3. Why did India reject J&J's patent on TB drug?

Prelims Syllabus: Economy

Mains Syllabus: GS-III Intellectual Property Rights

Why in News?

- An application by Johnson & Johnson (J&J) to extend its patent on the drug Bedaquiline beyond July 2023 was rejected by the Indian Patent office.
- Bedaquiline is used to treat drug-resistant TB.
- This would allow drug manufacturers to produce generic versions of Bedaquiline and make it more affordable.
- It would help in achieving India's goal of eliminating TB by 2025.

Drug-resistant TB and its treatment:

- India accounts for almost one-fourth of the world's burden of multi-drug-resistant (MDR) TB and extensively-drug-resistant (XDR) TB (as per 2017 findings).
- MDR TB resists treatment by at least two frontline drugs namely isoniazid and rifampicin.
- XDR TB resists treatment by isoniazid, rifampicin, fluoroquinolones, and any second-line injectable drug. There were approximately 2650 cases of XDR TB in 2017.
- It was found that in 2021, there were about 124000 cases of MDR TB in India.
- Despite the reduction of TB incidence in India, MDR and XDR TB endanger the efforts to locally eradicate the disease.
- Moreover, the COVID-19 pandemic has severely affected the treatment of the disease for two years due to supply chain disruption, inaccessibility of drugs, and shortage of healthcare workers.

- TB can be treated by strictly adhering to the drug doses. Deviation from the drug schedule might result in making the bacteria drug-resistant.
- A drug-resistant TB is harder to treat. The World Health Organization, in 2018, replaced two injectable drugs for MDR TB with an oral regimen comprising Bedaquiline.

BEDAQUILINE:

- It should be noted that second-line treatment options are mostly injected and can have severe side effects such as hearing loss. Bedaquiline is available in tablet form and is less harmful. However, it was found that it might have an impact on the heart and liver and thus it is recommended as a treatment of last resort.
- As per the guidelines prescribed by the Ministry of Health and Family Welfare, Bedaquiline should be used as part of the Programmatic Management of MDR TB under the National TB Elimination Programme.

Details about the rejection of patent treatment:

- The patent application of J&J was for a fumarate salt of a compound to produce Bedaquiline tablets.
- The application was opposed on the ground as the method used to produce a "solid pharmaceutical composition" of Bedaquiline is "obvious" and does not require an "inventive step".
- The Indian Patent Act 1970 Section 2(1)(ja) describes an 'inventive step' to be an invention that is "not obvious to a person skilled in the art".
- It was also argued that the current application was significantly based on the previous patent(WO 2004/011436). It is similar to the compound discussed in 2002.
- The opposing groups also highlighted the act of 'evergreening', which is disallowed in India. Evergreening is a method in which patent-owner continuously extends their rights and/or apply multiple patents for the same product.
- The Patent Office rejected the application on these grounds. It also referred to Sections 3d and 3e of the Act.

Consequences of the rejection of patent application:

- J&J's patent on Bedaquiline resulted in the cost of the drug being $400 per person.
- The rejection of the application will reduce the cost of the drug by 80%.
- After July 2023, other manufacturers of generic drugs can produce generic versions of Bedaquiline.