LITIGATION UPDATE FOR JULY 2020

Federal Court of Canada upheld Invega Sustenna® patent validity

Plaintiffs: Janssen Inc, Janssen Pharmaceutica NV

Defendants: Teva Canada Limited

Case Numbers: T-353-18; A-131-20

Drug: PALIPERIDONE PALMITATE

Patent: CA2655335

On 21 February 2018 Janssen filed a patent infringement suit in relation to the CA2655335 patent, covering the Invega Sustenna® product, against Teva in the Canadian Federal Court. This action started following notice of Teva submitting an Abbreviated New Drug Submission (ANDS) with Health Canada to import, manufacture and sell a generic product containing Paliperidone Palmitate. Invega Sustenna® is a prolonged-release injectable suspension of Paliperidone Palmitate, a long-acting atypical antipsychotic indicated for the treatment of schizophrenia or in maintenance treatment of schizoaffective disorder in adults.

The trial hearing was concluded on 20 February 2020 and on 5 May 2020, the Federal Court entered the final judgment in favour of Janssen as to the validity and infringement of Claims 1 to 16 and 33 to 48 of the asserted patent.

The patent concerned in this action claims a set of dosing regimens for long acting injectable Paliperidone Palmitate formulations to treat schizophrenia. According to the decision, the invention claims a dosage regimen, involving the administration of two loading doses at the beginning of the treatment, followed by a maintenance dose administered monthly, which ensures an optimal plasma concentration-time profile during treatment. A plasma concentration range of 7.5 to 40 ng/mL of Paliperidone after injection was targeted for optimum efficacy and reduction in adverse side effects. The Federal Court analysed the obviousness of these dosing regimens and found that there were differences between the state of the art and the inventive concept of the asserted claims, with no specific motivation to develop the claimed dosing regimens, thus being concluded as inventive.

The Federal Court also noted that the Teva product incorporates the formulation aspects of all claims and granted a declaration of infringement of Claims 1 to 16 and 33 to 48, related to prefilled syringes and “Swiss-type” claims. However, the Court held that Teva will not directly infringe Claims 17 to 32 and will not induce infringement of any of these “use of a dosage form” claims.

This was the second decision under the new Patented Medicine (Notice of Compliance) Regulations and the Federal Court enjoined Teva from making, constructing, using or selling prolonged release injectable suspensions of Paliperidone Palmitate in accordance with its ANDS until expiry of the CA2655335 patent. Teva appealed on 26 May 2020.