

# Drug Dispute Snags U.S.-Australia Pact

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WASHINGTON, Nov. 15 - Nine months ago, the United States and Australia completed negotiations on a landmark trade agreement that won unusually broad bipartisan support in Congress. But a dispute over drugs, both prescription and generic, is threatening to delay the effective date of Jan. 1.

Prime Minister John Howard of Australia has become one of Mr. Bush's strongest allies, one of the few who sent troops to Iraq, and the trade agreement is meant to draw the countries even closer together.

American manufacturers of things from tractors to computers are eager for the agreement to take effect because it promises \$2 billion a year in new industrial exports, which could create jobs.

But it has been dogged by disputes over the ability of American pharmaceutical companies to challenge decisions about which drugs will be covered, and at what prices, under Australia's national health insurance program. The pharmaceutical industry insists that the trade agreement should not take effect until its concerns are addressed.

In Australia, there has been a loud outcry that the pact could undermine the popular government program that makes prescription drugs available to all citizens at subsidized prices.

In the United States, American drug companies have complained for years about their inability to understand or influence government decisions about coverage of drugs in Australia. Prices for new drugs in Australia are among the lowest in the developed world, officials of both countries say.

In August, when the Australian Parliament approved legislation to carry out the trade agreement, Mr. Howard, then running for re-election, accepted amendments aimed at ensuring the availability of inexpensive generic drugs. The opposition Labor Party demanded those changes.

Those amendments infuriated American pharmaceutical companies and helped force trade negotiators back to the table. Both countries say they are optimistic that they can find a solution, but the agreement will not take effect unless the United States accepts the Australian legislation or Australia agrees to change it.

Frank Vargo, vice president of the National Association of Manufacturers, an American trade group, said: "It's unfortunate that the Australian Parliament chose to change the terms after the agreement was signed. We are urging all parties to be as flexible as possible and to move as quickly as possible to resolve these issues."

An American senior trade official said that the United States had raised concerns with Australia about how its legislation affected American drug products.

"We are not happy with it," said the official, who asked for anonymity because talks on the Australian legislation are continuing. The United States, she said, is concerned about copyright issues as well, but feels "very confident we can work this out."

Mark E. Grayson, a spokesman for the Pharmaceutical Research and Manufacturers of America, which represents brand-name drug companies, said the Australian legislation made it more difficult for them to enforce their patent rights.

Under Australian law, drug companies face fines of up to \$7.6 million if they make spurious or "vexatious" patent claims to delay the entry of cheaper generic drugs to the Australian market.

A brand-name drug maker can ask an Australian court to block the marketing of a drug that infringes its patents. But before doing so, the manufacturer must certify that the proceedings are "commenced in good faith and have reasonable prospects of success." If the court finds no reasonable basis for the litigation, it can fine the brand-name drug maker.

Critics of the trade agreement, like Peter Drahos, a law professor at the Australian National University, said the pact would undermine the government program that provides medicine to Australians. "The large pharmaceutical industry has had the program in its sights for a long time," Mr. Drahos said.

For Mr. Drahos, the agreement poses a fundamental question: Can trade agreements trump the domestic laws that underpin a nation's social contract? He strongly opposed allowing trade pacts to threaten those social programs.

Mark Vaile, the Australian trade minister, discounted those concerns.

"There is nothing in the free trade agreement that would increase drug prices in Australia or change the way the pharmaceutical benefits scheme operates," he said.

In the last five years, Americans have protested the fact that they often have to pay more for brand-name prescription drugs than people in other industrial nations. Rather than reduce prices in the United States, some pharmaceutical companies are trying to raise the prices they charge abroad, saying that American consumers bear too much of the cost of research to create new medicines.

Representative Tom Allen, Democrat of Maine, said he worried that the pharmaceutical industry had "undue influence over trade negotiations" and was trying to weaken other governments' ability to hold down drug prices.

"The risk is that the brand-name pharmaceutical industry will be able to write international trade rules that overrule domestic law," Mr. Allen said.

Drug companies contend, though, that the law adopted by the Australian Parliament, which includes the amendments, is inconsistent with Australia's obligations under international trade agreements.

Eric Noehrenberg, a trade specialist at the International Federation of Pharmaceutical Manufacturers and Associations, based in Geneva, said the Australian legislation would reduce the incentives for patent owners to introduce new drugs in Australia. As a result, he said, Australian patients will have less access to new and improved treatments.

Mr. Noehrenberg and Mr. Grayson, the spokesman for the American pharmaceutical group, said they believed that the Australian law discriminated against their industry, in violation of international trade agreements.

The administration agrees. Richard Mills, the spokesman for the United States trade representative, said the Australian legislation had to conform with international agreements protecting intellectual property, like patents, before the trade agreement could take effect.

Under the Australian law, drug company executives say, it is more difficult to enforce drug patents than patents on other products like computer chips and telecommunications technology. Moreover, they say, the law is vague about what constitutes a reasonable patent claim, but drug companies are subject to large financial penalties if they guess wrong.

Dr. Ken Harvey, a senior lecturer on public health at La Trobe University in Melbourne, said that drug companies were complaining too loudly.

The trade agreement, he said, already gives American drug companies new leverage in the Australian market, and it could ultimately lead to "higher drug prices and less generic competition."