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EXCLUSIVE

'THE LAST Lakshmi Mittal spoke to Guy Dollé was on 26 January, 9:43 at night, GMT. Dollé was in Toronto getting ready to board a flight to Frankfurt. Airport security forced Dollé to switch his phone off. The two barely spoke. And in that moment, one of the greatest takeover battles in history slipped into motion.

By next week, Mittal's hostile bid for Arcelor should finally open...'



THE INSIDE ACCOUNT

INDIA'S LARGEST SELLING
BUSINESS MAGAZINE

The \$50-billion Opportunity

Ranbaxy and Dr. Reddy's may have found the formula for cracking the US generics market. **By Gina S. Krishnan**

ANYONE tracking the pharmaceutical industry during the last two years would have come to one inescapable conclusion: the big two of Indian pharma — Ranbaxy Laboratories and Dr. Reddy's — were facing a rout in their generics battle in the US pharma market. But, even as analysts were preparing to write the obituary of the great Indian generics dream, the story took a dramatic turn.

If the first three months of this year are any indication, the duo has not only

bounced right back into the game, but it is actually looking at fairly hefty gains. The one big factor for this reversal of fortunes: while the Indian companies initially chased only the big prizes and ignored the smaller opportunities, now they are taking a vastly more pragmatic approach — picking up gains wherever they can. The big two of Indian pharma are getting their act together at just the right time. Over the next three years, the value of drugs going off patent will be almost equal to that of the previous five years. Between 1999 and 2005, drugs worth \$64 billion went off patent, allowing generic makers to get in. Between 2006 and 2008, more than 40 drugs worth \$50 billion would go off patent (see 'The Patent Expiry Trend').

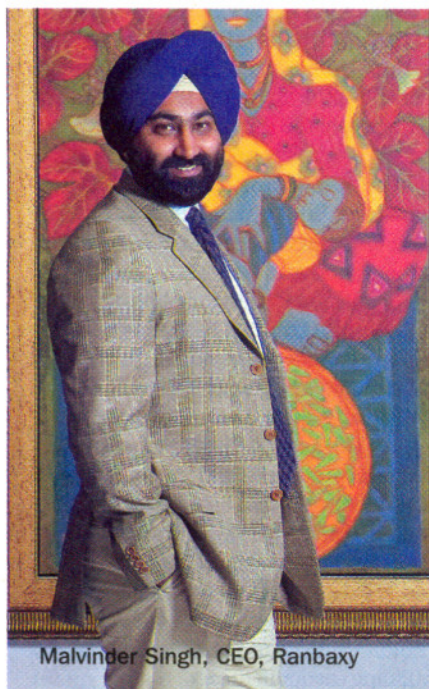
But before we get into the details of this reversal of fortune, consider all that went wrong in the past two years.

Nightmare On Generics Street

In 2005, things went wrong from the start. First, Ranbaxy's challenge of Pfizer's patent on Lipitor was thrown out by a US court. Lipitor is a true blockbuster — it is a \$8-billion drug in the US market alone, and belongs to a class of drugs called statins that are prescribed to reduce cholesterol. Statin sales are going through the roof in the US and Lipitor is considered the champion statin. If Ranbaxy had been able to win its case, it could have hoped to make big bucks by introducing its lower-priced generic, without having to worry about any other generic manufacturer getting into

the market for at least six months. That's because Ranbaxy had been the first to challenge the patent and US law allows the first generics company to file the application to launch a generic 180 days of exclusive marketing rights (EMR), provided it wins the patent challenge.

Earlier, in 2004, Dr. Reddy's challenge to Eli Lilly's Zyprexa (\$2.6 billion in sales) met a similar fate. Zyprexa is the current bestseller among drugs prescribed for schizophrenia and bipolar disorder. Like Ranbaxy, Dr. Reddy's would have been the only generic seller



Malvinder Singh, CEO, Ranbaxy

TRIBHUVAN SHARMA



G.V. Prasad, CEO, Dr. Reddy's

DILEEP PRAKASH

The \$1-billion-plus molecules going off patent

Brand/salt	For indication	Innovator	Sales (\$ mn)	Challengers	First to file	Comment
ACIPHEX (RABEPRAZOLE)	Ulcers, stomach	Eisai	1,262	Teva, Mylan, DRL	Teva	Trials expected in 2006. DRL expects to start marketing once 180-day exclusivity is over.
ACTOS/PIOGLITAZOLE	Antidiabetic	Takeda	2,152	Mylan, Watson, Ranbaxy, Alphaarma	Mylan, Watson, Ranbaxy	If the challengers win, it will mean that Ranbaxy gets to share 180-day exclusivity.
ALLEGRA/FEXOFENADINE	Allergy	Aventis	1,293	Barr, Impax Labs, Teva, Mylan, DRL	Barr	Teva & Barr joined hands. Now that 180 days is over, DRL has also launched.
ARICEPT/	Alzheimers	EISAI	1,154	Teva	Ranbaxy, Teva	Innovator hasn't reacted to the challenge. This one might come Ranbaxy's way even without a trial.
AVANDIA/ROSAGLITAZONE	Diabetes	GSK	1,776	Teva, DRL	Teva	Trial expected late 2006/2007. DRL is chasing it as well.
IMITREX/SUMATRIPTAN	Migraine	GSK	1,131	DRL, Cobalt, Spectrum	DRL	Trial pending, 30-month stay expires May 2006.
LEXAPRO/ESCITALOPRAM	Depression, GAD disorder	Forest	2,066	Ivax, Cipla	Ivax	Forest is seeking preliminary injunction. Settled with Alphaarma.
LIPITOR/ATORVASTATIN	Cholestrol	Pfizer	8,316	Ranbaxy	Ranbaxy	Ranbaxy filed an appeal on 5 January 2006.
LOTREL/AMLODIPINE/BENZAPRIL	High blood pressure	Novartis	1,264	Teva/DRL	Teva	Trial may begin end of this year. DRL will market the product after exclusivity ends.
NEXIUM/PRAVACHOL/ESOMEPRAZOLE	Acid reflux/GERD	Astra Zeneca	4,244	Ranbaxy	Ranbaxy	Complaint filing stage.
PLAVIX/CLOPIDOGREL	Peripheral artery disease	Sanofi	3,423	Apotex, DRL, Teva, Watson, Cobalt	Apotex	Trial scheduled for April 2006. DRL will launch along with others.
PROTONIX/PANTOPRAZOLE	Acid reflux	Altana	2,409	Teva, Sun	Teva, Sandoz, Ranbaxy	Discovery stage.
RISPERDAL/RISPERIDONE	Anti psychotic	JNJ	2,297	Mylan, DRL	Mylan	Possible trial in 2006. DRL will launch after exclusivity ends.
TRICOR/FENOFIBRATE	Cholestrol, lipid mgmt.	Abbott	1,020	Teva, Ranbaxy, Par, Cipher	Teva, Ranbaxy	Trial scheduled for 26 November 2007.
VALTREX/VALACYCLOVIR	Herpes	GSK	1,040	Ranbaxy	Ranbaxy	Trial pending.
ZOCOR/SIMVASTATIN	Cholestrol	Merck	4,378	FDA	Ranbaxy, Ivax/Teva	Ranbaxy and Ivax/ Teva got approval. DRL is authorised generic
ZOLOFT/SERTRALINE	Depression	Pfizer	3,093		Ivax/ Teva	Settled with Pfizer, Cipla likely to gain as Ivax's partner.
ZOFTRAN/ONDANSETRON	Severe nausea	GSK	1,244	DRL, Par, Teva, Westward, Mayne	DRL, Mayne	Decision on DRL expected.
ZYPREXA/OLANZAPINE	Depression	Lilly	2,624	Ivax/ Teva, DRL	Ivax, DRL	Appeals decision pending

DRL: Dr. Reddy's Laboratories

Source: Merrill Lynch report on pharmaceuticals

of the drug in the US for the 20 mg dosage while Ivax had other dosage forms. Had they won, they would have got 180-day EMRs for it.

As if these two failures were not bad enough, the duo faced cut-throat competition from the other global and Indian generic players in the few drugs they did manage to introduce in the US. Take the antibiotic ciprofloxacin for example — apart from Dr. Reddy's and Ranbaxy (which didn't enter directly, but licensed the drug to Bayer), four other players introduced their generics

in the US market on the same day. (No one had won the 180-day EMR on that one.) The competition ensured that ciprofloxacin prices crashed 80 per cent in a couple of weeks, making the market practically worthless.

Finally, last year, the US companies came up with one more strategy — authorised generics — to deny the Indian players any big wins. What this meant was that once an Indian company had won the right to market its generic exclusively for 180 days after the patent expiry, the US company owning the origi-

nal drug would quickly license another generic company to launch an 'authorised' generic. The latter was not seen by the US laws as infringing the 180-day exclusivity simply because it was considered an extension of the original branded drug. All that bad news showed in the stock prices of both Indian players. By mid-2005, Ranbaxy was trading at Rs 340 a share, its lowest in five years, and Dr. Reddy's at Rs 613 (May 2005).

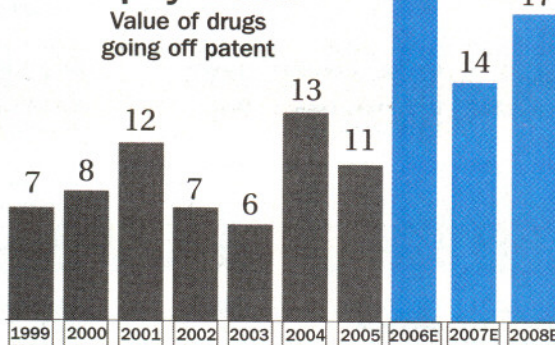
A New, Blockbuster Year

If the last two years were just gloom and

doom, this year is turning out to be radically different. First, in March, Dr. Reddy's got permission to launch its generic version of Aventis' Allegra in three dosage forms. True, this could not be considered a huge win because, in this case, the Teva/Barr combination held the 180-day EMR. But those 180 days are over now and Dr. Reddy's has been the first to introduce its generic after the exclusivity period. Sure, other generic players will soon get in, but Dr. Reddy's still has a window of opportunity when the competition is limited to just three players — Aventis, Barr and itself.

Then, last week, came more good news. Ranbaxy won the 180-day EMR for introducing a 80 mg dosage generic for the statin Zocor, with sales of \$4.3 billion, produced by Merck. (Teva has the 180-day exclusivity for the other dosage forms). Ranbaxy is awaiting commercial exclusivity for Pravastatin, where it gets 180 days exclusivity for 80 mg. Teva has already launched Pravastatin on 20 April. Meanwhile, Merck has already announced that Dr. Reddy's would make its authorised generic for Zocor, as well

The Patent Expiry Trend



Figures in \$ billion; E: Estimated
Source: Goldman Sachs Research estimates, company data, IMS data

as Proscar, a \$374-million prostrate drug.

The wins in 2006 point to one thing: Dr. Reddy's and Ranbaxy are finally getting their generics strategy right. File plenty and file fast. Sorting out the strategy this year was particularly important as 2006 marks the acceleration of the generics opportunity with some \$50 billion worth of drugs to go off patent in the space of just three years.

During 2006 and 2007, 40 cases will be decided in US courts. Of these, 19 are cases involving drugs with sales of more than \$1 billion (see 'The \$1-billion-plus molecules going off patent'). Dr. Reddy's

and Ranbaxy feature in practically all these 40 cases. Just half-a-dozen wins would propel either company into the big league. Which is why the strategies the two companies are following today are so radically different from what they did even last year.

Changing The Game Strategy

When Ranbaxy and Dr. Reddy's first started chasing the US generics opportunity, the focus of both was to file early and aim for the big prize — the 180-day EMR. The problem with that was it meant betting big on a few molecules and hoping that it would pay off. But big wins don't come easy. After Dr. Reddy's one big win — it got the 180-day exclusivity after the \$2.5-billion anti-depressant Prozac went off patent — the Indian firms didn't win a single other exclusivity case for the next three years.

Now both companies are taking a far smarter approach. They are still chasing the big prizes, but hedging their bets by spreading them over everything else in the generics market as well. For example, even where they are not getting the 180-day EMR, they are still launching their generics in the hope of getting at least a few million dollars in sales. They are also trying to become authorised generic makers for US companies. Finally, they are introducing generics in partnership with other generic companies and sharing both costs and profits. It works this way, one company might win the 180-day exclusivity, but it would actually license another generic player to market the drug. The costs of applying, fighting the cases, and marketing the drug would be shared between the two companies as would the profits. Teva and Ranbaxy were the first ones to try it with Quinapril, where Teva launched the drug using Ranbaxy's 180-day EMR and Ranbaxy got a share of the revenue.

Smaller moves than before, but smarter ones. That is what has tilted the score in favour of India's top two. And is likely to keep it that way for a while. ■

The European Opportunity

FOR Indian pharma companies, Europe is emerging as a key market and a growth driver. Like India, in Europe too, the doctor or the pharmacist decides which generic to use. The markets have high potential for generic penetration and, at present, the top players control a significant part of it. The four largest markets — Germany, France, the UK and Italy — account for over 50 per cent of the EU population.

There, originator drugs worth 11.8 billion euros would go off patent up to 2011; 1.5 billion euros of that in this year alone.

Indian companies are quickly entering the European market and, given their experience of Day One launches in the US, are positioning themselves for an aggressive sales and marketing growth. Dr. Reddy's acquired betapharm in Germany (No. 4 generics company there), Ranbaxy bought RPG Aventis in France (among the Top 5 generic players) and Terapia in Romania, and Matrix Laboratories has taken over Belgium's second largest generics player DocPharma. ■

Germany	4.8
UK	2.8
Netherlands	0.6
France	1.6
Italy	0.5
Spain	0.6
Portugal	0.2
Czech Republic	0.1
Hungary, Poland, and branded markets	2.0
Others	1.0
Total	14.2

Size of generics market in \$ billion

For the details of sub-\$1-billion drugs going off patent and Cipla's strategy

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