

# Drug makers pump up injectables as US patent cliff looms

Mumbai, March 12

INDIAN and foreign generic drug makers seem to be focusing increasingly on the relatively fast-growing injectables segment to ramp up their revenues. A slew of acquisitions in the last couple of years in this space bears this out. Analysts say even in the high-risk, high-reward Para IV space, injectables are now gaining traction.

Research agency Espion estimates the global generics injectables market at \$12.2 billion. This, of course, is quite small considering the mammoth size of the global

pharmaceutical industry (the world's largest drug-maker Pfizer's 2013 revenue alone was close to \$52 billion), but the growth potential is seen to be big. Some of the injectable products — like those in oncology segment — also offer very attractive margins of 75-80%, which is why generic drug companies are eyeing this market with new-found vigour. Shortage of injectables in the US market is adding to the trend.

The \$100-billion US branded-drug market will lose patent protection by 2018 as a patent cliff is approaching. Generic players see great scope in this unravelling of patents, not only in

conventional chemical drugs but also in complex biologics, vaccines, etc., many of which belong to the injectables category. The recent spate of deals in the injectables segment would find foreign and Indian firms among aggressive acquirers. Lupin Laboratories bought Dutch injectables maker Nanomion in February 2014, the latest such buy-outs in the space. In November 2011, The Mumbai-based drug maker had bought an aggressive Japanese specialty injectables company from Pharmacia — a transaction in one of the latest such buy-outs in the Japanese mar-

ket. The company did not disclose the size of either of the transactions.

The global leader in injectables and infusion medicines, US-based Hospira, bought Chennai-based Orchid Chemicals and Pharmaceuticals in August 2012.

Dr Reddy's Laboratories marked its entry into the sector with its \$193-crore purchase of Netherlands-based specialty injectables company OctoPlus in October 2012.

Mylan kicked off 2013 with a \$1.75-billion buyout of Bangalore-based Agila Specialties, an injectables company and a subsidiary of Strides ArcoLab. Private equity firm KKR announced its maiden investment in the pharmaceutical sector — a 35% stake in Hyderabad-based Gland Pharma, an injectables manufacturing company for \$200 million.

Injectables is already showing its importance, with Dr Reddy's US revenue in three quarters of 2014 fiscal seeing a strong growth, helped by niche injectable launches. JPMorgan analysts estimate its complex injectables portfolio, market share benefits and launch of smaller products should support growth over the next two years.

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## DEALS IN THE INJECTABLES SPACE - INDIA FOCUS

Date	Acquirer	Target	Deal value
Feb 2014	Lupin	Nanomion	n/a
Feb 2013	Mylan	Agila Specialties	\$1600 m
Oct 2012	Dr Reddy's	OctoPlus	\$44.76 m
Aug 2012	Hospira	Injectable manufacturing plants of Orchid Pharma	\$200 m
Nov 2011	Lupin	From Pharmacia	n/a

Source: Bloomberg and company reports  
N/A: Not announced

## ROLE OF INJECTABLES IN INDIAN PHARMA MARKET

Date	Value (₹ cr)	Growth (%)
Feb 2014	10,037	10.37
Feb 2013	11,560	11.56
Nov 2011	12,174	12.17

Source: AIOCD-AMACS

Regulation

## Drugmakers...

In August 2013, Hyderabad-based Aurobindo Pharma spun off its injectables business into a fully-owned subsidiary named Curepro Parenterals "to strengthen and provide focused growth to the injectable business and to leverage strategic opportunities," according to a statement issued at the time.

HSBC analysts estimate that about 50% of known para-IV generic drug approval applications are in specialty therapies – a terminology used to denote complex injectable medicines. A para-IV submission allows a generic firm to challenge a patent and launch a generic version of the drug at the risk of being sued by the innovator or sell a drug that has just gone off-patent with the patent holder being the only competition.

"There is an emphasis on biologics, vaccines and other such complex therapeutic products," PwC executive director (pharma life sciences) Sujay Shetty said. He said margins on injectable products range from 10% to 80%. "Vaccines have low margins and command between 10% and 15% while oncology products are high-margin drugs and has margins as high as 75-80%," he added.

In what reflects the shortage of injectables in the highly regulated markets, Johnson & Johnson could not supply the chemotherapy drug,

Doxil (doxorubicin) from October 2013 in the US due to issues with its manufacturing partner, Boehringer Ingelheim. India's Sun Pharma came to the rescue with the generic version of the drug. The growing significance of the injectable for top Indian companies is evident as doxorubicin, indicated for ovarian cancer and multiple myeloma, contributed about 11% to Sun Pharma's Q3FY14 revenue. With J&J still unable to get its drug to market, UBS analysts estimate the drug to contribute about 18% to Sun Pharma's FY15 earnings.

The US Food and Drug Administration says out of the 251 drug shortages in 2011, 183 or 72% were those of sterile injectable drugs. In 2012, 84 of the 117 reported shortages involved injectables. As of date, according to data hosted on the USFDA website, of the 194 drug shortfalls, 145 are those of injectables – about 75%. The regulator said there are fewer firms making older sterile injectable drugs and the problem is exacerbated by the limited number of raw material suppliers for the drugs.

"This small number of manufacturers and limited production capacity for older sterile injectables, combined with the long lead times and complexity of the manufacturing process for injectable drugs, results in these drugs being vulnerable to shortage. When one company has a problem or discontinues, it is difficult for the remaining firms to increase production quickly and a shortage occurs," the USFDA said.

The Indian generics injectables market is worth Rs 12,174 crore and is growing at 5.31% annually. There is renewed interest in this market too.

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