Indian Patent Office Granted Patent to Nivolumab After Dismissing Four Oppositions

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The Indian Patent Office granted a patent to Nivolumab (Indian Patent Application 5057/CHENP/2007) after dismissing 4 pre-grant oppositions filed by Indian Pharmaceutical Alliance, Pankaj Kumar Singh, Restech Pharmaceuticals, and Dr Reddy's Laboratories Ltd. Nivolumab, sold under the brand name Opdivo, is a medication used for treatment types of cancers.

The claims of the application were directed to an isolated monoclonal antibody or an antigen-binding portion thereof that binds specifically to human Programmed Death (PD-1) wherein the 6 CDR'S (SEQ ID No. 18, 25, 32, 39, 46 and 53) of the antibody were defined in the main claim. The main grounds raised in the oppositions were lack of novelty, obviousness and non-patentability under section 3(c).

The cited prior art document for lack of novelty was EP1537878 B1. As per the controller, the prior art document cited does not disclose the isolated monoclonal antibody or antigen-binding portion thereof that specifically binds to human Programmed Death (PD-1), comprising SEQ ID No. 18, 25, 32, 39, 46 and 53 as claimed in claim 1 of the present invention, hence the claims of the present invention are new or novel over the cited prior art.

The opponents also argued inherent anticipation by cited document EP1537878B1 as said document disclosed use of anti-PD-1 antibody for the treatment of cancer and while applying for the SPC based on EP1537878, the Applicant submitted that the product is Nivolumab, thus conceding that the antibody was inherently disclosed. Also, reliance was placed by the opponents on the complaints that were filed in the USA based on US equivalents of EP1537878B1 (US8728474, US9073994 and US9067999) and in said complaints it was stated that said patents were put into practice by developing an anti-PD-1 antibody called Nivolumab. However, the controller held that the disclosure of cited art cannot be forming basis for the lack of novelty in the absence of disclosure of the monoclonal antibody as claimed in claim 1 with six CDR sequences in cited document.

As far as obviousness is concerned, the controller agreed with the applicants assertion that it is not obvious for a person skilled in the art to arrive at the claimed antibodies with unique sequence and such unexpected properties with reasonable expectation of success from the teachings of prior art even if the method of manufacture of antibodies is known. The Controller agreed that the method of making monoclonal antibodies have been known for a long time, still patents have been granted to antibodies, if they cannot be arrived by a person skilled in the art during the normal course of action and considering the unexpected superior properties of claimed antibody over the reference

antibodies in tighter binding activity, higher binding specificity along with the therapeutic efficacy.

For section 3(c), the controller held that the claims and the claimed antibody cannot be considered as isolated from nature. The controller held that the sequence listing clearly identifies the sequences of the antibody as being artificial and the artificiality is well explained by the Applicant. The controller therefore also rejected this ground.