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Ranbaxy's woes add $900 million to US heart drug costs

Firm failed to win FDA nod to sell the generic of Diovan

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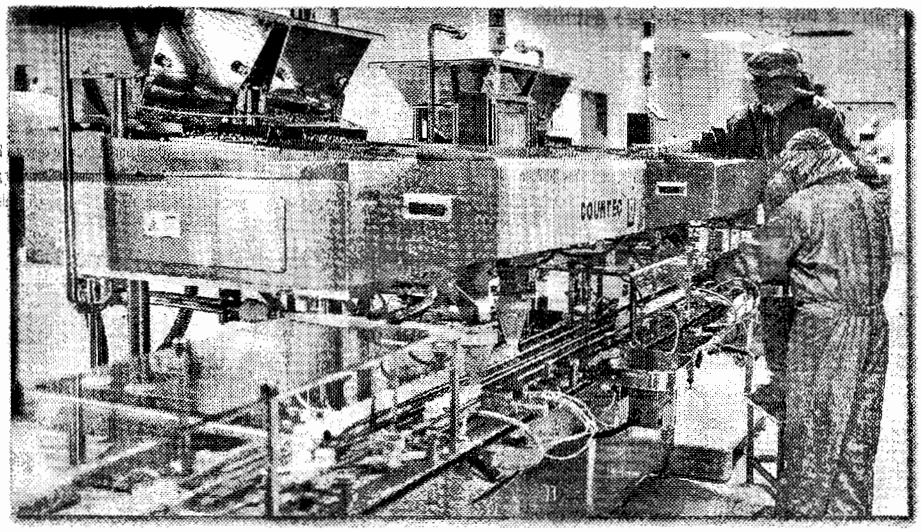

GENERIC DRUGS: A version of the therapy, called Diovan HCT, pairs it with a diuretic to help rid the body of salt and water.

LONDON: A gap in US patent law has kept cheap copies of Novartis's heart drug Diovan off the market for 18 months, costing US consumers and insurers as much as $900 million in potential savings.

While the Diovan patent expired in September 2012, the only company allowed to sell copies, Ranbaxy, hasn't been able to manufacture and market them after four factories it runs in India failed US inspections.

The approval process for generic drugs has two steps. While Ranbaxy gained exclusive, legal rights to sell the Diovan copies for six months by being first to apply, they failed to nail down clearance from regulators reviewing the company's ability to safely and properly make the drug. That's where the trouble arises The law doesn't say what happens if no final approval is given.

"Unless the law is amended, generic-drug makers agree to some arrangement, or there is a successful challenge, this situation may not be resolved," said Kurt Karst, an attorney at Hyman, Phelps & McNamara in Washington who advises drugmakers, including some affected by Ranbaxy's delayed entry.

AstraZeneca's Nexium acid-reflux pill and Roche's Valcyte antiviral, both of which Ranbaxy has the rights to, face the same situation in a month.

The conflict undermines the goal of the drug price competition and patent term restoration act, known as the Hatch-Waxman Act after its key congressional sponsors, passed in 1984.

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