

# Learning from India? A new approach to secondary pharmaceutical patents

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*LSE's Kenneth Shadlen asks whether a recent Indian Supreme Court decision on pharmaceutical patents will make the country's patent laws more effective, and how the decision may affect global access to affordable medicines.*

With the Indian Supreme Court's ruling on April 1, the long-running conflict between the Indian Patent Office (IPO) and Novartis over an application for a patent on Glivec has, at last, concluded (see [here](#) for background). In rejecting Novartis's application, the SC upheld and strengthened Section 3d of the Indian patent law, a clause designed to minimise the granting of "secondary" patents, i.e. patents on alternative forms or derivatives of existing drugs.



In July 2012, as the hearings were set to begin, my colleagues and I discussed the key issues of the case on [this blog](#). As we indicated then, though the Supreme Court case was, nominally, about a specific patent application, broader issues regarding how 3d is interpreted and applied were likely to be considered. The case did not disappoint: in its [112-page ruling](#) – which incorporates analysis of the history of the Indian pharmaceutical industry, patents, and the legislative making of India's reformed Patent Law – the SC ruled on Novartis's patent application itself and clarified key aspects of Section 3d for future cases.

The SC decision triggered a flurry of analyses and commentaries. Here I wish to make two sets of observations regarding the implications of the ruling for governments and consumers throughout the developing world that rely on Indian firms for the supply of affordable drugs, and for countries' efforts to establish limitations on the duration of pharmaceutical patent terms.

## **Access to Medicines**

For all the excitement that the case has generated, it is worth keeping in mind the limitations of the SC's ruling. Section 3d is designed to prevent the accumulation of multiple patents on single drugs that can extend periods of exclusivity. It is not, however, designed to prevent patents on drugs, full stop. New drugs are patentable – and are being patented – in India; the notion that this ruling and Section 3d mean that India does not grant pharmaceutical patents is highly misleading.

To understand these points, it helps to underscore what the case was – and was not – about. Specifically, the SC

ruled on an application for a patent on a crystalline form of the compound imatinib mesylate. Both the base molecule (imatinib) and the salt form (imatinib mesylate) are protected in many countries around the world by a 1993 patent, but they are not patented in India because their invention pre-dates the introduction of pharmaceutical product patents in that country. A key point that is often overlooked in discussions of this case is that the 1993 patent does not exist in India for reasons that have nothing to do with 3d, but simply because India at the time was not granting patents on pharmaceutical products—when it began to do so in 2005, it only recognised applications as far back as 1995.

If Glivec had been invented a few years later, however, it would most likely be protected in India. These details are important for two reasons. First, they indicate that, for all the hoopla, [Glivec is more a victim of timing than Section 3d](#). Second, this suggests that just as Glivec would likely be patented were it invented two years later, new drugs based on new molecules are patentable—and are being patented in India.

Taking a measured approach of the effects that Section 3d can have on the existence of pharmaceutical patent protection in India has important implications for access to medicines on a global scale. Indian pharmaceutical firms play an important role as [provider of affordable, high-quality, generic medicines](#) throughout the developing world. The drugs being supplied are not patented in India because, like imatinib, they pre-date the product patent regime. But it could present a grave threat to global public health campaigns if Indian pharmaceutical firms are no longer able to produce generic versions of new drugs. These concerns are real and clear, and it is much less clear how these fundamental challenges created by the introduction of pharmaceutical patents in India are altered by this decision. New drugs are patentable and will be patentable in India, even with a robust, improved and sharpened 3d. To assure access (locally and globally) to affordable versions of newer, patented drugs, 3d will have to be complemented by other instruments, such as [compulsory licensing](#).

### ***Section 3d, Secondary Patents and Generic Entry***

Section 3d was motivated by a concern that secondary patents can unduly extend periods of exclusivity. It aims to address this concern by prohibiting secondary patents from being granted unless the applicant demonstrates increased “efficacy” of the new substance. With these motivations and objectives, Section 3d, which addresses secondary patents “ex ante” at the point of examination, can be thought of as being functionally similar to “ex post” approaches, such as that in the USA, which rely on litigation at the end of patent terms to address the problems raised by secondary patents.

While India’s ex ante approach has been lauded by some (e.g. the United Nations and health activists) and lamented by others (e.g. transnational pharmaceutical firms, OECD governments), and while other countries have adopted similar (if not always identical) approaches, we know very little about how these approaches function in practice. Our [research](#) has tried to address this gap. In examining data on a set of more than 200 patent applications filed in India, we observed that 3d appeared to be playing a surprisingly small role. We found a low number of instances of applications being denied on 3d grounds, and even fewer cases of applications being rejected purely on 3d grounds. One of our tentative conclusions, then, is that despite all the attention being given to 3d, India’s approach was perhaps not as effective in blocking patents as either its supporters celebrated or its critics complained. We suggest that this may be thought of as a problem of “false negatives”, where a regulatory instrument designed to weed out certain applications instead lets them pass through.

While many factors might contribute to the seeming under-effectiveness of 3d, two potential causes may be ambiguities in 3d itself and a lack of resources to effectively apply the rules. The SC ruling addresses the first, directly, and might indirectly address the second too.

One of the key issues for 3d has been how to assess “[efficacy](#)”. The SC ruled that efficacy is to be judged strictly and narrowly in terms of therapeutic efficacy (in contrast to other, perhaps physical, properties of a drug). Though the questions of how therapeutic efficacy is to be demonstrated and how “increased” efficacy is to be assessed remain unresolved, [many observers sense that the SC’s ruling will make it more difficult to obtain patents on new forms of](#)

[existing drugs](#). In that sense one may infer that the SC did indeed treat the Novartis case as an opportunity to refine and strengthen 3d and thus make it a more effective instrument. Note that it is not clear if the false negatives revealed in our analysis were caused by how efficacy was being assessed or other factors (it is possible that the sources of weakness in 3d that our analysis revealed are different from the weaknesses addressed by the SC). Nonetheless, there are good reasons to expect the SC's refining of efficacy to be significant.

With regard to resources, the attention brought to the case, and the newfound appreciation of 3d and the challenges it was meant to address, may also inspire the Indian government to invest more resources.

The possibility that the SC ruling may make 3d more effective would certainly not be what Novartis and its allies were expecting when they launched their case. Indeed, for years health activists in India and globally have assailed Novartis for pursuing the patent in India and demanded that Novartis drop the case. Perhaps activists will now thank Novartis for its efforts, especially if the SC ruling ultimately makes 3d a more effective instrument.

The significance of the case may extend beyond India. After all, India is not unique in having a pre-emptive mechanism to address secondary patents, and the newfound attention to – and appreciation of – the Indian approach may provide lessons for other countries. Brazil, for example, also has a pre-emptive system, but one that has been [under strain](#). Will India serve as a model for Brazil? Or consider the case of South Africa: the timing may be coincidental, but in the wake of the Indian SC ruling the government of [South Africa announced](#) its own plans to subject secondary pharmaceutical patents to higher scrutiny.

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