Drug Patents Law in India

What is the issue?

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India’s rejection of secondary patents has kept blockbuster medicines affordable for many.

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How are patents and drug pricing related?

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- Patents offer their owners **market exclusivity** for a limited period of time.
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- For medicines, this exclusivity should last as long as the **primary patent** is in effect, typically 20 years.
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- Primary patent relates to the **active pharmaceutical ingredient (API)** of the medicine.
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- The **end of patent exclusivity** is referred to as a patent cliff.
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- This is because **drug prices fall** steeply by as much as 80% after the end of patent exclusivity.
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- The price fall is driven by the **generic competition** that sets in.
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- Resultantly, pharmaceutical companies witness **fall in profits**.
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What are secondary patents?

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- Secondary patents are **claimed for derivatives and variants of the API**.
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- This may include a physical variant of the API, a new formulation, a dosage

regimen, or a new method of administering the medicine.
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- The pharmaceutical companies, who face losses, attempt to **postpone their patent exclusivity** by filing secondary patents.
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- The secondary patents prop up before the expiry of a primary patent.
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- It thereby **stretches the patent exclusivity** beyond 20 years.
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- This practice of extension of patent exclusivity is called "**evergreening**".
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- The strategy is most lucrative when employed in the context of so-called **blockbuster medicines**.
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- These are medicines that reap annual revenues exceeding $1 billion.
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What is the recent Humira case?

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- Humira is one of the world's best-selling prescription drug.
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- Its main ingredient is adalimumab which is a biologic used for the treatment of arthritis.
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- In 2015, Humira faced imminent expiry of patent of its main ingredient.
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- AbbVie Inc, makers of Humira, reassured its investors by citing the option of filing secondary patents which is allowed in the US.
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- Humira thus continues to grow even after the expiry of the patent over its main ingredient.
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- Over the years, AbbVie has increased the price of Humira in the U.S. by 100%, by steadily filing secondary patents.
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What is the case with secondary patents in India?

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- The U.S. recognises and encourages secondary patents.
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- India, however, does not encourage and has limitations in securing secondary patents.
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- **Humira** - Indian Patent Office (IPO) had rejected Humira's secondary patents.
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- Consequently, cheaper versions of the drug were introduced in India.
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- Evidently, Humira costs Rs.85,000 in the U.S., and the same treatment costs only Rs.13,500 in India.
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- **Other cases** - Another patent case worth mentioning is the Novartis' Glivec, a crucial leukaemia cure.
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- The Supreme Court of India in 2013 upheld the rejection of a secondary patent for Novartis' Glivec.
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- Likewise, Spiriva, a medicine for asthma, enjoys patent protection until 2021 in the U.S., largely due to secondary patents; rejected in India.
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How is the Indian patent law unique?

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- As per the Patents Act, the product in question must feature a **technical advance** over what came before.
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- Secondary patents for pharmaceuticals are often sought for trivial variants.
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- They typically fail to qualify as an invention as prescribed in the Act.
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- Further, when a medicine is merely a variant of a known substance, the Patents Act necessitates a **demonstration**.
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- This is mandated in terms of showing the improvement in its **therapeutic efficacy**.
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- The provision also bars patents for new uses and new properties of known substances.
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- This additional requirement is unique to Indian law.
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- Thus, to be deemed patentable, applications for secondary patents have to clear significant hurdles.
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- The patent approval procedure ensures that bad patents stay out of the system.
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- Indian patent law is thus commendable in preventing the evergreening practices by pharmaceutical companies.
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- This is supportive in making affordable the blockbuster medicines which are crucial to the success of public health.
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Source: The Hindu

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