. Markers are polypeptides, when used with certain equipment, can measure the molecular weight of a sample of Glatiramer Acetate. The litigation has been dismissed as Mylan and Sandoz agreed not to use certain polypeptide markers to measure the weight of samples of Glatiramer Acetate.

The decision does not have any impact on the timing of generic entry in Copaxone. The timing of Copaxone (2014 or 2015) launch depends on the verdict of the federal circuit expected in 2Q FY-14. If the process patent around Copaxone expiring in 2015 is held invalid, we can expect a launch post May 2014 (expiry of NCE patent). Momenta/ Sandoz the other contender for Copaxone generic has expressed confidence that the process patent should be invalidated.

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