

## ***Drugs innovation is just what the Doctor ordered***

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An application by Dr Reddy's Laboratories to produce a generic version of Plavix, a blockbuster treatment for stroke victims, generated a predictable threat of litigation aimed at one of the leaders of India's generic pharmaceuticals market.

Sanofi-Synthelabo, the French maker of Plavix and the rival with most to lose from competition to the drug's \$1.1bn annual US sales, accused Reddy's of patent violation and instructed its lawyers to take action.

This is a familiar tale from India's \$4bn generic drugs industry, one of the biggest by volume in the world: copy a drug and then produce it 70–80 per cent cheaper.

Years of generic production have created "an aggressive attitude" to patents in India. G.V.Prasad, chief executive officer of Dr Reddy's – one of the country's largest generic manufacturers – describes the approach as "creatively overcoming" patent blocks.

The reward can be lucrative. Last year, Dr Reddy's "first to file" move in the US was rewarded with 180-day exclusivity on Eli Lilly's off-patent drug Prozac, which earned the company \$56m in six months. Dr Reddy's says it has several more patent challenges in its armoury.

While competitive generic drugs have formed the backbone of India's pharma sector, the development of new treatments is emerging as a new growth area.

"We want to emerge as a discovery-led company," says Mr Prasad. Dr Reddy's, a pioneer in research in India, says it has discovered nine molecules [with medicinal activity], licensed three to western drug groups for latter-stage clinical trials and is negotiating the licensing of the rest.

Indian companies are being forced to change their strategies because new global patent product rules will, from 2005, prohibit copying patented drugs.

Domestic manufacturers have been copying drugs with impunity since an Indian law dating from the 1970s scrapped recognition of foreign drugs patents. The aim was to allow the local production of cheap drugs in a country where modern medicine still reaches only a quarter of the population.

However, in May, legislators approved a new patent law designed to bring India into line with World Trade Organisation rules.

But foreign and top Indian companies are disappointed because, they argue, the changes fall short of WTO standards and are open to abuse.

Ranjit Shahani, chief executive of Novartis in India and president of the Organisation of Pharmaceutical Producers in India, says a tough patent regime is crucial to "protect discoveries, boost innovation and attract foreign investment".

Just 1.1 per cent of foreign direct investment goes into the pharma industry, where drug discovery costs are just 5 per cent of levels overseas.

Moreover, Indian scientists are abundant and globally admired.

Most of India's 22,000 licensed generic drugs-makers are small, with annual revenues of less than \$5m. Just over 110 plants match global

standards and barely 20 have approval from the US Foods and Drugs Administration to sell in the world's largest drugs market. Only a handful have a credible research arm and only a small elite is likely to meet the challenge of 2005 by discovering, patenting and marketing novel drug molecules.

The rest will continue to make commoditised drugs, either generically or under licence to a patent holder.

The graduation from copycat producer to drug discoverer is best illustrated by the progress of Dr Reddy's.

This week, Dr Reddy's announced a 217 per cent rise in net profit to Rs4.6bn (\$94m) for the year to March, mostly on the back of growth in generic sales in the US, which remains the focus of attempts to gain scale.

Its R&D spending totalled 6.3 per cent of revenues, three times the Indian average but two-thirds less than levels in the US and Europe.

The disparity puts even the biggest Indian companies at a disadvantage; because the cost of research and clinical trials is beyond their means, companies such as Dr Reddy's must license discoveries to western drugs majors, reducing their payback. Dr Reddy's, which raised \$133m from an American Depositary Share issue on the New York Stock Exchange last year, could return to the capital markets to scale up R&D. But the company does not want to commit risk capital on research that may fail to deliver, preferring to use cashflows.

The financial conservatism contrasts with the pioneering move into research by the founder-chairman, Dr Anji Reddy. In 1994, Dr Reddy's move was regarded as commercial suicide but "inevitable", says Mr Prasad. The benefits are beginning to trickle through.

Dr Reddy's three experimental medicines molecules have been licensed to Novo Nordisk of Denmark and Novartis of Switzerland, whose final-stage clinical trials should net Dr Reddy's about \$72m in milestone and upfront payments.

"Innovation is where long-term value lies," says Mr Prasad.

– By Khozem Merchant  
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