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FIRST THINGS FIRST: FULL FEDERAL COURT CLARIFIES THE LAW ON PATENT TERM EXTENSIONS

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Legal Briefings – By **Rebekah Gay, Emma Iles, Shaun McVicar and Bryce Robinson**

Last week, a Full Court of the Federal Court of Australia handed down two unanimous decisions on appeal, clearing up some key uncertainties in the application of Australia's patent term extension (PTE) regime.

KEY TAKEAWAYS

- A three-judge bench was convened to consider two important appeals relating to patent term extensions, comprising the Chief Justice and two respected intellectual property judges. Both decisions were handed down on 18 March 2022.
- In *Commissioner of Patents v Ono Pharmaceutical Co. Ltd* [2022] FCAFC 39 (***Ono***), the Full Court unanimously overturned the primary judge's decision, finding that pharmaceutical patentees must apply for a PTE within six months of the first inclusion on the Australian Register of Therapeutics Goods (**ARTG**) of *any* product containing a pharmaceutical substance falling within the claims of the patent, regardless of whether it is the patentee's own product.
- In *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd* [2022] FCAFC 40 (***Merck***), the Full Court unanimously upheld the primary judge's decision, thereby affirming that a PTE for a patent claiming more than one pharmaceutical substance must be calculated from the earliest regulatory approval date of *any* pharmaceutical substance disclosed in, and claimed by, the patent, even if that substance was not the basis of the PTE application.

- Pharmaceutical patentees should keep PTEs front-of-mind when filing patent applications, and will need to keep a close eye on regulatory listings that may impact PTE applications (including those by competitors).

PATENT TERM EXTENSIONS

In Australia, as in many major developed countries, the owner of a pharmaceutical patent can apply to extent the standard 20-year term for an additional period (e.g. up to five years in Australia, the US and Europe). We have previously explained the rationale behind this regime.

The *Patents Act 1990* (Cth) (the **Act**) establishes three basic conditions which must be met before a patentee is eligible to apply for a PTE:[1]

1. The patent must disclose one or more 'pharmaceutical substances per se' which fall within the scope of the claims[2]: s 70(2)

2. Goods containing the substance must be included on the Australian Register of Therapeutic Goods (**ARTG**): s 70(3)(a)

3. The first regulatory approval date (i.e. the date of first inclusion on the ARTG, or another prior marketing approval in some instances) must have been at least five years after the date of the patent: s 70(3)(b)

If all requirements are met, the term of the *entire* patent may be extended (not merely the claim to a particular pharmaceutical substance). However, the Act does place some limitations on what will constitute infringement during the extended term, for example, third parties can use the invention for non-therapeutic purposes.[3]

A QUESTION OF TIMING

The PTE regime strikes a careful balance between competing interests: those of pharmaceutical patentees whose exploitation of their patents has been delayed by regulatory hurdles, and the public interest in the unencumbered use of pharmaceutical inventions once patent protection has expired. As such, the Act includes two key timing requirements:

- **Applying for a PTE:** Patentees must apply for a PTE extension within six months from the date of the first inclusion on the ARTG of goods which contain a pharmaceutical

substance claimed in the patent (s 71(2)(b))

- **Calculating a PTE:** The length of a PTE is the period between the date of the patent and the first regulatory approval date, minus five years (although the maximum extension is capped at five years) (s 77).

It is these two provisions that were in issue in the *Ono* and *Merck* cases, respectively.

COMMISSIONER OF PATENTS V ONO PHARMACEUTICAL

BACKGROUND

We have previously reported on the facts of the *Ono* case and the Federal Court's decision at first instance.

THE FULL COURT'S DECISION

On 18 March 2022, the Full Court unanimously overruled Justice Beach's decision. The bench emphasised one of the most basic principles of law: statutory interpretation, above all, must be grounded in the words chosen by Parliament and, if the meaning of those words is clear, it cannot be replaced by a more commercial or desirable outcome.

Here, the Court held that the meaning of the Act was, in fact, clear: PTE applications must be filed within six months of the first ARTG listing of *any* product containing a pharmaceutical substance falling within the claims of the patent, regardless of whether it was the patentee's product or that of a third party. The Court rejected the primary judge's ruling that the relevant provision was limited to the goods of the patentee.

Chief Justice Allsop and Justices Burley & Yates explained that section 70(3), which is directed to the requirement that goods containing the pharmaceutical substance(s) claimed in the patent must be included in the ARTG, is a matter of "objective determination". Their Honours explained:

It concerns the state of the ARTG. As such, it looks to all relevant goods. The inquiry is not restricted to the goods of a particular person. The condition does not ask whom, or on whose behalf, the inclusion was sought or obtained. … [It] imposes no conditions beyond those stipulated in the provision. … It does not discriminate between goods that contain, or consist of, the one or more pharmaceutical substances.[4]

In turn, section 71(2)—which sets the six-month application deadline by reference to s 70(3)—is "directed, unambiguously, to the state of the ARTG". The Court therefore accepted the Commissioner's argument that the extra condition imposed by Justice Beach, which required that the goods must be the *patentee's* goods and implied the "notion of choice", simply had no foundation in the text, nor the surrounding context, of the provisions.

The Court rejected the primary judge's finding that the literal meaning of the provision resulted in absurdity or unreasonableness. Their Honours observed that the array of practical challenges for patentees, identified by the primary judge as arising from the Commissioner's interpretation, apparently had not materialised. They also emphasised that the PTE regime seeks to balance a range of competing interests, and not solely the interests of the patentee. It is to be accepted, they said, that the legislature decided on the correct balance and sought to achieve it by the exact words enacted.

MERCK SHARP & DOHME V SANDOZ

BACKGROUND

Merck's patent disclosed a substance called sitagliptin (marketed as Januvia), as well as a composition containing both sitagliptin and another substance, metformin (marketed as Janumet). Januvia and Janumet were included in the ARTG as "export only" listings in November 2006 and November 2008, respectively. Merck had successfully obtained a PTE for 17 months, which was calculated from the regulatory approval date of Janumet, the combination product.

Sandoz, who Merck sued for infringement that was threatened to occur within the PTE, sought to reduce the PTE to 'zero' years on the basis that "the earliest regulatory approval date" from which the PTE is calculated ought to have been the date on which Merck registered its sitagliptin-only product (Januvia) on the ARTG, some two years earlier than the date used by the Commissioner.

At first instance, Justice Jagot agreed with Sandoz.[5] Her Honour found that the Act required the extension to be calculated from the *first* regulatory approval date of "*any* pharmaceutical substance" disclosed by the patent which, in this case, was the regulatory approval of sitagliptin (Januvia). Adopting that approach, the extension to which Merck was entitled shrank down to zero; that is, although Merck was technically entitled to a PTE, the length of the PTE was '0 years'.

THE FULL COURT'S DECISION

Merck appealed the decision, challenging Justice Jagot's interpretation and application of the PTE calculation provision (s 77). On 18 March 2022, the Full Court unanimously dismissed Merck's appeal.

Like in *Ono*, the bench emphasised that statutory construction is a text-based activity, although this can be informed by policy considerations. Again, the Court ruled that the language and meaning of the Act was clear: where a patent claims more than one pharmaceutical substance, and there are multiple regulatory approvals for goods containing those substances, the length of the PTE must be calculated from the earliest ARTG inclusion of goods containing any of those substances.

This is because section 77 is directed to the earliest registration of goods containing the pharmaceutical substances referred to in section 70(2) (i.e. pharmaceutical substances disclosed in and claimed by the patent) and not, as Merck argued, the narrower subset of pharmaceutical substances referred to in section 70(3) (i.e. claimed in the patent *and* contained in goods registered on the ARTG more than 5 years after the patent date).

The Court also emphasised that section 77 expressly contemplates that a PTE can be zero (and theoretically below zero, although this is expressly prohibited). Their Honours explained that this could only be true if section 77 was, in fact, directed to the earliest first regulatory approval date in relation to *any* of the pharmaceutical substances in section 70(2). If Merck's interpretation was correct, then the words "reduced (but not below zero)" in s 77(1) would be entirely redundant.

Further, the Court saw no policy reason to divert from the words of the Act. Indeed, it identified policy considerations which supported Justice Jagot's interpretation. For example, if Merck's interpretation was right, a patentee who was ineligible for a PTE (because they had been able to register and commercialise their substance within 5 years) could register a product containing a different substance covered by the patent, *after* the 5 year mark, and thereby obtain a PTE for the whole patent (including the claims to the earlier, previously ineligible substance).

Once again, the judges emphasised that the PTE regime is designed not solely to protect the interests of pharmaceutical patentees, but to strike a careful balance between those interests and the competing public interest in unrestricted access to pharmaceutical inventions once their monopoly expires.

Finally, Merck raised an alternative basis for its appeal: contrary to an earlier Full Court precedent which it argued was wrongly decided, [6] the words "inclusion in the [ARTG]" are only directed to inclusion for marketing in Australia and should not include 'export only' listings. Ultimately, the Court did not find Merck's arguments persuasive and declined to depart from the earlier authority.

IMPLICATIONS

As we have explained in a previous article, the *Ono* decision now confirms an important point of departure from other key jurisdictions, including the US.

Pharmaceutical patentees will need to keep PTEs front-of-mind when drafting and filing patent applications in Australia. In particular, innovators will need to weigh up the risks and benefits of claiming more than one 'pharmaceutical substance per se' per patent (which, for example, may include a claim to a broad class of compounds).

One strategic approach may include exploring a divisional application strategy. While maintaining a broad parent patent to give broad protection for the invention, it may be possible to file separate divisional applications which are narrower and only claim a particular pharmaceutical substance per se, to avoid a PTE application being hampered by an earlier ARTG listing of a different substance claimed by the parent patent. Indeed, the Full Court recognised this as a possibility in *Merck* and observed that this would still appear "to meet the balance that Parliament sought to achieve between the interests of the patentee and the public interest".

There is also an increased need for pharmaceutical companies to remain vigilant for competitor activity and new listings on the ARTG, which may affect the timeline of their own PTE applications. Although the Full Court found that some of the practical challenges associated with the need for increased vigilance were perhaps overstated, they should not be dismissed entirely. We describe these challenges in our earlier article.

It is possible that Ono and BMS or Merck could seek special leave to appeal to the High Court of Australia. Special leave is discretionary and is reserved for cases that meet certain public interest thresholds, so it is unclear whether leave would be granted, particularly given the Full Court's application of uncontroversial principles of statutory construction. Unless and until this occurs, the Full Court has now clarified the law on PTEs—first things first.

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1. Section 70
2. Alternatively, the patent must claim a pharmaceutical substance when produced by a process involving the use of recombinant DNA technology.
3. Section 78(a)
4. At [121] and [129]
5. *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd* [2021] FCA 947
6. *Pfizer Corp v Commissioner of Patents* [2006] FCAFC 190; 155 FCR 578

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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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