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PHARMACEUTICAL PATENT TERM EXTENSIONS: FEDERAL COURT HEARS CHALLENGE TO "ABSURD" AUSTRALIAN PATENT OFFICE RULING

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Legal Briefings – By **Shaun McVicar and Bryce Robinson**

Two major pharmaceutical companies have challenged Australia's Commissioner of Patents in the Federal Court about the time limits within which an application can be made to extend a patent term.

KEY TAKEAWAYS

- Ono Pharmaceutical and Bristol Myers Squibb have sought judicial review by the Federal Court of an Australian Patent Office (**APO**) ruling which rejected their application for a patent term extension (**PTE**). The application was heard on 12 March 2021.
- In the ruling, described by the patentees as "manifestly absurd or unreasonable",[1] the APO confirmed its historical view that PTE applications under the *Patents Act 1990* (Cth) (the **Act**) must be filed within six months of the first inclusion on the Australian Register of Therapeutic Goods (**ARTG**) of goods containing or consisting of any pharmaceutical substance falling within the claims of the patent, regardless of whether it was the product sponsored by the patentee, or indeed was a product sponsored by a third party.
- This is the first time this issue has been directly considered by the Court. If the APO's decision is upheld by Justice Beach, a very experienced patent judge, this may impose additional practical burdens on patentees. Further, it would confirm another Australian point of departure from an increasingly harmonised international patent regime.

PATENT TERM EXTENSION

In Australia, as in most jurisdictions, the standard patent term is 20 years from the filing date. In many major developed countries, however, the holder of a pharmaceutical patent can apply for this term to be extended for an additional period (e.g. up to five years in Australia, the US and Europe).

Such regimes recognise that, in reality, the commercial protection afforded to pharmaceutical patent holders typically fall far short of the full 20 years, as much of that period will be lost to developing the product, establishing its safety and efficacy, and obtaining essential marketing authorisations from health regulators. Accordingly, extending the patent protection period aims to compensate patentees for at least part of the time spent on product development and to recognise the significant investment required for the development of novel therapeutics.

Typically, there is a limited timeframe within which patent holders can apply for a PTE once marketing approval has been granted. In Australia, applicants have six months from the date of first inclusion on the Australian Register of Therapeutic Goods (**ARTG**). The issue in the present matter is whether the clock starts running as soon as any product falling within the scope of the patent's claims appears on the ARTG, rather than the patentee's own product.

THE DECISION

BACKGROUND

Ono Pharmaceutical Co., Ltd. (**Ono**) and E. R. Squibb & Sons, LLC (a subsidiary of Bristol-Myers Squibb Company, **BMS**) hold a patent for monoclonal antibodies that block PD-1, an immune checkpoint, for use in the treatment of cancer. In addition to the patentees' own cancer drug (Opdivo), the APO found that a rival PD-1 inhibitor produced by Merck Sharp & Dohme (Keytruda) also fell within some of the claims of the patent. Keytruda was listed on the ARTG approximately nine months before Opdivo.

Ono and BMS filed a PTE application based on the first inclusion in the ARTG of Opdivo (and, in the alternative, a separate application based on the first inclusion of Keytruda). The APO issued a deficiency notice in respect of the primary application, as it was filed after the expiry of the six month window. This was because the relevant window was calculated as commencing on the date of first inclusion of Keytruda (being the earliest listing of a product falling within the patent claims).

The patentees requested an oral hearing in the matter.

APO DECISION

In September 2020, the delegate published his decision confirming the APO's position that first inclusion of Keytruda, not Opdivo, was the relevant ARTG commencement date. In doing so, he made reference to an earlier ruling in *G. D. Searle LLC* [2008] APO 31 (***Searle***), in which it was decided that "the intention of the Act is that an application for extension of term is to be made within 6 months of the ***earliest*** first inclusion in the ARTG", regardless of whether it is sponsored by the patentee.[2]

In their reasons, the delegates in both proceedings accepted that the relevant provision of the Act was ambiguous.[3] However, each delegate applied principles of statutory interpretation to ultimately conclude that the clock starts running from the first inclusion on the ARTG of any drug which falls within the scope of the patent, even if that belongs to a competitor or third party.

In their submissions before the delegate, Ono and BMS appealed to the core intention of the PTE regime, which was "to restore the time lost to patentees prior to gaining marketing approval, and compensate the patentee for the additional time, expense and difficulty in developing and commercialising a "new drug"."[4] The delegate accepted the premise, but disagreed with its implications:

> *…the purpose of the scheme is to encourage the development of new drugs. If a substance falling within the scope of the patentee's claim(s), but owned by a 3rd party, already exists on the ARTG, how is permitting the granting of an extension on a patent for effectively the same substance … an encouragement to development something new? If anything, it is an encouragement to develop something that is not new and place goods on the ARTG as late as possible, secure in the knowledge that a patent extension will be granted for the (not new) substance.*[5]

IMPACTS

CONSEQUENCES FOR PATENT HOLDERS

Ono and BMS, in their submissions to the APO, argued that the interpretation which the delegate ultimately adopted "would place an onerous burden on the patentee and the Commissioner as regards to monitoring regulatory approvals".[6] In reply, the APO emphasised that the law does not require the patentee, nor the Commissioner, to carry out searches of the ARTG for all pharmaceutical substances that may fall within the scope of their patent (although, it observed that "the Commissioner is not prevented from undertaking her own investigation").[7]

Despite these reassurances, not to conduct such checks may pose an unacceptable commercial risk for many pharmaceutical companies. Patent holders will want to assure themselves that their PTE application will not be obfuscated by the existence of a third party product registered on the ARTG earlier in time. If it appears that an earlier registered product falls within the scope of the claims, they would need to either use that date as the trigger for a PTE application, or allow themselves enough time to amend the patent itself so that the earlier registered product falls outside the claims of the patent, if possible (and otherwise desirable).

As argued by Ono and BMS, although the ARTG Public Summary provides details such as product name & type, active ingredient, sponsor, conditions, and so on, these details alone would not enable an applicant to determine whether the product might fall within the scope of their own patent.[8] To follow their argument, this would require complex analysis and expert advice, thereby imposing the need for a "forensic enquiry" rendering the PTE regime "practically unworkable".[9]

It might be countered that, in practice, a pharmaceutical patentee will typically know what its key competitor products are. While the concern might therefore be somewhat overstated, it is by no means fanciful. Establishing whether a competitor product falls within the scope of a patentee's own claims can be a highly complex exercise. Indeed, there are an increasing number of examples of Australian patentees failing in their attempts to obtain preliminary discovery from competitors so as to establish whether competitor products fell within the scope of its patent.[10]

BROADER IMPLICATIONS

The APO's ruling, if upheld, will confirm another potentially significant Australian departure from an increasingly harmonised international patent regime. The uniformity of patent laws across the globe has been driven by a series of international treaties and conferences, and continues to accelerate by virtue of the increasingly global presence of major pharmaceutical companies.

At a time when consistency of patent laws is paramount, confirmation of the APO's decision would place Australia out of step with key markets. In the US, the window for PTE applications is determined by reference to when the patentee's product received the relevant regulatory approval.[11] The position is arguably the same in Europe (although, due to a lack of direct authority, there remains some uncertainty on this point).[12] By contrast, the effect of the APO's interpretation is that the period is determined by reference to the first regulatory approval of goods that contain or consist of a pharmaceutical substance within the scope of the patent, regardless of whether that is the patentee's own product or that of a third party.

The favourability of Australia's intellectual property laws is a key to remaining competitive and incentivising investment in developing and marketing new drugs, particularly in crowded therapeutic areas. Due consideration should be given to whether the current provisions of the Act—as interpreted by the APO—strike the right balance between competing policy considerations.

We will provide a detailed commentary on the Australian position on PTEs once Beach J's decision is handed down.

ENDNOTES

1. *Ono Pharmaceutical Co., Ltd.. et al* [2020] APO 43 (***Ono***) at [34].

2. *Searle* at [18]–[21].

3. *Ono* at [25]; *Searle* at [5].

4. *Ono* at [15].

5. *Ono* at [43].

6. *Ono* at [35].

7. *Searle* at [19].

8. *Ono* at Annex A, [2].

9. *Ono* at [36].

10. See for example *Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd (No 2)* [2019] FCA 657.

11. See 35 U.S.C. § 156 and 37 C.F.R. § 1.720 and

12. See EC Regulation No 469/2009 of 6 May 2009 (Europe) and *Eli Lilly and Company v Genentech, Inc* [2019] EWHC 388 (Pat) (01 March 2019). In the *Eli Lilly* case, the UK High Court considered that the legality of using third party marketing authorisations as a reference point should be referred to the Court of Justice of the European Union ("CJEU"). The CJEU refused the application, as the patent had already been declared invalid by the High Court and so a preliminary ruling on the question would be hypothetical and therefore inadmissable: *Eli Lilly and Company v Genentech Inc.* (Court of Justice of the European Union, C-239,19, ECLI:EU:C:2019:687, 5 September 2019).

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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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