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Patent term extensions in Australia: when first isn't really first

John Collins, Kent Teague, Natalie Coulton (Clayton Utz) · Thursday, July 8th, 2021

In a surprising decision, the Federal Court has modified the law of patent term extensions in Australia, by clarifying that it's only the **patentee's** goods that are relevant to the proposed extension – not those of a **competitor**, even if the competitor's goods came first and also contain a "pharmaceutical substance per se" that is disclosed and claimed in the patent.

Justice Beach has reversed a decision of IP Australia, and with it, many years of Patent Office and industry practice, as well as Federal Court authority, on the operation of the patent term extensions (**PTEs**) regime in Australia, under Chapter 6 of the *Patents Act 1990* (Cth). The Court held that an application for PTE can be based upon, and the resulting extension can be calculated by, the earliest inclusion on the Australian Register of Therapeutic Goods (**ARTG**) of the **patentee's** goods. Until now, the orthodox approach (derived from the words of the statute), has been to identify the first goods included on the ARTG that contain or consist of **any pharmaceutical substance per se** disclosed and claimed in the patent, irrespective of the sponsor of those goods.

The two PTE applications

This case concerned a patent owned jointly by Ono Pharmaceutical Co and E R Squibb & Sons, LLC (together, **Patentees**), titled "Human monoclonal antibodies to programmed death 1 (PD-1) and methods for treating cancer using anti-PD-1 antibodies alone or in combination with other immunotherapeutics".

The effective date of the patent is 2 May 2006, meaning that, unless a PTE were granted, its standard 20-year term would expire on **2 May 2026**.

The Patentees filed two PTE applications, each of which was based on different goods on the ARTG:

Brand Name	OPDIVO®	KEYTRUDA®
Active ingredient	nivolumab	pembrolizumab
Australian sponsor	Bristol-Myers Squibb Australia Pty Ltd	Merck Sharp & Dohme (Australia) Pty Ltd
Relationship between sponsor and patentees	Related to one of the patentees	Not related to either patentee
Date goods containing the drug were first included on ARTG	11 January 2016	16 April 2015
Duration of PTE (if granted)	4 years, 8 months, 9 days	3 years, 11 months, 14 days

New expiry date (if PTE granted)	**11 January 2031**	**16 April 2030**

The Patentees' primary application was based on OPDIVO. If granted, it would yield a longer PTE duration (about 9 months longer) than if the application were to be based on KEYTRUDA. Significantly, unlike the application based on KEYTRUDA, the Patentees would not need to obtain an extension of time under section 223 in which to file the PTE application.

The parties and the Court proceeded on the basis that pembrolizumab was in fact a **pharmaceutical substance per se** disclosed in the complete specification of the patent and falling within the scope of at least claim 3 (despite the delegate having expressed some doubt about this in the Patent Office decision). Accordingly, the dispute ultimately turned on the parties' competing constructions of the PTE provisions under the Act.

Commissioner's construction: textual and literal

The Commissioner had relied on a textual and literal reading of the provisions, submitting that the earliest inclusion of any goods on the ARTG that contain any of the "**one or more**" pharmaceutical substances per se must be used to calculate both

- when an application for a PTE must be filed; and
- the duration of the extension of term,

regardless of whether those goods were sponsored by the patentee or a related body corporate of the patentee.

The Act contains no qualifying words to suggest that, if the first goods meeting the statutory criteria were sponsored by an unrelated entity, they must be disregarded for the purpose of the PTE regime. The regime provides a remedy to eligible patentees who develop "new" drugs, not drugs that have already been included in the goods of a competitor that were included on the ARTG at an earlier date.

The Commissioner relied on existing Patent Office authority (eg., *GD Searle LLC* [2008] APO 31), which followed the 2006 decision of a single judge of the Federal Court, Justice Bennett, in *Pfizer Corp v Commissioner of Patents (No 2)*.

The Patentees' construction: a purposive construction

The Patentees endorsed a more purposive construction, and contended that only the goods of the patentee (or a related body corporate of the patentee) should be considered for the purpose of the PTE regime. The Patentee emphasised the purpose for which the extension of term provisions had been inserted being to compensate patentees for the time involved in bringing a new drug to market, as well as the practical effect that the regulatory regime has, namely reducing the effective lifetime of the monopoly granted by the patent.

The Patentees submitted that the language of section 70 did not impose any restriction on **which** of the potentially suitable pharmaceutical substances contained within goods included on the ARTG had to be relied upon, for the purposes of a PTE application.

In relation to section 77 (which provides the formula for calculating the duration of the term

extension), the Patentees submitted that the requirement of identifying the "earliest first regulatory approval date" required the identification of the first regulatory approval date for any goods containing the specific pharmaceutical substance relied on by the patentee in the PTE application, and if there were multiple goods on the ARTG that contained that pharmaceutical substance, the extended term must be calculated by reference to the earliest date on which any of those goods was registered.

The Federal Court's judgment: liberal rather than literal

Justice Beach preferred the Patentees' construction. As a beneficial and remedial regime, his Honour preferred a liberal rather than a literal approach, and rejected the Commissioner's construction as being "dictated by strict textualism". His Honour disagreed with the Commissioner's submissions about the implications of Pfizer, and was not bound by the Patent Office decisions that followed, such as GD Searle.

In Justice Beach's view, if the Commissioner's construction were to be adopted, it would have the consequence of requiring patentees to be excessively vigilant of ARTG registrations. Until a patentee's own goods had been registered, every new ARTG registration would need to be fully investigated, to determine whether it could found a PTE application. There would be no account either, for the fact that a patentee may well have incomplete information about the substances contained within the competitor's product.

In the event, Justice Beach granted the extension of term based on the OPDIVO ARTG registration. It is expected that the Commissioner will appeal the decision as there must be doubt about the Court's willingness to read into the legislation restrictions that are not there.

Key takeaways for patent term extensions in Australia

- Patentees can take some comfort in the knowledge that a PTE can be obtained based on the earliest first regulatory approval date of goods **of the patentee** (or patentee's related body corporate). However, this comfort may be short lived.
- Even if a competitor's goods are registered on the ARTG earlier in time, for the purpose of seeking a PTE, the patentee need not trouble itself with investigating whether those goods contain a **pharmaceutical substance per se** that is disclosed in, and falls within the claims of, the patent.
- The decision raises new questions about when the relationship between the patentee and the sponsor will be sufficiently distant that the sponsor's goods are disregarded for the purpose of PTEs.

If you have any questions about the implications of the decision or would like advice on these issues, please contact Clayton Utz.

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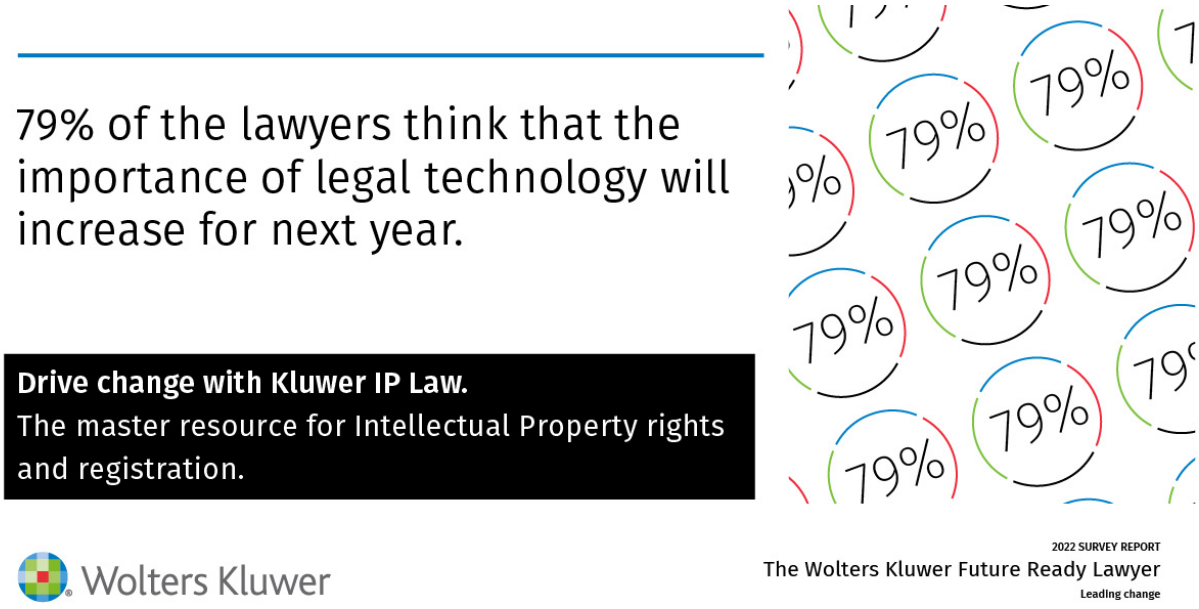

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