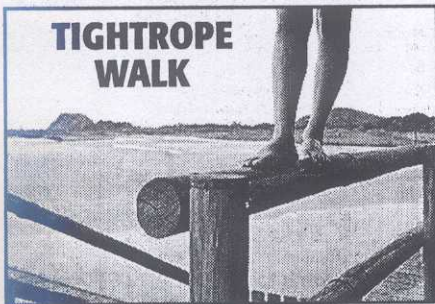


# Patent suits as growth model: Good but risky

## TIGHTROPE WALK



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**P**FIZER'S recent successive home runs in patent suits filed by daring Indian drug makers, have raised scepticism about the costly and risky patent challenges as a growth model. The high-risk high-return game has recently given quite a few bruises to Indian companies who have earlier tasted success in busting multinational monopolies by combining their chemistry skills with aggression.

Dr Reddy's Laboratories, which won against Eli Lilly in 2001 and lost to Pfizer in 2004 in two different patent infringement suits, has now adopted a hedging strategy of hiving off its 'research and filing for approval activities'

to a new vehicle supported by venture capital funds. "Patent challenge is quite risky and if succeeds, the returns are huge. Whether to adopt it as a growth model depends a lot on the company's priorities, the molecule

chosen and the patent holder. Supplementing the business of selling off-patent drugs with patent challenges would seem a good strategy. However, the high risk element leaves it a debatable subject," says Alok Gupta, Yes Bank country head for lifesciences and biotechnology. While some companies like to sell only active ingredients of medicines in the US, others like Lupin and Wockhardt sell their own finished formulations through their own marketing arms. DRL and Ranbaxy are more daring in challenging patents, he said.

Dr Reddy's first taste of success came when it won the right to sell a 40-milligram dose of Eli Lilly's anti-depressant fluoxetine brand Prozac for six months in the US after a successful court case

against the company. The case cost nearly \$1 mn but the firm reportedly made almost \$70 mn in the next six months during which period it was allowed to sell the cheaper copy exclusively. Later, the company got the marketing approval for a similar drug of Pfizer's block buster pill amlodipine besylate, and a favourable verdict from a lower court when Pfizer sued it. However, the court of appeals for the US federal circuit ruled in favour of Pfizer, dealing a huge blow to DRL by way of litigation cost.

In the US market, when a generic drug company seeks marketing nod for a patented drug, the company needs to tell the FDA whether the drug is off-patent, or whether it believes the patent is not valid or the copy does not infringe the patent. If convinced, the FDA gives the approval which triggers a patent litigation between the rights holder and the second applicant.

Ranbaxy too had its share of success in the past. It had fought a lengthy and successful battle against Glaxo-SmithKline to take its copy of antibiotic cefuroxime axetil to the US market.