

Inspire



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Welcome

Many of us have been living and working with a heightened sense of uncertainty for the past two years. Uncertainty can however offer a chance at a different outcome, possibly turning around an initially unfavourable position.

In this edition of Inspire, Jacqueline Leong analyses the successful appeal in *Allergan v Self Care*. While the Full Court agreed with the finding that consumers would not confuse Self Care's sign PROTOX with Allergan's BOTOX mark, that was not the end of the story. The commonalities between the signs and the goods on which they were used, gave rise to a likelihood that consumers would be confused as to whether the products were from the same source, and a finding of deceptive similarity. The appellants were also successful in overturning the first instance decision in *Hardingham v RP Data* resulting in a finding of copyright infringement.

Alexis Keating discusses the challenges of seeking to rely on implied terms which led to a finding that certain uses of copyright works had not been authorised and were therefore infringing.

In *Cytec v Nalco*, the patent office decision to reject a ground of opposition based on lack of support was overturned by the Federal Court, which found that the technical contribution made by the invention did not extend to all of the subject matter covered by the claims. As Danielle Burns explains, seeking broad patent protection based on a relatively narrow disclosure in a specification is becoming increasingly challenging in Australia.

Also in this edition, Annabella Newton looks at how patent term extensions can be impacted if the claims cover more than one pharmaceutical substance and we hear from the Australian Battery Society on the significance of an upcoming International Meeting on Lithium Batteries.



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2021: Living with COVID

We are nearing the end of yet another strange and unprecedented year. COVID-19 continues to impact all of us, from how people work to how we conduct our daily lives. We continue to manage the evolving situation and monitor closely how COVID-19 is affecting our communities, our team and our clients.

We are immensely proud of the resilience, flexibility, and professionalism of our team, which has stayed focused on delivering outstanding service to our clients.

While some Australian research institutions remain financially constrained, in general the Australian innovation sector has remained healthy during 2021. Increasing business confidence around the world has resulted in strong growth in IP rights filings from many of our international clients most notably in the telecommunications, IT, medical devices, pharmaceuticals and biotechnology sectors.

Australia has been able to keep community transmission of COVID-19 very low during much of the pandemic, but it has come at the cost of extensive lockdowns and state border closures. As our vaccination rate now climbs to be one of the highest in the world, our society is finally opening up.

We are planning to move to a hybrid model in the new year that lets everyone split their time between the home and office. Our goal is to deliver the benefits of work-life balance for our people, while still providing the in-office interaction and collaboration with workmates and clients that is so important.

Our thoughts and best wishes go out to our colleagues and friends around the world as we all learn to live with COVID-19. We remain focused on helping to support your business goals, and on ensuring that we continue to have a talented team and efficient systems to deliver great outcomes for you.

We look forward to working with everyone next year and we wish you a safe festive season and a happy new year.

Our offices will close at 3pm (AEDT) on Friday 24 December 2021. We will reopen with a limited number of staff on Tuesday 4 January 2022, prior to a full reopening on Monday 10 January 2022.



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Are your claims supported by your technical contribution to the art?

The Federal Court of Australia in *Cytec v Nalco*¹ overturned a decision by the Commissioner of Patents and confirmed that the Australian support provisions require:

- > an assessment of the technical contribution to the art disclosed by the specification; and
- > that the monopoly claimed be justified by that technical contribution.

Background

The technology in issue related to scale formation in alumina factories. The 'Bayer' process is the primary process by which alumina is extracted from bauxite ore, and is used to produce nearly all of the world's alumina supply. A major problem during the process is formation of sodium aluminosilicate scale in process pipes, vessels, and equipment. The patent application was directed to methods for reducing scale during the Bayer process, involving use of certain silane based small molecules. Claim 1 recites:

"A method for the reduction of aluminosilicate containing scale in a Bayer process comprising the step of: adding to the Bayer process stream an aluminosilicate scale inhibiting amount of a composition comprising at least one small molecule selected from....."

The judge construed the claim, owing to use of the term "at least one", as covering methods where a composition comprising one or a mixture of two or more silane based small molecules is used to reduce scale in the Bayer process. In particular, the claims covered use of a single silane based small molecule.

The technical contribution and lack of support

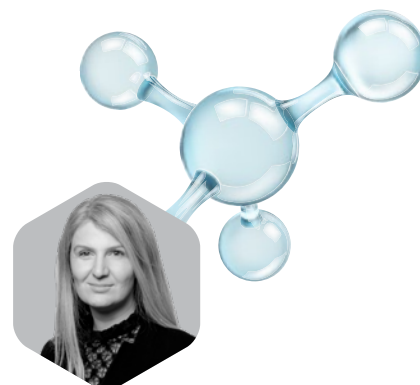
It was argued that the technical contribution to the art disclosed by the specification was the synthesis of a reaction product mixture by reacting an amine, an amine-reactive silane compound and an amine reactive hydrophobe to form a mixture of silane-based small molecules for reducing scale in the Bayer process.

The judge considered that the technical contribution did not extend to use of a composition comprising a single silane based small molecule – there was no supporting disclosure of the synthesis of any such composition or any supporting disclosure of isolating a single small molecule from the complex reaction product mixtures. And as such, the claims were considered to lack support.

Impact for the patentee

It is not uncommon when seeking patent protection to try and obtain coverage for not only your lead product, but variations of it so that you have broad scope to continue to develop your product or to keep competitors out of the field. However, it is becoming increasingly difficult in Australia to claim such variations, and the inclusion of experimental data in the specification is becoming more important to support broad product protection. It is important that the application include data demonstrating that all products claimed have the same surprising, advantageous effect or function that forms the essential crux of any technical contribution argument. At the very least, the data should make it plausible that the effect is shared across the products claimed. Further, the disclosure should teach the skilled addressee how to obtain all of the products claimed.

“
It is not uncommon when seeking patent protection to try and obtain coverage for not only your lead product, but variations of it...
”



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¹ *Cytec Industries Inc. v Nalco Company* [2021] FCA 970

PROTOX mark PROhibited in Full Court Decision

In *Allergan v Self Care*¹, the Full Federal Court overturned a first instance decision and held that the mark PROTOX, and the phrase “*instant Botox® alternative*”, are deceptively similar to the mark BOTOX, and therefore use of PROTOX and the phrase constituted trade mark infringement. The Full Court also found that none of the defences relied on by the respondents applied.

Background

Allergan is the manufacturer of the well-known anti-wrinkle injectable product BOTOX, and the registered trade mark owner of various marks for BOTOX. This includes the word mark² covering various classes including class 5 for “*pharmaceutical preparations for the treatment of wrinkles*”, and class 3 for “*anti-aging creams; anti-wrinkle cream*”. BOTOX is an invented word derived from the active ingredient in the product, botulinum toxin.

Self Care is a supplier of cosmetic products, including topical anti-

wrinkle skincare products using various marks including ‘Protox’, ‘Inhibox’ and ‘Night’ under the umbrella brand FREEZEFRAME. The director of Self Care came up with the word PROTOX – she intended that ‘PRO’ refer to ‘prolonging’ and ‘TOX’ to ‘botulinum toxin’, and the play on words was meant to convey that their product “*prolongs the effect of botulinum toxin*”.

Self Care applied to register the mark FREEZEFRAME PROTOX³ for “*Anti-ageing serum, anti-wrinkle serum*”, and successfully defended an opposition by Allergan. Allergan appealed the Registrar’s decision

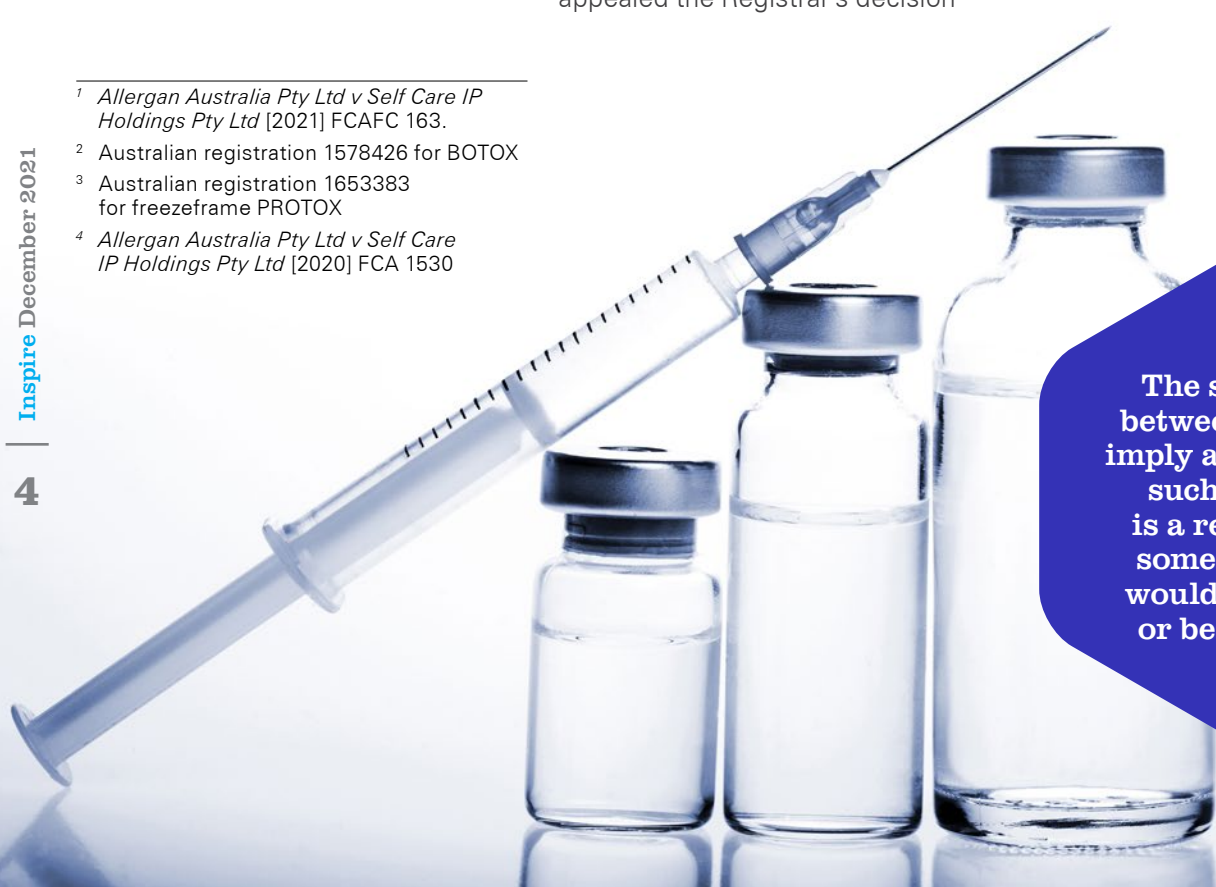
to allow the FREEZEFRAME PROTOX application to proceed to registration to the Federal Court⁴, and claimed that Self Care had infringed the BOTOX trade marks by using composite phrases such as “*instant Botox® alternative*”, “*long term Botox® alternative*” and “*overnight Botox® alternative*” in its packaging and advertising. Allergan also claimed that Self Care had contravened the Australian Consumer Law (ACL) by making representations concerning the efficacy of its products and affiliation with Allergan’s BOTOX product.

¹ *Allergan Australia Pty Ltd v Self Care IP Holdings Pty Ltd* [2021] FCAFC 163.

² Australian registration 1578426 for BOTOX

³ Australian registration 1653383 for freezeframe PROTOX

⁴ *Allergan Australia Pty Ltd v Self Care IP Holdings Pty Ltd* [2020] FCA 1530



“
The similarities between the words imply an association such that there is a real risk that some consumers would be deceived or be confused...
”

Stewart J held that neither the mark PROTOX, nor any of the composite phrases used by Self Care in its packaging and advertising were deceptively similar to the mark BOTOX, and consequently there was no trade mark infringement. Further, only 1 out of about 35 statements were in contravention of the ACL. Allergen's appeal of the Registrar's decision to allow Self Care's FREEZEFRAME PROTOX application to be registered was also dismissed.

Appeal

Allergen appealed the judgement as it related to the use of PROTOX and the phrase "*instant Botox® alternative*", and its claims of trade mark infringement and representations made by Self Care that contravened the ACL.

Deceptive similarity and trade mark infringement

The Full Court agreed that Stewart J was correct to conclude that PROTOX was used as a trade mark and that the following considerations were accurate:

- > The words are distinguished by their first syllable, PRO- and BO-, and that attention would more likely be directed to the first syllable;
- > the prefix PRO is a familiar and recognisable word that carries a meaning, whereas BO is not familiar and has no recognisable meaning;
- > the word BOTOX is so well known that the difference between that word and the mark PROTOX would be immediately apparent to consumers; and
- > PROTOX would remind consumers of BOTOX and consumers would not confuse PROTOX for BOTOX.

However, the Full Court held that Stewart J did not consider whether, due to the similarities between the marks, consumers would have wondered if the different products, claiming to have the same effect, came from the same source.

The Full Court found that PROTOX is deceptively similar to BOTOX. The similarities between the words imply an association such that there

is a real risk that some consumers would be deceived or be confused as to whether PROTOX was an alternative product being offered by the manufacturer of BOTOX.

The Full Court also disagreed with the finding that the phrase "*instant Botox® alternative*" was not used as a trade mark. Stewart J's main reason for finding that there was no trade mark infringement was the use of the word 'alternative', which indicated that the product was different to BOTOX. The Full Court was of the view that the word 'alternative' implies that the products are different and that there is choice between them, but it may still imply association as to the trade source. Although 'instant' and 'alternative' are descriptive words, the phrase "*instant Botox® alternative*" was not used in a purely descriptive way.

While Self Care used the ® symbol and attributed Allergan as the owner of the BOTOX mark in its packaging, this was not sufficient to dispel the implication of an association between the parties – even the most meticulous consumers noting Allergen as owner of the mark BOTOX might reasonably consider that Self Care was associated, or had authorisation to use Allergen's BOTOX mark on its packaging. The Full Court concluded that the phrase is deceptively similar to BOTOX as there is a real risk that the phrase would cause people to wonder whether the different products come from the same trade source – in particular, consumers may wonder whether the PROTOX topical cosmetic product was a new BOTOX product range.

Defences

Self Care relied on a number of defences but none of them were successful. Self Care contended that it had a defence to infringement because it had obtained a trade mark registration⁵ for FREEZEFRAME PROTOX. The Full Court held that this defence did not apply because Self Care did not use FREEZEFRAME PROTOX together, but the word PROTOX as a trade mark independently of FREEZEFRAME on its packaging.

Self Care also claimed that use of the phrase "*instant Botox® alternative*" was allowable because it was used for the purposes of comparative advertising⁶. The Full Court did not agree – comparative advertising involves differentiating two products factually in order to promote one's product over a competitor's product. It could not be comparative advertising if consumers would be misled or cause to wonder whether the compared products came from the same source. The Full Court also found that the phrase was used to leverage off the reputation of BOTOX, and not to promote Self Care's product comparatively with BOTOX, thus defeating the essence of comparative advertising. Finally, the Full Court refused to find that the phrase was used in good faith to indicate the intended purpose or characteristics of the product.

Key lessons

When comparing two trade marks for 'deceptive similarity', it is not enough to consider that the marks are sufficiently different because consumers would not be confused that one mark is the same as the other. An important question to ask is whether due to the similarities between the marks it is likely that consumers would have wondered or be confused as to whether products bearing the different marks would come from the same trade source.

The Full Court's findings on comparative advertising also serve as an important lesson to businesses to be careful when seeking to use a competitor's trade mark to promote their own products or services against a competitor's. Businesses should ensure that comparisons are accurate and are sufficiently meaningful comparisons of two different products or services, from different sources.




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⁵ Section 122(1)(e) of Trade Marks Act 1995

⁶ Section 122(1)(d) of Trade Marks Act 1995

⁷ Sections 122(1)(b) and (c) of Trade Marks Act 1995



The Australian Battery Society – leading the push for local, world-leading battery tech

Phillips Ormonde Fitzpatrick (POF) was proud to host the Australian Battery Society's (ABS) national online meeting this year on 28 and 29 October. The meeting featured a number of presentations from highly recognised members of the wider battery tech community. POF is delighted to be a foundational sponsor of ABS, and to be supporting the growth of the battery industry in Australia.

We asked the ABS about how the organisation was formed, its long-term goals for battery technology in Australia, and the significance of the upcoming International Meeting on Lithium Batteries (IMLB) being held in Sydney in June 2022...

ABS: In 2018, Assoc. Prof. Neeraj Sharma (UNSW), Dr. Rosalind Gummow (James Cook University), Prof. Shirley Meng (University of California, San Diego) and Dr. Adam Best (CSIRO) pitched to the Board of the IMLB in Kyoto, Japan, to host the meeting in Sydney, 2022. It was our third attempt, and this time we were successful. From this decision, ABS was born.

Dr. Adam Best, Assoc. Prof. Neeraj Sharma and Dr. Rosalind Gummow founded ABS due to a key condition of the contract to host the IMLB meeting. One third of any profit from the meeting is required to be donated to an entity that is committed to the promotion of electrochemical energy storage technologies. After reviewing the available societies and interest groups in Australia that are associated with electrochemical energy storage, the team felt that there was no existing group that was ideally placed to support this outcome. Consequently, the ABS was born with the vision to:

... build a strong, vibrant battery community, interconnected across the full battery value chain, and encompassing industry, academia, policy makers and members of the public, to support a globally competitive battery industry sector.

Since the founding of ABS, we have developed a constitution, website, and have held two events including a recent online conference generously supported by POF. The meeting featured speakers from across the country, speaking on topics across the value chain with approximately 150 people registering to be part of it. We have also announced the creation of the ABS Energy Renaissance Innovator Award, which offers 10 x \$2500 awards to support the ABS vision to build greater capacity in batteries across the battery value chain.

The first awards will be announced in late January 2022. It's just the start for ABS and our grand vision of supporting the creation of a globally competitive battery industry in Australia.

“

Registration and abstract submission are now open for the IMLB2022 and we invite you to join the IMLB in celebrating its 21st birthday with us.

As noted earlier, we are hosting the 21st IMLB from 26 June to 1 July 2022, at the International Convention Centre in Sydney. As the premier research meeting on lithium ion and next generation batteries, we are looking forward to hosting five Plenary speakers, including the co-winner of the 2019 Nobel Prize in Chemistry, Prof. M. Stanley Whittingham, who is credited with key discoveries that have enabled lithium-ion batteries as we know them today. Our other plenary speakers include Prof. Clare Grey (Cambridge University, UK), Prof. Jeff Dahn (Dalhousie University, Canada), Prof. Atsuo Yamada (Tokyo University, Japan) and Australia's Prof. Maria Forsyth (Deakin University). A further 76 speakers, headlined by Prof. Alan Finkel, Special Advisor to the Australian Government on Low Emissions Technology, will cover topics including policy in various countries, mining of battery

metals, cathode and anode materials development, cell fabrication, next generation batteries including all-solid-state systems, recycling, and more, to give attendees a world leading view of the field.

One of the key features of the IMLB is the vibrant poster sessions that occur on three days of the meeting. These sessions, covering the same topic areas described above, are an important part of the dissemination of scientific information, but also a great opportunity for attendees to network and rekindle old relationships and develop new ones. As part of this meeting, it is our intention to have invited posters to highlight key researchers and their research activities.

The meeting is also known for its exhibition program, highlighting battery, materials and scientific equipment suppliers. Here is an opportunity for delegates to meet with those companies, find out about the latest innovations in battery characterisation tools and more.

Registration and abstract submission are now open for the IMLB2022 and we invite you to join the IMLB in celebrating its 21st birthday with us. As the world's battery community gathers in Australia, now is a great time to come and hear about the latest innovations in electrochemical energy storage that will power a cleaner, greener and renewable future for the world. A successful IMLB will leave a legacy, as any profit from the meeting will be used to support ABS to continue to promote battery storage of all types in Australia.

We look forward to welcoming you.

POF is a Foundational Sponsor of the ABS, Graphite Level IMLB Sponsor and the official IP attorneys for the IMLB2022.



Hardingham v RP Data appeal: The risks of implied copyright licences

+

In *Hardingham v RP Data*¹, Thawley J held that RP Data was not liable for infringing copyright in various photos and floor plans reproduced on its website. However, on appeal², a majority of the Full Court reversed this decision, and in doing so, highlighted the risk in relying upon implied terms of informal agreements.

¹ *Hardingham v RP Data Pty Limited* [2019] FCA 2075

² *Hardingham v RP Data Pty Limited* [2021] FCAFC 148

Background

The appellants were Real Estate Marketing Australia Pty Ltd (REMA) and its sole director, James Hardingham. Hardingham granted REMA an exclusive licence to the copyright subsisting in works originated by him.

Real estate agents commissioned REMA over the phone to provide photos and floor plans for use in marketing campaigns for the sale or lease of properties. The agents then uploaded the photos and floor plans to the website operated by Realestate.com.au Pty Ltd (REA) for this purpose. The informal agreement between the parties was only ever an oral agreement and was never reduced to writing.

In order to upload the photos and floor plan to realestate.com.au, the agents agreed to the terms and conditions of REA. These included the grant to REA of an express, royalty-free licence to “*licence to other persons*” any content provided by the agents. Pursuant to this, REA provided the appellants’ photos and floorplans to RP Data. RP Data then published the photos and floorplans on its website corelogic.com.au.

The appellants claimed that, in so doing, RP Data infringed Mr Hardingham’s copyright.

First instance decision

The appellants were unsuccessful at first instance in their copyright infringement claim. Thawley J found that the appellants authorised the agents to upload the photos and floor plans to realestate.com.au, and granted to REA a licence in the form contained in REA’s usual terms and conditions. This much was to be inferred from the parties’ conduct, or alternatively should be implied into their agreements to give them business efficacy.

Key to this finding was that the appellants were aware that the agents were going to upload the photos and floor plans to realestate.com.au, and that REA was going to share this content with RP Data.

Appeal decision

A majority of the Full Court upheld the appeal. Greenwood J found, and Rares J agreed, that the parties made an informal, oral arrangement which expressly granted the agencies permission – or a licence – to use the works for the purposes of the marketing campaign for the sale or lease of the property. That licence included an authority conferred on the agents to sub-license others (including REA) to use the works for the purposes of the marketing campaign. However, their Honours found this did not include a grant of authority to the agents to sub-license REA on REA’s usual terms and conditions.

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The decision is a useful reminder of the importance of clearly defining and documenting the scope of any licences granted.

In reaching this finding, their Honours applied foundational principles from *Codelfa Construction v State Rail Authority of NSW*³ (*Codelfa*) and *B. P. Refinery v Shire of Hastings*⁴ (*B. P. Refinery*) to determine whether a term is to be inferred or implied into an oral contract.

Citing *Codelfa*, their Honours noted that an implied term is one that it is “*presumed that the parties would have agreed upon had they turned their minds to it — it is not a term that they have actually agreed upon*”. Their Honours considered that a term conferring authority on the agencies as per the REA terms and conditions would have been

significantly against the appellants’ interest. It was, therefore, difficult to conclude that the parties would have agreed to such a term, had they turned their minds to it.

Further, in applying the criteria in *B. P. Refinery*, their Honours considered that the scope of such a term would not be “*so obvious that it would go without saying*”. In the circumstances, their Honours were not satisfied that the principles governing the inclusion of an implied or inferred term had been met.

Licensing Lessons

The decision is a useful reminder of the importance of clearly defining and documenting the scope of any licences granted. This includes the extent to which the licensee may grant sub-licenses, under a written agreement.

Photographers and other creatives would be wise to include in their standard terms and conditions, a term dealing with copyright ownership and the rights that they licence to the customer. It is preferable to have a written agreement, rather than relying on oral agreements or implied terms. Whilst it may be that these standard terms don’t suit everyone, it provides a starting point for the parties to negotiate terms that work for both of them. Any departures from the standard terms and conditions could then be agreed in writing.



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³ *Codelfa Construction Pty Ltd v State Rail Authority of NSW* (1982) 149 CLR 337

⁴ *B. P. Refinery (Westernport) Pty Ltd v Shire of Hastings* (1977) 180 CLR 266



It all adds up:

how a term extension can be impacted if a patent covers more than one pharmaceutical substance

A recent Federal Court decision¹ has further considered Australia's patent term extension (PTE) provisions. Merck Sharp & Dohme (MSD) is the registered proprietor of Australian patent 2002320303, which relates to the treatment or prevention of diabetes.

The date of the patent is 5 July 2002 and the original term of the patent was for 20 years, until 5 July 2022. MSD successfully applied for PTE in 2009 and the term of the patent was extended until 27 November 2023. MSD contended that the respondent (Sandoz) threatened to infringe the patent. Sandoz had undertaken not to exploit the patented invention before the end of the original term (5 July 2022) but refused to provide any such undertaking during the extended term, as they contended that the PTE was invalid.

Legislative Background

S 70 of the Patents Act specifies that to be eligible for an extension of term, a patent must meet the following requirements:

- (2) The patent must both claim and disclose one or more pharmaceutical substances per se (and/or one or more pharmaceutical substances when produced by a process that involves the use of recombinant DNA technology);
- (3)(a) goods containing, or consisting of, at least one of those pharmaceutical substances must be included in the Australian Register of Therapeutic Goods (ARTG);
- (3)(b) 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; and
- (4) the term of the patent must not have been previously extended.

S 71(2) outlines the deadline for filing a PTE request, which is the latter of either:

- (a) 6 months from the date the patent was granted; or
- (b) 6 months from the date of commencement of the first inclusion in the ARTG of goods that contain, or consist of, any of the pharmaceutical substances referred to in subsection 70(3).

S 77 provides that term of the extension is equal to the period beginning on the date of the patent and ending on the earliest first regulatory approval date in relation to any of the pharmaceutical substances referred to in s 70(2); reduced (but not below zero) by 5 years, up to a maximum of 5 years.

¹ *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd* [2021] FCA 947

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MSD has appealed the decision but, as it stands, it is significant for pharmaceutical patentees.

Relevant Facts

The patent in suit disclosed and claimed each of (i) sitagliptin, and (ii) a composition containing sitagliptin and metformin (sitagliptin/metformin). Sitagliptin and sitagliptin/metformin are both considered a ‘pharmaceutical substance’ and, further, are different pharmaceutical substances from one another.

Goods containing or consisting of sitagliptin were included in the ARTG on 16 November 2006. The period beginning on the date of the patent (5 July 2002) and ending on the date of commencement of the first inclusion in the ARTG of goods that contain or consist of sitagliptin (16 November 2006) is 4 years, 4 months and 11 days.

Goods containing or consisting of the composition of sitagliptin/metformin were included in the ARTG on 27 November 2008. The period beginning on the date of the patent (5 July 2002) and ending on the date of commencement of the first inclusion in the ARTG of goods that contain or consist of sitagliptin/metformin (27 November 2008) is 6 years, 4 months and 22 days.

Only the sitagliptin/metformin product satisfies the s 70(3) requirement outlined above. The sitagliptin product does not satisfy s 70(3) because the period between the date of the patent and the first regulatory approval date for the substance was not at least 5 years.

Federal Court Decision

MSD referred to the recent decision in *Ono*², (previously reported on [here](#)), as basis for the position that the patentee may nominate the pharmaceutical substance for the purpose of applying for PTE.

MSD also argued that when calculating the length of extension using s 77(1), the earliest first regulatory approval date “in relation

to any of the pharmaceutical substances referred to in subsection 70(2)” means either:

- > The earliest first regulatory approval date of **any** substance satisfying s 70(3); or
- > the earliest first regulatory approval date of **all** substances satisfying s 70(3).

On both of MSD’s constructions, the *earliest first regulatory approval date* of any and all pharmaceutical substances in the patent satisfying s 70(3), was the date of inclusion in the ARTG of sitagliptin/metformin (27 November 2008).

Sandoz contended that the *earliest first regulatory approval date* “in relation to any of the pharmaceutical substances referred to in subsection 70(2)” in s 77(1) means what it says.

On this construction, the earliest first regulatory approval date of any pharmaceutical substances in the patent as referred to in s 70(2) is the date of inclusion in the ARTG of sitagliptin (16 November 2006).

When considering the legislative framework, the Court agreed with Sandoz’s interpretation. Jagot J noted that s 77(1) refers to s 70(2) and not s 70(3), whereas s 71(2)(b) refers to s 70(3). On this basis, the Court found that when calculating the length of PTE, earliest first regulatory approval date relates to any of the one or more pharmaceutical substances which may be claimed and disclosed in the patent. Therefore, while it may be possible to fulfil the requirements of s 70 with a later-registered product, the relevant earliest regulatory approval date for s 71 may result in an extension of zero.

Jagot J distinguished the present facts from *Ono* on the basis that, in *Ono*, Beach J was considering a case where the earliest first regulatory approval on which the Commissioner relied to refuse the grant of an extension of term was

that of a *third party competitor* of the patentee. The Court held that an unconnected third party’s ARTG listing will not provide the relevant “*earliest first regulatory approval date*” and the PTE request must be based on the earliest included good of the patentee.

Conclusions

MSD has appealed the decision but, as it stands, it is significant for pharmaceutical patentees. This decision confirms that when a patent covers two or more pharmaceutical substances that are also included on the ARTG by the patentee, or with their consent, the relevant date for calculating the length of extension available is the earliest regulatory approval date of any of the substances. If this earliest regulatory approval date is within 5 years of the date of the patent, then the extension of term available will be zero.

This decision also confirms that if the earlier approved product belongs to a third party then an extension of term may still be available to the patentee based on their own product, providing that their own product was approved more than 5 years after the date of the patent.

Consideration should be given to strategies which might allow a pharmaceutical patentee to maximise the lifetime of their patents such as planning regulatory approval for after the 5-year threshold and separately claiming different pharmaceutical products in divisional applications.



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² *Ono Pharmaceutical Co. Ltd v Commissioner of Patents* [2021] FCA 643



PROUD TO BE AN
INCLUSIVE EMPLOYER
2021–2022

POF proudly recognised as a DCA Inclusive Employer (2021–2022)

POF is pleased to announce that we have been recognised as an Inclusive Employer for 2021 – 2022 in the Diversity Council of Australia’s latest Member Index. Additionally, we are the first Intellectual Property firm to have been awarded this status since the DCA began the Index in 2017. We are proud of this achievement, and to be recognised for our efforts towards diversity and inclusion both within our firm, and the IP profession.

In tandem with this achievement, we are also pleased to announce a number of substantial changes to our parental leave policy. We believe these changes better address the needs of our staff and their wellbeing, and reflect our commitment to fostering an inclusive and equitable workplace. The new policy aims to improve workforce participation rates by women, narrow the pay and superannuation gap, and allows

families to better combine work and caring responsibilities. Titles such as primary and secondary carers have also been done away with, allowing both women and men the same opportunity in accessing parental leave. We are proud of these changes for what they can provide for our staff and their families. We have many other initiatives for diversity and inclusion on the horizon too, such as Public Holiday substitution so that our staff may

observe any cultural or religious days that are significant to them in lieu of others that may not apply. We have also established a Diversity and Inclusion Subcommittee within the firm, to take the helm in shaping and implementing these and future initiatives. We are very proud to be recognised as an Inclusive Employer, and POF remains committed to ensuring it is a diverse and inclusive firm.



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