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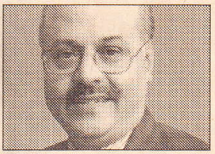
How Pharma, Govts will Change post-Glivec Ruling



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The Supreme Court's landmark judgment on the Novartis Glivec case — disallowing a patent on minor modifications — has started a global debate. How will the ruling impact patents and patients, in India and elsewhere? It's obviously impossible to predict the future. But some informed guesses can be made. We should start with a clear idea who the main stakeholders are.

The list of stakeholders will be as follows: innovator companies or Big Pharma, headquartered mostly in the US, Europe and Japan; generics companies headquartered mostly in India and Israel; suffering patients in need of affordable medicines including life-saving and live-extending ones, located worldwide; NGOs; governments; and health insurance companies.

This list makes it clear that with the exception of Big Pharma, other stakeholders will be active in the areas of accessibility, affordability and availability of medicines. But everything's not black and white.

Agreements between Big Pharma and generics companies in R&D and supply or sale of products already exist, indicating a symbiotic relationship. And India is one of the fastest-growing pharma markets. Note that Sandoz, the world's second-largest generic pharma company, is a Novartis subsidiary.

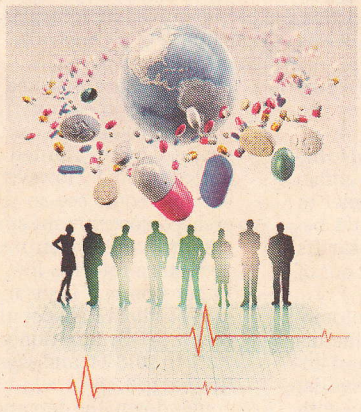
But it is also likely that post the Glivec judgment, lobbying by governments for companies will increase. Foreign governments will try to help their constituents through diplomatic pressure or retaliatory trade initiatives. India has had to handle intellectual property rights (IPR) issues in trade agreements; there has been pressure to change our domestic laws.

Wisely, to repel such pressure, the government formed an inter-ministerial Trade & Economic Review Committee, chaired by the Prime Minister.

But it is also true that governments all over the world are struggling to manage their healthcare budgets. Even Japan, the last bastion of branded patented drugs, is slowly opening up to low-cost generics. Therefore, irrespective of pressure on IPR issues, India's place as "pharmacy of the world" will remain intact.

Will India lose out to China in its quest to be the pharma R&D hub? If it does, it will not be because of the Novartis judgment or because of Section 3(d) of the patent law (this section disallows patents on minor modifications). Whether India can become an R&D hub will depend on our commitment by way of resources to research.

Patient groups and NGOs will always be concerned about patients and not patents. We will witness very aggressive pre-grant and post-grant opposition to pharma patents. There will be constant pressure for issuance of compulsory licence.



Therefore, Big Pharma may have no alternative in the future but to engage constructively with NGOs and not-for-profit organisations, as well as governments and generics companies to negotiate voluntary licences with reasonable payments and royalties. They will have to depend more on volumes and less on prices. Gilead, a pharma innovator, has already taken this path.

Patented medicines cannot be priced in a manner that makes them unaffordable for most. At the same time, we must all remember that innovation comes at a cost and companies need to recoup the investment.

We should read the Glivec judgment carefully to see how this conundrum can be solved. Justices Aftab Alam and Ranjana Desai have gone through all the aspects of the case brilliantly. The judgment quotes retired Chief Judge Paul Michel of the Court of Appeals, Federal Circuit, US, "Patent systems are not created in the interest of the inventor but in the interest of the national economy. The rules and regulations of the patent systems are not governed by civil or common law but by political economy."

Section 3(d) of the Patent Act was introduced to protect the healthcare needs of India's millions. It is now being emulated by other countries.

But let our generics companies beware: there is every likelihood that if they infringe patent rights granted in India, our courts will punish them if it's proved they are "infringers".

Perhaps this Latin phrase sums up the post-Novartis judgment world: *cura te ipsum*. Translated, it means "take care of your ownself".

The writer is former executive director, Ranbaxy Laboratories