

# Policy Perspective

## Intellectual Property Rights Innovation, Accessibility and Public Interest

### Summary

The Supreme Court of India's judgment in the Novartis case has intensified concerns and dilemmas surrounding the prevailing global intellectual property rights (IPR) regime. In reality, the Supreme Court has only upheld an Indian law which conforms to the WTO framework. This case has done more than just highlight concerns about the affordability and accessibility of life-saving drugs. It has prompted an assessment of the global IPR framework in areas of entertainment, and communication and agricultural technologies among others. The verdict has underscored the need for new business models that can cater to humanitarian compulsions of accessibility and also nurture the knowledge commons in ways that boost greater innovation and invention.

### Dimensions

**1. Ever-greening of patents:** Many other countries, including Brazil, South Africa, Indonesia and Australia, have laws against extending the life of a patent – a process called ever-greening. Ever-greening is used by companies to introduce minor variations to an existing drug in order to extend the life of the patent when it is about to expire. Under the amendment to section 3(d) of the Indian Patents Act, 1970, “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance” is not regarded as an invention and therefore not granted a patent. Section 3(b) of the Act also “prohibits grant of patent on inventions, exploitation of which could create public disorder among other things”.

**2. Inclusiveness:** Concern about accessibility and affordability of drugs has been on the rise globally. This culminated in the adoption of the ‘Declaration on the TRIPS agreement and public health’ at

the WTO's Ministerial Conference at Doha in 2001 which affirmed that "the TRIPS Agreement does not and should not prevent member countries from taking measures to protect public health".

**3. International treaties and inherent flexibilities:** The World Intellectual Property Organization (WIPO) and the WTO administer various treaties which govern the global IPR framework, such as -- The Paris Convention for the Protection of Industrial Property, The Berne Convention for the Protection of Literary and Artistic Works, The Patent Law Treaty (PLT), TRIPS, etc. These treaties provide for some flexibility, for example the compulsory licensing provision and the Bolar provision - which allows countries to use patented inventions for research purposes - etc. These flexibilities are now being deployed by many stakeholders.

**4. Role of governmental institutions:** While Indian IPR laws are WTO compliant, the courts have often stepped in to safeguard the public interest whenever there is a discrepancy. For instance, in September 2012, the Delhi High Court dismissed the Swiss company Hoffmann-La Roche's suit accusing Cipla of alleged infringement of a patent for its lung cancer medicine Tarceva. In April 2013, the Supreme Court dismissed the appeal filed by Novartis claiming a patent for its cancer treatment drug Glivec. Many experts have confirmed that the judgment in the Novartis case was in conformity with Indian laws which are WTO-compliant and thus in compliance with international laws.

**5. Validity of projected costs and transparency:** There is no universally-agreed data on the costs involved in drug development. It has been widely claimed by the pharmaceutical industry that it costs about \$1.3 billion to develop a new drug and bring it to market. According to research conducted by a pharmaceutical research organization called Cutting Edge Information, about \$100 mil-

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lion to \$550 million of the total cost is spent on the marketing of blockbuster drugs. Moreover, many drugs are based on work done in publically-funded labs. There is need for much greater transparency regarding the huge expense of development.

**6. Geographical indications (GI):** GI and industrial designs, which have the status of trademarks and copyrights respectively, have the potential to deliver an additional competitive edge in the area of IP. India has about 193 registered geographical indications which include Darjeeling tea, Basmati rice, Lucknow zaradozi, etc. Geographical indications can act as a quality mark and help in enhancing export markets and revenues for a country.

## Perspective

A system of checks and balances, such as competition laws, price and advertising regulations, exists in every branch of intellectual

property. However, there is a fine line between obligation to society and the rights of the patent-holder. The aberrations and infirmities that arise in the process must be tackled both from within relevant branches of government and private enterprises which foster business models, with a balance between innovation, public goods and profit.

It is important to incentivise innovation by allowing innovators a period of market exclusivity but it must be done in ways which ensure further innovation and discovery rather than by locking up formulas in silos.

Since innovation drives economic growth, investing in innovation even in times of an economic downturn is vital. It can kick-start economic growth in the future by enabling enterprises to take advantage of the business upswing when it comes.

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