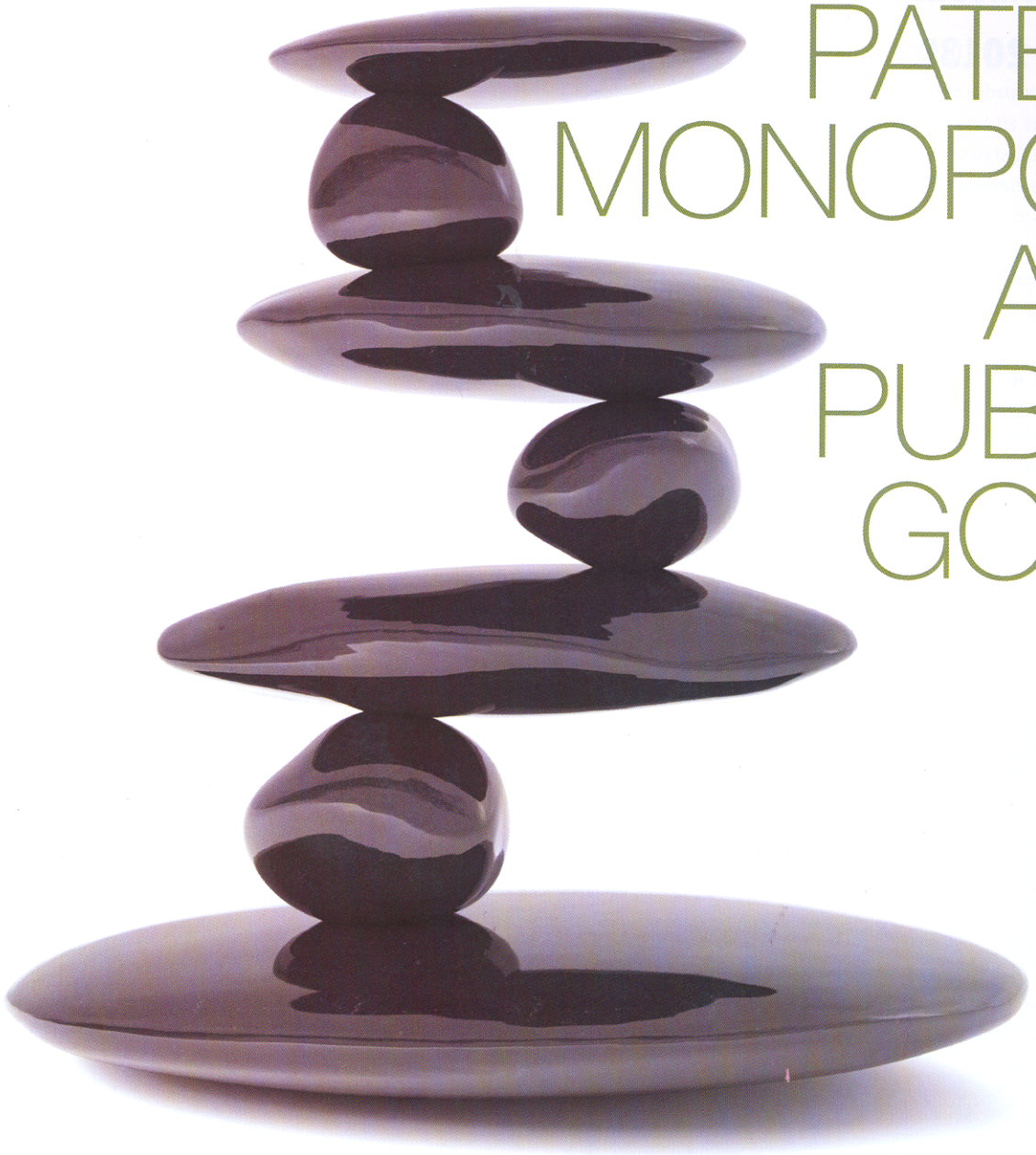
# BALANCING PATENT MONOPOLY AND PUBLIC GOOD



The compulsory licence recently awarded in India for cancer drug Nexavar has provoked extreme reactions across the board, but as Pankaj Soni and Satyoki Koundinya argue, it's all about finding the right balance.

In March 2012, as he was walking out of the door, India's former Controller General of patents etched his name in the annals of patent history when he granted India's first compulsory licence for manufacture of the cancer drug Nexavar (sorafenib). According to the decision, depriving Bayer of its right to exclude Natco Pharma from commercially exploiting its invention was acceptable because the public interest in access to Nexavar in sufficient quantities and at a reasonable price was more important than Bayer's private interests.

A plethora of reactions followed: joy, relief, discouragement and, for some, shock. As the bouquets and brickbats continue, the Health Ministry in India has stirred the pot again by recommending the issuance of compulsory licences for three additional anti-cancer drugs. And now, the appellate tribunal (IPAB) has rejected Bayer's appeal and upheld the compulsory licence granted to Natco.

Are these first steps in compulsory licensing leading us down the right path? Is the broad brush usage of compulsory licensing envisaged in India a cure for the problems with access to healthcare? Time will tell, but this journey has begun with a bang, and must now strike the right balance between patent monopoly and public good through the necessary evil of compulsory licensing. It's 'necessary' because

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given a patentee's right to create a monopoly over a market, a framework needs to be in place to handle strategies that damage the public at large; and 'evil' because it is an exercise that fundamentally takes away from one, the patentee, and rewards another, the licensee.

To be effective and to ensure that the public actually enjoys the desired benefit, this necessary evil must be backed by a coherent and practical policy supported by the right structural framework. Here are some points to ponder.

## The right to healthcare

Compulsory licensing of medicines is the second of a two-step approach to solving India's healthcare issues. The first step is to safeguard a citizen's right to life (a constitutional duty) by ensuring access to affordable healthcare. Before providing access to affordable medicines, we must ensure that patients have access to facilities/resources through which they can be diagnosed with the ailments that require such medicine. Simply stated, a robust healthcare system must be a condition precedent to any policies directed towards compulsory licensing. Only after such a system is in place can the government make an informed decision as to whether it wants to use the necessary evil, or to choose less aggressive alternatives such as buying drugs in bulk and subsidising the price for lower income groups or providing incentives to help the innovator companies bring down their prices.

## Impaired commercialisation

Simply allowing compulsory licences does not ensure that the people who need the medicines will receive them at the right time, in the right quality and at the right price. This is a framework issue, and the government needs to ensure that the proper supply chain networks are in place before a licence is granted. Then, checks have to be designed to ensure that quality is not compromised in the interest of lower prices. Finally, there has to be a mechanism to prevent the price advantage being reversed because third parties, who have managed to get their hands on the medicines, end up selling it at higher prices—unfortunately, this situation is not unheard of in India.

## The right price

There has been little, if any, discussion on the sanctity of the price offered by the licensee. Is the reduced price still affordable? For example, while Natco purports to sell the generic version of Nexavar at a 97 percent discount (approximately $161 for a month's supply), some reports suggest that this is still unaffordable for more than 50 percent of cancer patients, especially given that an average Indian earns approximately $90 per month. To correct this anomaly, special pricing guidelines for compulsory licensing should be considered. After all, if compulsory licensing is about public interest, shouldn't the burden of this public interest be borne by the licensee and the patentee, both of whom should be made to give up their share of profits for the public good?

## Innovate or copy

Innovators argue that frequent use of compulsory licensing will discourage the introduction of new medicines, since this framework fundamentally weakens patent protection—the very system that underpins the ability of the private sector to undertake essential new drug innovation. In India, unfortunately, the trend is not promising. Recent statistics show that the Indian pharmaceutical industry, which produces 10 percent of the world's pharmaceuticals and is the 14th-largest country producer by value, invests a scant 7 percent of global revenue in research and development as compared to the 20 to 25 percent invested by innovator companies.

So if the ultimate goal is public good through self-reliance on cheaper medicines, Indian generics are heading in the wrong direction. While doing it more cheaply is good, if India does not start investing more money in new drug research the current benefit achieved through compulsory licensing will be a only temporary solution, and we will remain copycats.

The list can continue, but suffice to say that there are several factors which show that compulsory licensing must be used judiciously, because it remains a tool, but not the only tool, we can rely on to make inventions available at an affordable price to all sections of the society. But, the burden is not India's alone. Before India is expected to change its position on compulsory licensing, multinational companies looking to India must accept that in India, reaping benefits from the commercialisation of patented drugs involves an emotional and social dimension different from that in the western world, and that India cannot be bullied into becoming a purely capitalistic, patentee-dominated environment.

For a lasting solution, there needs to be a proactive effort by multinational patentees to engage in a dialogue as equal partners in solving a serious problem. Only then will we embark on a journey towards balancing patent monopoly and public good. ■

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