Pharma companies need to do more to cure the country of its health care ills

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Ainapur, an arid village near the district town of Gulbarga in north-eastern Karnataka, seems an unlikely location to discuss pharmaceutical research, or the pricing strategy of the big pharma companies. Yet, two young men, both brothers, one a teacher in a government school and the other a taxi driver, scan the newspapers every day for news on these subjects.

The brothers' interest was ignited by a report in the local newspaper on March 13 that the Indian Patent Office had the previous day ended German company Bayer's exclusive rights to a cancer drug. With Hyderabad-based Natco Pharma getting a 'compulsory licence' to make and sell the drug, Nexavar, the brothers will have to spend Rs 8,800 on a month's dosage of 120 tablets for their father, 72-year-old Ambegar Shanker, diagnosed with liver cancer. Bayer's price is Rs 2.8 lakh.

With this, India became only the second country to issue a compulsory licence for a cancer drug after Thailand. Under the Indian Patents Act, a compulsory licence to make the generic version of a life-saving drug can be issued three years after the patent was granted if the price is still seen as too high. Interestingly, the Nexavar ruling comes after the relevant wording in the Act was changed from "reasonably priced" to "reasonably affordable priced".
With the threshold for compulsory licensing thus lowered, Nexavar is hardly likely to be the last of such cases. It sets a precedent that could be extended to other treatments, especially HIV, in which Indian companies have emerged as a big source of cheap drugs for the global market. As a case in point, Thailand has issued compulsory licences for at least four cancer drugs and also for drugs to fight heart diseases and HIV.

As more compulsory licences are issued, they will open another battlefront between the domestic and multinational pharma companies, which are already on the opposite sides in a long-running patent battle over Swiss company Novartis' cancer drug Glivec. The multinationals think of India as a lucrative market - worth $12 billion with a growth rate in high double digits - more so after the country began to recognise product patents in 2005, but have begun to express greater discomfort with the way it protects their intellectual property. The domestic companies will obviously benefit, as they will get to make cheaper versions of patented drugs. But will this be enough?

MALIGNANT GROWTH

Ambegar Shanker's form of liver cancer, hepatocellular carcinoma, is not very common in India. According to the patent office, there would be about 20,000 such cases in the country. Yet, doctors are now finding new seekers for the drug. D. Raghunadharao, professor of medical oncology at the state-backed Nizam's Institute of Medical Sciences in Hyderabad, sees a new patient every week and, in a voice tinged with sorrow, says: "Most of them are in the age group of 45 to 50 years; many of them the sole bread winners for their families."
The more common cancers in India are oral, cervical, breast, blood and colon. India does not have a national cancer registry, but the instances of each are estimated to be on the rise. The United States, which does have a registry, reports 1.5 million new cases of cancer each year.

According to B.S. Ajai Kumar, Chairman of HealthCare Global, a chain of cancer care hospitals, the number would be much higher in India simply because its population is three times that of the US, although India is a younger country and some correction will have to be made for age.

And it's not about cancer alone. There are many diseases for which, just like cancer, you have to be on expensive, long-term medication. Satish Kulkarni, a gastroenterologist in Navi Mumbai, sees close to 100 patients every day. "The need for low-cost treatment is seen not just in cancer care but also in liver diseases like Hepatitis B and C," he says. Pegylated Interferon, a medicine to treat Hepatitis, costs Rs 16,500 a dose. It is an injection which has to be taken every week for six months to a year. Mesalamine, for inflammatory bowel disease, costs Rs 1,500 a month and has to be taken for life. Then there is the rapidly spreading menace of diabetes, for which it is not uncommon for a patient to take insulin injections, which cost at least Rs 1,500 a month, to be taken for life.

But cancer, as the title of the Pulitzer-winning book by Siddhartha Mukherjee put it, is The Emperor of All Maladies. Biotech-based breast cancer drug Herceptin, made by Swiss company Roche, the world's largest maker of cancer drugs, is sold for close to Rs 1 lakh a vial. The total treatment, depending on the severity and dose, could cost up to Rs 15 lakh.

A visit to the Nizam's Institute in Hyderabad, or the All India Institute of Medical Sciences in the heart of
New Delhi, can make a person reset her priorities in life. Till the farthest wall, with its paint peeling, would be patients in various stages of disrepair - if one could use that word for humans - and despair. They are obviously poor and are there because they cannot afford to go to one of swanky private hospitals, which, like the malls, are mostly middle and upper middle class haunts. At the traffic signal outside AIIMS, one can see beggars thrusting prescriptions at car windows.

In a country where nearly 30 per cent of the vast population is estimated by the Planning Commission to live at less than Rs 30 a day, there should be no need to debate the expensiveness of health care. Yet, a debate rages on.

**THEIR PRICE, OUR PRICE**

Multinational companies say they face the classic globalisation dilemma in India. It is true that India has a vast number of poor patients, but not all the patients are poor. "There is huge wealth in India," Ian Read, CEO of the world's largest drug maker, Pfizer, told news agency Reuters in London on March 12, the day Natco got its licence. "There are maybe 100 million people in India who have wealth equivalent to or greater than the average European or American, who don't pay for innovation. So this is going to have to be a discussion at some point."

Bayer, which earned $2.5 billion over the last three years from Nexavar, says it is deeply disappointed by the licence to Natco. "We will appeal the order and defend our intellectual property rights, which are the prerequisites for bringing innovative medicines to patients," says a spokesperson.

On the other hand, the domestic lobby, including doctors, believes that regardless of the income inequality the drug prices should be a tenth of what MNCs charge for them, simply because the number of poor patients would run into millions.

The Indian companies are strident in their advocacy of price regulation. **Dilip Shanghvi**, Chairman of Sun Pharmaceutical, says: "If you price
products at a level at which it is not possible for anybody to afford them, that remains a distortion of the system." Compulsory licensing, he believes, will force international companies to make their pricing more appropriate for India.

Y.K. Hamied, the usually upbeat head of Cipla, a generics giant, believes Indian companies will soon rid the patients of the problems created by pricey drugs. "Give Indian companies another two years and you will see many of them, including us, launching Herceptin and Avastin-like drugs in India," says Hamied. Like Herceptin, Avastin too is a cancer drug from Roche's stable. Together, they earn billions of dollars for their patent holder.

Hamied's confidence may stem from the fact that Cipla shook up the global pharma industry in 2001 with the launch of its anti-AIDS drug Triomune. A cocktail drug, it cost $300 for a year's treatment, against $12,000 a patient in the West had to spend on similar treatment.

Hamied is firm in his belief that the government must bring under price control all drugs sold under monopoly, a view that is finding resonance in the government. The Prime Minister's Office was initially backing market-driven prices but has of late, according to officials, been in favour of making sure that essential drugs are available at low prices.

Trade Minister Anand Sharma, whose ministry administers patents, trademarks and copyrights, said days after the licence was issued to Natco: "India will resist any attempt to malign the generic drug industry in India. There is a campaign to showcase generics as substandard; that they are not real. We are determined to ensure that the poor people in our country have access to these medicines."

Right now, there are 348 essential drugs in the health ministry's list of essential medicines, whose prices are fixed by the National Pharmaceutical Pricing Authority. These include 33 anti-cancer drugs. "We understand that companies invest in research to develop a molecule, but our goal is to increase the ambit of health care and give the poor and the needy access to good medicines," says a health ministry official.

MORE THAN MONEY
The poor and the needy need more than just access to cheap medicines. And generic drugs, despite their ageold association with low prices, are hardly the panacea when it comes to critical illnesses. In many cases, even generic versions, while cheaper than their patented counterparts,
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cost thousands of rupees for a dosage.

What's more, India's generics drive, which earned its companies the unkind sobriquet of "copycats", is running out of gas. It received a setback when the country finally recognised product patents seven years ago. Earlier, as the country granted only process patents, an Indian company would take up a medicine, unravel it and work backwards to develop its own process - a method called reverse engineering.

And then it would sell the medicine at a fraction of the price charged by the patent-holding MNC and grab the market. As a result, many MNCs exited India in the 1970s. They began to come back after 2005, launching their drugs, filing for patents, and filing lawsuits against infringement.

The Indian industry had been preparing for just such a scenario. From the late 1990s onwards local companies began to invest a lot more in research and look for new molecules. Unfortunately, they did not get much success, only sporadic breakthroughs like Ranbaxy's once-a-day Ciprofloxacin.

And compulsory licensing will take you only so far, not all the way. Kiran Mazumdar-Shaw, biotech company Biocon's Chairman and Managing Director, is quick to point out the limitations of the Nexavar licence to Natco. "Nexavar is an orphaned drug in the US," she says. "This means very few patients benefit from it. It does not come under the eligibility criteria for compulsory licensable drug because it is not a life-saving drug. This particular drug only gives a six-month lease of life. What was the need for the government to give a ruling on such a drug?"

There are other signs of the local industry's limitations. With due respect to Hamied's ambition, no one has yet been able to replicate Herceptin, which was patented before 2005 and Indian companies could make and sell it legally in India. Ranbaxy, which under Parvinder Singh dreamed of becoming a research-based multinational, has passed into the hands of Japanese multinational Daiichi Sankyo. The latest blow to Indian research came a day after the licence to Natco, when Pfizer scrapped a partnership with Bangalore-based Biocon.

According to G.V. Prasad, CEO of Dr Reddy's, another early devotee of the research strategy, India
will never be a major force in drug discovery because "we do not have the critical mass for it."

At a time cheap new medicines are not exactly oozing out of our laboratories, better insurance coverage and public health programmes would go a long way to alleviate patients' pain. According to a paper published in the Economic and Political Weekly by economists Sakthivel Selvaraj and Anup K. Karan, as India spends around 4.2 per cent of its gross domestic product on health care, the government's contribution is just onefifth; households' out-of-pocket expenditure is more than two-thirds. This limits people's ability to spend on health care, especially of the low and middle-income groups, which comprise 95 per cent of the population.

It does not help that India's per capita out-of-pocket expenditure to pay for health care costs has gone up from Rs 41.83 in 2005 to Rs 68.63 in 2010. Hospitalisation costs, which rose 11.20 per cent in 2004/05, rose 22.47 per cent in 2009/10. At Rs 30,702 crore, the health allocation in the Budget for 2012/13 is 15 per cent higher than the previous year's. But as a proportion of the GDP it has been stagnant at 0.3 per cent for several years.

Against this background, no medicine can get too cheap. For instance, much before the compulsory licence to Natco, generics giant Hamied had launched Cipla's own version of Nexavar. It fetched Cipla a lawsuit from Bayer, but, priced at Rs 30,000 for a month's dosage, it did not achieve a lot for the poor patients.

**Postscript:** As BT went to print, Roche announced in Basel, Switzerland, that it would offer "significantly" cheaper versions of its popular cancer drugs, Herceptin and MabThera, in the Indian market under an alliance with local firm Emcure Pharmaceuticals. Far away in Ainapur, Ambegar Shanker died a quiet death, an event not reported in the newspapers his sons no longer scan.

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