



## PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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### **Litigation clouds Sun Pharmaceutical**

**Whichever way the judgement in the Protonix case goes, it is likely to be a trendsetter for companies looking to launch generic drugs in the future in prized markets such as the US**

Wyeth, a Pfizer group company, recently slapped damages to the tune of \$960 million (around Rs 4,700 crore) against Indian pharma firm Sun Pharma for infringing on patents of its anti-ulcer drug, Protonix, raising the stakes for generic drug companies hoping to prosper in the world's largest drug market, the US. The outcome could be crucial since it could set an important precedent for the pharma industry: If Wyeth wins the case and its damage claim is accepted it will dent Sun Pharma's balance sheet and deter future at-risk launches by generic players. If Sun Pharma manages to win or the damage claim is substantially reduced, it will embolden generic players. The outcome of the case is thus likely to be studied carefully and could decide the question "to launch or not to launch" a generic drug at-risk in the US.

#### **The \$960 million damage claim**

Eight years since it tried to stop Sun Pharma from selling the generic version of its own heartburn drug, Wyeth believes that it should be compensated for the \$960 million losses it says it had to bear due to the at-risk launch by Sun Pharma. During the 27-month period between January 2008 and April 2010 when Sun Pharma was selling the product, the company grossed \$250 to \$260 million worth of sales, estimates Edelweiss Securities analyst Manoj Garg. The damages claimed against Sun and Teva by Pfizer, which acquired Wyeth last year, allegedly represents Wyeth's and Nycomed's combined lost profits due to Teva's and Sun's at-risk launches, including interest and other expenses incurred as a result of the generic launches, according to Pfizer. Nycomed had licensed the drug to Wyeth for sale in the US.

#### **So how much would be the damages if the generic players lose?**

Elara Capital's pharma analyst Surjeet Pal says that Wyeth has claimed triple infringement damage against Sun Pharma and Teva due to the loss of sales suffered by Protonix, post generic launch. Teva too in a recent statement has said that if the court finds a willful infringement of the patent, the damages may be up to three times the profits lost by the patent owner. Analysts observe that since Wyeth must be estimating the loss of profits to the tune of \$1 billion, the company is claiming the total damages of about \$3 billion, (\$2.1 billion from Teva and \$0.96 billion from Sun Pharma).

#### **Sun's defence**

However, Sun Pharma says that the damage claims are unjustified. The company believes that it has sound reasons to disagree with the overstated claims of Wyeth. It says that the patent is invalid and unenforceable and will pursue all available legal remedies including appeals. Analysts such as Deepak Malik of Emkay say that the damages might not be as high as claimed since Sun Pharma was the last to launch the drug. Teva launched the generic followed by the launch of the authorised generic by Wyeth. Sun launched the generics later after the two had already launched and thus did not

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“disturb” the market; neither did it undercut prevailing prices. Malik reckons that about 50 to 70 per cent of the liability is insured and thus Sun Pharma may have to pay a maximum compensation of \$100 to \$150 million only. Sun Pharma, however, has not commented on the insurance cover for this at-risk launch.

Most analysts believe that the Wyeth claim is exaggerated. Sushant Dalmia, analyst at Pinc Research observes that Protonix was a \$2 billion brand for Wyeth before the launch of generic. After the launch of generics by Teva and then Sun, Wyeth still generated revenues of \$806 million (including authorised generics contribution) from Protonix in CY2008. Given Sun launched after other companies he reckons that claims could be in the range of \$300 to \$500 million if Sun is unable to get a favourable judgement on the patent litigation.

### **Impact**

If Sun were to pay the damages as claimed by Wyeth it will wipe the entire cash kitty for the Indian company. Sun Pharma has around \$ 1 billion cash on books. This cash is important as the company can utilise the same for future acquisitions to propel growth. The company’s success with Taro, its Israeli acquisition is an example how inorganic growth can work wonders. Taro Pharma, the 66 per cent owned subsidiary, recorded 44 per cent jump in revenue to \$148 million during the December’ 11 quarter and has been driving Sun’s growth since the past few quarters. During 2011, Taro has filed three abbreviated new drug application (ANDAs) and has received seven approvals. Additionally, ANDAs for 23 products (including four tentative approvals) and an NDA await US FDA approval. This strong pipeline strengthens Sun’s US product pipeline and growth outlook. Pal feels that there could be an 8 to 10 per cent drop in yield on current cash chest, with pressure to meet capex through debt putting additional pressure on margins (operating profit margins for FY12 estimated at 35 per cent) and profitability. His views lead to concerns rising manifold.

### **Conservative approach going ahead?**

Over the last 17 years the company has had a successful track record of acquiring pharma assets and turning them around. Between FY 1996 and FY 2004 the company acquired and turned around 16 companies. Pal of Elara Capital expects Sun Pharma to however adopt a more conservative strategy now. The company could go slow on acquisitions over the next 2 to 3 years so as to conserve cash for damage claims, if any. The company in a recent conference call post December’ 11 quarter results had indicated that it is looking for right opportunities and assets to be acquired in the US markets for further growth.

### **Outcome**

Thus far the legal battle has been a mixed bag for the defendants, Sun and Teva. While the courts refused to interfere in the sales of the drug in 2007, jury verdicts/rulings in 2010 have been in favour of Wyeth. Pfizer, said in a statement that in April 2010, the jury found the Protonix patent was valid and infringed by Teva’s and Sun’s generic products. The jury’s verdict was upheld by the District Court, and the next phase of the trial will be a contested damages proceeding, where the amount of damages owed by Teva and Sun will be determined by the court after the parties have presented their evidence. The trial court decisions will be subject to appeal.

### **Advantage generic firms**

While Sun Pharma is on a sticky wicket, what has been the success rate for generic firms in these litigations? An RBC Capital Market report in January 2010, which analysed 370 court rulings during the preceding ten year period, says that generic drug companies had won 48 per cent of patent litigations that had gone to trial. Their success rate however increased to 76 per cent when settlements were included, if settlements were considered as a win for generics. However, if the Top 3 US courts,



which accounted for 69 per cent of such cases is taken into consideration, success rate in these courts is just 36 per cent, says Jose Madan head of IP Practice, Khaitan & Co, quoting the report.

**Sun may settle**

Also, looking at the legal battles being long drawn (in Sun's case battle has continued since 2005 and may continue for a few more years) companies have to incur huge litigation costs. According to Mark Pohl, Patent Attorney, New Jersey, during 2010, the legal fees per party per patent case in New York stood at an average \$7.69 million. He adds that this case is several times more acrimonious than the average case, which means a few million dollars above the average.

This is a key reason for a large number of out of court settlements. Thus while Sun has not indicated that it may go for out of court settlement, analysts say the option cannot be ruled out.

Source: Business Standard