

# Reddy For Anything

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*One Critic went so far as to call him delusional. Others were more polite, though unfailingly sceptical. But Dr Anji Reddy confounded them all, putting Indian pharma not just on the map but onto the New York Stock Exchange. Anju Ghangurde meets the man they loved to berate.*

The matted but tastefully arranged vineyard that lines the approach road to Dr Reddy's Research Foundation in Hyderabad is perhaps symbolic of the difficult terrain the man himself had to traverse before outlicensing his first new molecule, an insulin sensitiser, to Novo Nordisk. Last year, the journey finally led to his company being listed on the New York Stock Exchange.

"Time and again, people tried to discourage us, talking about the prohibitive costs involved in drug discovery," says the 60-year old founder chairman of India's Dr Reddy's Laboratories (DRL), Dr K Anji Reddy. "One expert went as far as to say that Indian companies should not delude themselves. But I've done it with an annual R&D spend of just Rs100 million (US\$2.05 million)." The soft-spoken Reddy is, however, quick to add that "maybe there was an element of luck and fate involved". Perhaps a mix of luck, fate and guts as well.

Reddy began R&D in the area of insulin sensitisers in 1995, approximately nine years after that class of compounds was known and at a time when there were 130 valid patents. Moreover, it was during the same period that big names like Pfizer had moved out of insulin sensitisers to focus on other areas. That's the guts part. Says Reddy: "I remember Pfizer's R&D chief coming here and while one of our people was making presentation, he said 'Oh! You started where we left off.'" Now for the luck part. While Pfizer in its wisdom moved on, others, like SmithKline and Reddy's, continued to pursue this class of compounds. "It's a question of intuition," says Reddy. "I believe that if your gut feeling says you can succeed, then jump into it. If not, don't. You should be able to see the future, sometimes create it, to be a successful entrepreneur."

Reddy, a diabetic himself, says that while type 2 diabetes patients have conventionally been given drugs to stimulate the pancreas to produce more insulin, the real problem lies in insulin resistance. Reddy believes that once that's corrected, the current therapies will vanish. DRL has licensed its novel dual-acting insulin sensitiser for type 2 diabetes, DRF 2725, to Novo Nordisk and the compound is currently in phase III. "Many of the current drugs survive because they are given in combination. The Avandias of this world are not as potent by themselves, so who knows, maybe our drug or someone else's will replace some of the existing ones," he says.

That statement seems almost too modest coming from the man who started DRL with an initial capital of just Rs25 lakhs(US\$0.05 million) in 1984, built up the revenue stream to Rs15 million (US\$0.31 million) in sales by 1985 and to Rs9.84 billion(US\$202 million) by March 2001. This achievement is reflected in the company's current assets, which include 113 US/PCT (Patent Cooperation Treaty) patent filings, 14 ANDA (abbreviated new drug application) submissions in the US and Canada, and nine new compounds in various stages of development.

## **Small Beginnings**

"DRL is just part of my story," says Reddy, who began his career at a public sector company, Indian Drugs & Pharmaceuticals (IDPL), honing his skills to replicate laboratory processes for drug development. Reddy, who rates himself a "good scientist", said that at some time during his stint at IDPL he suddenly thought that if he were indeed smart, why wasn't he rich? So he quit IDPL and in 1973 set up two bulk drug companies, Uniloids and Standard Organics, in partnership with two others.

Reddy, however, makes no bones about the fact that he did not share the ideology of his partners at Uniloids and Standard Organics and soon decided to go it alone, calling his new company Dr Reddy's Laboratories. "In retrospect, I may have wasted time between 1978 and 1984, and I wish that period had been compressed." DRL which started its operations as a manufacturer of active pharmaceutical ingredients (APIs), was soon in the vanguard of domestic companies that had not only mastered the technology to make APIs but also went on to stun competition by introducing branded formulations at 50% of the prevailing prices. "Very often I tell our politicians to imagine what would have happened had we not started the production of the anti-ulcer drug, ranitidine in India," Reddy said in a speech last year. "Now, with total domestic production estimated at about 1,500 tons, ranitidine pills cost just Rs1 here and even a rickshaw driver in a remote village can afford it."

"Ours is a story about bringing affordable medicines to people in India, then moving on to compete in the advanced markets of the world, and finally, to drug discovery," Reddy sums up.

What began with exports of bulk methyl dopa in 1986 has now evolved into a full-fledged generics business, helped considerably by the formal merger with Cheminor Drugs. As well as providing DRL with the critical mass to compete in the global market, the merger also ensured that DRL participated in every link of the pharmaceutical value chain. Says Reddy, "We are sitting pretty and I believe we possess the capability to do 95% of all activities in the pharmaceutical industry right through from drug discovery, with the exception of global marketing. For the remaining five percent, alliances should bridge the gap."

DRL now has ten ANDAs awaiting approval with the US FDA, including five filed in the third quarter of 2001. This was a productive quarter in other ways, too. Sales soared, driven primarily by fluoxetine, a generic version of Lilly's Prozac. DRL, which enjoyed 180-day marketing exclusivity for fluoxetine 40mg until January this year, saw its generics turnover touch Rs1.13 billion (US\$23.2 million) for the third quarter of 2001, with fluoxetine contributing 87% of these sales. Other generics already in the US market include ranitidine and oxaprozin.

The company believes that the dynamic generics market will reward nimble players who can innovate and evolve constantly. However, Reddy admits that he was worried when the company was "just a generics manufacturer." He remembers: "My chemist came and told me he'd developed a very simple process for a drug. But in the same breath, he added that he was worried it would be copied. Of course now, with the product patent regime almost here and our levels of innovation high, we are very comfortable." As a developing country, India is obliged to apply the TRIPS agreement to pharmaceutical product patents in 2005, and the first challenge, experts suggest, will be the hiatus in copying in the post-GATT era.

### ***Innovation***

Reddy believes there is little correlation between innovation levels and size. "If there's knowledge that only you have access to, it's dynamite," he exclaims with his usual exuberance. And maybe that's what drew the attention of Novo Nordisk, a world leader in diabetes care, to DRL's novel insulin sensitiser compound, DRF 2593, in 1997. "Actually the phone call came from them. And we created history in March 1997, when we licensed our first compound to Novo Nordisk," he says excitedly, almost recapturing the mood of that day.

But Reddy knew that if his company was to make its mark as a real innovator, it could not remain a one-product wonder. So DRL continued working on insulin sensitisers and the very next year, the company licensed out its second diabetes compound, DRF 2725, to Novo Nordisk. At the time of listing its shares on the New York Stock Exchange, DRL had filed 36 patent applications in the US, 14 PCT applications and 26 patent applications in India in the area of diabetes alone. Since then, DRL has been regularly churning out new compounds, and last year it out-licensed yet another new compound for type 2 diabetes, DRF 4158. This is a second-generation dual acting PPAR alpha and gamma agonist, out-licensed to Novartis for upfront and milestone payments of up to US\$55 million, as well as royalties. At the same time, DRL's US

research subsidiary, Reddy US Therapeutics, has had some early success. It has validated drug targets in cell proliferation, inflammation and diabetes and is in licensing talks for one of its molecules.

But DRL has had its share of hiccups in R&D. Late last year, Novartis pulled out of an arrangement with Novo Nordisk under which the Swiss multinational had the exclusive rights to commercialise DRF 2725 in the US, Canada and Mexico, with Novo Nordisk retaining certain retailing rights for the US. While the actual reasons behind Novartis' exit continue to be hazy, Reddy says he was actually relieved when the arrangement was aborted. "I was never comfortable with the fact that a company which is developing one of our competing molecules is also marketing DRF 2725. I'm confident that Novo Nordisk will find a good US partner for the product."

Hiccup number two revolves around the growing concerns of cardiac risk associated with COX-2 inhibitors such as rofecoxib and celecoxib. DRL has been working on a COX-2 compound, DRF 4848, and Reddy now says the company is rethinking its position. "Until we have a method of evaluating whether our compound is different from the other COX-2s, we're not going ahead. We'll take a decision on this within six months."

But Reddy brushes aside such aberrations, and says his job is simply to sustain the high levels of innovation at the company. "We are very ambitious," he says matter-of-factly, adding that within the next five years he wants DRL to be among the top 50 global pharmaceutical companies, and among the top 25 in the next ten years.

### ***Intellectual Capital***

And where does he see the Indian industry heading by then? While many Indian companies have already carved a niche for themselves in the US generics market, what gives Reddy "great satisfaction" is seeing a small company like Glenmark Pharmaceuticals doing discovery research, and doing it rather well. Glenmark, which is currently about the same size as DRL was when it began its basic research, has recently established proof-of-concept in animal studies with its antidiabetic, GRC-1087 – a highly potent selective human beta-3-andrenoceptor agonist. "It is instances such as these that make me hope that India will one day emerge as a nucleus of drug discovery," he says. There's probably another reason why he wants his dream for India to come true. "I hate the term 'Third World country'," he said at a recent lecture in Mumbai. "Maybe if we produce 30 Merck-like companies in India, this nomenclature will be dropped." He added that, like Merck & Co, DRL too guarded and nurtured its R&D/intellectual assets more closely than its financial assets.

In one of DRL's past annual reports, Reddy observes that the management of intellectual capital is potentially a greater source of competitive advantage than its mere possession. "Smart companies know how to manage intellectual capital. That is how they uncover the hidden value within every transaction and relationship," he points out. And, at least for the moment, Reddy appears to have done a competent job in nurturing in-house talent. Reddy's son, Satish, is DRL's managing director and chief operating officer, and his son-in-law, GV Prasad, is DRL's executive vice-chairman and CEO. They have been running the company for a while now, Reddy says, adding, "We are so open with each other that both of them once told me if I could get a better COO and CEO, they'd like to relax! And I couldn't find anyone. Relationships aside, I believe you can't get a better team than them. DRL is in very safe hands."

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