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Abbott unit's divisional patent application for drug rejected in India

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NOD DENIED

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- According to documents filed with the Delhi patent office, the claimed invention is related to Adalimumab, a medication marketed under the Humira brand

Chennai, Dec 25: The country's patent office has rejected a divisional patent application by AbbVie Biotechnology Ltd, the biopharmaceutical arm of US-based Abbott Laboratories, for multiple-variable dose regimen for a tumor necrosis factor alpha (TNFa) drug, treating disorders including Crohn's and Psoriasis diseases. According to documents filed with the Delhi patent office, the claimed invention is related to Adalimumab, a medication marketed under the Humira brand.

In a setback to the company, the Chinese patent office too had in September this year rejected the same patent application, titled 'multiple variable dose regimen for treating TNFa related disorders', citing the lack of novelty and inventive steps.

Back in India, AbbVie faced faced a rather stiff opposition. Opposing the application, the Indian Pharmaceutical Alliance (IPA), which represents research-based national pharmaceutical companies, had filed a pre-grant opposition against the application.

While AbbVie argued for the patent initially, the company later informed the patent office that it lost interest in the application and would not pursue it further.

Anita Jatav, assistant controller of patents and designs, Delhi, while rejecting the patent application, said that the claimed composition was a mere admixture of known ingredients resulting only in the aggregation of the properties of the components.

The patent office further said it was not clear if the combined agents act together to provide a technical effect that was greater than just the sum of the two or more agents alone, or whether the combination was in fact a mere juxtaposition with no interaction of the agents.

"The cited documents and the documents in the filed pre-grant representation show that the antibody is known in the prior art with its use in the disorders as disclosed. Thus, the present invention lacks novelty and inventive step in view of of the cited documents," the assistant controller said.

The IPA, in its opposition, said that the presently claimed invention is also related to pharmaceutical composition comprising the claimed antibody, also referred to as Humira and Adalimumab, and that the present application was not fit for divisional under Section 16(1)(3) of the Patents Act, 1970.

The claims of the present invention falls under Section 3(d) of the Patents Act, as the present invention was the mere use of an already known antibody TNFa antibody in the form of composition for the treatment purpose in the given dosage amount. "Thus, the invention is the mere use of an already known substance in different dosage amount, with no increased efficacy over the known substances," it said.

However, AbbVie, in its detailed description of the claims, had submitted that the invention pertains to isolated human antibodies, or antigen-binding portions with high affinity, low off rate and high neutralising capacity. Various aspects of the invention relate to antibodies, antibody fragments, and pharmaceutical compositions, among others, it claimed.

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