TPP IMPACT: PHARMA AUSTRALIA

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After many years of negotiations and multiple rounds of final negotiations, the final text of the Trans-Pacific Partnership (**TPP**) agreement was released to the public on 5 November 2015.

PHARMA - AUSTRALIAN PERSPECTIVE

One of the mostly hotly debated topics both in the media, and between Australia and the USA at the negotiating table, was the nature and extent of protections for pharmaceuticals and the impact those protections may have on consumer access to pharmaceuticals and public health policy in TPP nations. Indeed, immediately after negotiations were concluded, Prime Minister Malcolm Turnbull assured the Australian public that there would be "no change to our laws at all, in terms of data protection, drug laws, patents and so forth, they all stay in place … [t]his deal has no impact on the Pharmaceutical Benefits Scheme, it's not going to make drugs more expensive in Australia whatsoever."

The final text of the TPP confirms that the Prime Minister's comments are largely correct. The impact on Australia's pharmaceutical sector will be substantially less than many had been predicting, given that:

- only limited changes, if any, will be required by the TPP to Australia's current intellectual property laws; and
- the TPP's Investor-State Dispute Settlement (**ISDS**) mechanism is likely to have limited application to the regulation of public health in Australia, in particular to the Pharmaceutical Benefits Scheme (**PBS**).

TPP GENERALLY CONSISTENT WITH AUSTRALIA'S CURRENT IP LAWS

As we have discussed in a related article, Australia's current intellectual property laws generally conform with the TPP and will require little, if any, legislative changes. This is also the case with laws and regulation relating to pharmaceuticals, including data protection and procedural fairness mechanisms relating to listing on the PBS.

DATA PROTECTION

The issue of data protection for biological pharmaceutical products proved to be a key sticking-point in the most recent round of negotiations. Nevertheless, Australia successfully resisted the United States' push to include an extended data exclusivity period for biological pharmaceutical products to 12 years.

The final TPP agreement provides for a general data exclusivity period of 5 years from the date marketing approval is received, which reflects the existing law in Australia. In the case of biological pharmaceutical products, although the TPP provides for a period of 8 years data exclusivity, it also allows for a period of 5 years, provided the signatory state also provides effective market protection through "other measures", and recognises that market circumstances may also contribute to effective market protection. Although it remains unclear precisely what these "other measures" may include, the Australian Department of Foreign Affairs and Trade (**DFAT**) has issued a statement confirming Australia's view that "other measures" include "existing measures in the case of Australia … [such as] regulatory settings, patents, and the time it takes for follow-on medicines to become established in the market." DFAT confirmed that "Australia will follow the 5 year option, which reflects our current system and requires no changes."

TRANSPARENCY AND PROCEDURAL FAIRNESS FOR PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

The TPP includes provisions dealing with transparency and procedural fairness requirements for listing pharmaceuticals for reimbursement which have been the focus of attention in the media following leaks of various draft copies of the TPP text. One area of public debate was whether pharmaceutical companies would be afforded greater opportunity to challenge the recommendations of domestic drug regulators and whether this would undermine Australia's existing pricing system by allowing challenges to the recommendations made by the Pharmaceutical Benefits Advisory Committee (**PBAC**), such as, for example, a recommendation to not list a drug on the PBS.

However, the final text of the TPP appears to be largely consistent with Australia's existing transparency and procedural fairness rules. This has recently been confirmed by DFAT, which has also stated that the these particular provisions of the TPP "will not require any changes to the Pharmaceutical Benefits Scheme." DFAT has also sought to provide reassurance by explicitly stating that the TPP's transparency and procedural fairness provisions do "not include commitments relating to the pricing of pharmaceuticals…[and] is not subject to any form of dispute settlement, including ISDS."

ISDS AND PHARMACEUTICALS

A significant amount of the public debate generated by the leak of draft texts of the TPP focussed on whether it would allow foreign companies to sue Australia under the ISDS provisions of the TPP, including in relation to regulatory decisions made in relation to pharmaceuticals, if those decisions impacted upon investments made by foreign businesses in Australia. Although the investments chapter of the TPP is complex (and our analysis of its many provisions and exceptions remains ongoing) it appears that the regulation of pharmaceutical pricing and subsidy decisions in relation to the PBS are likely not within the ambit of ISDS. This is because the TPP specifies that a decision to not issue, renew or maintain a subsidy or grant, or modify an existing subsidy or grant (absent a specific commitment under law or contract), does not constitute an expropriation. DFAT has specifically confirmed this, saying that a refusal to issue or grant a subsidy (or to reduce that subsidy) under the PBS will not breach Australia's investment obligations under the TPP.

Government regulation of public health in Australia may also fall outside the ambit of ISDS because regulatory actions "designed and applied to protect legitimate public welfare objectives, such as public health … do not constitute indirect expropriations, except in rare circumstances." Importantly, the TPP also clarifies that regulatory actions to protect public health "include, among others, such measures with respect to the regulations, pricing and supply of, and reimbursement for, pharmaceuticals (including biological products), diagnostics, vaccines, medical devices, gene therapies and technologies, health related aids and appliances and blood and blood-related products." ISDS will also not apply to compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS agreement' (notably, Australia's compulsory licensing laws are already compliant with the TRIPS agreement).

KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.

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