

The bitterest pill

Drugs firms have found new ways to keep generic medicines at bay

“IF WE have the feeling that something is rotten in the state, then let's take the opportunity to find out.” So said Neelie Kroes, the European Commission's competition commissioner, seeking to justify a spectacular raid last week on big pharmaceutical companies. Officials are investigating whether sellers of expensive branded pills conspired together to delay the launch of cheap generic rivals. America's Federal Trade Commission (FTC) is also looking into it.

Many of Big Pharma's biggest blockbusters will soon lose their patent protection. Deloitte, a consultancy, estimates that \$55 billion of products will go off patent in 2009 and will then face competition. At the same time, pharma bosses are being asked to defend patents in costly legal battles against an increasingly confident and litigious generics industry. As generics firms evolve from mere copycats into innovators in their own right, many such firms—led by Israel's Teva, India's Ranbaxy and Dr Reddy's Laboratories—are vigorously challenging patents.

The best way out for the established drugs industry would be to find lots of clever new blockbusters to replace the ones going off-patent. But as the industry's sagging share valuations suggest, the new-drugs pipelines at big firms have run dry. So their managers are relying on two controversial new strategies. First, they are settling the lawsuits brought by generics firms, sometimes paying them to delay launching cheap pills. Novartis, a big Swiss firm, recently made a private settlement for Dr Reddy's to drop a lawsuit in return for the Indian firm delaying the launch of a generic rival to Exelon, its Alzheimer's remedy. This month it emerged that GlaxoSmithKline (GSK), a big British pharmaceutical firm, has also settled a patent lawsuit with Ranbaxy concerning the generics firm's launch of a cheap version of Imitrex, GSK's migraine reliever.

Under American laws designed to encourage generic drugs, which save money for patients, the first generic maker to win regulatory approval for its version of any given branded drug is supposed to enjoy a six-month monopoly. This promised pot of gold was designed to support small generics firms—but Big Pharma has found a loophole. It is pre-emptively launching generic versions of its own branded pills, which wipes out those six months of monopoly profits and undermines the economics of generics firms.

Merck, a big American pharmaceuticals firm, is soon expected to launch an authorised generic version of Fosamax, an osteoporosis drug that is due to lose patent protection in February. A recent survey of global branded-drugs firms by Cutting Edge Information, a consultancy, found that a third of them had launched authorised generics between 2005 and 2007—and the number will grow to 44% between 2008 and 2010. Pfizer has set up an in-house division to handle such generics.

The recent steps taken by regulators in America and Europe to investigate Big Pharma looks like good news for generics firms—unless, that is, some of them turn out to have been complicit in the alleged dirty tricks. Earlier this month, America's FTC extended its probe to include generics companies. And during last week's raid by European investigators, one of the

firms targeted was Teva, a generics pioneer. The generics industry is defiant, arguing that it remains the consumer's best friend despite its settlements with the enemy. Kathleen Jaeger, head of the Generic Pharmaceutical Association, insists that officials must avoid taking action that “sweeps the bad settlements in with the good settlements”. It remains to be seen whether the upstart pillmakers have been playing for time or selling out.