Concerns due to Patenting of Secondary Drugs

What is the issue?

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- Pharmaceutical industry has provisions to ban anti-evergreening during secondary patenting of drugs.
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- Indian Patent Office (IPO) abstains from following such provisions and has been granting more secondary patents.
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What is Evergreening in intellectual property?

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- The first step that pharmaceutical corporations take on discovering an entirely new drug is to secure intellectual property rights for it in the form of a patent.
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- A primary patent covering a new molecular/chemical entity, rewards innovation with a free reign over the marketplace for a period of 20 years, which is the term of the patent.
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- Once this expires, generics enter the fray with cheaper versions and compete in this lucrative marketplace to drive prices down.
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- This entails the pharma companies to go through an entire cycle of discovery, clinical trials, marketing and distribution, replete with the risk of failure at every step.
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- To resolve such issues Innovators seek to reset the 20-year time frame by subsequently filing patents that are minor variants of the parent compound, called secondary patents.
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- This practice, known as evergreening which allows a prolonged monopoly that unfairly denies the public access to medicines at equitable prices.

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What is Patent Act in India?

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- The present Patents Act, 1970 came into force in the year 1972, amending and consolidating the existing law relating to Patents in India.
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- India has been at the forefront of developing an alternative model of patent law which many developing countries have since emulated.
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- The IPO incorporated following anti-evergreening provisions into the Patents Act
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1. **Section 3(d)** - Covers combinations and other derivatives of known substance.
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2. **Section 3(e)** - Covers substance obtained by a mere admixture resulting only in the aggregation of the properties of the components or a process for producing such substance.
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3. **Section 3(i)** - Excludes methods of treatments from the purview of patent protection.
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- These provisions were introduced to restrict patentability of a host of secondary patents, which were basically alternative forms of already existing patented drugs aimed to further extend their term of protection.
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- In case of objections in these provisions, the law requires the patent applicants to submit efficacy data for the former drug and demonstrate synergism for the later.
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What are the existing concerns in patenting of drugs?

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- In recent times, the IPO has been focussing on granting patents expeditiously and reducing the backlog of pending applications.
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- Despite high standards for granting patents, the IPO has been granting patents for merely tweaks in drugs.
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- Due to this the IPO is also operating at an error rate of more than 70% corresponding to all secondary patents granted.
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- Stringent rules are being bypassed by the patent applicants which allows the IPO to grant patents only for new form of substances and not combination of known substances.
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- Thus the application of law with regard to anti-evergreening, by IPO has been far from satisfactory.
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Source: The Hindu

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