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The Unknowns

While one view is that Trump's aim to **reduce drug prices will benefit Indian makers of affordable generic medicines**, the clamour to Make in America may result in import barriers like a "border tax"

Indian pharma leaders like Sun and Dr Reddy's have their factories under USFDA import alert

Six Indian pharma companies are under investigation by US Department of Justice over cartelisation of drug prices. If proven guilty, the fines will be a burden on the balance sheet

US Big Pharma has been putting **pressure on India to amend its patent laws**, which subsequent **Indian governments have refused**

The Way Forward

No more just generics, **companies have to diversify** to speciality or branded generics portfolio

Invest in innovative drug products; **Sun Pharma, Dr Reddy's and Glenmark are betting big on IP**

Diversify into emerging markets, look at **Eastern Europe, Latin America as backups**

Clean up USFDA mess, with top management playing a direct role in quality and compliance issues

Increase focus back home, a market that continues to generate profits for Indian pharma

business, delay in approvals of major launches coupled with erosion of our base business," said Abhijit Mukherjee, chief operating officer of Dr Reddy's in the company's earning calls in early February.

If this was not all, the price cartelisation investigation of the DOJ is an overhang that companies have to watch out for. Research by brokerage firm IIFL shows that leading Indian generic drug makers have their own share of "super inflated generics" as companies have hiked the price of their drugs anywhere between 150% and 800% in the US markets. Some have been smart to sense the storm and been cautious over increasing the prices, as data shows that the number of super-inflating generics has declined from a peak level of 247 in August 2014 to a historical low of 60 in August 2016.

Down But Not Out

DG Shah, secretary general of the Indian Pharmaceutical Alliance (IPA), the lobby group of leading Indian drug companies, reckons the worries might be overblown. "The bureaucracy in the US would advise that China and India cannot be antagonised, so it is unlikely that the Trump administration would be hard on India." He adds that Indian companies' investments in the US have jumped six-fold over the past five years and created jobs too. "We save US healthcare $80 billion in healthcare expenditure."

According to the USFDA's own data, 40% of drugs consumed in the US come from India. India exports close to $13 billion or close to ₹70,000 crore worth of drugs across the world, a fifth of which are to the US. There are nearly 200 USFDA-approved manufacturing plants in India, and over the last few years although the agency has tightened its presence in the country by increasing its inspection staff, the number of new product approvals that Indian companies have received have also doubled.

But analyst are also being cautious. Once touted as the defensive stock for investors, the pharma sector seems have to become a selective play. In the last three quarters brokerage firms have revised their guidelines. Their concerns are USFDA inspection and slow approval rates.

The IPR Bully

The macro worries of a trade tussle over intellectual property rights (IPR) is an old sore point between the US and India. The US Trade Representative (USTR) continues to corner India over its intellectual property (IP) laws, India was once again included in Special 301 of the USTR which considers India's IP as a barrier to American businesses. In a tennis match of sorts, both countries keep trading barbs over IP, but with a new administration in the US, how this will pan out is yet another matter of uncertainty. The Indian government, meanwhile, is firmly behind its industry and laws.

"Those who are making these (allegations) are not challenging that there is any violation of trade-related intellectual property. Some countries are trying to push the regime to TRIPS + but that is what we are not signatory to. Our commitment is to TRIPS, and that is the position we have maintained," Sudhanshu Pandey, joint secretary, commerce ministry, told *ET* last week. Trade-Related Aspects of IPR, or TRIPS, lays down minimum standards for IP regulation for WTO member countries. TRIPs+ is a collection of higher standards of protection that some countries – not India – have agreed to.

Pandey also thinks that the brouhaha over quality issues is overplayed in the media, as he thinks Indian companies are "honest" in their approach. On the possibility of a trade war between India and the US, the Indian pharma lobby thinks if at all there is one it could be with countries like Mexico and China. "I doubt if the US would want a trade war with India, considering we recently bought arms worth $15 billion from the US," points out Shah.

Even as a clutch of mid-size pharma companies like Glenmark persist with their plans to build manufacturing units in the US (see *"We Will Manufacture More in the US"*), they're also stepping up the pace in emerging markets. Russia, a few parts of Latin America and Japan are where these companies are moving their focus to. And, of course, there is always the domestic turf, where relatively lax regulations and an envious monopoly ensure that MNC Big Pharma has to play second fiddle. ■

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"We Will Manufacture More in the US"

Glenmark Pharma, an Indian generics maker, is taking the innovation route by focusing on complex generics. In an exclusive interview with *ET Magazine*, Robert Matsuk, president, North America and global API business, talks about the company plans in the US market. Edited excerpts:

On how generics makers in the US are looking at the current political climate

I think every political party before election was talking about pharma and price increases. We said that we are not banking on unconstrained price increases for growth; our strategy is continuous evolution of growth for our pipeline. Right now we have about 114 ANDAs (Abbreviated New Drug Applications, which contain data that determine approval for a generic drug), another 65 waiting for approvals, so the first point is that you constantly evolve our portfolio. A year from now you can expect us to have another 10-15 approvals and another 15 products that have moved to development. If you think about it, whether it is branded or generic companies, they constantly need new products to be successful in the business.

On revamping the portfolio

We are getting into complex generics in various areas like derma, another big one is drug device combination, another one is respiratory technology that we will in-license. So we are not going to look at in-house development, we already have five. And there is more to come.

On possibilities of price increases in the Trump administration

On the branded side in the US, there are single-digit net price increases. However, on the generic side, the price increase is 7-9%. We have come out and publicly stated that our price increase is going to be 10%.

In terms of manufacturing, Glenmark, well before the existing political climate, started investing in manufacturing in the US. We started that in 2014, so yes Glenmark will manufacture more in the US. Taking a broader industry perspective, approximately 40% dosage forms come from outside the US (to the US), and something like 80% of finished components come from outside of the US. So it is not just Indian manufacturing, most manufacturers will be evaluating how legislation goes, but we are well prepared for this.

On how generics players should look at the US

I think the first strategy is to move up the value chain into differentiated products. Differentiated products start with more complex generics. The second step would be filing 505(b)(2) (approval for a drug that isn't new but significantly different). And finally on the innovation thread, there is novel research and pure ANDA filing that would have a significant market.

On whether he expects changes in regulation in the US

In the recent past we have seen improvements in the number of approvals. We will monitor that situation. As you know we pay a user fee for our product filings. In recent meetings we saw positive comments from USFDA, but there is still a significant backlog at USFDA. And we still have to work through a number of things.