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Pharmaceutical patent term extensions now back to the "earliest first" approach, the Full Federal Court confirms

Natalie Shoolman, Kent Teague, Rose Jenkins (Clayton Utz) · Wednesday, March 30th, 2022

In two separate judgments, the Full Court has provided much needed clarity on how to identify the pharmaceutical products that can support a valid patent term extension in Australia, as Natalie Shoolman, Kent Teague and Rose Jenkins explain in this article.

Takeaways:

- Patent term extensions must be based on the "earliest first regulatory approval date" of goods containing any of the substances disclosed and claimed in the patent, regardless of whether those goods are "goods of the patentee" or goods of a competitor or third party.

The Full Court's judgments are Commissioner of Patents v Ono Pharmaceutical Co. Ltd [2022] FCAFC 39 (**Ono**) and Merck Sharp & Dohme Corp. v Sandoz Pty Ltd [2022] FCAFC 40 (**MSD**). In the *Ono* proceeding, the Full Court reversed the decision of Justice Beach at first instance. In *MSD*, the Full Court upheld the approach of Justice Jagot at first instance. In doing so, the Full Court confirmed the Australian Patent Office's approach to patent term extensions (**PTE**s) under the Australian Patents Act 1990 (Cth), established over several years.

The statutory regime

In each decision, the Full Court considered the specific provisions of the PTE regime contained in Part 3, Chapter 6 of the Patents Act, and in particular, sections 70, 71 and 77. In summary:

- **Section 70** deals with a patentee's **eligibility** to apply for a PTE. A patentee must satisfy three conditions:
  - one or more pharmaceutical substances *per se* (or pharmaceutical substances when produced by recombinant DNA technology) must be disclosed and claimed in the patent (section 70(2)); and
  - goods containing or consisting of the substance must be included in the Australian Register of Therapeutics Goods (**ARTG**) (section 70(3)(a)); and
  - the period beginning on the date of the patent and ending on the first regulatory approval date for the substance must be at least 5 years (section 70(3)(b)).

The term of the patent must also not previously have been extended.

- **Section 71** deals with the **form and timing** of the application. As to timing, the application must

be made during the term of the patent, and within 6 months after the latest of the following dates:
    - the date the patent was granted;
    - the date of commencement of the first inclusion in the ARTG that contain, or consist of, any of the pharmaceutical substances referred to in section 70(3);
    - 27 January 1999 (being the date of commencement of the section).

- **Section 77** sets out the formula for calculating the **duration** of the PTE, once an extension has been granted by the Commissioner. The extension is equal to the period beginning on the date of the patent and ending on the "*earliest first regulatory approval date*" (as defined by section 70) in relation to **any** of the pharmaceutical substances referred to in subsection 70(2), reduced (but not below zero) by 5 years. However, the term of the extension cannot be longer than 5 years.

Summary of decisions

The *Ono* decision considered the proper construction of sections 70(3) and 71(2) of the Patents Act, in circumstances where a third party has registered a pharmaceutical substance on the ARTG before the same pharmaceutical substance was registered on the ARTG by a competitor. In the first instance decision, Justice Beach found that only the **"goods of the patentee"** should be considered for the purpose of the PTE regime, despite there being no such qualifying words in the Patents Act, and despite the fact that, in that particular case, neither of the co-owners of the patent was the legal entity that was the sponsor of the relevant goods on the ARTG. The Full Federal Court overturned the decision of the primary judge, confirming the orthodox approach that calls for PTE applications 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. In the *Ono* case, that meant the goods of a competitor, MSD.

In the *MSD* decision, the Court considered the PTE provisions (in particular section 77) through a slightly different lens: what should happen where a patent covers two or more pharmaceutical substances contained in two or more products listed on the ARTG, where both of the products are owned by the patentee (or a related entity). In *MSD*, the patentee had already been granted a PTE, which had been based on goods included in the ARTG that contained the pharmaceutical substance composition "sitagliptin/metformin". The PTE was challenged by Sandoz, on the basis that, earlier in time, goods had been included in the ARTG by the patentee containing the pharmaceutical substance "sitagliptin", which was also disclosed and claimed in the patent. Both of these goods were sponsored by the patentee (or a related entity). At first instance, Justice Jagot held that the extension was invalid because calculation of the extension required "*the earliest first regulatory approval date*" in relation to any of the pharmaceutical substances disclosed. As the date of the patent was less than 5 years before the earliest first regulatory approval date for goods that contained sitagliptin, the term of extension of the patent was zero. The Full Court upheld the decision of the primary judge in the interpretation of s 77 of the Act, finding that where a patentee is the sponsor of two products disclosed and claimed in the patent, only the **first** product listed on the ARTG will be relevant for calculation of the duration of a PTE.

The "liberal" arguments unsuccessfully pursued by the patentees in both cases

The patentees in *Ono* submitted that the requirements of section 70(3) are satisfied by any one of the pharmaceutical substances referred to in sections 70(2)(a) and (b) that are disclosed and claimed in the patent. They also submitted that any of these substances may be used for the purpose of calculating the time by which an extension of term application must be filed under

section 71(2), and it is for the patentee to nominate the substance. Along with this reasoning, they submitted that the term of extension is to be calculated by reference to the "*earliest first regulatory approval date*" of the substance **that the patentee has nominated.** Further, it was submitted that the expression "*pharmaceutical substance*" in the PTE provisions means the substance that is the subject of the patentee's PTE application, and not that of a stranger or competitor. On that approach, the patentees submitted, only the later ARTG registration of Opdivo could support the PTE, and not the earlier regulatory approval of Keytruda, which was sponsored by a competitor.

In *MSD*, as to the construction of section 77, MSD argued that the term of the PTE is calculated by reference to the "*earliest first regulatory approval date*" of any of the pharmaceutical substances referred to in section 70(2) **which is the subject of a compliant application** for an extension of term. On that approach, MSD submitted, only the application based on the later ARTG registration of sitagliptin/metformin could support a PTE. MSD also argued an alternative case that sought (unsuccessfully) to challenge earlier Full Court authority in *Pfizer v Commissioner of Patents* (2006) 155 FCR 578 that held that relevant inclusion in the ARTG for the purpose of calculating the PTE includes a listing for "export only".

Object of the extension of patent term regime

In both cases, the Full Federal Court discussed the rationale for the current extension of term regime, by reference to the comments made by the High Court in *Alphapharm Pty Limited v H Lundbeck A/S* [2014] HCA 42; (2014) 254 CLR 247. The Court also referred to extrinsic material, such as the explanatory parliamentary material accompanying the *Intellectual Property Laws Amendment Bill 1998* (Cth), which introduced the current form of PTE regime. The Full Federal Court, in *Ono*, accepted that while the object of the extension of term regime is to compensate a patentee of a pharmaceutical substance for time lost in obtaining regulatory approval before it can exploit its invention, "*it does not follow that ss 70, 71 and 77 should be construed so as to achieve what might be described as a commercial outcome for a patentee*". Rather:

"… the extension of term regime seeks to balance a range of competing interests, not just the interests of the patentee. It can be taken that the legislature saw the correct balance as being achieved by the very words it chose to implement that regime." – Full Court in *Ono*

The Full Court in *MSD* also commented that it is appropriate to consider policy considerations but "*not insofar as they deflect from a consideration of the policy and purpose of the scheme"* by reference to the language of the statute. The relevant interests to be balanced include those of patentees and the public interest in unrestricted use of the pharmaceutical invention, including competitors after the expiration of the patent term.

Statutory construction: literal construction over a liberal construction

The Full Federal Court, in *Ono*, stressed that in undertaking statutory construction, it is the "*fundamental duty of the Court*" to give meaning to the legislative command according to the terms in which it has been expressed. It was held that the balance of interests is clear from the text of the PTE provisions and it was not necessary or appropriate for the primary judge to apply a liberal rather than a literal construction.

In *Ono*, it is made clear that neither section 70(3) nor section 71(2)(b) involves a choice for the patentee. Rather, section 71(2)(b) looks to the set of pharmaceutical substances satisfying the conditions of section 70(3) and fixes, as the relevant date, the date of commencement of the *first*

inclusion of goods that contain, or consist of, *any* of the substances. These are matters of objective determination. There is nothing in the statute that would suggest that the scope of section 70(3) should be limited to be concerned with only the patentee's goods.

In *MSD*, it is acknowledged that the legislature clearly contemplated the circumstance where an application for a PTE could be made within section 71 but which resulted in an extension of term under section 77 of zero, namely, where the period between the date of the patent and the date of the first regulatory approval is less than 5 years. This is supported by the text of section 77(1), which:

- intentionally refers in terms to section 70(2) and not section 70(3), and therefore refers to the "*superset*" of pharmaceutical substances that may be identified as pharmaceutical substances per se disclosed in the complete specification and claims rather than the subset identified in section 70(3);
- explicitly contemplates that an extension of term may be zero, but not less than zero; and
- identifies that the relevant calculation takes into account the "*earliest*" first regulatory approval date.

Accordingly, the Full Court did not consider there was any policy reason to divert from the language of section 77(1), in the determination of the term of the extension. Where more than one pharmaceutical substance per se is in substance disclosed and claimed in the relevant patent and there are multiple regulatory approvals for goods that contain or consist of those substances, the length of the extension is to be calculated from the earliest first inclusion in the ARTG of goods relating to any of those substances.

The future of patent term extensions in Australia

The decisions of the Full Federal Court in *Ono* and *MSD* support the view that, when a patent application discloses and claims multiple pharmaceutical substances, there may be strategic benefit in dividing the application into separate divisional patent applications, each claiming only one pharmaceutical substance, each of which could potentially support a valid PTE in Australia. In circumstances where it is not possible to file divisional applications, patentees may seek to amend their patent to exclude earlier registered ARTG goods so that they are not precluded from applying for a PTE due to those goods. However, this will need to be balanced with other considerations such as the right to sue for patent infringement in relation to the earlier registered ARTG goods.

The Full Court's judgments are likely to influence the decisions in other pending matters, such as the pending Federal Court proceeding where Bayer is currently seeking to overturn the decision of the Commissioner in *Bayer Pharma Aktiengesellschaft* [2022] APO 7. In that case, the patent in question covered two of Bayer's products, each of which was listed on the ARTG. A third party challenged the PTE seeking rectification of the patent register to void the PTE. The Commissioner decided that the extension of term of a patent was incorrectly based on the registration of the second product, YAZ, in 2008 and should have been based on the first product, Yasmin, that was registered on the ARTG in 2001. The Commissioner directed that the Register be amended to remove the PTE given it would have been zero. Bayer's appeal appears doomed to fail. The Full Court decisions in *Ono* and *MSD* will also no doubt lead patentees and companies developing biosimilars or generics alike to scrutinise any previously granted PTEs to identify any that may have been granted incorrectly and which are vulnerable to challenge.

Patentees should review their granted PTEs, to ensure they have been based on the correct pharmaceutical goods, or risk a competitor applying to have the PTE removed from the Register. They should also monitor the ARTG for competitor/third party registrations that may impact on the timing of PTE applications and the duration of PTEs.

If you have any questions about the implications of either of these decisions, please contact Clayton Utz

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