Robustness of the Indian Patenting Framework

What is the issue?

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- Indian has evolved strong standards for patents.
- This has led to the promotion of real innovation and protection of the consumers, with lowest financial burden.

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What is Section 3(d)?

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- In 2005, India made some remarkable amendments to the Indian Patents Act of 1970, to promote genuine innovation.
- It includes, Section 3(d), which is responsible for over 65% of all pharmaceutical patent rejections.
- This section provides for rejecting applications that are mere variants of known compounds and lack a demonstrable increase in therapeutic value.
- Basic patentability criteria are that the invention should be new, involve a significant inventive step, and should be capable of industrial application.
- Not meeting one of these was the most frequently used grounds for rejection.
- The section 3(d) was challenged in the Madras High Court and the Supreme Court on separate occasions, both of which decisively upheld its validity.

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How did it make Indian patents structure strong?

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- This means weeding out non-serious patent applications.
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- In all, 1,723 pharmaceutical applications were rejected by the nodal agency, Indian Patent Office (IPO) between 2009 and 2016.
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- Yet it still was in perfect compliance with the WTO norms.
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- Such strong standards for patents resulted in effectively keeping medicines lowly priced and affordable in the country.
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- This created significant opposition from global pharmaceutical majors and the countries of the developed world.
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- e.g Novartis Case - patent for its anti-cancer drug Gleevec, rejected by invoking Section 3(d).
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- Significantly, these countries continue to have weaker patent standards due to massive corporate lobbying.
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- Hence they reject far lesser **bad patents** than India.
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How section 3(d) reduces financial burden?

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- In the last 10 years, Indian Patents Office (IPO) had rejected about 95% of all pharmaceutical related rejections on its own.
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- Only 5% of the rejections were through the intervention of a third party, such as a pre-grant opponent.
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- This is mainly because of Section 3(d), which provides the advantage of questioning an application at the IPO itself.
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- Without the provision, the expensive and time consuming litigation will be the only alternate.
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- In such cases, disputes are often settled before reaching a conclusion, in pay-for-delay settlements negotiated by patent owners.
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- Patent claimers usually pay off generic manufacturers to stay off the market,

which effectively increases the cost of medicines.
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- Hence, without Section 3(d), Indian public would have to either bear the burden of invalidating a bad patent through litigation or the cost of expensive medicines.
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- It would hence be wise for other countries to incorporate similar provisions in their patent laws to reduce the medical bills of its citizens and prevent undue profiteering by pharma companies.
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Source: The Hindu

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