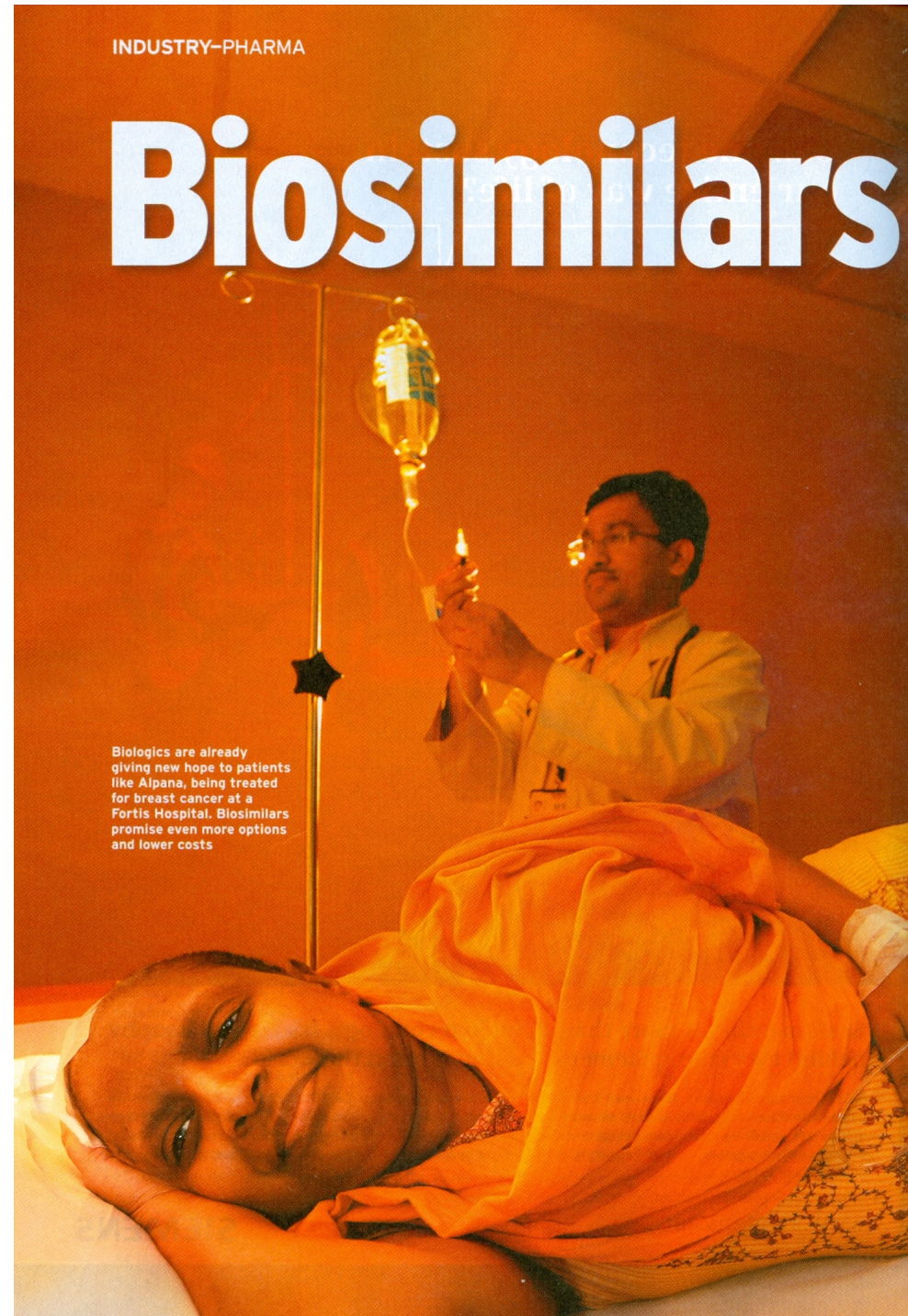


INDUSTRY-PHARMA

Biosimilars

Biologics are already giving new hope to patients like Alpina, being treated for breast cancer at a Fortis Hospital. Biosimilars promise even more options and lower costs



Beckon

Indian pharma companies are targeting generic versions of biotech-based drugs, which can slash treatment costs for killer diseases like cancer. BY E.KUMAR SHARMA

A decade ago, Yusuf Khwaja Hamied jolted the global pharmaceutical community when he proposed to sell anti-AIDS drugs at less than 4 per cent of the price charged by international drug makers. Cipla, the company he chairs, is today one of the world's largest producers of antiretroviral (ARV) drugs to fight HIV/AIDS; and one estimate a few years ago had it that 40 per cent of HIV/AIDS patients undergoing ARV therapy were on Cipla drugs.

The 74-year-old Hamied is now gearing up for his next challenge: He wants to make cheaper versions of pricey biotech-based drugs that can cure different types of cancers, with minimal side-effects. "This will be much like what we did with anti-AIDS drugs 10 years ago, when we brought down prices from \$12,000 to \$300 per year," declares the veteran of the Indian pharma industry. "I am not young any more but this is a crusade that I am planning to take on at Cipla," adds the good doctor who many believe has managed the fine balance of making profits and paying heed to his social conscience.

A visit to a cancer ward of any Indian hospital will explain why Hamied is embarking on this crusade. Most of the patients suffer silently as a cure is beyond their means. But there may be hope on the horizon, as patients slowly but surely begin to

WHERE BIOSIMILARS CAN HELP



LYMPHOMA, A TYPE OF BLOOD CANCER

The treatment cost in cases like non-Hodgkin's lymphoma was Rs 1.2 lakh* per cycle three years ago. A patient needs 6 to 7 cycles — a bill of over Rs 7 lakh

BIOSIMILARS HAVE HELPED BRING DOWN COSTS OF THIS TREATMENT BY ROUGHLY 50%

*excluding costs of other medication and hospitalisation



BREAST CANCER

Some of these drugs today cost Rs 1.3 lakh per cycle; a patient typically needs 8 to 12 cycles, which means a total cost of treatment of at least Rs 10 lakh

BIOSIMILARS CAN MAKE THIS TREATMENT MORE AFFORDABLE

COLON, KIDNEY AND LUNG CANCERS

In some cases, the cost is around Rs 40,000 per month and the patient needs to be on constant medication



access cancer treatments. "Earlier, say about three years ago, I used to get around five cases of non-Hodgkin's lymphoma (a type of blood cancer) in a year, but last year we got 22 patients; and this year we have already treated around eight patients," says Dr Shailesh R. Singi, an oncologist at Care Hospitals in Hyderabad. If more patients are beginning to visit hospitals for a cure for cancer, it's because of heavy subsidies provided by innovator companies that make biopharma drugs that can effectively treat certain cancers.

But subsidies can never be a sustainable solution. What is sustainable is reducing prices of biopharma drugs by making biosimilars. Also known as follow-on biologics, biosimilars are versions of innovator biopharma products that are produced on the expiry of the relevant patent and period of exclusivity for the innovator company. They are copies or generic versions of medicines made using a biological source as against a synthetic chemical substance used in the allopathic medicines that rely on knowledge of chemistry. Biologics, and their biosimilars, are medicines that are based on some biological base, and could be proteins or a complex combination of several biological substances that are all custom-designed to target specific cells in the human body. The targets could be

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INDUSTRY-PHARMA

Kamal K. Sharma, Managing Director, Lupin
"In five years we hope to see 7 to 10 per cent of our top line coming from biosimilars"

specific cell types (say, cancer cells) or specific disease-causing proteins within cells.

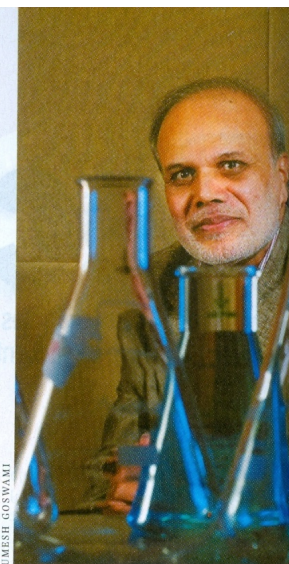
When this writer met Dr Singi, he was treating a patient who is a driver by profession and whose company had agreed to support his medical costs, for non-Hodgkin's lymphoma. The drug: A biosimilar called Reditux launched by drug-maker Dr Reddy's Laboratories three years ago. For the patient, Reditux means he can now access an immensely affordable treatment for his cancer. Three years ago, the cost for a treatment for non-Hodgkin's lymphoma was Rs 1.2 lakh per cycle; a patient typically needs six to seven cycles, resulting in a total bill of over Rs 7 lakh (excluding the cost of other medication and hospitalisation). The cost of that treatment is now down by over 50 per cent. Other than non-Hodgkin's lymphoma, breast, colon, kidney and lung cancers too can be treated with affordable biosimilars (see *Where Biosimilars Can Help*).

Cipla and Dr Reddy's are just two

of many Indian pharma companies that are putting the skills honed in reverse engineering (or making copy cat drugs, as the Western drug companies prefer to see it) to use in biologics. Lupin, Ranbaxy Laboratories, Biocon and now even Mukesh Ambani's Reliance Life Sciences, have taken up the challenge to make biosimilars — with good reason.

"About 40 per cent of all the new drugs entering the market every year are biotech drugs," says Kamal K. Sharma, Managing Director, Lupin. Sharma, who puts in 17 hours a day and teaches at IIT Bombay on week-ends, is the man behind the biosimilar foray at Lupin. "In five years from now we hope to see 7 to 10 per cent of our top line coming from biosimilars." That would translate into some \$300 million from biosimilars, what with Lupin aiming to become a \$3 billion company by 2013, up from \$1 billion currently.

Dr Reddy's biosimilars charge is being led by 40-year-old Cartikeya Reddy (no relation to the promoter



UMESH GOSWAMI

Reddy family), who came on board in 2004. Within three years of joining, he was made a part of the management council, which is the think-tank of the company. A senior engineer at Genentech, a leading biotech firm that Swiss pharma giant Roche paid \$46.8 billion to acquire, he started out at Dr Reddy's as a director in the biologics development centre; in three years he was made the head of biologics business.

This seems to have worked well so far for Dr Reddy's. Other than Reditux, it has launched two other biosimilars and has a pipeline of seven, with a plan to launch one product a year. Capital expenditure on biosimilars is around Rs 150 crore with Rs 30 crore to Rs 40 crore going into research and development annually. The company's pipeline of biosimilars today includes a molecule in late stage clinical trials, two products in late-stage development, and several others in early-stage development. The areas of focus are oncology and auto-immune diseases.

Lupin began its efforts in biosimilars three years ago for which it set up a state-of-the-art biotech facility on the outskirts of Pune as well as the Lupin BioResearch Centre, also in Pune. "In

INDUSTRY-PHARMA

Phase I, we are investing Rs 100 crore and hope to have our first product out in October 2011. This could be either in the area of rheumatoid arthritis or in cancer," says Sharma. Lupin has some six proteins in different stages of development and, after the first launch, hopes to hit the market every three to four months.

Cipla is investing \$65 million or around Rs 300 crore to acquire a 40 per cent stake in a Goa-based company called Mab Pharm and a 25 per cent stake in Bio Mabs of Shanghai. Both Mab Pharm and Bio Mabs are setting up biosimilar units. Cipla is focusing on areas like cancer and rheumatism. Those who work closely with Hamied say this means biosimilars of drugs like Herceptin (to treat breast cancer; innovator company: Roche), and Avastin (innovator company: also Roche) for colon, kidney, lung and gall bladder cancers. Cipla is also apparently looking at a biosimilar for the drug Eribix, sold by Merck KGaA, to treat

Biosimilars Breakdown

PRODUCT	ESTIMATED MARKET SIZE IN INDIA (Rs Cr)
Insulin	650
Erythropoietin+	150
GCSF*	75
Hormones	75
Interferon Alpha^	50
Thrombolytics#	10
Others**	190
Plasma Proteins++	400
Vaccines	900
Total	2,500

* A protein that stimulates red blood cell production

^ A protein that stimulates white blood cell production

A protein used to treat hepatitis B and hepatitis C; can also be used to treat some types of blood cancer

** Drugs that are used to help dissolve clots

** Includes monoclonal antibodies, typically drugs that deal with cancers and those used in cardiology

++ Proteins found in human blood that are used to treat liver diseases and immune deficiencies

Source: Industry

K.V. Subramaniam, CEO, Reliance Life Sciences

"Biopharmaceuticals constitute about 70 per cent of our revenues"



RACHTI GOSWAMI

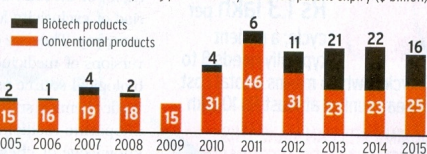
certain types of head and neck cancers. These products are not covered under patent in India and China, which means Hamied can sell the generic versions legally.

For a newer company like Reliance Life Sciences, biopharma is the largest area of focus. "Biopharmaceuticals constitute about 70 per cent of revenues of Reliance Life Sciences," says CEO K.V. Subramaniam, the man driving this initiative at Reliance. Subramaniam says Reliance Life Sciences currently "has the largest portfolio of biosimilars (14) under development in the industry globally, many of which would be launched for the first time as a biosimilar". Reliance plans to launch two or three biosimilars each year for the next five years. The company operates, what it describes as, "the largest mammalian cell culture facility (10,000 litres capacity)" in Navi Mumbai. The Ambanis' penchant for scale — manifest in commodities-driven businesses like refining and petrochemicals — is visible here too. "Reliance Life Sciences is able to offer its range of biosimilars at competitive prices due to its scale and the fact that it has capabilities to carry out clinical trials in-house, giving a significant time and cost advantage," explains Subramaniam.

The huge opportunity — the market for biosimilars is today worth Rs 2,500 crore and, according to industry estimates, growing at close to 20 per cent annually — is doubtless there for the taking. Yet, unlike chemistry-based drugs, the manufacturing process in biologics is more complex. The process is also more expensive than developing new chemical entities, and the regulatory landscape is not uncomplicated. But it's precisely such roadblocks that raise the entry barriers in this space, and the ability to manoeuvre past these hurdles will eventually separate the men from the boys. ☺

Biosimilars Are Set to Take Off by 2012

Worldwide sales of expiring products in year of US patent expiry (\$ billion)



Molecules coming off patent (number)



Source: Industry estimates