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INDIA REJECTS JOHNSON & JOHNSON'S ATTEMPT TO EXTEND MONOPOLY ON LIFESAVING TB DRUG

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Currently, Bedaquiline tablets are priced at $400 per six-month treatment course. File

In a victory for patients fighting for wider access to crucial anti-tuberculosis drug Bedaquiline, the Indian Patent Office on Thursday rejected U.S. pharmaceutical giant Johnson & Johnson's (J&J) attempt to extend its monopoly on manufacturing the drug in India beyond July 2023.

J&J's primary patents on Bedaquiline expire in July, paving the way for generic drug manufacturers such as Lupin and Macleods, among others, to produce Bedaquiline, thus ensuring cheaper and wider access to the drug. Currently, Bedaquiline tablets are priced at $400 per six-month treatment course.

Bedaquiline is a crucial drug in the treatment of multi-drug resistant TB patients for whom the first-line drug treatment — using Isoniazid, Rifampicin, Pyrazinamide and Ethambutol — has stopped working.

Since 2007, J&J had indulged in 'evergreening' — a strategy to extend the life of patents about to expire in order to retain revenues from them — by making multiple claims in its applications for patent extensions.

When the company filed for evergreening of its patent on fumarate salt (a formulation salt of Bedaquiline), the practice was challenged by two TB survivors, Nandita Venkatesan and Phumeza Tisile. "We filed a patent challenge in 2019, because we wanted to ensure that safer, oral and efficacious drug Bedaquiline was available to all people who need it. Our attempt to break the monopoly of a pharma company over this life saving drug has been successful," Ms. Venkatesan told *The Hindu.*

J&J had sought a patent extension on the basis of its claim that it had invented the method for making a derivative of quinoline in its salt form. However, in her order passed on Thursday, Latika Dawara, Assistant Controller of Patents and Designs stated that the invention claimed was obvious and does not involve any inventive step, and is therefore non-patentable.

Ms. Venkatesan and her team provided evidence that the preparation of water-soluble compounds through salt formation, which is used to prepare the drug Bedaquiline, has long been known to pharmaceutical manufacturer and is even cited in chapters of Remington's

Pharmaceutical Sciences and other common textbooks on the subject.

Section 3(d) of the Patents Act states that salt forms and derivatives of known substances are not patentable. “The applicant cannot claim a patent on these methods and compositions of salt forms that have been known in scientific world for more than three decades,” the Patent Office order says.

The order further stated that the claims of J&J’s present application are liable to be rejected as the claimed compounds are mere admixtures, resulting in mere aggregation of properties and not a new invention under Section 3(e) of the Patents Act.

According to the latest available estimates, in 2019, over 55,000 patients who had developed multi-drug resistant TB could have benefited from access to Bedaquiline. As of March 2020, only a little over 10,000 of these patients had accessed the drug.

“It is high time that alternate manufacturers start supplying Bedaquiline at lower prices, especially as TB programmes around the world plan to scale-up the all-oral, shorter, six-month drug-resistant TB regimen,” said Leena Menghaney, Global Intellectual Property Advisor for Medecins Sans Frontiers’ Access Campaign. However, she noted that the good news is restricted to India for now, as J&J continues to hold the patent on Bedaquiline in other major markets such as South Africa, meaning that Indian generic manufacturers will be unable to export the drug there.