PATENTWATCH

Pharma allowed to make own generics

A US Appeals Court has ruled that pharmaceutical companies can sell cheap versions of their own branded drugs, in a decision that could heavily affect the operation and revenues of generic drug companies worldwide. The decision resulted from a lawsuit in which Teva Pharmaceutical Industries sued Pfizer for selling its own generic version of its anti-epilepsy drug Neurontin (gabapentin).

Neurontin, a blockbuster anticonvulsant drug and one of Pfizer's top money-spinners, initially came off patent in 2001. The company then obtained a production patent to protect the drug until 2014, enabling it to maintain its market share and buy time before the launch of follow-up anti-epileptic pregabalin (Lyrica). But in the rush to get a piece of the market for gabapentin, generics companies have challenged this patent, and despite being sued for patent infringement by Pfizer, several companies have started to manufacture and sell their own cheaper formulations of gabapentin on a 'launch-at-risk' basis.

In 2003, Teva and Alpharma were awarded first-to-file status for a generic capsule version of gabapentin, giving them 180-day exclusivity to market once the product is approved. But in the middle of the resulting legal wrangle, Pfizer retaliated by selling its own cheaper, authorized generic version of gabapentin. Teva and Alpharma then sued Pfizer for attempting to thwart competition, on the grounds that authorized generics undermine the basic incentive that drives the generic drug industry — the 180-day period of market exclusivity. Teva also urged the FDA to block the sale of Pfizer's unbranded version, but the regulator said it had no authority to stop a company selling drugs for which it already has approval. The US Appeals Court sided with Pfizer, stating that although Congress intended to provide an incentive to challenge brand-drug patents, it does not follow that the incentive it created is without limitation.

The launch of 'authorized generics', such as Pfizer's version of gabapentin that was produced through the company's Greenstone generic drug subsidiary, is a relatively new approach for big pharma. Pfizer, among other companies, has previously used the strategy known as 'parking', in which a pharmaceutical company strikes a deal with the first generics company to challenge their patent, allowing the generics company their period of exclusivity while also limiting competition against the innovator company's brand drug. But winning the right to sell in the generics market could mean the end of such cooperativity by big pharma, and has far-reaching implications that extend further than the immediate effect on the anticonvulsant market. The Federal Trade Commission, urged by some US Senators, is currently investigating whether authorized generics are anticompetitive. If the Commission also sides with big pharma, the result could be a huge boon to consumers and the cost of healthcare, but could well leave the generics industry out in the cold.

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