Bedaquiline for TB

Why in news?

Johnson & Johnson's patent on bedaquiline expired recently which will allow generic manufacturers to supply this crucial drug for Tuberculosis.

What is Tuberculosis (TB)?

- Tuberculosis (TB) is an infectious disease that most often affects the lungs.
- TB is caused by a type of bacteria called *Mycobacterium tuberculosis*.
- **Symptoms -**

- **Transmission -** TB bacteria spread through the air from one person to another
- It spreads through the air when infected people cough, sneeze or spit.
- **Treatment -** Tuberculosis is preventable and curable.
- Globally, DR-TB is a major contributor to antimicrobial resistance.

> *Each year, nearly half a million people develop drug-resistant TB and nearly 10.4 million people develop drug-sensitive TB.*

To know more click - The Road to End Tuberculosis (TB)

What is Bedaquiline?

- Bedaquiline is the core drug for the treatment of drug-resistant TB (DR-TB).
- Bedaquiline is a crucial drug in the treatment of multi-drug resistant TB (MDR-TB) patients for whom the first-line drug treatment has stopped working.
- It is also an oral medicine with minimal side-effects as compared to other such medicines like Kanamycin.
- Janssen Pharmaceutical (a subsidiary of J&J) made bedaquiline around 2002 and was approved in 2012.
- So far, J&J has claimed sole ownership of bedaquiline.

What is the issue with J&J patent?

- J&J has filed secondary patents over bedaquiline till 2027, which were granted in 66 low-and middle-income countries.
- It includes 34 countries with high burden of TB, multidrug-resistant TB (MDR-TB) and TB/HIV.

- J&J is maintaining its monopoly over the bedaquiline market through this patents.
- J&J is planning a deal with Global Drug Facility (GDF), a non-profit distribution agency, which could expand access to the drug.
- J&J has sought to extend its patent on bedaquiline and is facing has faced public outrage for it.
- **In India -** The Indian Patent Office rejected J&J's secondary patent which would have extended its monopoly for 4 more years.
- Indian measures against evergreening of patents -
    - **Section 3(d) of the Patents Act of 1970** does not allow 'evergreening' of patents to ensure that the monopoly does not exist.
    - This section prevents innovator pharma companies from extending the patent beyond the stipulated period of 20 years.

What are the implications of J&J's patent expiry?

- On the expiry of Bedaquiline patent, the drug makers can make the generic versions as per the law.
- Generic competition of drug manufacturing will *decrease the prices* of the drugs.
- **In India -** National TB programmes will benefit from the generic supply of bedaquiline from Indian manufacturers to reduce prices.
- With patent inforce, the drug was procured only through the government and costs about Rs.21,000 for a 6-month course.
- The government has restricted the supply of the drug, in view of the cost.
- With the advent of generics at a lower price, the reach of the drug to the drug-resistant TB patients in the country will expand in due course of time.

Will the J&J-GDF deal make the generic of bedaquiline accessible?

- Some of the countries hardest hit by DR-TB will not benefit from this deal.
- Eastern European countries and China with high burden of TB are out of the agreement.
- Countries like South Africa are not purchasing from GDF so far.
- South Africa cannot access generic Bedaquiline until 2047 as the ever-greening patent is still inforce.

Quick Facts
• A ***primary patent*** protects directly an active ingredient. • A ***secondary patent*** protects a range of chemicals related to an active ingredient such as crystalline forms of the original compound, methods of use, formulations, dosages, etc. • **Ever-greening of patents -** To extend the patent period when companies make slight changes to the formulation. • The **Global Drug Facility** (GDF) for tuberculosis (TB) was launched by the Stop TB Partnership. • It aims to provide equitable access to affordable high-quality anti-tuberculous drugs and diagnostics.

References

1. The Hindu | Will generic supply of bedaquiline be accessible?
2. Business Line | Expiry of J&J's patent

