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MEDIA RELEASE

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US pressures Australia for even stronger TPP monopolies for biologic drugs

"We are alarmed by reports that US Senate Finance Committee Orrin Hatch says the US administration has "made progress" in talks with Australia and other TPP countries to find a way to increase data protection for costly lifesaving biologic drugs from eight years in the current TPP text to twelve years," Dr Patricia Ranald, Convener of the Australian Fair Trade and Investment Network said today.

According to the Bloomberg report copied below. Senator Hatch said "They're going to have to find a way of having the countries agree to change that formality in the TPP to 12 years...If Australia wants to be part of it, they have to meet our terms," Senator Hatch added that he and the Australian trade minister discussed how they might solve this problem.

Doctor Ranald said that global pharmaceutical companies already have 20 years of monopoly patents on medicines before cheaper versions become available. Biologic medicines under patent, which treat cancer and other serious disease, cost thousands of dollars per treatment. They are only accessible to patients because they are subsidised by the Pharmaceutical Benefits Scheme. Data protection is a separate monopoly which further delays the availability of cheaper forms of those medicines. The current Australian law is five years for data protection, but the TPP text requires administrative measures which would deliver a "market outcome" equivalent to an [extra three years of monopoly](#), a total of eight years. Studies show that each year of delay in cheaper versions of these medicines would cost the PBS [hundreds of millions of dollars](#).

"The extra three years of monopoly in the current TPP text is already unacceptable. It is outrageous that the US is demanding an even greater increase from 8 to 12 years. We call on the Australian and other governments to reject this proposal," said Doctor Ranald.

"This demand highlights the flaws in the TPP, which is not about free trade, but is about the extension of monopolies and corporate rights. The TPP would also enable pharmaceutical and other global companies to bypass national courts and sue the Australian government in unfair international tribunals over domestic laws. US pharmaceutical company [Eli Lilly](#) is currently suing the Canadian government over a court decision which refused a patent for a medicine.

The Australian government has refused to conduct independent assessments of the economic, health and other impacts of the TPP. [Sixty community organisations](#) representing over two million Australians last week called for a Senate inquiry into the TPP, to enable a proper assessment of the TPP before Parliament votes on the implementing legislation." said Dr Ranald.

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September 8, 2016

Sen. Hatch Says Progress Made on TPP Drug Issue

By *Len Bracken*

Sept. 7 — Progress has been made between the administration and Congress on a key drug-related issue in the trans-Pacific trade pact, Senate Finance Committee Chairman Orrin Hatch (R-Utah) said Sept. 7.

Hatch would not provide details to reporters at the Capitol on the progress, but he expressed hope that a solution could be found and noted that President Barack Obama was involved in the discussions on the issue of intellectual property rights protections for biologic drugs in the 12-nation Trans-Pacific Partnership (TPP) agreement.

“We haven't decided the final terms, buy they have indicated to me that they know they have to make” an acceptable offer, Hatch said. “It's up to the White House—I've told them this is a serious situation and not one they can blithely step aside on.”

The administration would like the TPP to be ratified during the lame-duck session of Congress, and Hatch said resolving what he called “the biggest problem” with the pact would “go a long way” toward improving prospects for post-election consideration of the agreement.

Officials at the Office of the U.S. Trade Representative could not be reached for comment.

Without a biologics solution, the TPP would not pass Congress, he said. However, even with a solution, the agreement would have a “rough time passing,” he added.

Exclusivity Period

At issue is the discrepancy between the 12 years of intellectual property protection for name brand manufacturers under U.S. law and the shorter-term options in the TPP, after which other manufacturers could make lower-priced “biosimilar” drugs using the original test data. The other TPP countries need to commit to a 12-year term, Hatch said, adding that a binding side agreement involving all other parties to the agreement would be one way to do this.

Australia, New Zealand and Peru have all indicated at various points during the last six months that they will not change their positions concerning biologics and stand by the agreed-upon language contained in the TPP.

“I don't know what they're going to offer, but they know I'm at 12 years of data exclusivity,” he said of the administration. “They're going to have to find a way of having the countries agree to change that formality in the TPP to 12 years or come up with something that will be acceptable.”

Hatch said he knew which TPP countries would be willing to go up to 12 years but would not identify them. Australia, Chile, New Zealand and Peru put up the most resistance in the TPP negotiations to U.S. efforts to secure a longer term of protection for brand name biologics, with Canberra taking the lead in this opposition.

“If Australia wants to be part of it, they have to meet our terms,” Hatch said, adding that he and the Australian trade minister discussed how they might solve this problem.

Steven Ciobo, Australian's minister for trade and investment, said after his meeting with Hatch in July that he told the Utah lawmaker Australia would try to help sort out the problem but intended to keep its current law, which provides a five-year exclusivity period (136 ITD, 7/15/16)

Incentives have to be in place so that drug manufacturers can recoup their investments, Hatch said. But he acknowledged that some drugs were overpriced and expressed his support for creating as much competition as possible.

The issue of the exclusivity term for biologics is a major one for both the TPP, which was signed in February, and the Transatlantic Trade and Investment Partnership (TTIP), which is under negotiation with the European Union, Hatch said. The Europeans, he said, have indicated that they effectively have a 12-year exclusivity period.

Warren Opposes ISDS

On another TPP front, Sen. Elizabeth Warren (D-Mass.) said on a conference call hosted by Public Citizen that she supported a [letter](#) signed by more than 200 law and economics professors urging lawmakers to oppose the TPP because it includes provisions that allow investors to bring cases against nation-states on the basis of commitments in the agreement. Warren noted that Democratic presidential candidate Hillary Clinton and her running mate Sen. Tim Kaine (D-Va.) oppose the TPP in part because of these provisions known as the investor-state dispute settlement mechanism (ISDS).

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For More Information

The letter from the law and economics professors is available at <http://www.citizen.org/documents/isds-law-economics-professors-letter-Sept-2016.pdf>.