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Indian generic drug firms court US off-patent market

Pallavi Ail
Mumbai, March 24

WITH $32 billion worth of drugs going off patent in the next two years, Indian pharma companies are going all out to launch generics in the US market, the world's largest; patent-related litigation for at least 18 drugs is pending in US courts. While the generics opportunity may not seem very large in the near term, the total sales of these drugs by innovators was $29 billion in 2013. Eight of these are blockbusters — industry term for medicines that generate more than $1 billion in sales. Moreover, all 18 are specialty drugs — commanding relatively high margins and generating double the return on investment compared with traditional therapies.

These drugs target complex health conditions such as cancer, multiple sclerosis and rheumatoid arthritis.

A glance at the major generic drug litigation shows that the top Indian players — Sun Pharmaceutical Industries, Lupin, Dr Reddy's, Cipla and Glenmark — are contesting for the next crop of drugs under the auspices of the Hatch-Waxman Act, a type of litigation specific to drugs where innovators can sue generic drugmakers seeking to infringe on the innovators' patent. It is not immediately known whether any of these firms would launch any of the drugs "at-risk". An at-risk launch is when a generic company puts a product on the market before resolving outstanding patent lawsuits against it.

While historically Indian firms have won cases in US courts, there are some exceptions — a landmark judgment in June 2013 was for Protonix , a drug used to treat acid reflux and which earned for its innovator, Pfizer, sales of about $2 billion in CY07.

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IMPORTANT GENERIC LEGAL CHALLENGES UNDER HATCH-WAXMAN ACT

DRUG	INNOVATOR	INDIAN COs LITIGATING	2013
Abilify	Otsuka	Wockhardt	6.909
Alimta	Eli Lilly	Sun Pharmaceutical Industries	0.012
Celebrex	Pfizer	Lupin	2.883
Copaxone	Teva	Natco Pharma	2.055
Gleevec		Dr Reddy's Laboratories	1.017
Lyrica	Pfizer	Wockhardt	2.862
Mozobil	Sanofi	Dr Reddy's Laboratories	0.011
Nexium	AstraZeneca	Aurobindo Pharma, Wockhardt	8.149
Niaspan	AbbVie	Cadila Healthcare, Zydus Pharma	1.455
Reclast	Novartis	Wockhardt, Dr Reddy's, Sun Pharma, Strides, Gland Pharma	0.015
Revlimid	Celgene	Natco Pharma	0.813
Sustiva	Merck; Bristol-Myers	Cipla, Aurobindo	0.158
Treanda	Teva	Dr Reddy's Laboratories, Hetero Labs, Sun Pharma, Glenmark, Intas	0.01
Truvada	Gilead	Cipla, Lupin	2.11
Vimovo	AstraZeneca; Merck; Pozen	Dr Reddy's, Lupin	0.051
Vimpat	UCB	Alembic Pharma, Aurobindo Pharma, Glenmark, Hetero Labs, Ranbaxy, Sun Pharma, Zydus Cadila	0.479
Zometa	Novartis	Wockhardt, Sun Pharma	0.005
		TOTAL	28.997

Source: Bloomberg Industries

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Generic...

Israel-based Teva Pharmaceuticals Industries and India's Sun Pharma launched generic versions in 2007 and 2008, respectively, but Sun Pharma had to shell out $550 million. In fact, Pfizer managed to get 72% of the initial asserted claims of $3.1 billion from all generics companies.

"The Protonix settlement does have implications for the entire sector...as it may dissuade companies from attempting 'at-risk' launches and the implied corollary of reduced 'at-risk' launches means that innovators likely to have an upper hand during settlement negotiations in a litigation," Credit Suisse analysts had observed.

Under the HW Act, a generics player has 20 days from the day the US Food and Drug Administration accepts its abbreviated new drug application (ANDA) to notify the branded company of its intention to challenge a patent. The innovator has 45 days from date of receipt of this notification to challenge this application and file a patent infringement lawsuit. On filing of this lawsuit, the USFDA stays the approval of the ANDA for 30 months or until the court resolves the patent issue, whichever is earlier.

However, there are situations where a generic drugs company wins a case against an innovator company and the branded drug company appeals against the judgment. If during this period the 30-month stay expires and the USFDA grants approval to the copycat version, the generic drugs company may launch the drug before the verdict on the appeal.

"If the decision rendered by the appeal court is in favour of the innovator company, ie, decision of the district court has been reversed than the generic company can be sued for innovator drug company's actual damages, treble damages and attorney fees depending on the facts and circumstances of the case. The amount of damages paid by generics in cases of at-risk launches, if the patent is held valid and infringing will entirely depend on the facts and circum-

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stances of each case," said Ajay Chandru, senior member, IP team, Nishith Desai Associates.

"This would be an at-risk launch," Motilal Oswal analyst Alok Dalal said. "If the innovator wins the appeal, the generic drugmaker becomes liable for potential damages depending on the losses incurred by the innovator company." Data over the years show that companies are engaging in fewer cases under the HW Act. However, the rate of decline is higher with respect to foreign drugmakers like Teva, Actavis and Mylan as compared with Indian players.

HSBC analyst Girish Bakhru said that on an average, most specialty therapies have competition limited to less than five players which leads to a reasonable market share and generates at least double the return on investment as compared with traditional therapies where there can be instances of more than 10 players in the market.

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