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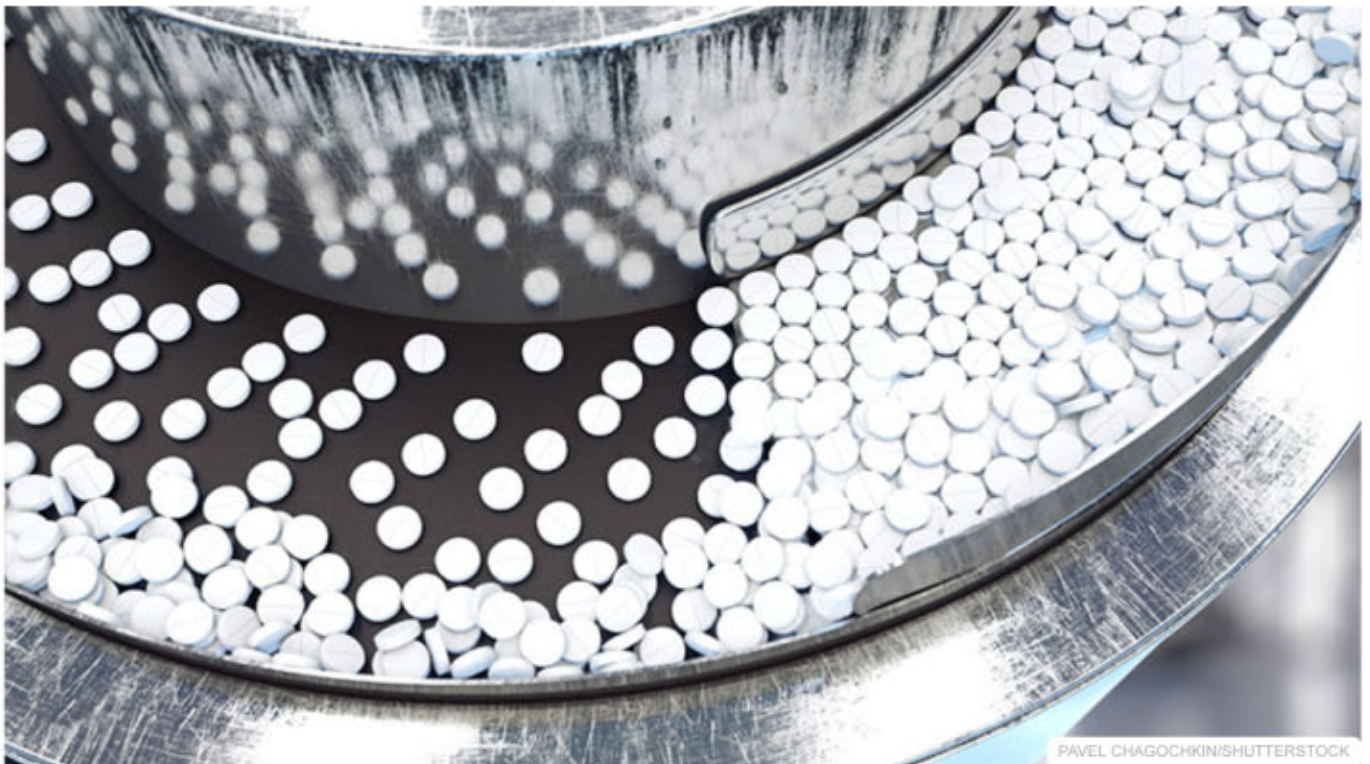
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PATENTS

India's patent office is being too lenient on pharma patents

Research shows the error rate in grant of pharma patents is as high as 72%. In many cases, patent claims are made even without clinical-trial data.



PAVEL CHAGOCHKIN/SHUTTERSTOCK

Global innovation and intellectual property rights lobbies often castigate India for its weak intellectual property framework that fails to recognise innovation and grant patents.

Could it be that the problem is the opposite: India is actually granting patents when it should not?

A comprehensive academic study shows that India's patent office has an extremely high "error rate" of 72% in granting pharmaceutical patents for marginal improvements over drugs for which primary patents exist. (Details of the study are at the end of this article.) Error rate refers to the number of patents granted by the patent office that should not have been passed, and, in common parlance, can be termed suspect.

The background

- Following the filing and grant of the primary patent, drug companies continue research for incremental product improvements.
- They file secondary patents to safeguard those improvements and extend exclusivity.
- Secondary patents may be for a combination of two drugs:
 1. Physical variant – crystal or amorphous powder or defined particle sizes
 2. Isomers or enantiomers – drugs with the same chemical formula but different structural configuration

The apex court had set a strong precedent for rigour

In 2013, the Supreme Court in a landmark judgement rejected a patent claim by Swiss drug maker Novartis for imatinib mesylate, branded as Glivec, the blockbuster drug used to treat chronic myeloid leukaemia, a rare form of blood cancer.

In that case, Novartis had questioned the constitutionality of Section 3(d) of the Indian Patent Act that essentially restricted patentability of a host of

secondary patents such as new forms of known substances, new property, new use of known substances, admixtures without synergistic effect, and method of treatment.

Section 3(d) stipulates that the mere discovery of a new form of a known substance, which does not enhance its efficacy, is not patentable.

India's patent office has not adhered to the Supreme Court's standards

Patent expert Feroz Ali, one of the authors of the report cited earlier, tells ET Prime that inconsistencies were found in the way India's patent office handled these cases. He claims in the report that a detailed analysis of the prosecution history of these cases proves that in none of the cases has the applicant satisfactorily complied with the Novartis standard. All the applicants convinced the patent office that Section 3(d) did not apply to them.

In almost all the cases, applicants managed to get Section 3(e) applied. It meant that even if a drug did not involve a new form of a known substance, as long as it was a different formulation or composition, it could get a secondary patent.

In other instances, applicants pointed towards stability and bioavailability data in lieu of efficacy data. In 50 cases, initial objections raised under the anti-evergreening provisions — Section 3(d), 3(e), and 3(i) — were overcome, and resulted in grants.

Sandeep Rathod, a senior industry executive specialising in Indian intellectual property laws, says the study is an eye-opener and establishes the concern of the industry that patent examination lacks technical rigour.

“Besides the disregard for Section 3(d), equally worrisome is the observation that patent applicants are escaping the boundaries of Section 3(e), which expressly requires that compositions show some form of synergy or interplay between the components,” says Rathod.

Another legal expert adds that the patent office needs to train its examiners and issue more detailed internal checklists and guidelines to implement the standard laid by the Supreme Court in the Novartis case. The patent office needs to make the examiners and controllers more vigilant so that the applicants get a patent only after appropriately submitting right technical data and passing the examination under Section 3(d) and (e) — not by furnishing roundabout legal arguments.

In their analysis, the authors of the study note that *they had not seen a single instance where the applicant had satisfactorily demonstrated therapeutic efficacy using clinical data.*

“On the contrary, there were cases where the applicant had indicated that clinical trials would be done in the future,” says the study.

This is in contravention of the Supreme Court’s decision, which had clarified that efficacy of medicines implied “therapeutic efficacy”, which can only be proven through clinical trials.

The authors recommend a revision of the patent-examination guidelines and the creation of an anti-evergreening checklist for examiners.

The counter argument

Krishna Sarma, managing partner at Corporate Law Group, a Delhi-based law firm working closely with global research-based drug companies, disagrees with the thesis.

“Innovations, howsoever incremental they might seem to a layperson, are eligible for patents as long as they fulfil the three parameters of innovation, non-obviousness, and industrial application,” says Sarma.

“The Indian criteria for patentability, especially in respect of biopharmaceutical inventions, are among the most stringent in the world. We have additional hurdles, like Section 3(d), which many a time restrict patent

grants for otherwise eligible incremental innovations.”

About the study

‘Pharmaceutical Patent Grants in India: How our safeguards against evergreening have failed and why the systems must be reformed’ is a 61-page study by Feroz Ali, Sudarsan Rajagopal, Venkat S Raman, and Roshan John. It shows 1,654 secondary patents, from a cohort of 2,293 patents, were granted between 2009 and 2016 by overcoming anti-evergreening provisions and other rejections that could be raised by India’s patent office.

Ali is IPR Chair Professor at IIT Madras. Rajagopal is a London-based biologist who works on intellectual-property issues. Raman is a chemist and researcher at Tufts University. John is a lawyer and researcher.

The paper is part of a series of arguments from Accessibsa: Innovation & Access to Medicines in India, Brazil & South Africa, a project supported by the Shuttleworth Foundation. The foundation says it does not accept money or support from the pharmaceutical industry.

Recommendations of the report to improve patent grants



Update the guidelines
for examining pharmaceuticals



Implement an
anti-evergreening
checklist for examiners



Amend Indian patent law
to remove conditions for
certain exclusions under section 3(e)