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THE CENTRE FOR INTELLECTUAL PROPERTY RIGHTS | WEEKLY STUDENT BULLETIN

J&J FINALLY FOLDED ITS EXCLUSIVE RIGHTS OVER BEDAQUILINE

The Success story of Nandita

Venkatesan

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In early September this year, Nandita Venkatesan, the freelance journalist known for her survival against tuberculosis along with Phumeza Tisile, a South African health activist and a TB survivor herself, was named in the top 100 emerging leaders globally in TIME magazine's TIME100 Next list. This was pursuant to their successful challenge against the secondary patent application by Johnson & Johnson for their tuberculosis drug, Bedaquiline, marketed in the name of SIRTURO. They were supported by Médecins Sans Frontières (MSF), an international independent medical humanitarian organisation.

There has been opposition against the monopoly of the drug in many countries as it deprived a large number tuberculosis patients from accessing "a safer and more effective drug" by Johnson & Johnson and disabled the sale of generic variations. Nandita, along with Phumeza Tisile filed a pre grant opposition, following which the Indian Patent Office rejected the patent application for secondary patent application on Bedaquiline.

Nandita, who was born and brought up in Mumbai, was diagnosed with Intestinal Tuberculosis in 2013. Although she survived two stints of TB, she lost hearing due to the side effects of a drug administered to her. After over six surgeries, she recovered her confidence through dancing, overcoming even the bar set by her impaired hearing. Had Bedaquiline been available to her she would not have suffered the same extent of hearing loss.

Her efforts have in fact culminated in the groundbreaking statement made by Johnson & Johnson on 29th September that it does not intend to enforce patents for SIRTURO in 134 low- and middle- income countries, opening the roads for generic drug manufacturers. This to stress the fact that as rightly reported by MSF, "the first crack in Johnson & Johnson's shield occurred with the rejection of patent application by the Indian Patent Office". Nandita's story is a living example of how we, as citizens, have the power to prevent the atrocities of big pharma companies from misusing the patent laws, and that humanitarian values always outweigh monetary gains.

The provision in the Indian Patents Act, 1970 that enabled Nandita Venkatesh to file the opposition is Section 25(1) of the Act, which allows any person to file an opposition by way of representation against grant of patent application.



BEDAQUILINE - FACTS

1st novel TB drug to be produced in 50 years.

The drug is on WHO's list of essential medicines.

The drug is essential in the fight against Multi Drug Resistant TB.

Brand Name – *Sirturo*

Since 2003, Janssen (subsidiary of Johnson and Johnson) holds a patent in the compound of this drug (including free base, enantiomers and isomers and its various salts, in general). This patent expired in India in July 2023.

The latest patent application was for the Bedaquiline fumarate composition over the previous Bedaquiline compound (this is what is called a secondary patent application).

The current price for the drug for a 6-month treatment course is \$272. This is expected to fall to \$48-\$102 with the introduction of generics.

J&J has agreed to license the generic versions of this drug to Stop TB Partnership's Global Drug Facility (GDF) so as to make the drug available at a cheaper price to middle income and low-income countries.



FAQ

Generic Drugs - A pharmaceutical product, 'identical—or bioequivalent—to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use' and manufactured and marketed by pharma companies other than the original patent holder of the drug (FDA definition).

Evergreening of Patents - In the pharmaceutical industry, when brand-name companies patent drugs as "new inventions" that are really just slight modifications of old drugs, it's called "evergreening" (Collier, 2013).

SOURCES

1. Meredith Wadman, Major drug company bends in battle over access to key TB treatment, (July 14, 2023)
2. Sandeep K. Rathod, Pre-Grant Opposition Filed Against Janssen's Bedaquiline Fumarate Application in India, Intellectual Property Watch (08/02/2019)
3. Prathibha Sivasubramanian, A Ray of Hope for TB Patients: Indian Patent Office Rejects a Secondary Patent on TB drug Bedaquiline, Third World Network (27 March 2023)
4. Leena Menghaney & Vidya Krishnan, Will generic supply of bedaquiline be accessible? The Hindu, July 24, 2023.

LEGAL CHALLENGE

CHALLENGED PATENT APPLICATION

Pre-Grant Opposition filed under Section 25, Indian Patent Act, 1970

Application (numbered 220/MUMNP/2009) is specifically for Bedaquiline fumarate and its compositions

OPPONENTS

Network of Maharashtra People Living with HIV (NMP+) filed opposition applications in 2013 & Nandita Venkatesan and Phumeza Tisile filed opposition applications in 2019.

CONTENTIONS

Janssen is attempting evergreening of patents (prohibited by Section 3(d) of the Indian Patent Act, 1970) since it does not establish the enhanced efficacy of the Bedaquiline fumarate composition over the previous Bedaquiline compound.

Secondly, the composition patent is not patentable under S. 3(e), since it is a mere admixture/ aggregation of 'Bedaquiline Fumarate with known excipients, without showing any synergism between such excipients and the drug.'

OUTCOME

On 23 March 2023, the Mumbai Patent Office rejected the patent application for Bedaquiline fumarate and its compositions. The Patent Office ruled that the drug lacked inventive step since there had been disclosures of the invention in prior published documents.