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ON
HUGE SHIFTS IN

Outlook Business

When the world's best-selling drug goes off patent, you know it's big news for pharma companies everywhere. At Ranbaxy India, though, the drama was magnified. For three years, it had been wrangling with the US Food and Drug Administration over charges of falsified data and quality issues. And as the deadline for the expiry of Pfizer's Lipitor patent neared, the Indian company was no closer to getting approval for its generic version of the cholesterol-lowering drug. The approval came in early November 2011,

dangerously close to the November 30 deadline. Even then the suspense continued with the FDA announcing its approval, withdrawing it and then announcing the go-ahead once again. Still, Ranbaxy did become the first to launch a generic version of Lipitor. As the first company to have successfully challenged the Pfizer patent, the company held the privileged first-to-file (FTF) status, giving it the right to market its copycat version exclusively for 180 days (the only competition during this period was the original innovator product).

But, really, was it worth all the tension and effort? The original brand-name drug retailed for about \$165 for a 30-day supply (less in the case of insurance co-payments) but generic atorvastatin sold for about 70% less. When the exclusivity period ended on May 29, eight firms were already prepared to enter the market with their own versions of the drug, and prices are now down 96%. It hasn't helped that Pfizer has been on a marketing offensive for Lipitor, offering insane discounts to persuade insurers and patients to not switch to generic substitutes.

It's not just Lipitor and its copycats: all generic drugs bear the brunt of sharp price erosion, especially in the competitive American market. And Indian pharma companies, which get a significant share of their revenues from selling generic drugs to the US (see *Earnings from Uncle Sam*), know that

all too well. Which is why they're changing the way they operate and sell off-patent drugs globally.

CHANGING DYNAMICS

Until recently, the most important numbers in Indian pharma weren't topline and bottomline but the number of abbreviated new drug application (ANDA) filings and approvals. ANDA is a mandatory submission to the US FDA by any generic drug company looking to market its reverse-engineered version of a branded drug that's going off patent. And companies took pride in citing their ANDAs at investor meets. The strategy was about building scale — that is, growing one's portfolio by launching as many generic drugs as possible and being among the first few to enter the market. Dr Reddy's Laboratories (DRL) managing director and chief operating officer Satish Reddy explains the rationale, "When we started out in the US, the three big boys of the generics game [Teva, Mylan and Watson] had a huge portfolio of over 100 products. We only had a few dozen. Playing the scale game was the only way out for us."

That was a decade ago. Now, the focus at all pharma companies (not just DRL) seems to be switching from scale play to scale-plus-value play, where building a differenti-

PROGRESSIVE LANE: Price erosion of generic drugs and Indian pharma's hold in the US results in a change of the way they operate

PHOTO BY AP

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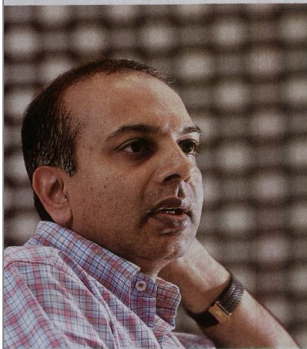
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ated portfolio is as important as ANDA filings. There's a good reason for the climb up the value chain. Ramesh Swaminathan, Lupin's president, financial and planning, says, "Branded product portfolio in the US is very important for us because it helps mitigate the risk of volatility arising out of the sharp price erosions in the plain vanilla generic drug market."

Price erosion is only a part of the problem. In the US generics market (the world's largest at \$75 billion), there are plenty of factors playing out. First, the large wave of blockbuster drugs (with annual sales over \$1 billion) losing patent protection will taper post 2014. According to industry analysts, there's a \$4 billion generic lottery waiting to be won annually between 2011 and 2014 with blockbuster drugs like Plavix, Seroquel, Actos and Nexium facing patent expiry. But thereafter, the flow starts to dry up. Second, the whole concept of blockbuster drugs is undergoing a dramatic change. While the cost of launching a new patented drug has gone up, averaging around \$800 million currently, the returns haven't kept pace — only one in five drugs now generates a higher return than the cost of capital. In

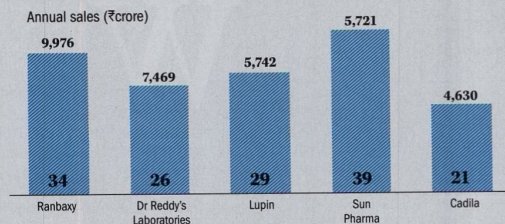
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Earnings from Uncle Sam

Major Indian pharma companies get nearly a third of their sales from the US



fact, most of the potential blockbusters launched in the last few years are yet to cross sales of \$1 billion. For instance, Gilead's Sciences and Johnson & Johnson's HIV combination product Complera failed to live up to the hype — the company had been hoping it would be a replacement for its previous generation Atripla (sales of \$3.2 billion in 2011). On the other hand, potential blockbusters like Roche's Dalcetrapib (to increase good cholesterol) and Bayer's Nexavar (anti-cancer) faltered at the trial phase itself. Focus is, therefore, shifting to smaller but more targeted drugs, such as Genentech's breast cancer drug Herceptin, Roche-Daiichi Sankyo's Zelboraf for late-stage melanoma and Pfizer's Xalkori for lung cancer.

Then, there'll be fewer FTF opportunities going forward: till some years ago, limited competition, which ensured price erosion was not severe, made FTF a very lucrative opportunity for generic manufacturers. But not after 2003,

"You can't play the scale game anymore. Creating value-added products is essential for differentiation"

—SATISH REDDY
MD & COO, DRL

when the provision was diluted allowing more than one generic drug company to enjoy 180-day exclusivity, provided they filed their ANDAs the same day. As the spoils are shared under this 'shared exclusivity', returns are proportionately lower. Plus, each generic maker seeking FTF takes on huge spends (of up to \$20 million) in patent-challenge litigation.

And finally, the conventional pharma business model itself is changing — the line is starting to blur between innovator companies and generic drugs. The past two years have seen a number of mergers, acquisitions and alliances that are narrowing the distance between these conventionally separate business models. The result: a new playing field.

NOTHING ORDINARY ABOUT THIS

In the last few years, Indian generics players grew their sales almost entirely by focusing on building a generics pipeline and then scaling up. DRL, for example, grew its US baseline business (that is, excluding one-off windfalls like FTF exclusivity and authorised generics) from less than \$30 million five years ago to more than \$400 million last year.

But while the Indians were busy doing so, the four global biggies (Teva, Sandoz, Mylan and Watson)

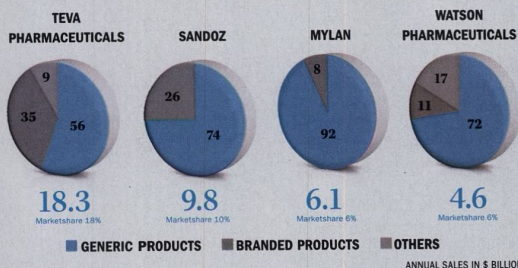
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THE FOUR MUSKETEERS

With a 40% share of the US generics market, the biggest players already have a substantial branded-generics portfolio



leaped ahead in the US market through acquisitions, building up a differentiated portfolio that included plain vanilla products, branded generic and super generic drugs (see: *The Four Musketeers*). Unlike plain vanilla generics, which are clones of the original drug and are sold by their chemical names, branded generic drugs have a brand identity. An example is Lupin's Suprax, a branded generic equivalent of antibiotic Cefixime. While Suprax has a distinct brand identity, its vanilla generic equivalents sell as Cefixime, with little to distinguish among themselves. Super generics (or proprietary generics), on the other hand, differ from the original innovator product either in formulation or delivery mode. These products typically involve time-consuming clinical trials and additional approvals by the drug regulator before they can be commercially launched, unlike plain vanilla generics that take up to 18-24 months for development and cost \$1-2 million.

But global generic players have recognised much in advance there are no short-cuts to take them to the next level. Since selling branded generics also requires companies to promote their prod-

ucts through sustained interactions with healthcare providers and physicians, apart from, of course, building relationships with distributors and wholesalers in the US, they have also been stepping up their clout with distributors. By expanding their global footprint and building a portfolio of high-barrier-to-entry generic products, the big guns of the generic drug world managed to not just increase sales substantially, but also de-risk

There's an annual \$4 billion generic opportunity between 2011 and 2014 with blockbuster drugs going off patent. But the flow dries up after that

their businesses. "To compete with the global generic players you can't play the scale game anymore. Creating value-added products is essential to differentiate yourself in the marketplace," says Reddy.

Differentiated products can either be difficult-to-manufacture generic drugs or products that require a complex technology platform for development. Obviously, these offer better profit margins than plain vanilla generics — in fact, Lupin's Swaminathan says that it may even give companies the opportu-

nity to increase prices, especially when new dosage versions are launched. For example, syrups are usually priced higher than tablets. Same is the case with paediatric dosages. "Margins vary from product to product," he says, refusing to share absolute numbers.

Although moving up the generics value chain holds promise of rich dividends, it also entails high risk. Typically, it requires larger up-front investments, both to develop a product and to build capabilities. In addition, selecting the right product is critical. In plain vanilla generics, one does everything that others are doing.

SEEKING COMPLEXITY

Indian companies are now heading in the same direction as their global generics peers. "Companies will start adding differentiated products bit by bit, depending on risk appetite and cash pile," says the spokesperson of Mumbai-headquartered Sun Pharmaceuticals. Sun's pipeline for the US is a mix of simple generic filings and complex products like injectibles and sprays and a few patent challenges.

One example of a differentiated product from DRL's stable is fondaparinux sodium, the generic equivalent of GlaxoSmithkline's Arixtra, which is used to prevent deep vein thrombosis (a potentially fatal blood clot in a deep vein in the body) in people undergoing hip or knee surgery. The patent expired in 2002, but until last year there was no generic version in the market because of the complex technology involved (it requires 90 chemical processes). By collaborating with Australian biotech firm

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Even though moving up the generics value chain is rewarding, it requires larger upfront investments, both to develop a product and to build capabilities

Alchemia, which had a patented process technology to develop this product, DRL managed to formulate the drug and scale it. The whole process, from development to filing for regulatory approvals and commercial launch took the Indian company about five to six years. Apart from limited competition products, DRL's Reddy says the company also plans to look at super generics and biosimilars opportunities going forward. Biosimilars are generic equivalents of biotech drugs (examples include insulin, growth hormones and interferons). Reddy says his company's portfolio currently comprises mostly plain vanilla products with probably one or two differentiated products (like fondaparinux sodium), but insists this will increase in the coming years. He, however, refuses to share further details, saying it is competitive information.

Lupin's Suprax is the poster boy of Indian pharma's branded story in the US. Initially sold by Wyeth, it was pulled off the market by the innovator on patent expiry in 2003. Lupin acquired this drug and relaunched it subsequently. Today, the branded generic product has annual sales of \$70 million. Buoyed by this success as well as the favourable initial responses to three of its other branded products in the US (cholesterol-regulating drug Antara, AeroChamber Plus used in the treatment of asthma and AllerNaze for allergic rhinitis), Lupin plans to accelerate its branded generics forays. So far, the company has taken the inorganic route to build its branded generics portfolio (though the company is mum on the amount of money it coughed up to acquire these branded products, news agencies have put the

figure at \$38 million for Antara and \$20-30 million for AllerNaze). Swaminathan says Lupin will develop its own branded products from scratch, although the inorganic strategy will continue.

He adds that the branded generics journey in the US isn't easy. Apart from setting up a sales-force in the US (either in-house or outsourced), which is very expensive, it calls for skills in lifecycle management. One needs to learn how to evergreen a brand whose patent has expired and revenues dwindled because the innovator no longer promoted the product. Lupin, for example, started off with a small internal field-force promoting a

“The branded generics journey in the US isn't easy. Apart from setting up a sales force, it calls for skills in lifecycle management

—RAMESH SWAMINATHAN,
President, financial and planning, Lupin



single strength dosage of Suprax to healthcare providers in the US. It then added a double strength, followed by chewable tablets and, finally, drops. “These different variations have increased the utility of our product, which now reaches out to a much larger patient population,” says Swaminathan. Suprax started off as a paediatric medicine but today finds usage in other therapeutic areas like urinary tract infection and respiratory diseases.

Apart from four or five branded generics in its US portfolio, courtesy its subsidiary Taro (acquired in 2007), Sun Pharmaceuticals wants to stand out from the crowd by focusing on technology differentiation (like sustained release or extended release systems) and complex products (like the formulation of controlled substances). Its portfolio includes technologies like bio-degradable injections/implants (helps reduce patient trauma and pain), gastro-retentive devices (for retention in the stomach beyond eight hours) and dry powder inhalers (aids delivery of drugs to the lungs). “We select drugs that are difficult to make and use our drug-delivery platforms to ensure our margins stay protected even with the entry of other generic players,” says the company spokesperson. Sun is believed to have one of the highest profit margins among Indian pharma so far as the US business is concerned. Overall profit margins (at the company level) are in excess of 40%, but a break-up by geography is not available.

These are early days, so there's lot of buzz around value creation and being different. But whether companies actually follow up on this initial excitement and go beyond baby-steps in developing a differentiated portfolio is anybody's guess. One thing is clear — they can't hope to retain their historical growth rates if they continue with business as usual. ☞

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