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PRICE CONTROLS AND COMPULSORY LICENCES LEAD TO DOUBLE TROUBLE IN INDIA

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Last week, an Indian panel of ministers proposed that that the government put all 348 drugs on the country's National List of Essential Medicines under price control, including a number of patented drugs. The structure of the scheme provides incentives to target patented drugs on the list

The panel was made up of a number of government ministers and headed by Agriculture Minister Sharad Pawar.

The National List of Essential Medicines lists 348 medicines and 489 formulations, and by some estimates makes up over 50% of total healthcare costs in India. If the Cabinet approves the proposal, all the drugs on the list would be brought under price control compared to just 37 at present.

Under the panel's proposal, the maximum price for each drug will be calculated using a weighted average price method, said Rachna Bakhru of Ranjan Narula Associates in Gurgaon.

The price of a drug will be based on the average price of the same drug sold by the companies having 1% or greater market share, she explained. "So if a multinational sells a version of the drug for Rs100 per dose, and a generic sells a version for Rs50, and they both have 50% of the market, then the price cap would be set at 75 rupees."

Bakhru noted two implications of the proposal. The first is that the price control only affects drugs where generic versions are available. Where only one version exists, there would be no lower average price.

The second concerns the quality of the generics, and whether such a pricing scheme would cause multinationals to cut costs to make up for lower profit margins. Bakhru said a number of doctors have said that certain generics appear to be inferior due to lower-quality ingredients being used.

Still, she thinks that the plan will be implemented quickly. "Drug prices in India in the last two years have gone up nearly 40%, so there is a lot of pressure to address the issue."

PRICE CONTROLS AND COMPULSORY LICENCES – THE TWO-HEADED BEAST

The issue of drug affordability is a hot one in India, and the main driver of the compulsory licence battle being fought before the Intellectual Property Appellate Board (IPAB) in the *Bayer v Natco* matter. Though the IPAB has yet to hand down its final decision, it recently denied Bayer's motion to stay the compulsory licence that had been granted to Natco.

In her written order, Chairperson Prabha Sridevan acknowledged the use of both price controls and compulsory licencing in addressing affordability issues: "Traditionally, nations have used two forms of mechanisms to balance the impact of patent monopoly as tools to make medication accessible to the population. Both the tools – compulsory licences and price controls – are employed where public interest concerns outweigh patent- holders' rights."

The weighted average model in the proposed price control plan confirms the complementary nature of these two approaches; the plan relies on generics to bring down the average cost of a particular drug, and that is likely to require compulsory licences.

A CALCULATED MOVE

Given the rising concern about affordability, therefore, will there be more compulsory licences issued for drugs in India?

Natco CEO Rajeev Nannapaneni practically promised such in an interview back in July. Though he refused to say which patented drugs he will seek a compulsory licence for, he told Live Mint that his company had already identified a few drugs as possible candidates.

A number of IP attorneys echoed these sentiments, though the science needed to reverse engineer a drug was cited as an important deciding factor. In particular, they said that the Bayer case is part of the generic manufacturers' larger strategy of targeting essential drugs with relatively simple molecules.

"My view is that the Bayer case was a very calculated move", said Essenese Obhan of Obhan & Associates in New Delhi. "I believe that they picked this particular drug, because it is a small molecule, and the facts are in their favour." A smaller molecule, he explained, tends to be easier to figure out and to manufacture.

The particular facts of this case may also have been favourable to compulsory licensing. A compulsory licence may be granted on one of three grounds: (a) if the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) if the patented invention is not available to the public at a reasonably affordable price, or (c) if the patented invention is not worked in the territory of India.

The Controller's decision found that all three conditions existed . In particular, the issue of affordability probably weighed strongly in favour of granting the licence.

"Bayer's version cost roughly $6,000 a month", Hemant Singh of INTLL Advocare explained. "Furthermore, it was not curative, so as long as you're alive you have to use it."

"Except for the very rich and affluent no one could afford it," he added.

Bakhru also identified affordability and availability as the main factors. She pointed to a number of drugs, such as Janssen Pharmaceuticals' HIV/AIDS drug Etravirine, and cancer drugs Elrotnib (Pfizer) and Ixempra (Merck), as high-priced drugs that stand out as "expensive drugs" that may be prime targets for compulsory licensing.

INEVITABLE, BUT NOT AS EASY AS IT LOOKS

"For an Indian company to get a compulsory licence, it must invest in upgrading a factory so that it is capable of producing the drug", Obhan explained. It must also dedicate a line in the factory to its production, which often means taking away a line previously used to produce an already selling drug, and then show that it can produce the drug at a low enough cost.

All these investments have to be made before the application is granted, so there is a lot of planning, and risk.

These might be some of the reasons why Natco chose sorenfenib for a compulsory licence, Obhan said. It is less costly and risky to prepare a production line to manufacture the relatively simple molecule.

Bakhru also said that sometimes it is the complexity of a drug that stops the generic manufacturers. "There are some drugs that could not be reverse engineered by the Indian generics and therefore there are no competitors in the market," she said. "A good example for such drugs is Herceptin which was patented before 2005 and is not patented in India, yet no generics are available."

Despite the costs involved in getting a compulsory licence, the issue will likely be an important topic even after the *Bayer* case is decided.

"The law is not a new development. It was always there, but nobody had sought to use it, said Singh. "But now that it has come into the limelight."