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First attempt to dent a compromised patent system

Chan Park and Achal Prabhala

Some key conclusions of the Mashelkar report are borrowed, without acknowledgement, from U.K.-based research funded by Interpat, an association of major multinational pharmaceutical companies.

THE 'REPORT of the Technical Expert Group on Patent Law Issues,' was released recently. Following the introduction in Parliament of the Patents (Amendment) Bill, 2005 and the debate that took place, the Government of India referred certain contentious issues to an expert committee headed by Dr. R.A. Mashelkar for detailed examination. Authored by technical experts, the 56-page Mashelkar report (available at <http://www.dipp.nic.in/>) is unlikely to rivet us or elicit swift reactions from the Government.

However, it will be a pity if the report continues to go unnoticed, because buried in its arcane language are recommendations, which if accepted, could dramatically increase the price we pay for essential medicines. To cite one instance, leukaemia patients could see the cost of their medication increase 12 times. The story of the Mashelkar Report begins in the growing clamour over patents and the dubious role of multinational pharmaceutical companies in affecting national intellectual property laws.

Patents are limited monopolies granted by national governments and, on the insistence of the corporate lobby, regulated by multilateral institutions like the World Trade Organisation. In theory, the logic is deceptively straightforward: the discovery of new medicines costs money; companies need an incentive to make this investment; patents provide that protection. In practice, there is a big problem. Multinational pharmaceutical companies have turned the system on its head. As their pipeline of truly new and innovative drugs slows to a trickle, they have chosen to focus their energies on patenting minor tweaks to existing drugs in order to squeeze out an ever-extending monopoly whenever possible. In trade circles, this is called "evergreening" — a process that the Mashelkar Report asks us not to confuse with "incremental innovation" although, honestly, it is hard to tell them apart. This translates into an infinite monopoly — instead of merely a 20 year one — a lifetime of artificially high prices for essential medicines because only one manufacturer is

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allowed to supply the market.

The furore over affordable medicines in India reached a crescendo in 2005, when India amended its patent law to comply with a WTO agreement known as TRIPS. The amendment left local patients and foreign corporations equally dissatisfied. Among the problems to be ironed out was this: could India limit patents on medicines to those that are truly new and innovative and yet keep in line with TRIPS? Enter a technical expert group on patent law issues headed by Dr. Mashelkar, eminent Indian scientist. Charged with two questions, one of which was whether it would be TRIPS-compatible to "limit the grant of patent for a pharmaceutical substance to a new chemical entity or to a new medical entity involving one or more inventive steps" — his committee concluded that it would not, adding that it is not in the "national interest."

Analysis thin

Consider how it reached these conclusions. The committee, chaired by Dr. Mashelkar and comprising four other experts (Professors Goverdhan Mehta, Asis Datta, N.R. Madhava Menon, and Moolchand Sharma) was constituted by the Ministry of Commerce and Industry in April 2005. Its report was submitted to the Ministry in December 2006. For a year-and-a-half of work, the analysis is thin, spread across a few pages in a report otherwise populated by secondary data and summaries of submissions by outside parties.

It is surprising then that many of the conclusions with respect to new chemical entities (and half the exercise of the entire report) have been extracted, almost word for word, from a paper published earlier in 2006 ("Limiting the Patentability of Pharmaceutical Inventions and Micro-organisms: A TRIPS Compatibility Review") by the Intellectual Property Institute, a United Kingdom-based industry-friendly think-tank and submitted to the group by its author, Shamnad Basheer. A doctoral student and an Associate at the Oxford Intellectual Property Research Centre, University of Oxford, he discloses in a footnote in his paper that his research was commissioned by the IPI and financially supported by Interpat — "a Swiss association of major European, Japanese and US research-based pharmaceutical companies committed to the improvement of intellectual property laws around the world."

On his blog [spicyipindia.blogspot.com], Mr. Basheer was jubilant about the Mashelkar group's conclusions: "... A very sensible suggestion to me — not least because these conclusions were extracted from a report that I submitted to the Committee. This report was commissioned by the Intellectual Property Institute (IPI), UK, in my capacity as an independent/objective consultant with some modest knowledge of Indian patent law/policy. It flatters one to know that the extraction happened verbatim, though I would have been happier had the Committee cited the source — but perhaps this is too much to ask of a Committee caught in between a political crossfire and a deft stalling exercise."

So a committee of five renowned experts takes a year and a half to deliberate over a patent law issue that is crucial to millions of people in India, and finally produces a report whose key conclusions are borrowed, without acknowledgement, from a paper funded through a U.K.-based think-tank by Interpat, an association of major multinational pharmaceutical companies.

When India amended its patent law in 2005, it included some

unique provisions to ensure that pharmaceutical companies could not "evergreen" with impunity. It stipulated that if a pharmaceutical company wanted a patent for an improvement on an already existing drug, it must show that the improvement actually made the drug more effective. However logical this may seem to us, it is clearly not in the interests of the multinational corporate lobby — although the fact remains that India should have set patent standards even higher, since TRIPS explicitly leaves this flexibility in sovereign hands.

The strange logic in the Mashelkar technical group's report overlooks these flexibilities, even the judgment of the WTO on this matter — and, in effect, declares it incompatible with TRIPS for India to set stricter standards for patenting. Now the multinational pharmaceutical lobby is planning to use this same twisted logic to cast doubt even on the few, hard-won protections that are in place in our existing law.

There are a large number of people afflicted with cancer and HIV/AIDS who need cheap medicines from India in order to stay alive. The Mashelkar group's report frankly identifies the focus of its fantasies: the Indian pharmaceutical industry. Nothing wrong with this per se, except that the report's purported beneficiaries do not agree with their benefactor. They seem to want stricter patent criteria just as much as us. The Indian Pharmaceutical Alliance, which represents 90 per cent of the R&D expenditure in the domestic pharmaceutical sector, recently intervened to defend the validity of precisely such an existing legal provision that multinational pharmaceutical giant Novartis (and contributor to Interpat) is currently challenging. Furthermore, the Indian Pharmaceutical Alliance has explicitly said that the conclusions of the Mashelkar report are not in their interests.

This report is among the first attempts to dent an already compromised patent system. Certainly, more attempts will follow — such as the issue of pharmaceutical data exclusivity designed to delay the entry of affordable generic medicines.

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