

The global significance of a row over drug prices in Australia

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GEORGE BUSH was supposedly rewarding his ally, John Howard, for his support over Iraq. Instead the president landed the Australian prime minister--who, like Mr Bush, is embroiled in a tough re-election battle--in political hot water with the bilateral trade agreement between America and Australia that he signed on August 3rd. Although the agreement will bring tariff reductions that could boost Australia's GDP by up to 1% a year, Australian hackles have been raised by an unusual clause in the agreement about drug prices--a clause that America would dearly love to replicate everywhere.

According to Mr Howard's critics, the agreement will mean higher drug prices in Australia--where prices are currently much lower than in America. Though denying it would raise prices, Mr Howard accepted opposition amendments in order to get the agreement through parliament on August 13th. As a result, America may, but probably will not, renege on the deal.

Currently, Australia's Pharmaceutical Benefits Scheme (PBS)--much like similar bodies in many other countries--assesses every drug for effectiveness and price before deciding whether the government will pay for it. Under the new trade deal, if the PBS decides not to pay for a drug, its manufacturer can now ask the head of a new review organisation to obtain and publish an independent expert's second opinion. As the PBS is free to ignore the review, the process will not drive up prices, says Mr Howard. But if so, why did America want that clause? The boss of one of the world's biggest drug firms says that the right of appeal will at least introduce valuable transparency into the PBS process. And yet there seems more to it than just this. According to a recent article in the Medical Journal of Australia, a provision of the agreement could let America retaliate if an American drug is not approved.

The agreement also bars Australia's patent agency from approving generic versions of a drug while a patent application is pending. This could potentially allow American drug firms to use a tactic known as "evergreening" to delay competition from generics. In America, as the patent on a drug's active ingredient expires, its manufacturer will typically file (allegedly) frivolous patent applications based on its delivery method or capsule. As a result, it enjoys extended monopoly protection while the applications are considered.

The opposition Australian Labor Party insisted on anti-evergreening amendments in exchange for its support for the agreement. These require drug companies trying to prevent generic entry to their markets to submit a certificate saying that their application is filed in good faith and has "reasonable prospects of success".

This seems unlikely to deter the drug firms. If the certificate is found to be "false or misleading", drug firms can be fined--but only up to \$7.2m, peanuts to most of them. And what is false or misleading? "It's too easy for a law firm to give an opinion to a drug

company, 'yes, there is some reasonable prospect of your patent being upheld.' That could be a one-in-ten chance," says Kevin Outterson, a law professor who has studied the American-Australian trade agreement.

Mr Outterson is sceptical about Mr Howard's claims that the deal will not raise drug prices. "A betting man would predict that three to five years from now, Australia's PBS prices will be higher. Howard claims to have snookered [the industry] on this one, but I have rarely seen them lose a sophisticated game like this," he says. **If drugmakers were able to extend patents on the five drugs on which the PBS spends most, they would be paid an extra \$1 billion in 2006-09, according to the Australia Institute, a think-tank.**

Why is America fighting so hard for the drug firms? High drug prices in America have become a big political stick with which the Democratic presidential candidate, John Kerry, is bashing Mr Bush. American politicians have long complained that Americans bear a disproportionate share of the cost of developing new drugs, that are then sold much more cheaply to foreign free-riders. The drug firms are a powerful lobby in Washington, DC. If he is to crack down on prices at home, Mr Bush feels he must appease the drug firms by--don't tell Mr Howard--helping them to earn more profits abroad.

America now seems likely to accept the amendments because, even if Australian drug prices remain only 25% of America's, the agreement sets a precedent that America can use in negotiations with bigger fish, such as the European Union and Japan. Miles White, the new head of America's Pharmaceutical Research and Manufacturers Association, calls the agreement a "first step" towards addressing "the harmful health and economic consequences of foreign price controls."