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Financial Chronicle, Delhi
Tuesday 12th August 2014, Page: 6
Width: 4.25 cms, Height: 16.70 cms, a4, Ref: pmin.2014-08-12.33.46

Teva may move court against DRL

TRUSHNA UDGIRKAR

Hyderabad

ISRAELI pharmaceutical company Teva, seems to be geared up to drag Indian generics producer Dr Reddy's to the courts, over patent infringement of their blockbuster drug Copaxone, used for multiple sclerosis. Dr Reddy's is keen to manufacture the copycat version of this drug, and was hoping to launch the drug in FY 16.

For Teva ,the drug fetched sales of $ 4.3 billion globally in 2013, bringing the company more than 20 per cent of total sales.

Last week, Teva confirmed of receiving para IV notice for its Copaxone 40mg/ml dosage drug. "Teva will continue to vigorously defend its Copaxone intellectual property rights against infringement wherever they are challenged. Teva intends to file a lawsuit for patent infringement against Dr Reddy's within the 45 day period provided under the Hatch-Waxman Act," the company said.

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Patent

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डॉ. रेड्डी के खिलाफ कोर्ट जा सकती है तेवा

हैदराबाद। जेनेरिक दवा बनाने वाली इजराइली कंपनी तेवा फार्मास्युटिकल्स इंडस्ट्रीज कोपएक्सोन (ग्लैटिरामर एसीटेट) इंजेक्शन के पेटेंट अधिकार के कथित उल्लंघन को लेकर डॉ. रेड्डी के खिलाफ अदालत में जा सकती है। यह दवा स्क्लेरोसिस के इलाज में काम आती है। तेवा ने बयान में कहा कि उसे रेड्डी से इस लोकप्रिय दवा को लेकर भारतीय कंपनी से पेटेंट कानून के तहत पैरा 4 का नोटिस मिला है।

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Hindustan Times, Delhi
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Width: 12.73 cms, Height: 15.08 cms, a4, Ref: pmin.2014-08-12.42.236

Sun Pharma poised to go up in US mkt rank

POLE POSITION Company set to become leader in generic dermatology segment once Ranbaxy deal gets approval

Himani Chandna Gurtoo
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NEW DELHI: Mumbai based drug maker, Dilip Shanghvi-led Sun Pharmaceutical Industries is all set to consolidate its position in the United States.

The company, which is in the process of acquiring control of Ranbaxy Laboratories from Japanese drug maker Daiichi Sankyo, will become the leader in the generic dermatology segment in US and capture the third position in the branded dermatology segment after the acquisition is finalised.

The $4-billion (₹24,000 crore) deal announced in April that is currently awaiting few regulatory clearances, will boost Sun's revenues from US market by about 40%.

"Ranbaxy's anti-acne drug Absorica is one of its major drugs and currently generates annual sales of over $150 million (₹900 crore) and the acquisition of Ranbaxy will phenomenally boost Sun's business size in US market and will further enhance combined revenues by around $2.2 billion (₹13,200 crore)," said people familiar with the financials and plans of the company. Last financial year, Sun Pharma's revenues in US market stood at $1.6 billion (₹9,600 crore), posting a 43% growth.

The company now plans to leverage its newfound leadership position to establish greater speciality presence in the US, according to a source. Sun Pharma's spokesperson, however, declined to comment.

US had always featured among top geographies for the company. It established a strong presence in the segment after the acquisition of US dermatology firm Dusa Pharmaceuticals in 2012 for ₹1,249 crore.

"Sun Pharma, with the recent acquisitions of DUSA, URL Pharma and Ranbaxy Laboratories, has now become strong in the US region, with the geography accounting for 60% of its sales in financial year 2014," said Sarabjit Kour Nangra, pharma analyst, Angel Broking.

SUNRISE IN THE WEST

- Sun Pharma will also acquire the third position in the branded dermatology segment
- Its US revenues in 2013-14 stood at $1.6 billion posting a 43% growth
- It established itself in the segment after the acquiring US drug firm Dusa Pharma in 2012

Dilip Shanghvi

Company

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Arvind Remedies Q1 net up 53 %

CHENNAI: Arvind Remedies a leading producer of branded and generic pharmaceutical products increased its net sales by 40 per cent to Rs. 258 crore in the first quarter ended June 30, 2014, from Rs.184 crore in the year-ago period. The net profit has risen by 53 per cent to Rs. 26 crore from Rs. 17 crore. — Special Correspondent

Company

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Arvind Remedies profit up 58%

Chennai, August 11

Chennai-based drug-maker Arvind Remedies has reported a 58 per cent jump in net profit at ₹26 crore for the quarter ended June 30, mainly on the strong performance of its cardiovascular and anti-diabetes drugs.

Revenues surged 41 per cent to ₹258.6 crore during the quarter; earnings before interest, taxes, depreciation and amortisation grew 57 per cent to ₹63 crore. "We had launched two brands in the domestic market during the last three to four months in the chronic diseases segment. Higher sales in these segments contributed to the growth," said Managing Director and Chief Executive Officer Arvind Shah. OUR BUREAU

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PHARMA

Sanofi to pay up to $925 mn for rights

Geneva:Sanofi agreed to pay **MannKind Corp.** as much as $925 million for rights to the world's only available inhaled insulin less than seven weeks after the drug won regulatory approval in the US. Sanofi will take 65% of profit or loss related to sales of the drug, Afrezza, while MannKind will get 35%.

BLOOMBERG

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Economic Times , Delhi
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Width: 10.66 cms, Height: 25.49 cms, a4, Ref: pmin.2014-08-11.29.63

Sun Banks on Daiichi to Crack Japan Mkt

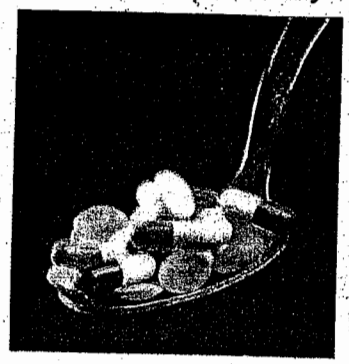
Drugmaker chalks out turnaround plan for Ranbaxy

SOMA DAS
NEW DELHI

Sun Pharmaceutical Industries, which is in the process of acquiring control of Ranbaxy Laboratories from Daiichi Sankyo, will soon put its purchase to work through the exclusive marketing opportunity offered by two drugs in the US, rationalising research and other costs and eventually using its association with the seller to crack the Japanese market.

Sun Pharma's Japan entry will take place three to four years after it closes its deal to acquire Ranbaxy and once basic issues at the company have been fixed, said people familiar with the plans. The $4-billion deal, announced in April, is currently awaiting various regulatory clearances.

Spokespersons at Sun Pharma and Ranbaxy declined to comment.



JAPAN MARKET: TEMPTING BUT TRICKY

Japan, the world's largest drug market after the US and Europe, has proved tough for Indian players to succeed. The penetration of generic drugs is less than 25% compared with more 80% in the US drug market. But the Japanese government's intent to raise this share to 60% by 2017 has prompted analysts to dub it as the next big frontier for Indian drugmakers. "In Japan, Indian players cannot simply succeed by replicating the strategies that have paid off in the US—of launching at the lowest price, garnering high market share and playing a volumes game," said Amit Chander, partner at Baring Private Equity. "That is because Japan is an acutely brand-conscious market, where the dominant perception is that high quality and low prices do not go together," said Chander, who heads the pharma and healthcare vertical at the private equity fund. In this context, Sun Pharma's strategy of partnering Daiichi, a top local drugmaker, seems to be a prudent strategy, he added.

Thus far, Indian drugmakers have adopted two models to enter Japan. While most have begun by manufacturing raw materials for a Japanese partner in the hope of entering into formulations later, some, like Lupin, have taken over local companies. "For a company of Sun's size and scale, selling just raw materials in Japan wouldn't move the needle. The Daiichi platform has the potential to offer a sure-footed entry in this tricky market," Chander said.

RANBAXY TURNAROUND PLAN

Within a year of deal closure, Sun Pharma hopes to have brought to the US market two of Ranbaxy's pending exclusive marketing opportunities — generic versions of Nexium and Valcyte. The latter earns its parents — Astra Zeneca and Roche—more than $5 billion in annual US sales.

"Also within a year of closing the deal, Sun could assess R&D project overlaps between the two companies and cut costs by scrapping duplications, keeping only best projects alive," said one of the people cited earlier.

This is in addition to reining in corporate expenses and general administration expenses in overlapping markets.

"Ranbaxy's R&D expense has been to the tune of 9% of sales in the past, a low-hanging fruit for Sun Pharma to cut costs. If you look at the areas where R&D spend of India's top five drugmakers go, you will not find significant difference, barring a few therapy preferences here and there," said Chander. "Beyond access to the ANDAs (abbreviated new drug applications) filings of Ranbaxy, there would not be much to gain from the capabilities, different from what it already has in-house."

The share of generic drugs is less than 25% in Japan compared with over 80% in the US

Between the first and third year of acquisition, Sun Pharma plans to focus on realigning Ranbaxy's sales division and reap benefits flowing from integrating procurement and supply chains. During this period, it also aims to boost efficiencies in key markets, such as India and the US, to deliver $250 million of operational synergies it has promised by the third year.

Sun Pharma believes that about 60% of synergies would accrue in the third year and aims to improve Ranbaxy's EBITDA margins to 15-16% by then, up from the single-digit figure at present, another person aware of Sun's plans said.

Between the third and fifth year, Sun plans to use Ranbaxy's infrastructure in emerging markets —in many of which it is not present — to launch its own products. By the end of this period, Sun hopes to have sorted out Ranbaxy's prolonged regulatory troubles with the USFDA, the person aware of the company's plan said.

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Width: 13.25 cms, Height: 14.31 cms, a4, Ref: pmin.2014-08-09.42.46

Aurobindo Pharma's Q1 profit surges to ₹415 crore

fe Bureau

The company said the figures were not comparable as during the quarter, Agile Pharma BV-Netherlands, its subsidiary, acquired select European business of Actavis

Hyderabad, Aug 8: Aurobindo Pharma on Friday reported a consolidated net profit of ₹415.43 crore for the June quarter compared to a mere ₹18 crore in the corresponding quarter of the previous year. Total revenues went up 70% to ₹2,911 crore.

The company said the figures were not comparable as during the quarter, Agile Pharma BV-Netherlands, its subsidiary, acquired select European business of Actavis. The results for the quarter include the results of the operation of the said business.

On a y-o-y basis, Ebitda improved by 460 bps due to a better business mix and a decrease in material consumption. "We have started integrating the acquired western European business of Actavis. We believe this acquisition will augur well for the company in terms of market access and scale of operations in Europe. The company delivered yet another strong quarter on US generics, injectables, anti-retrovirals (ARVs) and rest of world (RoW) formulations, and has built a strong foundation for sustained growth in each of these segments. Net debt has also reduced considerably during the quarter," N Govindarajan, MD, said in a release.

Formulation sales were up 106.7% to ₹2275.0 crore while API sales were up 3.6% to ₹670.3 crores. Formulations sales constitute 77.2% while the share of APIs is 22.8%. Net debt as on June 30, 2014 stood at ₹2,695.6 crore. The company filed 40 ANDAs in the US during the quarter and its cumulative filings reached 376 ANDAs. Similarly, it filed 45 DMFs, with cumulative filings reaching 2,282 as at end of June 2014.

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Separate policy to promote APIs production: Govt

New Delhi, Aug 8: The government is working on a separate policy to promote and strengthen domestic production of active pharmaceutical ingredients (APIs).

In a written answer to the Rajya Sabha, MoS for chemicals and fertilisers Nihal Chand said a panel of secretaries under the chairmanship of secretary, department of health has been constituted to look into the matter.

APIs are ingredients used for making drug formulations. Minister said: "The committee has been constituted to study and identify APIs of critical importance and to work out a package of interventions/concessions required to build domestic production capabilities and examine the cost implication." *PTI*

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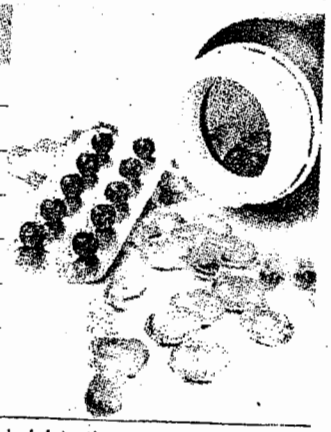
USFDA to restaff as reviews hit

Inspection track record

FY	All foreign countries	India	China
2007	333	64	19
2008	324	64	36
2009	424	59	52
2010	440	72	48
2011	558	98	89
2012	624	141	61
2013	637	111	78
2014*	598	90	88



* (till Aug 4) Source: US Food and Drug Administration
*USFDA fiscal year is from Oct 1 to Sept 30

Pallavi Ail
Mumbai, Aug 8

THE number of inspections by the US Food and Drug Administration (USFDA) in India has come down in the last one year, but the development does not denote that the record of Indian drug manufacturers vis-a-vis compliance with US regulatory standards has improved. Rather, the fewer inspections during the period is due to the fewer staff at the regulator's India office.

The USFDA follows the October-September fiscal year. In FY13 it conducted 111 inspections, which is down to 90 till August 4 of FY14. In FY12 it carried out 141 inspections (see table).

Of 90 inspections done till August 4, there were 70 or so instances where Form 483 — the first observation report on conclusion of an inspection documenting the issues identified — was issued, against 101 such forms issued in FY13 and 107 in FY12.

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Regulatory

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USFDA...

The USFDA conducted 598 investigations in foreign countries excluding China, where it conducted 88 inspections till August 4. There are 517 registered firms in China and 519 in India, which makes India the host to the highest number of USFDA-approved facilities outside the US.

USFDA has a staff strength of 14 in India, of which only six are for probing medical products, which is quite low considering that the agency had an approval to raise the medical products investigators to 19 from 12 in March 2013. Again, of the six, only three are permanent. "USFDA has six medical products investigators in India — three are permanent, and three are long-term detailees (staff who are in the country typically for 90-120 days)," spokesperson Christopher Kelly said.

Altaf Lal, who was the director of the agency in India, resigned from his post in May 2014. He had held the post since June 2013. Carl Sciacchitano, senior science adviser in USFDA's Office of International Programmes, is serving as acting director, India. His appointment began on June 1. Kelly said USFDA expects to name a permanent director in the coming months, and is in the fi-

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nal stages of hiring additional investigators. "Once fully staffed, this will increase our presence to 19 permanent American staff based in-country, including 10 dedicated to medical products," Kelly added.

In comparison, China has 13 staff posted in three locations: Beijing, Shanghai and Guangzhou. This includes eight US civil servants and five Chinese staff. The regulator has plans to expand the China office and when fully staffed, it will include 27 US civil servants and seven Chinese staff, according to Kelly. The China employees include policy and technical experts in Beijing, and inspectors in Shanghai and Guangzhou, who inspect firms that export USFDA-regulated goods to the US.

"Since the opening of its China office in 2008, USFDA has dramatically increased the number of Chinese firms it inspects each year," Kelly said.

India is an important market for the US regulator as it accounted for 40% of US generic drug imports in FY13, which makes it the largest supplier of generic drugs to the country by volume, according to a May 7 India Ratings & Research report. "India Ratings believes that Indian pharmaceuticals manufacturers will face increased USFDA inspections. This is considering the US' increasing dependence on Indian pharmaceuticals manufacturers and the bad press earned by Indian pharmaceuticals on account of the recent spate of import alerts," the report said.

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Sun-Ranbaxy deal comes under CCI scanner

PRESS TRUST OF INDIA
New Delhi, 8 August

Putting the multi-billion dollar Sun Pharma-Ranbaxy deal under close scrutiny, fair trade watchdog CCI has sought more information from them to ascertain whether the deal would skew fair competition in the pharma sector.

Competition Commission of India (CCI) would take a final view on the deal after receiving details from the companies and could seek more information if it is not satisfied with the responses.

"We have sought more information from the two companies. We will take a final view after getting the required information," a senior CCI official said.

Sun Pharma declined to comment on whether it has submitted the responses to CCI, while queries sent to Ranbaxy did not elicit any response.

For CCI, this is one of the biggest M&A deals and also the first major transaction in the pharma sector and therefore its decision in this case could have big implications.

In case CCI finds the deal in the current form could hurt fair competition in the domestic pharma market, it can even direct the companies to divest some assets as a pre-requisite for approval.

The $4 billion worth deal would create the fifth-largest speciality generics company in the world and the largest pharmaceutical company in India.

The combined entity would have operations in 65 countries, 47 manufacturing facilities across 5 continents, and a significant platform of speciality and generic products marketed globally.

In April, Sun Pharmaceutical Industries announced it would acquire troubled rival Ranbaxy Laboratories in a $4-billion deal that includes $800 million debt. The transaction has valued Ranbaxy at 2.2 times its $1.8 billion revenue for 2013, or about Rs 457 per share.

Last month, the deal was approved by leading stock exchanges the BSE and the NSE.

The 'no-objection' from the two exchanges would allow the two companies to file their scheme of amalgamation with the High Court for further clearance of the deal.

M&A

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Width: 5.80 cms, Height: 6.54 cms, a4, Ref: pmin.2014-08-09.31.14

SC stays order related to Pfizer

The Supreme Court on Friday stayed a Bombay High Court order and issued notice to drugmaker Pfizer on the appeal of the central government on the dispute over the pricing of a cough syrup Benadryl. The high court had asked the drug price control authority to review its order against the company. The authorities had questioned the pricing of the medicine saying the increase of 20 per cent in a year was unreasonable and against public interest. The company tried to justify the increase but its arguments were rejected by the officer hearing its petition. So, the company moved the high court. It held the official had no power to pass the order and to fix the price. It asked the authority to review the application.

BS REPORTER