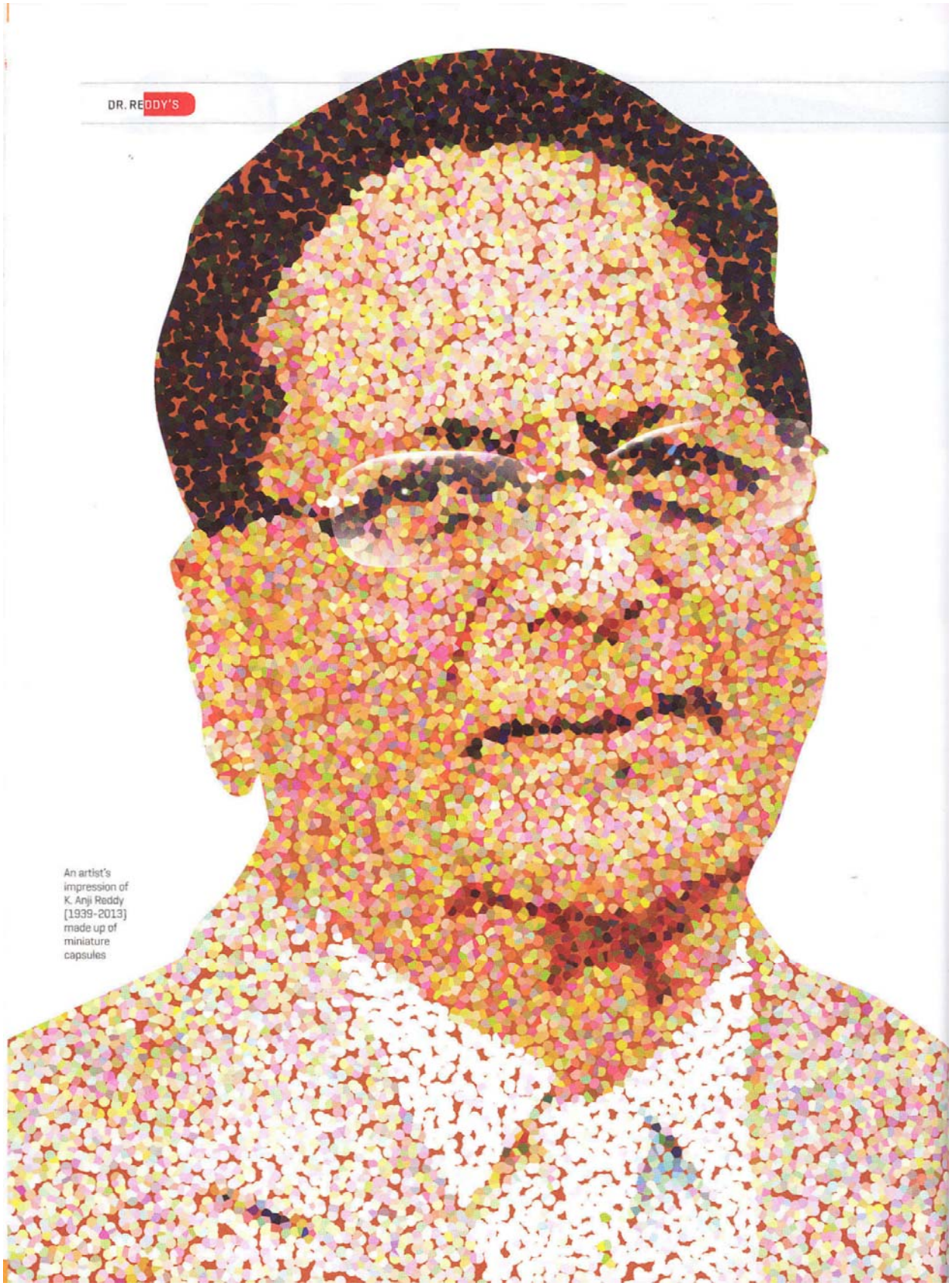
PUBLICATION: FORTUNE	
EDITION: NATIONAL	DATE: JANUARY,2014



An artist's impression of K. Anji Reddy (1939-2013) made up of miniature capsules

RESHAPING THE LEGACY

IS DR. REDDY'S LABORATORIES MISSING ITS ICONIC FOUNDER?

By T. SURENDAR | *Illustration by* NILANJAN DAS

IN MARCH 2011, DR. REDDY'S Laboratories (DRL), ranked 88 on the *Fortune India* 500, moved to a glittering new office, done in glass at Hyderabad's Banjara Hills. Though he had a brand new room there, founder K. Anji Reddy still preferred his earlier room at Ameerpet, north-west of Hyderabad, from where he'd built DRL into a pharma powerhouse. At his insistence, the room at Ameerpet was untouched, his books kept as they were, his table undisturbed. Son Satish, DRL's managing director, says his father also forbade him from selling the first S-Class blue Mercedes he'd bought in 1994, and would excitedly show off to friends when it was new. Till recently, the car was parked at the basement of the new office; it's since been moved to the family farmhouse for safekeeping. K. Anji Reddy died of liver cancer on March 15, 2013, a year and a half after the disease was detected. Satish is planning to build a museum of sorts that'll house his father's personal belongings, correspondence, the car, and maybe even the office. There are plans to posthumously publish Anji Reddy's autobiography, co-written by Raghu Cidambi, an advisor to DRL and a close associate of Anji Reddy. What remains of DRL are the vestiges of what Anji Reddy once set out to do. He'd set up the company

in 1984, and though he began by synthesising raw materials for medicines or active pharma ingredients (API) as they are called in the trade, his heart lay in new drug discovery. Any conversation on business, preferably over a Chinese meal, his favourite, would invariably meander into molecules he was betting on. By 1997, when DRL was Rs 350 crore in sales and not even a decade and a half old, it had licensed out its first molecule, Balaglitazone, an anti-diabetic, to Novo Nordisk. DRL's business model had two parts: One, the predictable bit, revolved around APIs, and making generic versions of innovator drugs, including gunning for first-to-files in the U.S. which gave market exclusivity. The other was new drug discovery.

Anji Reddy took huge risks; in fact, he had a penchant for them. Call him brazen, risk-taker, disruptor, larger-than-life, or as he described himself, sometimes with characteristic jest, 'a game-changing techno entrepreneur'. Not just with the molecules he set his heart on or the money he was willing to throw behind them, but also his willingness to take on Big Pharma, battle them in courts, etc. Such acts of defiance defined him. An example: Back in 2004, after eight straight quarters of tumbling profits, plummeting market capitalisation, and unforgiving analysts on every earnings call, Anji Reddy still kept throwing money into drug discovery—and had his board back him.

Anji Reddy's fervour to speak of science and technology rather than the nitty-gritty of running the business made DRL look like a cool, edgy company that could surprise the market with a winner. Even a few months ago, when his cancer was advancing rapidly, he wanted to speak to a scientist in the U.S. with whom DRL had recently collaborated. He wanted to understand and discuss the methods the scientist used but that call could not be put through on two occasions due to his illness.

Anji Reddy used to say that only a "mad man" like him would push deep into the costly and capricious world of drug discovery and everything that came with it. His dreams died with him—and today his son and son-in-law, G.V. Prasad, DRL's chairman, are reshaping his legacy.

After expensive failures, DRL has given up on new drug research. (The closest it ever got to launch an innovator product was Balaglitazone, which was ready to be launched after it passed phase III trials, but after a similar compound was banned in Europe, DRL couldn't find any takers to partner a launch.) From a 2005 peak of 14.4%, research spend as a percentage of turnover is down to 6%. DRL even changed its mission statement a few years ago: from a research-led pharmaceutical company to providing affordable and innovative medicines for healthier life. This shift away from research, including the tapering of R&D spends, had begun when Anji Reddy was alive. Satish says his father took part in the decision.

Companies that are built around innovation often miss their founders, the innovator-in-chief, when they are gone. Apple is the best example of it, though there are other cases such as Dell or Microsoft. Satish agrees and admits that building on his father's legacy is a "huge responsibility". But he adds that though Prasad and he miss Anji Reddy's long-term vision and big thinking, "because we benefited from it", DRL's next phase of growth will depend more on execution than the big idea. The objective: Build predictability.

The historic model, where big pharma produced blockbusters and generic companies thrived in their slipstream, has broken down due to a variety of factors: rising R&D costs, fewer targets, greater regulation, and push towards generics to contain health-care costs. (Neither Pfizer nor GlaxoSmithKline has put out a blockbuster in the last decade.) These have pushed innovators to try multiple options—branded generics, emerging markets, hybrid models (like the partnership of Ranbaxy and Daiichi Sankyo)—because they are not sure which of these will ultimately work. On the one hand this means that lines between the innovator companies and generic players are slowly blurring. On the other, the absence of a set model and uncertain outcomes mean many different business models will be tried.

FOR THE LIKES of DRL, that'll mean many more opportunities. And to grow bigger (at Rs 11,626 crore or roughly $2 billion, it is still a minnow in global pharma) it doesn't need to take the chances that Anji Reddy took. Equally, now that the organisation has hit a respectable size, there's much more to lose if things go wrong. Satish says that after 2006, when DRL hit the $1 billion turnover mark, it fell on Prasad and him to build a more sustainable organisation. He identifies different types of sustainability, such as viability of business, consistency in delivering turnover and profits, moving away from individuals, and building leaders. "This has led us to be more predictable; some may call it boring," says Satish. "But we also evolve with the changing industry."

One outcome is that DRL is reexamining the whole notion of innovation. The thinking: not to stop innovating altogether, but equally, not approach it the way it was done in the past. Satish begins saying, "It has to be a balance of amounts spent," and then stops mid-sentence. "Amount is a wrong word because it is doing disservice to my father's thinking." He finally settles on the idea of "increasing the chance of success". "How much would you bet on NCEs,

THE NEW ORDER: SATISH REDDY (LEFT), VICE CHAIRMAN AND MD, DR. REDDY'S, WITH G.V. PRASAD, CHAIRMAN AND CEO

[new chemical entities, essentially drug discovery], how much on proprietary products, and then ensure there's a viable organisation built around that," concludes Satish.

Then, is DRL's NCE dream finally buried, I ask. Satish pauses, and answers thoughtfully. "It's not buried, but it's not the most important thing. I could use the words 'de-emphasised it' or 'reprioritised it'," he says.

So, what's *their* big idea to take the organisation forward and convince analysts that there is enough juice left in the stock? After all, though bigger by Rs 230 crore than Sun Pharmaceuticals, DRL's valuation at Rs 43,300 crore is nowhere near Sun's Rs 118,000 crore.

Analysts say this year Sun will overtake DRL in sales on the back of strong growth in the U.S., the biggest pharmaceutical market. Lupin's drugs are already the most prescribed in the U.S. These two companies have grown much faster in recent years, thanks to their laser-like focus on generics in a few key markets such as the U.S. and Japan. Sun's sales in the U.S. amounted to $1.1 billion in FY13, compared to $660 million for DRL. Once, DRL's biggest strength lay in selling generics in the U.S. But as the numbers show, it's a trick several other Indian companies, particularly Sun, have successfully laid claim to. (Apart from the U.S. and Europe, DRL is present in several emerging countries in Africa; in the CIS, including Russia; and Australia.) Again, DRL does not have a strong franchise in any specific area as Sun does in dermatology or Lupin in branded generics.

An investment banker who has been tracking DRL closely for years, but doesn't want to be quoted because of his regular dealings with the company, says: "There is an impression that DRL is having to do a lot more to achieve the same results as some of its competitors and, therefore, a question arises about what the company is focussed on."

The answer: biosimilars, or copies of biotech drugs. If the hunt for an NCE defined the Anji Reddy era, his son and

son-in-law may well come to be defined by their attempts at building a huge, global, biosimilars business. Of course, this bet will push the company further from the path Anji Reddy envisioned. In a remarkably candid appraisal, Prasad says, "If the biosimilars business succeeds, the payoff will be huge. If it does not, we will have to see what we want to do." With the industry in a state of flux, it can't get any more certain than that.

TO BE FAIR, though Anji Reddy may have championed the NCE cause, he saw the biosimilars opportunity early on. Satish says back in the early 1990s, when he was still at university in the U.S., his father, on a visit, took him along to meet some folks who were dabbling in biosimilars. DRL's first attempts in biosimilars, somewhat botched (more of that later), happened when Anji Reddy was still around.

The big push, however, is more recent. In the last three years, DRL has invested more than $100 million to make biosimilars. It is the single largest commitment to a new project. DRL has over 700 people working on the business. A core team of 50, of which 15 are located overseas, looks at important functions like clinical development and technology. The company has also set up a factory on the outskirts of Hyderabad, which is out of bounds to most of its employees, given the highly regulated nature of the business. DRL has put out four biosimilar products in India and emerging markets in Latin America where the regulatory processes are not so stringent as in the U.S. and Europe. It has also tied up with Switzerland-based Merck Serono to help it to get approvals for its biosimilars in the U.S. and Europe, for which clinical trials are under way.

All this makes DRL the only one among the top five domestic pharma companies to make a significant investment in biotechnology drugs as opposed to chemical ones. Wockhardt tried its hand in the business, tying up with German firm Rhein Biotech in 1996. After an acrimonious split six years later, Wockhardt's biotech programme stalled.

A consequence of the biosimilars move: Analysts like Ken Cacciatore of the U.S.-based Cowen & Company now classify DRL among the growing breed of specialty pharma firms in the U.S., which play in evolving areas such as biotech drugs, highly regulated injectable drugs, and specialised hospital supplies. It is the only Indian firm to make it to Cowen's exhaustive research report on specialty pharmaceutical firms in early 2013 that also enlists larger competitors like Israel-based Teva and the U.S.-based Mylan and Actavis. The classification is important as it repositions DRL in the U.S. Other top Indian companies, including Sun and Lupin, are called generic companies as they largely peddle chemistry-based drugs.

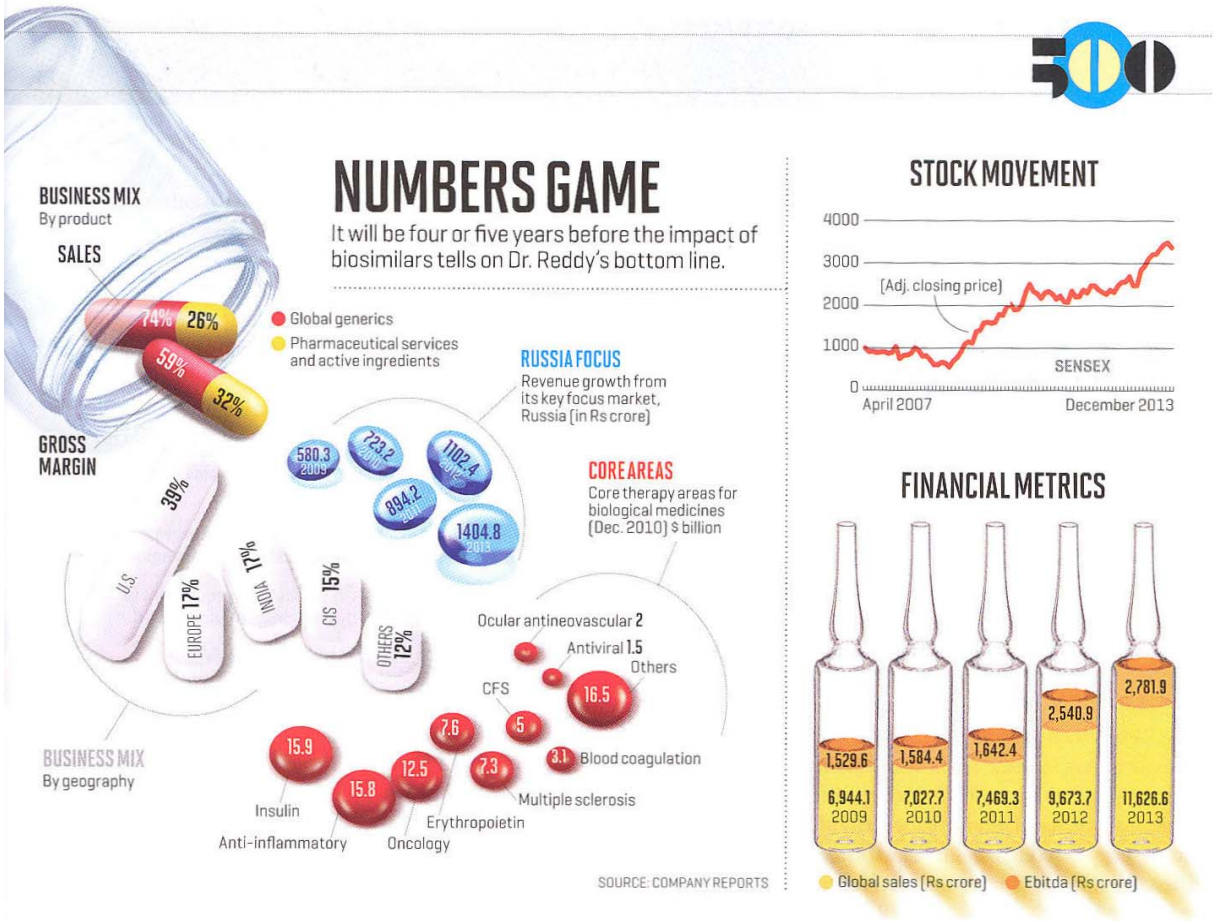
In three decades after the first biotech drug was discovered, this class of drugs crossed $120 billion in sales in 2012, or a little over 13% of the global pharmaceutical industry. Further, nearly half of the drug approvals pending with the U.S. Food and Drugs Administrator (FDA) are for biotech drugs, an indication of the role they will increasingly play. An October 2013 report of Mumbai–based research firm Espirito Santo Securities says that there are more than 350 biological products currently under clinical trials. The same report estimates that the market for biosimilars in highly regulated markets is likely to exceed $15 billion by 2020 from less than $1 billion currently. Another report from Vadodara-based pharma research agency MP Advisors claims that nearly $50 billion worth of biologics will go off patent by 2020.

While there is no denying the opportunity, DRL's success isn't guaranteed. Even though the uncertainties of drug discovery are eliminated, other challenges remain. Analysts Chirag Talati and Rakesh Nayudu of Espirito Santo Securities, who penned the October report, say, "Given the stage of its [DRL] growth as well as geographic and product concentration [in the U.S. and Russia], plus its strategy of concentrated product filings for its U.S. portfolio, we believe this rising capital allocation to biosimilars creates a risky growth profile."

Till recently, there was little clarity if regulators in advanced countries would approve clones of biologics. Chemical drugs are usually small in size, and measured by the molecular weight. The small size allows easier prediction of a molecule's structure and shape and, therefore, makes it easier to standardise and replicate. From a regulator's standpoint, generic companies have to prove that their version is equivalent to the original and will be as effective.

Biological drugs are different. They are often long amino acid chains with molecular weights that are a few hundred times more than their counterparts in chemical drugs. The long chain makes it difficult to predict their 3-D structure accurately. In other words, an amino acid with a specific molecular weight can have multiple 3-D structures. Now, since the structures of these compounds affect their medicinal properties, regulators can't be sure if a copy will behave like the original. The only way to find out is by testing it all over again on humans. Says Cartikeya Reddy, executive vice president of biologics in DRL: "It is like being told that you are guilty until proven innocent."

Further, the actual manufacture of biosimilars is onerous. They are usually injectables produced in annual capacities between 5,000 litres and 10,000 litres. Filgras-



tim, used for faster recovery after chemotherapy, is made using recombinant DNA technology. A protein is inserted into the genetic material of bacteria Escherichia coli which then produces the final drug. The conditions that facilitate this process are exacting, and have to be highly controlled. To succeed in biosimilars, DRL will have to ensure that the yields of the injectable are high enough to price the drug cheaper than the innovator. Unless DRL can ensure better synthesis of the biosimilar, profitability is not a given in the global markets, unlike say in chemical drugs, where Indian companies have a proven advantage.

There are also impediments to selling a biosimilar. Chemists are not allowed to substitute a cheaper biosimilar for the original, as innovators insist that copies can never be exact. So, DRL will have to set up its own sales force to sell its version of the drug to doctors, adding to costs.

Given all this, regulation has so far favoured innovators. But, in the last six years, European regulators have been selectively approving biosimilars for filgrastim, somatropin (a growth hormone used in regeneration of cells) and erythropoietin (to control production of red blood cells). The Europeans have been more accepting of the clinical trial data for biosimilars than the FDA which wants biosimilars to be more exact copies of their patented counterparts. However, the FDA, too, recently approved Sandoz's somatropin and Teva's filgrastim, signalling that it is relaxing its processes. Sandoz, the generic arm of Novartis, has already built a $335 million (up 35% from the previous year) biosimilar business with two successful products—somatropin and erythropoietin—grossing $100 million each.

The outcome: a flurry of moves. Every big pharma company now has a biological play in its portfolio. In 2009, Pfizer bought Wyeth for its biological technology. Actavis bought Amgen. Today, Pfizer wants to do more biopharma contract manufacturing work and has a microbial and yeast-based manufacturing plant in Sweden which is approved for that. Indeed, it's even willing to work for rivals. A website, outsourcing-pharma.com, quoted a Pfizer official with words to that effect.

The shifts in Big Pharma strategy have cascaded down,

with large generics firms, too, acquiring biologic capability. Teva and Mylan have collaborated with Lonza from Switzerland and Bangalore-headquartered Biocon to expand their biosimilars portfolios.

Small, single-product biologics firms, which produce drugs for rare diseases, are commanding high valuations. Amgen picked up San Francisco-based Onyx Pharmaceuticals for $10 billion. Onyx's revenues: $700 million. Prasad likens this to "whirlwinds". He says DRL entered South Africa and Russia when both markets were undergoing systemic changes, and created value in the long run. He quotes Infosys founder N.R. Narayana Murthy that ships are not meant to be in the harbour. "We have always felt that those who weather a whirlwind will emerge stronger."

THIS IS DRL'S SECOND COMING in the biotech space. In the late 1990s, Jayaram Chigurupati was hired by Anji Reddy to kick off new businesses in areas such as biologics and oncology. The biosimilars business suffered initial setbacks after innovator Roche pointed out that DRL's version of filgrastim had a different sequence of amino acids compared to its own and that the copy could not claim to be the same drug. Nicholas Piramal, the local company which marketed Roche's product branded Neupogen, wanted DRL to clinically prove the efficacy of its filgrastim. Chigurupati left the company in 2003 and the biologics business was in a limbo for a while.

The business was again revived in 2004 after Cartikeya came on board. This time around, Prasad wanted to build his own capabilities from scratch. Says Cartikeya: "We are putting the building blocks to ensure a fair degree of continuity in the business in future." He says that if you didn't consider the investments in Merck Serono, the biosimilars business is already profitable—sales touched Rs 140 crore in FY13.

But that's no consolation. If it takes $1 million to $2 million and three years to five years to put out a copy of a chemical drug, it can cost anywhere between $50 million and $100 million and seven years to eight years for approval for a biosimilar. (Remember, companies wanting to put a biosimilar in the market have to conduct a full-fledged clinical trial to prove their drug's efficacy. This accounts for increased costs and time for approvals.)

DRL and Merck Serono are together conducting phase one clinical trials for Rituxan, a drug for follicular lymphoma, to be able to afford the development for global markets. Without getting into names, the Cowen report predicts that an Indian generic biologic drug is likely to hit the U.S. market within the next five years.

NEW COPIES

Biosimilars, or clones of biotech drugs, will be the focus this time round.

CHEMISTRY-BASED GENERICS	BIOSIMILARS
Low molecular weight 100-200 units	**High weight 20k-200k units**
Predictable shape and pharmaceutical properties; copies are exact replicas	**Tough to define shape accurately; copies vary marginally**
Generics can be launched using innovators' established data	**Launch requires proving compatibility with original**
In most cases, expensive clinical trials are not needed	**Clinical trials equivalent to new drugs mandatory**
Solids, injectables, sprays, etc.	**Only injectables**
Costs $300,000 to $1 million to launch in regulated markets	**At least $100 million to launch**
Time to market: 3 years to 5 years	**5 years to 8 years**
Regulatory pathways clearly defined	**Still evolving; the U.S. is hard, Europe is easier**
Generics cost 10% to 20% of original drug	**Biosimilars cost 65% to 75%**
Chemists can substitute brands prescribed by doctors with generics	**Substitution not allowed; biosimilars have to be branded and sold as a separate product**

SOURCE: *FORTUNE INDIA* RESEARCH

Though Prasad says it will be four years to five years before he can decide if the biosimilars bet has worked well enough, any success could mean big bucks. Biologic drugs don't experience the same fall in prices on the launch of a generic as chemical drugs do. On average, biologics prices fall by around 30% after the launch of a biosimilar, compared to at least 70% in chemical drugs. In India, DRL's filgrastim is priced at Rs 39,000, though it sells for an effective price of Rs 25,000 a vial because of discounting and special offers, compared to Rs 70,000 of Roche. That leaves DRL with adequate room to play with prices if volumes increase. Analysts estimate that DRL's biologics business could touch sales of $200 million by 2017, a third of it coming from non-regulated emerging markets.

Seen through Prasad's eyes, selling biosimilars in emerging markets is also doing what other domestic generics companies are not. Though Biocon is following a DRL-like strategy to first launch products in India and emerging markets before going to developed markets, Prasad feels the opportunity for biological drugs still remains unex-

plored elsewhere. DRL's experience with filgrastim shows that Brazil and Russia could be much larger in biosimilars, but for the high prices of these drugs. Biologics account for nearly 10% of the Russian pharma market. It is also estimated that the rest of the world, apart from highly regulated markets such as the U.S., Western Europe and Japan, could be worth 20% of the overall global biosimilar market. "We have a long experience in markets like Russia which we still classify as a growth market," says Prasad. DRL's bet: Enter with cheaper products.

BETWEEN 1992 AND 2006, Anji Reddy blew up between $50 million and $60 million on drug discovery. Evidently, the biologic bet will be no cheaper. Equally, biologics isn't entirely risk-free. So, why not stick to generics? The DNA of DRL holds clues to that poser. In the days the triumvirate ran the company, Anji Reddy and Prasad were the ones always willing to back the big bets. Satish was more cautious. The caution allowed the company to build itself incrementally, while the risk-taking gave big wins sporadically. Like in 2000, when DRL fought a bitter battle against AstraZeneca and lost a 180-day market exclusivity to launch omeprazole, an anti-ulcer drug. A year later, DRL won against Eli Lily to launch a 40 mg generic version of Prozac (fluoxetime), giving it windfall profits of $70 million in six months. But as the drug discovery narrative shows, the risks often didn't bear any returns.

That willingness to take bets hasn't entirely been leached out of the company's thinking: It's just been calibrated. As Prasad says, there's always a strong sense of wanting to be different from others. "Our bet on biosimilars shows we are still willing to take risks, but instead of taking a leap, we have put the plumbing in place. We have tried to connect the dots to get somewhere." In his scheme of things, unlike in drug discovery, where the product is unproven, in biosimilars, it is. The only variable is the clinical trial, but while that can be time consuming, it's less of a risk than launching a new drug. "My problem is that I always seem to underestimate the time a project will take to be successful," he says.

Meanwhile, in the last three years, every year, DRL had a 'Para 4' permission that gave it exclusive 180-day marketing rights for generics, bringing it $50 to $100 million in additional revenues each year. DRL has now moved the game a few notches up. It is focussing on products that are difficult to make, like prostaglandin, which has over 40 intermediate steps before the drug can be made. It is also focussing on oncology injectables that require expensive clinical trials before the generic can be sold. The idea is to keep moving ahead of competition and play in areas that have either a cost-, or a technology-based entry barrier.

The more eclectic strategy of focussing on niche, specialty areas is also paying off. Consider the over-the-counter store brand business in the U.S., where DRL is now the No. 2 after local leader Perrigo. Analysts at Cowen expect that this business could double to $350 million, which consists of drugs that have been converted into over-the-counter brands from previously being prescription-based. Unlike generics, which are open to price erosion, this business could contribute a stable 10% to 15% of the company's revenue. The Cowen report says: "DRL's capabilities in this space are not appreciated by the street and revenues from the OTC effort provide durability and growth to its North America line."

Given the company's history, Satish knows the street can be fickle. Though the stock returned 40% in the last year, he says it's essentially a valuation of the U.S. business. He knows multiples could jump on the news of some positive development in biosimilars, like it did earlier with NCEs.

Analysts agree that the parts do add up, giving a good growth visibility for earnings in the near future. In its usual business of generics, DRL has a good line-up that will give it exclusivity; there are also the high-margin injectables. Also, since DRL's U.S. sales are still small compared to competitors such as Mylan and Teva, it won't have too much pressure growing its traditional generics business even if the number of drugs going off-patent falls dramatically going forward. Says Tarun Shah of MP Advisors: "There are always enough complex products out there which few companies have the capability to copy, and that should keep DRL going much longer that the others."

Anji Reddy would often joke that his original vision had been changed. He would also admit that he was party to it. Today, if there is anything conspicuous by its absence, it is the talk of research at DRL. Prasad, though a chemist by training, rarely talks of science and never of research. He says that in future DRL will take a leaf out of consumer giant Procter & Gamble's strategy book and collaborate much more with partners to make or sell drugs. He also wants to emulate Novo Nordisk to find ways to help patients use their medicines better. Novo Nordisk used technology to make it simple for chronic diabetes patients to administer insulin to themselves. And neither Prasad nor Satish seem to be in a hurry to fulfil Reddy's unfinished agenda to bring a novel drug to the market.

+ FEEDBACK *letters@fortuneindia.com*