

Section 107A - Indian Patents Act

Why in news?

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The Delhi High Court has ruled that Indian companies Alembic and Natco Pharmaceuticals can export generic versions of two of German drug maker Bayer's medicines for research and regulatory purposes.

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What is the case about?

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- Bayer owns the patent of the kidney cancer drug Sorafenib, which is marketed as Nexavar.

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- Natco Pharma was given compulsory license to produce the generic version of the drug for the local population, on the payment of royalty to Bayer.

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- Nexavar was at that time priced at Rs. 2.8 lakh per patient per month, while Natco's version of the drug was pegged at Rs. 8,800.

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- Similar was the case for Alembic Pharmaceuticals which was manufacturing generic form of Bayer's blood thinner drug 'Xarelto'.

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- Bayer had initiated proceedings against the two Indian pharma companies to stop them from exporting the drug.

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- Indian companies claimed that they were being exported for purposes of experimentation and generation of valuable clinical trial data.

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- Bayer had claimed that under the compulsory license provided to Natco, the company could only sell drug 'Sorafinac' within India and export of 90 kilograms of drug worth 3 crore is not covered under the exception provided under Section 107A of the Indian Patents Act, 1970.

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What did the Judgment say?

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- **Section 107-A** of the Patents Act explains what will not constitute infringement of a patent, and includes selling of a patented invention for the purposes of development.
- The court held that the export of the pharmaceuticals for informational and data gathering purposes is in line with the global Agreement on TRIPS and also covered under the constitutional right enshrined under Article 19(1)(g).
- Thus, the court disposed of Bayer's pleas saying that sale for the purposes prescribed in section 107A would not be an infringement and thus cannot be prevented.

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What might happen because of the judgment?

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- This could create a rift between the US and India on intellectual property.
- India's Patents Act has been a subject of controversy, particularly Section 3(d), which seeks to prevent 'evergreening' of patents.
- India and the rest of the developed world have sought to use flexibilities in TRIPS to produce cheaper versions of life-saving drugs.
- e.g South Africa has benefited from firms such as Cipla bringing about a drastic reduction in the prices of HIV medicines.
- With the US Trade Representative's IP report card, **the Special 301 report**, is expected later next month, the issue is expected to be brought again.

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- The shortage of patents and innovation in India is a larger ecosystem issue, related to the standards of science and technology education.

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- But, to attribute inadequate R&D to a weak patents system and to put the health of people over profit would be a gross oversimplification.

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Source: Business Line

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