State of the Art

Key Australian IP developments

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Foreword

So far, this year has seen a number of significant developments affecting the Australian intellectual property landscape. In this edition of *State of the Art*, we explore some of the most notable of these.

The Australian Aboriginal Flag is a significant and powerful symbol of Aboriginal identity. Corrs was privileged to act pro bono for Mr Harold Thomas, artist and author of the copyright in the Aboriginal Flag, on the deal to assign copyright in the flag to the Commonwealth.

In a major development in Australia's longest running patent dispute, Danish pharmaceutical company Lundbeck was successful in an appeal before the High Court of Australia. The effect of the High Court's decision is to restore one of the largest damages awards granted by an Australian court for patent infringement in a decision which has a number of implications for patentees and exclusive licensees.

The Full Federal Court of Australia unanimously overturned an earlier decision relating to patent inventorship by artificial intelligence. The earlier decision, which received global media attention, found that an AI system could be an inventor for the purposes of the *Patents Act 1990* (Cth). We discuss the Full Court's decision, which brings Australia (back) into line with the vast majority of jurisdictions. We also consider a May 2022 judgment of the UK Court of Appeal, which serves as a useful reminder for e-commerce retailers to be aware of the risk of trade mark infringement when advertising and selling their products online given the territorial nature of trade mark rights.

In light of a recent provisional decision by the Australian Competition and Consumer Commission to deny authorisation of a proposed settlement between a pharmaceutical originator and a prospective supplier of a biosimilar product, we look at how competition law risks arising from patent settlement agreements are being addressed in Australia. Separately, we unpack a pair of significant appeals handed down by the Full Federal Court which have provided clarity in relation to Australia's patent term extension regime for pharmaceutical substances.

Finally, while wearable electronic medical devices are emerging as an effective and convenient way of monitoring and maintaining individuals' health, robust cybersecurity remains a critical consideration for the industry. We consider the cybersecurity risks for manufacturers of digital medical devices.

We hope you enjoy this edition of *State of the Art*. If you wish to discuss any of these pieces or other developments, please contact us. We look forward to working with you over the remainder of 2022.

Eugenia Kolivos

Partner and
Head of Intellectual Property

+61 2 9210 6316
+61 407 787 992
eugenia.kolivos@corrs.com.au

David Fixler

Partner and Editor,
State of the Art

+61 3 9672 3173
+61 407 086 955
david.fixler@corrs.com.au

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The authentic digital representation of the Australian Aboriginal Flag, approved by Mr Harold Thomas

Copyright in the Australian Aboriginal Flag assigned to the Commonwealth of Australia

By Chrystal Dare, Special Counsel and Jaimie Chapman, Lawyer

The Australian Aboriginal Flag is a significant and powerful symbol of Aboriginal identity.

At the beginning of 2022, Mr Harold Thomas, artist and the creator of the Australian Aboriginal Flag, entered into a landmark deal to assign copyright in the Aboriginal Flag to the Commonwealth of Australia. Corrs acted pro bono for Mr Thomas, and led the negotiations with Colin Golvan AM QC, while Clayton Utz acted for the Commonwealth of Australia, represented by the National Indigenous Australians Agency.

When Corrs commenced acting for Mr Thomas in the beginning of 2020, it was clear that there needed to be a resolution to the complex issues that sat behind the Free the Flag movement in Australia, in the unusual situation where the copyright in a national flag remained privately held.

After almost two years of negotiations, the transaction was ultimately concluded in the year following the fiftieth anniversary of the Flag's creation.

The deal was announced by then Prime Minister Scott Morrison on 25 January 2022, and the A$20.05 million total transaction amount included a payment to Mr Thomas of A$13.5 million as consideration for the copyright assignment, and buy-out of contentious licences to WAM Clothing and Wooster Holdings.

Mr Thomas retained his moral rights in the Flag after the assignment, including the right of integrity. The previous Flagworld licence to reproduce the artistic work on flags, banners, bunting and pennants also remained on foot, carrying with the assignment under section 196(4) of the *Copyright Act 1968* (Cth).

This has become one of the biggest art transactions in the history of Australia, both in dollar figures and in terms of its significance. One of the core goals in the matter was to protect Mr Thomas' legacy as an artist who has been practising art his whole life. The significance of the Aboriginal Flag as an artistic work is not in spite of, but because of its simplicity – a work of hard-edge modern art and an unparalleled form of expression of Aboriginal identity.

History of the Australian Aboriginal Flag

In 1995, the Aboriginal Flag was declared an official Flag of Australia under the *Flags Act 1953* (Cth).

In 1997, in the case of *Thomas, Harold Joseph v Brown, David George* [1997] FCA 215; 37 IPR 207, represented by Colin Golvan AM QC, Harold Thomas' authorship and ownership of the Flag was contested. Ultimately, Sheppard J of the Federal Court declared Harold Joseph Thomas the author of the artistic work, being the design for the Flag.

The case provides an illuminating history of the period and the Flag's inception, and removed any questions around authorship and ownership entering into the negotiations.

The deal with the Commonwealth

The negotiations involved five contracting parties and their legal representatives, a three-week Senate inquiry in the second half of 2020, and some unique tax dimensions given the age of this intangible tax projects. Nine partners and 15 lawyers across Corrs' IP, tax, projects, and corporate teams were involved.

Aside from the A$13.5 million consideration for the assignment, the public interest dimensions of the deal were critical, and, as such, were enshrined in the deal document – a public document to reside in the National Archives of Australia at the instigation of former Indigenous Affairs minister, The Hon Kenneth Wyatt AM.

Those key planks included:

- assignment of the copyright in the Flag to the Commonwealth so that the Flag may be permitted by the Commonwealth to be open for public use, including for reproduction or communication to the public by any person in any way without licence fee (subject to any continuing exclusive licences);
- establishment of an Australian Aboriginal Flag Legacy not-for-profit by Mr Thomas with $2 million of the consideration payment amount;
- ongoing royalty payments received by the Commonwealth from Flagworld (the continuing licensee) to be directed to support the ongoing work of NAIDOC;
- A$100,000 per year allocated by the Commonwealth in furtherance of the development of Indigenous governance and leadership; and
- establishment and maintenance of an online repository of information and educational material relating to the Flag.

Under Mr Thomas' instructions, Corrs minted the non-fungible token (**NFT**) of the Australian Aboriginal Flag on 12 December 2021, within the final weeks of the fiftieth year of the Flag. Mr Thomas took this step in advance of assigning the copyright in the Flag to the Commonwealth, while he still held the copyright, with a view to holding the NFT on behalf of Indigenous Australians, rather than ever transacting upon it. Blockchain technology can verify the authenticity of this NFT, being the authentic digital representation of the flag depicted above.

Colin Golvan AM QC has commented:

> *It is unquestionably the most important copyright work we have. The fact that we have a truly unifying flag which is free to the Aboriginal people in particular for usage as their representative flag is an important step in our reconciliation journey.*

Reflective of this significance is the level of public interest around this matter and press attention in Australia. The matter brought up questions around artistic works, copyright ownership and licensing, and the nature and value of intellectual property assets.

Corrs is establishing the Australian Aboriginal Flag Legacy not-for-profit on Mr Thomas' behalf with A$2 million of the transaction proceeds, and it is anticipated that Corrs will have ongoing involvement with that charity, which will focus on Indigenous men's and women's health.

As for the Flag now, Mr Thomas says:

> *The Aboriginal flag is in a safe place where the Commonwealth will protect and be the custodian of it, and I like that… because it's freed up to be accessed for all Australian people… and allows the Aboriginal flag to breathe a new life in itself…in partnership with the Australian flag.*

High Court reinforces the role of context in construing agreements and provides clarity to patentees and licensees

By Stephen Stern, Partner, David Fixler, Partner, James Beavis, Senior Associate and Sarah Catania, Associate

We are pleased to report on the success of long-term Corrs Chambers Westgarth client, Danish pharmaceutical company H. Lundbeck A/S (**Lundbeck**) in its appeal before the High Court of Australia (**High Court**) in *H. Lundbeck A/S v Sandoz Pty Ltd* [2022] HCA 4.

The decision concerns the proper approach to construction of an agreement where unforeseen events arise and has implications for patent infringement matters including the rights of licensees.

History of the dispute

The High Court's decision in this matter is the latest instalment in Australia's longest running patent infringement case which has included a previous High Court decision and one of the largest damages awards on record for patent infringement (approximately A$26 million).

The case concerns Lundbeck's antidepressant escitalopram (sold as Lexapro). Escitalopram is the pharmaceutical substance the subject of Australian patent no 623144 (the **Patent**). Lundbeck Australia Pty Ltd (**Lundbeck AU**), a subsidiary of Lundbeck Denmark, was the exclusive licensee of the Patent (which expired in December 2012).

Lundbeck initially obtained an extension of term of the Patent from June 2009 to June 2014 on the basis of delay in obtaining marketing approval for Lexapro from the Therapeutic Goods Administration (**TGA**).

A number of generic companies, including Sandoz Pty Ltd (**Sandoz**), subsequently contested Lundbeck's entitlement to the five year extension of term, arguing that any extension ought to have been based on Lundbeck's earlier antidepressant Cipramil (a racemic mixture containing the molecules (+)-citalopram and (-)-citalopram) with the effect that any extension of term ought to expire in December 2012. The generic companies also sought to revoke the patent in its entirety.

Against the backdrop of those court proceedings, in February 2007, Lundbeck and Sandoz entered into a settlement agreement which ended Sandoz's involvement in the court proceeding then on foot (**Settlement Agreement**). Under the Settlement Agreement Sandoz was entitled to a royalty free licence to enter the market two weeks prior to the date on which 'the Patent expires'.

The proceedings concerning the Patent continued without Sandoz as a party. Ultimately, the Court upheld the validity of the Patent but found that the extension of term should be cancelled on the basis that any extension ought to have been based on Cipramil.

Following the Court's decision and the expiry of the original (unextended) term of the Patent in June 2009, a number of generic pharmaceutical companies, including Sandoz, launched generic escitalopram products.

Prior to the launch of generic products, Lundbeck applied for an extension of term of the Patent based on Cipramil. It also applied for an extension of time within which to make that application and put the generic companies, including Sandoz, on notice that, if the extension applications were granted, they would infringe the Patent. The generic companies nevertheless proceeded to launch their products and opposed Lundbeck's applications.

The generic companies' oppositions were ultimately unsuccessful and in June 2014 the Commissioner of Patents granted Lundbeck's extension of term application reflecting an expiry in December 2012.

Lundbeck and Lundbeck AU then commenced proceedings for infringement of the Patent in the period between June 2009 and December 2012. The proceedings were defended by the generic companies and resolved with each generic company save for Sandoz.

Primary judgment

At first instance, Justice Jagot found that Sandoz infringed the Patent and awarded Lundbeck and Lundbeck AU A$26 million in damages and interest.

Relevantly, Her Honour:

- rejected an argument by Sandoz that the licence granted to it under the Settlement Agreement extended for the entire duration of the period from June 2009 to December 2012 – Her Honour found that the licence had a two-week operation only;
- awarded pre-judgment interest under the *Federal Court of Australia Act 1976* (Cth) (**Federal Court Act**) accruing from the date on which the infringing conduct commenced (i.e. June 2009);
- found that Lundbeck AU as exclusive licensee had standing to sue under s 79 of the *Patents Act 1990* (Cth) (the **Act**);
- found that Lundbeck AU's related entity, CNS Pharma, had established misleading or deceptive conduct on the basis that Sandoz failed to warn pharmacists of the risk that they might be exposed to proceedings for infringement if the extension of the term of the Patent was granted; and
- found, in assessing Lundbeck's damages, that Sandoz was entitled to a 25% discount on the basis of the availability of other generic products in the market (this reduction was reflected in the damages figure referred to above).

Full Court judgment

On appeal, Justices Nicholas, Yates and Beach overturned Justice Jagot's findings and held:

- Sandoz had a complete defence to infringement due to the terms of the licence in the Settlement Agreement;
- if their findings regarding the Settlement Agreement were wrong, the 25% discount applied by Justice Jagot should be reduced to 2-3%;
- any pre-judgment interest should run from the date on which the extension of term was granted (i.e. June 2014) rather than June 2009;
- Lundbeck Australia as exclusive licensee does **not** have the right to sue under s 79 of the Act; and
- the misleading or deceptive conduct claim necessarily fell away given that the findings on infringement were overturned.

High Court's findings

In its decision of 9 March 2022, the High Court unanimously upheld Lundbeck's appeal and overturned the Full Court's finding that Sandoz had not infringed (on the basis of a licence under the Settlement Agreement). The majority judgment was delivered by Chief Justice Kiefel and Justices Gageler, Steward and Gleeson. Justice Edelman delivered a separate judgment, agreeing on all issues with the majority.

1. Construction of the Settlement Agreement

The relevant provision of the Settlement Agreement (clause 3) provided:

> (1) Lundbeck Denmark and Lundbeck AU jointly and severally grant Sandoz an irrevocable non-exclusive licence to the Patent effective from:
>
> (a) 31 May 2009 if the Patent expires on 13 June 2009;
>
> (b) 26 November 2012 if the Patent expires on 9 December 2012;
>
> (c) 31 May 2014 if the Patent expires on 13 June 2014; or
>
> (d) Two weeks prior to the expiry of the Patent if the Patent expires on a date other than a date described in clause 3(a) to (c).

'Patent' was defined in the agreement to mean the Patent.

The majority of the High Court acknowledged that the 'commercial result' intended by the parties at the time of entering into the Settlement Agreement was to allow Sandoz to sell its generic escitalopram products during the final two weeks of the term of the Patent. This was viewed as a 'valuable commercial benefit' to Sandoz, and was given in exchange for it withdrawing its challenge to the validity of the Patent.

The High Court considered that the relevant clause 3(1) could not be interpreted as contemplating the extension of term of the Patent (granted following the expiry of the original term), which was not within contemplation:

> [59]… *it is not easy to regard the parties as having* ***bargained away substantially the whole*** *of the commercial benefit to Lundbeck Denmark of obtaining a grant of an extension of the term after the original term had expired in the event that what seemed to be a* ***remote possibility became a reality****.*
>
> [60]: ***Objectively construed*** *in the context within which the parties entered into the Settlement Agreement, the language of the settlement clause* ***cannot be interpreted as saying anything about*** *any right to bring proceedings against Sandoz that Lundbeck Denmark or Lundbeck Australia might have* ***under s 79 of the Act*** *in the event of an extension of the term of the Patent being granted after the original term of the Patent expired.*
>
> (Emphases added)

Justice Edelman's separate judgment also warrants consideration. His Honour emphasised there is no hard line between construction of terms and implication – the key difference is the extent to which reliance should be placed on context, and how far the literal language can take the parties. Justice Edelman had regard to the pre-contractual communications between the parties (which referred to the licence as an 'early entry licence') and the context of the licence (including the fact that the other generic entities were keen to launch their own escitalopram products). His Honour found that a slight implication was available in the circumstances to clarify that the licence was limited to the term of the Patent:

> [102]: *It requires* ***only a slight inference*** *beyond the literal meaning of the words to conclude that the reference in cll 3(1) and 3(2) to a "licence to the Patent"…carries the implication* ***that the freedom to exploit the invention is limited to the term of the Patent****.*

Both the majority judgment and Justice Edelman's separate judgement reinforce the importance of context in the construction exercise and the need to ascertain what would have been intended by a reasonable person in the position of the parties.

2. Accrual of cause of action and pre-judgment interest

Section 51A(1)(a) of the Federal Court Act empowers the Federal Court in 'any proceedings for the recovery of any money' to 'order that there be included in the sum for which judgment is given interest…on the whole or any part of the money for the whole or any part of the period between the date when the cause of action **arose** and the date as of which judgment is entered' (emphasis added). The current pre-judgment interest rate is 4.85%.

Interest awarded pursuant to section 51A can be substantial, particularly in pharmaceutical patent cases in which patentees can often wait a long time for Federal Court proceedings to be resolved (including the determination of any appeals).

The High Court upheld the Full Court's finding that Lundbeck's cause of action did not 'arise' until the extension of term had been granted in June 2014. While the High Court recognised that s 79 of the Act is designed to provide the patentee which rights to pursue infringement with retrospective effect, it did not follow that the cause of action would therefore arise earlier.

The position that interest is not available from the date of the infringing acts is inconsistent with the position in the United Kingdom[1] (although this difference can be explained by differences in the language of the relevant statutes). The consequence is that the delay caused by Sandoz's efforts (and those of other generic companies) to prevent the extension of term from being granted (by pursuing oppositions) has had the effect that it was not liable for interest during that period.

The circumstances in which section 79 of the Act operate are relatively rare (i.e. an extension of term granted following original expiry). However, the same language can be found in section 57 of the Act which provides a patent applicant with retrospective rights to pursue infringement in respect of acts following a patent application becoming open for public inspection and before the patent is granted. Patent applicants should carefully consider the implications of this decision in that context.

3. Exclusive licensee's standing to sue

As mentioned above, section 79 of the Act fills the temporal gap in circumstances where a patentee is granted an extension of term following the expiry of the original term. It ensures that the patentee has the same rights in respect of conduct in the 'gap' period.

The High Court upheld the Full Court's finding that because section 79 only refers to 'the patentee' and does not mention an 'exclusive licensee' – an exclusive licensee does not have rights to commence proceedings. The High Court found that the text in section 79 of the Act was 'intractable and unambiguous'.

Although section 79 of the Act applies in relatively rare circumstances, for the same reasons discussed above, the High Court's decision on this aspect may well have implications in the context of applications in the pre-grant period which is covered by section 57 of the Act (which includes the same language). If the same construction were applied, exclusive licensees would have no right to recover pecuniary relief during that period.

Finally, an anomaly arises as section 78 of the Patents Act imposes restrictions on the rights of patentees during an extension of term but does not refer to exclusive licensees and, if not read to include exclusive licensees, would have the effect that they are not subject to those restrictions.

1 See, e.g. *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co. Ltd.* [1975] 1 W.L.R. 819 and *Sevcon Limited v Lucas Cav Limited* [1986] 1 WLR 462.

4. Failure to warn – misleading and deceptive conduct

Claims under the Australian Consumer Law (**ACL**)[2] are often run in addition to allegations of patent infringement in circumstances where there may be a question about the standing of an applicant to sue for patent infringement (e.g. where there may be a question about whether the licensee has an 'exclusive licence' within the meaning of the Act). Only the patentee and exclusive licensee can commence proceedings for infringement under section 120 of the Act, whereas any person has standing to commence proceedings under the ACL.

The 'failure to warn' customers of the risk of patent infringement has previously been found to constitute misleading or deceptive conduct contrary to the ACL.[3] Similar allegations have been pursued in a number of cases.[4]

In this case, CNS Pharma alleged that Sandoz engaged in misleading or deceptive conduct by supplying generic escitalopram products from June 2009 without warning customers of the risk of infringement.

The High Court rejected the argument by CNS Pharma on the basis that they did not establish, by evidence, that pharmacists would have had a reasonable expectation that they would be informed of the risk of infringement.

The High Court's finding that positive evidence is required of a customer's expectation may make it more difficult to establish a contravention of the ACL by way of a failure to warn of patent infringement. No such evidence was referred to in the leading authority of *Ramset Fasteners (Aust) Pty Ltd v Advanced Building Systems Pty Ltd* (1999) 44 IPR 481.

Key takeaways

The High Court's decision has a number of implications for contract law as well as for patent law and practice.

First, the decision reinforces the importance of context and purpose to the exercise of construing terms in agreements – even terms which may appear to have an 'ordinary meaning'. As this case demonstrates, the context of the agreement may well favour an alternative meaning. In this case that meaning excluded a remote and unforeseen possibility (which, in fact, eventuated). Second, Justice Edelman's minority judgment suggests that where only a 'slight' implication is required by the context, it may not be necessary to satisfy the strict five-part test in *BP Refinery (Westernport) Pty Ltd v Shire of Hastings* (1977) 180 CLR 266.

Patentees and exclusive licensees should carefully consider the implications of this decision in respect of their rights in the period before a patent is granted and during an extension of term, including the right to recover for infringements and interest.

Licensees should not assume that, to the extent they may not be eligible to make a patent infringement claim, they will be able to establish a contravention of the ACL. In order to establish a failure to warn of patent infringement, it will be necessary to prove that the relevant consumers would reasonably expect to be warned of the risk of patent infringement. Depending on the commercial context, that may be difficult.

2 Schedule 2 of the *Competition and Consumer Act 2011* (Cth).

3 *Ramset Fasteners (Aust) Pty Ltd v Advanced Building Systems Pty Ltd* (1999) 44 IPR 481.

4 See, eg, *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 3)* [2011] FCA 846; (2011) 196 FCR 1 at [275]–[282], *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd (No 2)* [2012] FCAFC 102; (2012) 204 FCR 494 at [91] and *Sandvik Intellectual Property AB v Quarry Mining & Construction Equipment Pty Ltd* [2016] FCA 236; (2016) 118 IPR 421 at [272] – [277].

Can an AI system be an inventor? Full Court says no

By Grant Fisher, Partner, David Fixler, Partner, Alex Dunlop, Special Counsel, Suman Reddy, Senior Associate, Jaimie Chapman, Lawyer and Suvradip Maitra, Lawyer

In a decision that brings Australia into line with recent decisions in the US, Europe and the UK, the Full Court of the Federal Court of Australia has unanimously found that an artificial intelligence (**AI**) system cannot be an 'inventor', while also identifying a number of policy issues to be addressed.

The Full Court overturned Justice Beach's decision, in which his Honour found that an AI system could be an inventor for the purposes of the *Patents Act 1990* (Cth) (**Act**) and *Patent Regulations 1991* (Cth) (**Regulations**).[1] Instead, the Full Court held an 'inventor' must be a 'natural person' – based on the historical centrality of the role of a human inventor in patent applications, the scheme of the Act and Regulations, and the natural reading of section 15(1) of the Act.[2]

The Full Court's decision follows similar outcomes in the UK,[3] US,[4] NZ[5] and EU[6] where Dr Stephen Thaler had filed similar patent applications.

While the Full Court's decision seemingly represents a setback for industries employing AI systems in research and development, it has helpfully set the stage for a policy debate around this issue in Australia. Importantly, the Full Court identified several policy questions raised by AI inventorship and clarified that there may be scope for patents to be granted where an invention developed using AI might be regarded as having a human inventor.[7]

As was widely assumed to be the case prior to Justice Beach's decision, innovators seeking patent protection for inventions created utilising AI systems must name human inventors.

The Deputy Commissioner and Federal Court's decisions

Dr Stephen Thaler filed Australian Patent Application No. 2019396177 for 'Food container and devices and methods for attracting enhanced attention' (**Application**),[8] in which his AI system 'DABUS' was named as the 'inventor'.[9]

As we reported early last year, the Deputy Commissioner of Patents found the Application had lapsed for invalidity as it was a legal impossibility for DABUS to be 'the name of the inventor of the invention' which was required to be provided in the application by Regulation 3.2C(2)(aa).[10]

Dr Thaler sought judicial review in the Federal Court where Justice Beach held that an AI system could be the 'inventor' for the purposes of the Act and Regulations.[11] His Honour reasoned that 'an inventor is an agent noun; an agent can be a person or a thing that invents' and nothing in the Act or Regulations precluded an AI 'inventor'.[12] His Honour recognised the benefits of AI based inventions in, for example, the pharmaceutical industry, and considered that a finding of AI inventorship was consistent with the object of the Act to 'promote economic wellbeing through technological innovation'.[13] The Commissioner of Patents appealed to the Full Court.[14]

1 *Thaler v Commissioner of Patents* [2021] FCA 879.
2 *Commissioner of Patents v Thaler* [2022] FCAFC 62.
3 *Thaler v Comptroller General of Patents Trade Marks And Designs* [2021] EWCA Civ 1374.
4 *Thaler v. Hirschfeld*, No. 1:20-cv-00903 (E.D. Va., Sept. 2, 2021).
5 *Stephen L. Thaler* [2022] NZIPOPAT 2 (31 January 2022).
6 European Patents Office, 'Press Communiqué on decisions J 8/20 and J 9/20 of the Legal Board of Appeal' (21 December 2021).
7 *Commissioner of Patents v Thaler* [2022] FCAFC 62 at [119]-[121].
8 *Stephen Thaler v Commissioner of Patents* (Federal Court of Australia Number: VID108/2021).
9 *Stephen L. Thaler* [2021] APO 5 at [1].
10 Ibid.
11 *Thaler v Commissioner of Patents* [2021] FCA 879.
12 Ibid at [10], [118]-[120].
13 Ibid at [10], [44]-[56], [122]-[134].
14 *Commissioner of Patents v Thaler* [2022] FCAFC 62 at [6].

The Full Court's decision

The Full Court considered 'the central question' before it was 'whether a device characterised as an artificial intelligence machine can be considered to be an "inventor" within the meaning ascribed to that term' in the Act and Regulations.[15] The Full Court adopted a conventional text based approach to statutory construction,[16] cautioning against an approach whereby the Court imputes what it regards as desirable policy to the legislation and then characterises that as the purpose of the legislation.[17]

The Full Court identified that 'inventor' was not defined in the Act and Regulations,[18] and then considered the Explanatory Statement, which stated that the purpose of Regulation 3.2C(2)(aa) was 'to ensure that *the entitlement of the applicant to be granted a patent is clear*'.[19] This statement provided the starting point for the Full Court's subsequent analysis of an inventor's role in the 'path to entitlement to the grant of a patent', particularly in relation to s 15(1) of the Act.[20]

The Full Court's analysis revealed that patent law had proceeded on the assumption that the inventor was a natural person whose ingenuity was to be rewarded by a grant of monopoly over their invention.[21] The Full Court found that historically the inventor had to have human attributes, including the ability to make representations on the nature of the invention and possess a legal personality, being the person from whom an entitlement to the grant of a patent had to be derived.[22]

Further, the concept of an 'inventor' had to be workable within s 15(1) of the Act, which regulated the entitlement to a grant of a patent.[23]

Section 15(1) of the Act provides that a patent for an invention may only be granted to a person who:

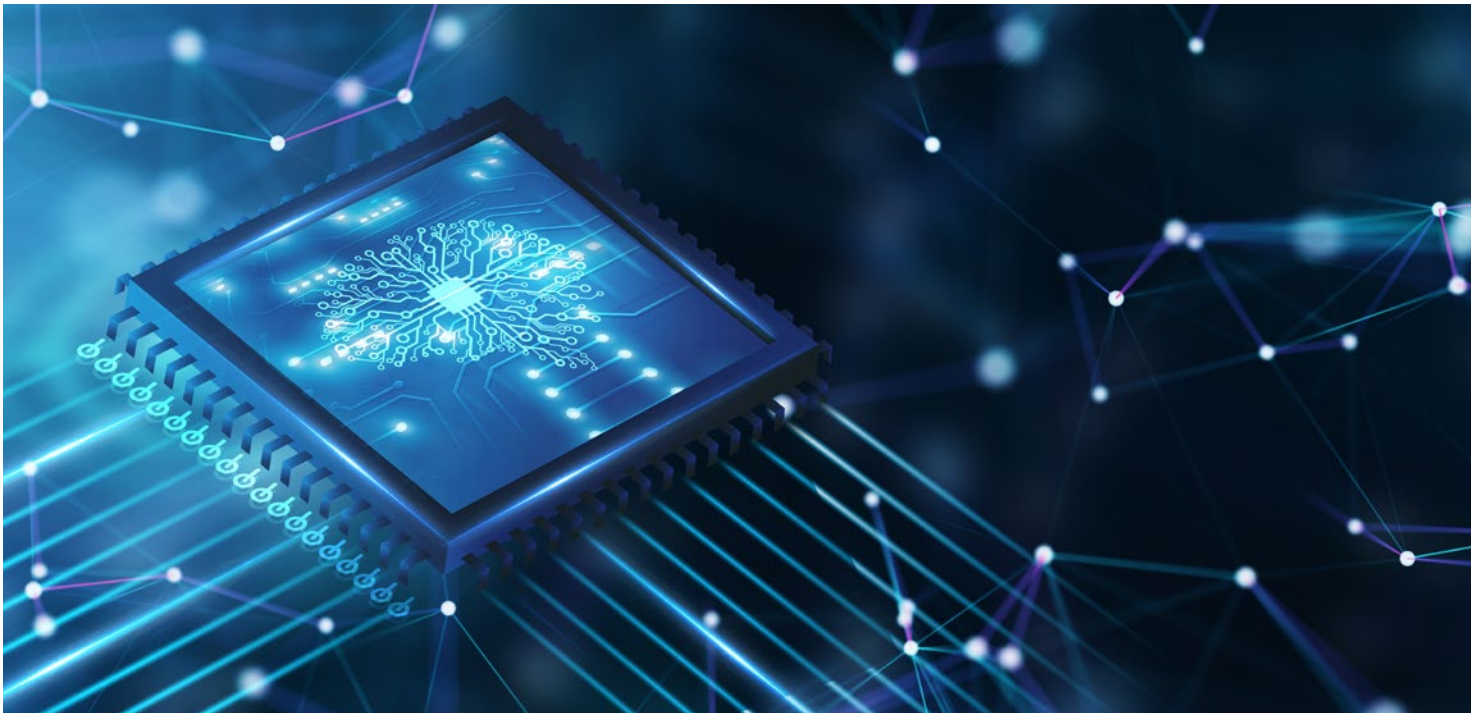
a. is the inventor; or
b. would, on the grant of the patent for the invention, be entitled to have the patent assigned to the person; or
c. derives title to the invention from the inventor or a person mentioned in (b); or
d. is the legal representative of a deceased person mentioned in (a), (b) or (c).

The Full Court found that the term 'inventor' within s 15(1)(a) denoted any person who materially contributes to or supplies the inventive concept.[24] The Court found that 'the law relating to the entitlement of a person to the grant of a patent is premised upon an invention for the purposes of the Act arising from the mind of a natural person or persons'.[25] Moreover, as s 15(1) specifically referred to a 'person' it was clear the 'inventor' in s 15(1)(a) had to be a 'natural person'.[26]

On a 'natural reading' of s 15(1), 'each of ss 15(1)(b), (c) and (d) provide for circumstances where a person becomes entitled to the grant of a patent by ultimately receiving that entitlement from the inventor in s 15(1)(a)'.[27] For the purposes of s 15(1)(b), considered in context, the assignment had to come from the inventor in s 15(1)(a) who also had to be a natural person to give effect to an assignment.[28] Similarly, s 15(1)(c) required derivation of title from the same natural person who was the 'inventor' in s 15(1)(a), as the Full Court doubted the Parliament would have intended to ascribe a different meaning to 'inventor' in s 15(1)(a) and (c).[29]

Having noted their agreement with important aspects of the UK Court of Appeal's reasoning in Dr Thaler's UK application, where the outcome was the same, the Full Court clarified that their task had been focused on the language of the Act, which materially differs from equivalent UK patents legislation.[30]

15 Ibid at [1].
16 Ibid at [83].
17 Ibid at [120].
18 Ibid at [66], [100].
19 Ibid at [73]-[75], [84].
20 Ibid at [75]-[79], [84].
21 Ibid at [85]-[88], [115].
22 Ibid at [87]-[99].
23 Ibid at [15], [84], [99].
24 Ibid at [100]-[105].
25 Ibid at [105].
26 Ibid at [106].
27 Ibid at [107].
28 Ibid at [108].
29 Ibid at [109].
30 Ibid at [122].



Key policy implications

While the decision brings the Australian position on inventorship in line with other major jurisdictions, the impact on investment and innovation requires consideration from a policy perspective. There remains uncertainty about the extent to which IP rights can ever subsist in AI-devised inventions.

The concern, expressed in a recent UK IP Office public consultation paper, is that 'if AI-devised inventions are unable to be patented, there may be less investment in this technology' or this 'may encourage the use of trade secrets, which could harm follow-on innovation'.[31] On the other hand, it is recognised that if an AI system could be classified as an inventor, there is the potential for large volumes of patents to be held by a small number of companies with access to the best AI technologies and training data.[32]

The UK Government has sought responses on four policy options related to AI-generated inventions:[33]

- Option 0: Make no legal change

  Only humans can be named as inventors in patent applications. Some stakeholders noted this approach was sufficient as most inventions involving AI would have a human inventor in the short term.
- Option 1: Make the term 'Inventor' expanded to include humans responsible for an AI system which devises inventions

  Where no humans qualify as inventor, the inventor could be the human 'by whom the arrangements necessary for devising of the invention are undertaken'. The people involved in the following activities could potentially be considered human inventors: 'programming the AI, configuring the AI, operation the AI, selecting input data such as training data for the AI, or recognising applications of the output of AI.
- Option 2: Allow patent applications to identify an AI system as an inventor

  It would be transparent that a non-human has devised the invention, either by amending legislation to allow an AI system to be named as inventor, or to remove the requirement to name an inventor if the invention is devised by an AI system. The human who made the arrangements necessary for an AI system to devise the invention would own the patent rights, i.e. those undertaking the activities listed in Option 1.
- Option 3: Protect AI-devised inventions through a new type of protection

  A *sui generis* right, parallel to the patent system, for inventions that fail to qualify for patent protection as no human can be identified. The right could involve alterations to the traditional system including a modified test for inventive step and shorter term of protection.

31 UK Intellectual Property Office, *Artificial Intelligence and Intellectual Property: Copyright and Patents* (29 October 2021).
32 Ibid.
33 Ibid.

Where to next for AI inventors in Australia?

The Full Court observed that debate as to 'the role that artificial intelligence may take within the scheme of the *Patents Act* and *Regulations'* was 'important and worthwhile'.[34]

The policy questions identified by the Full Court closely resemble those posed by the UK IP Office suggesting the findings from the UK consultation may be influential in the Australian context.

The Full Court identified several 'urgent' policy questions including whether an 'inventor' should be redefined to include AI, and if so, to whom such an AI invented patent could be granted in respect of its output, what the standard of inventive step would be or what would be the continuing role of the ground of revocation for false suggestion or representation.[35]

Similar to the suggestions in Option 1 and 2, the Full Court considered possible candidates for the grant of a patent based on an AI's invention would include 'one or more of: the owner of the machine upon which the artificial intelligence software runs, the developer of the artificial intelligence software, the owner of the copyright in its source code, the person who inputs the data used by the artificial intelligence to develop its output, and no doubt others'.[36]

The Full Court's observations were made on the basis of the uncontested fact that 'Dr Thaler is not the inventor',[37] implying a factual possibility that DABUS was capable of being the inventor. In contrast, according to IBM, for example, 'intelligent machines will remain tools that assist humans, rather than invent independently, for a considerable time.'[38]

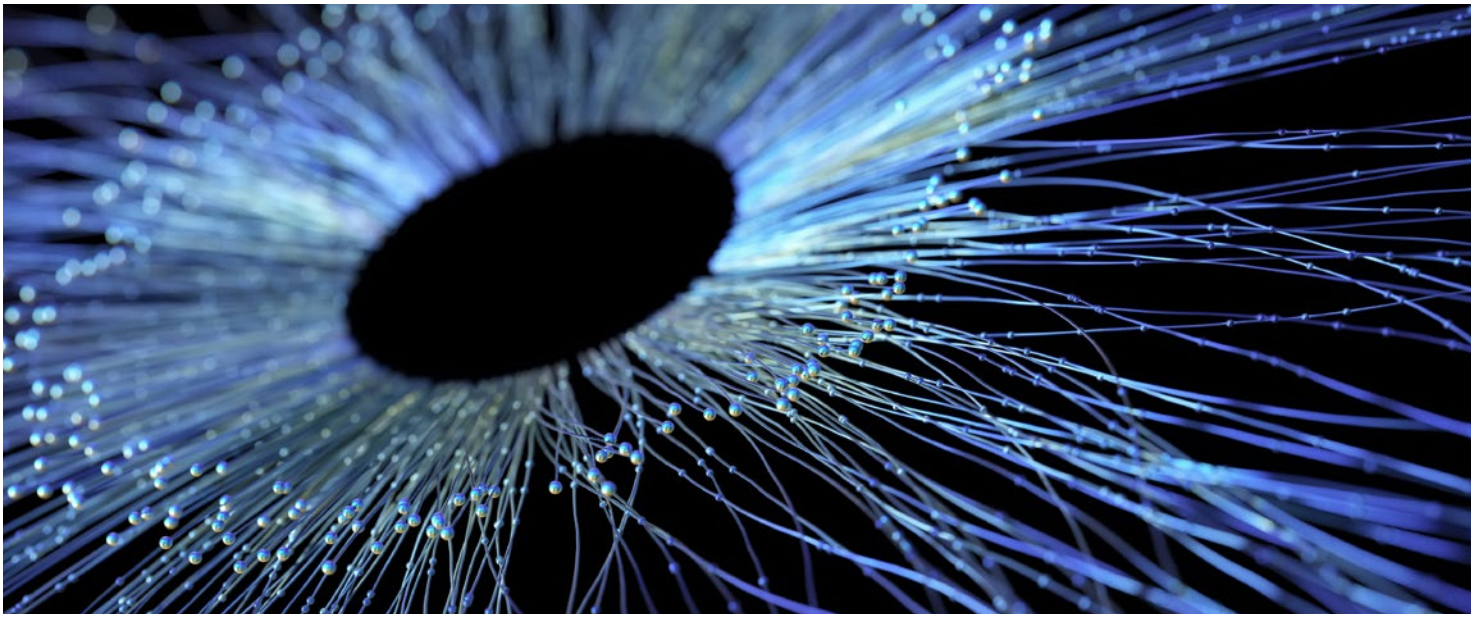
It will be necessary to consider whether empirical evidence can establish if in fact:

- current AI systems are sufficiently advanced to independently invent; and
- legal recognition of AI as an inventor in patent applications will incentivise innovation.

The issue of inventorship will likely need to form part of a broader law reform conversation focusing on patents and copyright in particular. For instance, unlike the unique position in the UK,[39] Australia does not yet have copyright laws which deem the person by whom the arrangements necessary for the creation of the work are undertaken to be the author of computer generated literary, dramatic, musical or artistic work.

Dr Thaler's counsel has filed a special leave application in the High Court. Subject to the outcome in the High Court, the Full Court's decision clarifies that an Australian patent application naming an AI system will be unable to proceed.

In the meantime, we will watch this space for the outcome of Dr Thaler's special leave application and any responses by the Australian Patent Office to the Full Court's decision.



34 *Commissioner of Patents v Thaler* [2022] FCAFC 62 at [119].
35 Ibid.
36 Ibid.
37 Ibid at [8], [120].
38 IBM Corporation Comments in Response to "Request for Comments on Patenting Artificial Intelligence Inventions", 84 Fed. Reg. 44889 (August 27, 2019) (November 8, 2019).
39 Copyright, Designs and Patents Act 1988 (UK) s 9(3).

Global E-commerce, trade mark use and managing infringement risk

By Odette Gourley, Partner and Grace Griffiths, Associate

A 4 May 2022 judgment of the UK Court of Appeal, *Lifestyle Equities CV & Anor v Amazon UK Services Ltd & Ors*[1], revisits the issue of territorial 'targeting' by websites with exposure to trade mark infringement risk. The issue, at least in Australia, has received less attention in the courts than might have been expected, given widespread online selling by platforms and other traders.

The Australian authority most often referred to, *Ward Group Pty Ltd v Brodie & Stone PLC*[2] (***Ward Group***), dates from 2005 and is a first instance decision only. A Full Federal Court looked at the issue in 2015, in *Christian v Societe Des Produits Nestle SA*[3] (***Christian v Nestle***) with relatively little additional analysis. In *Lifestyle v Amazon*, the UK Court of Appeal adopted a modern approach that provides international businesses with improved guidance on avoiding infringement risk in territories/markets not intended to be targeted.[4]

Early development of the 'targeting' principle

Decided almost 20 years ago, Ward Group involved a UK trader selling hair care products online, the website accessible in Australia, and an Australian supplier of the products that owned the mark in Australia but not in the UK.

After a small number of Australian deliveries by the UK trader in response to what were trap purchases by the Australian supplier, the Federal Court rejected the infringement claim finding: "*the use of a trade mark on the internet, uploaded on a website outside of Australia, without more, is not a use by the website proprietor of the mark in each jurisdiction where the mark is downloaded*. *However, … if there is evidence that the use was specifically intended to be made in, or directed or targeted at, a particular jurisdiction then there is likely to be a use in that jurisdiction when the mark is downloaded*."[5]

In *Christian v Nestle*, evidence of Australian contact details and shipping information was found to be sufficient to amount to targeting of Australian customers.[6]

Bringing the position up to date

Previous UK authority, not inconsistent with *Ward Group*, is somewhat more recent.[7] *Lifestyle v Amazon* brings the position up to date, taking account of the realities of international online trade.

Lifestyle were the owners of the UK trade mark BEVERLY HILLS POLO CLUB, owned in the US by an unrelated party which markets identical goods, profiled on Amazon's US platform, amazon.com – which is also accessible in the UK.

1 *Lifestyle Equities CV & Anor v Amazon UK Services Ltd & Ors [2022] EWCA Civ 552* (Lifestyle v Amazon).
2 *Ward Group Pty Ltd v Brodie & Stone PLC and Others* (2005) 215 ALR 716 (Ward Group).
3 *Christian v Societe Des Produits Nestle SA and Others (No 2)* (2015) 327 ALR 630 (Christian v Nestle).
4 Whether there has been trade mark use in a particular jurisdiction will also be relevant to other issues such as priority of use and susceptibility of a mark to cancellation for non-use.
5 *Ward Group Pty Ltd v Brodie & Stone PLC and Others* (2005) 215 ALR 716 [43].
6 *Christian v Societe Des Produits Nestle SA and Others (No 2)* (2015) 327 ALR 630 [76]-[87].
7 *L'Oreal SA v eBay International AG* [2011] ECR I-6011; *Merck KGaA v Merck Sharp & Dohme Corp* [2017] EWCA Civ 1834; Argos Ltd v Argos Systems Inc [2018] EWCA Civ 2211

In finding against Lifestyle that Amazon had not infringed (other than for minor instances admitted), the trial judge found no targeting, assessing the relevant factors as follows:

- 'targeting' imports the notion of taking 'deliberate aim at the consumers in another country'[8] and Amazon primarily directs its website to US customers;[9]
- customers, such as those in the UK, would be aware of the disadvantages of shopping from a foreign website, including prohibitively high shipping and import costs and longer delivery times;[10]
- the volume of traffic from UK visitors to amazon.com was much less than the volume of traffic from the US;[11] and
- UK customers would be aware that amazon.com was primarily a US platform.

The Court of Appeal reversed the trial judge, assessing the factors differently:

It was a matter for objective assessment as to whether a website targeted customers in a particular geographic market and the subjective intention of the website operator with respect to its target audience was of limited relevance.[12]

The customer journey needed to be considered at each step – on the search results page, customers were advised that certain products would ship to the UK, on the product details page, customers were again advised that the selected product would ship to the UK, on the order review page, a shipping estimate to the UK was provided and currency was shown in GBP.[13]

Customers would not be aware of differences in shipping and import costs between goods listed on amazon.com and those on the UK website.[14]

Even if Amazon is primarily directed at US customers, it is plainly not restricted to them.[15]

The Court emphasised that each advertisement or product listing should be separately assessed in its context, as opposed to the website as a whole.[16] The Court refrained from addressing whether there was infringement by importation, given that purchases were made by individual consumer customers on terms and conditions that addressed passing of title and risk.

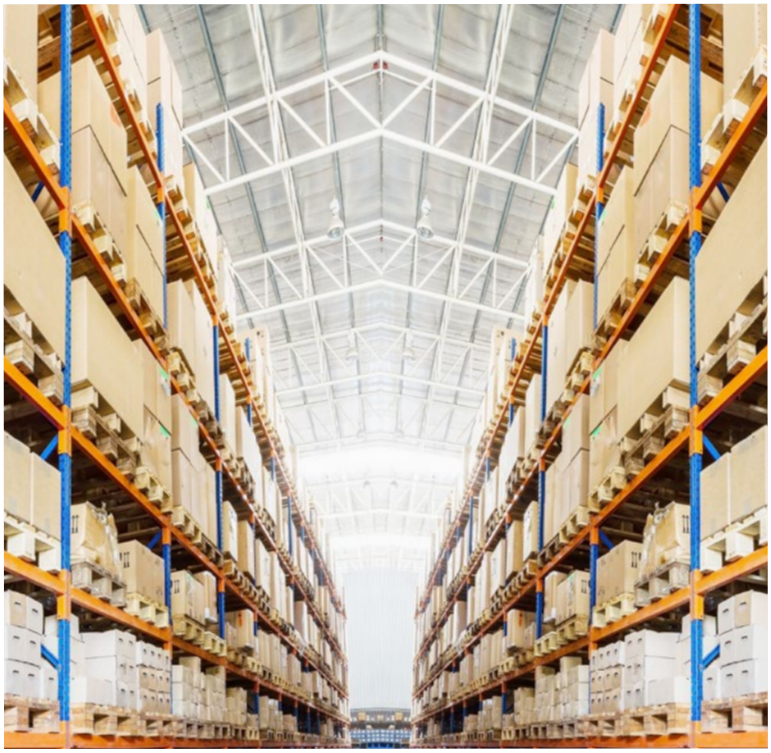
All advertisements and product listings were found to amount to trade mark infringement by way of advertising, offering for sale and selling.

Takeaway for online sellers

As was acknowledged by the Court in the *Lifestyle v Amazon* decision, the internet is global, and in the absence of geo-restriction users can access websites hosted anywhere in the world. This sits in contrast with the territorial nature of trade mark rights.

Ward Group adopted the targeting principle but, judged against *Lifestyle v Amazon*, did not address the matters required for a complete analysis. Also, in finding it relevant that Australian customers would be disinclined to meet the higher transaction costs associated with use of a foreign website, the Court adopted an approach that today could lead into error of the kind made by the primary judge in *Lifestyle v Amazon*.

Whether or not it is appropriate now to re-consider *Ward Group, Lifestyle v Amazon* provides guidance by way of a useful checklist of matters for sellers to address in minimising the risk of unintended trade mark infringement in overseas jurisdictions.



8 *Lifestyle Equities CV & Anor v Amazon UK Services Ltd & Ors* [2021] EWHC 118 (Ch) [174].
9 Ibid [171].
10 Ibid [174].
11 Ibid [164]
12 *Lifestyle v Amazon* (n 1) [69]-[70].
13 Ibid [67]; [[74]-[76].
14 Ibid [72].
15 Ibid [69].
16 Ibid [69].

Patent settlement agreements: ACCC options and challenges

By Odette Gourley, Partner, Richard Flitcroft, Partner, David Fixler, Partner and Ian Reynolds, Partner

The following article refers to a December 2021 application to the ACCC for authorisation of a proposed settlement of certain patent infringement and validity proceedings, and the ACCC's draft determination indicating an intention to decline authorisation. On 29 July 2022, prior to the ACCC issuing a final determination, the application was withdrawn.

Since the repeal of an exception to certain prohibitions in the *Competition and Consumer Act 2010* (Cth) (**CCA**) in September 2019, industry participants have sought to manage the legal risks of entering into patent settlement agreements in different ways.

One option is Australian Competition and Consumer Commission (**ACCC**) authorisation. The ACCC can confer statutory immunity on certain conduct where the public benefit outweighs the public detriment, including any lessening of competition. In a recent draft determination, understood to be the first of its kind in the pharmaceutical industry, the ACCC proposes to decline to authorise a patent settlement agreement that sought to permit early entry for generic versions of two cancer treatment drugs. The draft determination demonstrates that, while ACCC authorisation remains an option, applications need to be supported with significant evidence to satisfy the ACCC.

Background to the application

Juno Pharmaceuticals Pty Ltd (**Juno**), Natco Pharma Ltd (**Natco**), Celgene Corporation and Celgene Pty Ltd (together, **Celgene**) are involved in legal proceedings in Australia in which Juno and Natco are seeking to invalidate Celgene patents relating to the cancer treatment drugs Revlimid® and Pomalyst®.[1] Celgene has filed a cross-claim against Juno and Natco for threatening to infringe the Celgene patents. Following expiry of a compound patent in July 2022, the expiry dates of the relevant patents are 13 April 2023, 16 May 2023 and 2 August 2027.

Juno, Natco and Celgene (the applicants) sought authorisation for a patent settlement agreement made between them that seeks to end the proceedings and enable Juno and Natco to supply generic Revlimid® and Pomalyst® from a specified launch date (said by the applicants to be significantly earlier than would have been possible without the patent settlement agreement).

The applicants sought to avoid the risk that certain operative provisions of the patent settlement agreement may be found to substantially lessen competition[2] or could give rise to possible cartel conduct, i.e. making or giving effect to a provision of a contract between likely competitors that has the purpose of preventing, limiting or restricting the supply of one or more products by one or more of them,[3] which is strictly prohibited without regard to effect on competition in Australia.

The applicants submitted that the patent settlement agreement would result in a range of public benefits, including the early launch of competing generic products, increased competition, price reductions and litigation cost savings.

On 23 March 2022, the ACCC issued a draft determination proposing to deny authorisation.

1 Celgene is the manufacturer of Revlimid® (active ingredient lenalidomide) and Pomalyst® (active ingredient pomalidomide), which are immunomodulatory drugs indicated for the treatment of some blood cancers.

2 CCA, s.45 and 47, which respectively prohibit contracts, arrangements and understandings, and exclusive dealing, which has the purpose of effect of substantially lessening competition.

3 CCA, s.45AD(3)(a)(iii) and/or (b). The CCA strictly prohibits the making of, or giving effect to, a provision of a contract, arrangement or understanding between competitors, or potential competitors, that has the: (i) purpose or likely effect of fixing, controlling or maintaining prices (including discounts, credits and allowances); or (ii) purpose of preventing, restricting or limiting the production, capacity, supply, or acquisition of goods or services.

Why did legal risk arise?

Prior to its repeal, s.51(3) of the CCA provided a limited exemption for conduct relating to intellectual property rights from the prohibitions in the CCA referred to above.[4] Following its repeal, conduct involving intellectual property rights is subject to those prohibitions in the same manner as all other conduct.

The repeal enlivened a prospect of terms of patent settlements falling within the CCA prohibitions referred to above and requiring mitigation. The ACCC's Guidelines on the repeal of s.51(3) suggest that where businesses are concerned that proposed conduct would or might contravene the CCA, they seek authorisation from the ACCC.[5] If parties obtain authorisation from the ACCC, they receive statutory protection from legal action under the CCA for that conduct.

The ACCC may grant authorisation where proposed conduct is likely to result in a net public benefit (i.e. where the likely public benefit resulting from the conduct outweighs the likely public detriment).[6]

Authorisation is a public process. Subject to confidentiality claims, the application, interested parties' responses and the ACCC's draft and final determination are publicly available.

Why did the ACCC propose to deny authorisation?

The ACCC considered the applicants' claims that the patent settlement agreement would likely give rise to a public benefit in the form of increased competition and cost savings to the Australian Government, greater supply security and litigation cost savings.

The applicants claimed that the early launch of Juno/Natco's generic products would trigger a 25% price reduction under the Australian Government's Pharmaceutical Benefits Scheme (**PBS**). Further, the ACCC received a submission from a patient body[7] and had meetings with government and other health-related parties,[8] noting generally the benefits of early availability of a generic in increasing availability and bringing price down. It appears no pharmaceutical companies provided comment.

The applicants were unable, however, in the ACCC's initial assessment, to provide sufficient evidence (including from relevant health authorities), as to the significance of any potential PBS savings. It was also uncertain whether and to what extent the patent settlement agreement in and of itself would be likely to result in cost savings. That was because, if the litigation proceeded and Juno/Natco were successful, it would still be open to the Australian Government to seek damages against Celgene to recover PBS expenditure, which would reduce the cost savings directly attributable to the patent settlement agreement. The ACCC also found no evidence of supply issues (in fact, third parties suggested that the proposed conduct itself could result in supply issues) and was not satisfied that the litigation would proceed without the patent settlement agreement.

While the public benefits were uncertain, the ACCC was able to identify public detriment. First, the ACCC found that the patent settlement agreement could reduce competitive tension. The ACCC drew this conclusion because Celgene would have greater control and certainty over the timing of generic entry by Juno/Natco, which would reduce Celgene's commercial risk and provide it with the ability to better plan to account for that entry. It would allow Celgene to negotiate a 'first mover' advantage with Juno/Natco and conditions of entry (including timing), which in turn could dampen competition between Celgene and Juno/Natco.

Second, the ACCC said that a competitive process determining the outcome of who obtains a 'first mover' advantage could be beneficial for competition, e.g. if the first to enter achieved that lead because it is a more innovative or vigorous competitor than its rivals. The ACCC considered any 'first mover' advantage obtained by Juno/Natco may affect the investment decisions of other generic manufacturers which may deter or delay their entry into the market, to the benefit the applicants, but at a cost to competition.

A key driver of the ACCC's decision appears to be a lack of evidence. The ACCC suggested that the applicants did not provide sufficient documentary evidence about what would occur in the absence of the patent settlement agreement (i.e. the 'counterfactual') or the claimed public benefits, and claimed confidentiality over much of the information provided to the ACCC. The ACCC said that it was 'exceptional and unusual for the full details of the relevant counterfactual to be unable to be made public, to allow interested third parties to make fully-informed submissions on it',[9] and that the applicants provided very few internal documents. As such, the ACCC was unable to properly test the applicants' propositions, including with market participants.

4 Conduct in breach of CCA s46 Misuse of Market Power was outside the scope of the exception, and the possible risk of such conduct continues to require consideration in the context of patent settlement agreements.
5 Guidelines on the repeal of subsection 51(3) of the Competition and Consumer Act 2010 (Cth), August 2019, section 6.2.
6 CCA, section 88(1).
7 Myeloma Australia.
8 For example, Pharmacy Guild, Society of Hospital Pharmacies, and the Tasmania and Northern Territory Departments of Health.
9 Draft determination, [4.40].

Given the lack of information received from interested parties, the ACCC could only conclude that the public benefits were 'uncertain, minimal or unlikely to arise at all',[10] and identified public detriments that it was uncertain could be outweighed.

Learnings for future applications

Future applications will have to contend with significant forensic challenges, and provide significant documentary evidence relating to the counterfactual and claimed public benefit to satisfy the ACCC. This may include independent expert evidence from economists/econometricians as to the market parameters in the claimed counterfactual and from patent litigation experts as to the possible course of the litigation, if the settlement agreement is not authorised, so as to demonstrate the savings in court time and resources. Parties will need to allow for additional cost and time to gather such evidence.

Importantly, the evidence will likely need to include business records of forecasts and strategy planning for loss of market exclusivity, on the part of the patentee, and the cost/benefit assessment of at-risk entry and alternative options, on the part of the intending entrant.

Also, as to the terms of patent settlement agreements, it is unclear the extent to which the uncertainty about the timing of market entry and the duration of the first entrant's 'headstart' or first-mover advantage was a factor in the ACCC's consideration and whether earlier entry and a shorter headstart may have provided a more promising basis for addressing the ACCC's concerns.

More controversially, parties seeking authorisation of patent settlement agreements like this one, may need to consider whether, beyond providing for non-exclusivity, agreement terms should address the position of other potential intending generic entrants.[11]

As to confidentiality, parties will also need to carefully consider the extent of their confidentiality claims to enable the ACCC to test their claimed benefits, and what would occur absent the proposed conduct, with a broad range of market participants and regulatory agencies.

10 Draft determination, [4.75]

11 Contemplated regulatory changes to require that the patentee receive notice of the first regulatory approval sought by a generic, in advance of entry of a generic product on the Australian Register of Therapeutic Goods, have not yet been implemented.

Extensions of term for patents covering multiple approved pharmaceutical substances clarified

By Odette Gourley, Partner, Grant Fisher, Partner, David Fixler, Partner and Angus Michael, Senior Associate

In a significant pair of appeals handed down on the same day, both of which refer to the other, the Full Federal Court has clarified extensions of term for patents covering more than one pharmaceutical substance with regulatory approval.

In Commissioner of Patents v Ono Pharmaceutical Co. Ltd [2022] FCAFC 39 (***Ono***),[1] the first approved substance covered by the patent was a third party's. The Court overturned the trial judge and confirmed that the regulatory approval date of the third party's product, not the later approval date of the patentee's product, was to be used for the purpose of calculating regulatory delay – resulting in a shorter extension.

In *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd* [2022] FCAFC 40 (***MSD v Sandoz***),[2] both approved substances were the patentee's. MSD sought an extension based on the product with later regulatory approval, as that would have resulted in an enforceable extension of almost 18 months. The Court upheld the trial judge and confirmed that the earlier regulatory approval date applied for the purpose of calculating regulatory delay. As a result, the Full Court reduced the extension of term to zero. This would be the case even if the patentee had not marketed the relevant approved substance in Australia.

Key takeaways

When considering extensions of term for patents covering more than one pharmaceutical substance with regulatory approval, it is important to note:

- a patent term extension is to be calculated by reference to the product containing the pharmaceutical substance covered by the patent which first obtains regulatory approval;
- this product may be a third party product;
- the patentee does not have a choice as to which product it might rely on in seeking an extension of term;
- if a product covered by a patent obtains approval less than five years after the filing date of the patent, there will be no effective extension of term;
- divisional filings claiming different and specific subsequently approved commercialised products may provide scope for patentees to benefit from different term extensions.

Ono – additional regulatory approval for third party product

This case concerned an extension of term application for Ono Pharmaceutical Co. Ltd (**Ono**) and E.R. Squibb & Sons LLC's patent (AU2011203119) for anti-PD-1 antibodies. Ono applied for an extension of term based on the regulatory approval date for its drug Opdivo® (nivolumab), but MSD's drug Keytruda® (pembrolizumab) had an earlier regulatory approval date and also fell within the scope of the claims.[3]

In the Patent Office, Ono's application was unsuccessful. The delegate of the Commissioner found that the application should have been based on the regulatory approval date of Keytruda as '[t]he good with the earliest first regulatory approval date containing, or consisting of, the substance that falls within the scope of claim 3 of the patent'.[4]

1 *Commissioner of Patents v Ono Pharmaceutical Co. Ltd [2022] FCAFC 39.*

2 *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd [2022] FCAFC 40.*

3 To account for this, Ono separately applied for an extension of term based on Keytruda's regulatory approval to be considered by the Commissioner in the event the application based on Opdivo was unsuccessful.

4 *Ono Pharmaceutical Co., Ltd. et al* [2020] APO 43, [45].

Ono applied for judicial review of the Patent Office's decision in the Federal Court where the primary judge set aside the delegate's decision and ordered that the application based on Opdivo be granted. Given the language of the provisions, their legislative history, extrinsic materials and a finding that the Commissioner of Patents' construction of the relevant sections would lead to what His Honour considered to be potentially absurd consequences, the primary judge found that an application for an extension of term must be based on the first regulatory approval date of a patentee's own (and not a third party's) product falling within the scope of the claims.

The Full Court reversed the primary judge's decision and found (as had the Commissioner) that Ono's application should have been based on the earliest first regulatory approval date of any substance falling within the scope of the patent (i.e. Keytruda). The Full Court rejected the primary judge's 'liberal rather than a literal' approach to interpreting the legislative provisions in favour of the language chosen by the legislature.[5]

Specifically, the Court found that limiting the relevant goods in the extension of term application to those of the patentee 'reduce[d] the scope of section 70(3) to a more limited subset of goods than is provided for by the actual words of the provision.'[6] Further the Full Court clarified that, where a patent claimed multiple pharmaceutical substances, it was not open to the patentee to choose which substance would form the basis of the extended term calculation under section 77(1)(a) of the Patents Act 1990 (Cth) (the **Act**).[7] The calculation will always be based on the earliest first regulatory approval date of a product containing, or consisting of, a pharmaceutical substance falling within the scope of the patent.

More generally, the Full Court found that:

> *"in balancing the range of competing interests—not just providing for the patentee's interests—it can be taken that the legislature saw the correct balance as being achieved by the very words it chose in order to implement the extension of term regime. If, in its operation, that regime has not achieved, and is not achieving, its intended policy objectives, or is providing difficulty for patentees in its application, then it is for the legislature to drive the outcomes it seeks by undertaking the necessary legislative changes."* [8]

As a result of the Full Court's decision, the only extension of term open to Ono will be based on Keytruda. Such an extension will be eight months and 26 days shorter than if the term was extended by reference to Opdivo.

MSD v Sandoz – regulatory approvals for more than one product of the patentee

In this case, patentee Merck Sharp & Dohme Corp. (**MSD**) sued generic pharmaceutical company Sandoz for threatening to infringe MSD's compound patent which claimed both sitagliptin (Januvia®) and sitagliptin/metformin (Janumet®). The trial judge dismissed the infringement claim at trial and further allowed Sandoz's cross-claim, ordering revocation of MSD's patent term extension which her Honour found had been wrongly granted by the Patents Office.[9]

In dismissing the appeal and upholding Her Honour's decision, the Full Court approved the trial judge's reasoning which – in a situation which the Full Court described as an 'oddity' – resulted in an extension of term of zero.[10] That is, MSD's patent met all the eligibility criteria for the grant of an extension, but the duration of the extension had to be reduced to nothing.

5 *Commissioner of Patents v Ono Pharmaceuticals Co. Ltd* [2022] FCAFC 39, [116].
6 Ibid, [135].
7 Ibid, [136].
8 Ibid, [139].
9 *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd* [2021] FCA 947; 162 IPR 409
10 *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd* [2022] FCAFC 40, at [40], [80].

The Full Court confirmed that section 77 of the Act, which sets out the calculation of duration of an extension 'means what it says'.[11] That is, an extension of term is equal to the amount of time between the date on which the patent was filed and the date on which any pharmaceutical substance which is disclosed and claimed by the patent first obtains regulatory approval,[12] minus five years. However, the extension cannot be longer than five years or less than zero.[13] This means that in any case where a product disclosed in a patent obtains regulatory approval within five years of the patent date, the patent term is not able to be effectively extended. This is true even if the patentee seeks to base its application for the extension on a second product disclosed in the patent which obtains regulatory approval more than five years after the patent date.

This was the situation in the present case. MSD's products for sitagliptin and sitagliptin/metformin both fell within the scope of the patent in issue.[14] The duration between the patent date and the first regulatory approval date for goods containing or consisting of each of those two pharmaceutical substances was (approximately):

- **four and a half years** for sitagliptin; and
- **six and a half years** for sitagliptin/metformin.[15]

MSD's application for the extension of term was based on the sitagliptin/metformin product. However, because the patent also disclosed and claimed sitagliptin, the calculation of the extension had to be based on that substance, as it was approved first. Accordingly, the patent was entitled to an extension of term equal to four and half years 'reduced (but not below zero) by 5 years'. [16]In practice, the end result is no extension.

The Full Court agreed with the trial judge that MSD's arguments to the effect that this interpretation produced a 'senseless paradox' and other absurd outcomes should be rejected. MSD submitted that this reasoning would, in practice, lead to:

- situations where a patentee would seek extension and the Commissioner would be forced to assess that application then grant an extension of term equal to zero; and
- situations where a patentee would be unable to obtain an extension for a subsequent product disclosed, claimed and later commercialised in the same patent.[17]

In the view of their Honours, as to the argument in (a), the legislature has inferred that patentees will not make an application in circumstances where they would not obtain any enforceable extension.[18] Regarding the argument in (b), a patentee could solve this problem by amending the patent to remove the claims to the subsequent product, filing a divisional application claiming the subsequent product and then applying for an extension of that divisional.[19]

The Full Court also dismissed MSD's challenge to a previous decision of the Full Court in *Pfizer Corp v Commissioner of Patents* [2006] FCAFC 190, confirming that relevant inclusion in the Australian Register of Therapeutic Goods (**ARTG**) for the purpose of calculating the extension includes a listing for 'export only' substances. It could not be said that the legislature sought only to compensate for delay in marketing in Australia.[20]

What's next?

These judgments restore the perceived orthodoxy as to term extension based on regulatory delay. The extension is to be calculated from the earliest approval of a product covered by the patent (if more than one), whether the additional approved product was that of a third party, or another product of the patentee.

Further, any suggestion that the patentee has choice in the product or approval by reference to which extension is determined has been scotched, and matters of the 'earliest first' approved pharmaceutical substance are objectively determined based on the facts, including the state of the ARTG.

Somewhat relatedly, in a recent interlocutory decision, the Federal Court has expressed a preliminary view, consistent with the perceived orthodox view, that extensions of term are only available for claims to new pharmaceutical substances (rather than processes).[21]

The results in these three decisions reinforce the conventional understanding that the Australian patent extension of term provisions are reasonably restrictive.

11 Ibid, at [63].
12 The 'first regulatory approval date' is defined in s 70(2). In this case (and most others) this date is in effect the date on which goods that contain or consist of the relevant pharmaceutical substance are included on the Australian Register of Therapeutic Goods.
13 *Patents Act 1995* (Cth), ss 77(2) and 77(1)(a).
14 *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd* [2022] FCAFC 40, at [6].
15 Ibid.
16 *Patents Act 1995* (Cth), s 77(1).
17 *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd* [2022] FCAFC 40, at [49]-[53].
18 Ibid, at [80].
19 In this case, such a process would not have benefited MSD as it was suing Sandoz for infringement of the claims to the earlier product (sitagliptin).
20 *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd* [2022] FCAFC 40, at [108].
21 *Biogen International GmbH v Pharmacor Pty Ltd* [2021] FCA 1591, at [137]-[138].

Medical devices and cyber security: can manufacturers keep up in the digital age?

By Eugenia Kolivos, Head of Intellectual Property and Piper Fraser, Lawyer

While wearable electronic medical devices are emerging as an effective and convenient way of monitoring and maintaining individuals' health, robust cybersecurity remains a critical consideration for the industry.

Examples such as last year's product recall of certain Medtronics insulin pumps, which were identified as vulnerable to hacking, demonstrate the significant cybersecurity risk in medical devices with the potential for serious injury or death.[1]

Alongside potential access by unauthorised users, the cybersecurity vulnerabilities of wearable medical devices include the hacking of personal devices for improved use and customised medical care. The hacking of devices, whether for insidious or therapeutic purposes, presents a live issue and ethical dilemma for those organisations responsible for the design, production and distribution of devices.

Effective cyber security measures

Medtronic's October 2021 product recall uncovered that, using specialised equipment, an unauthorised person (a person other than a patient, patient caregiver or health care provider) could instruct the pump to either over-deliver insulin to a patient, leading to low blood sugar, or stop insulin delivery, leading to high blood sugar, diabetic ketoacidosis and even death.

Medical devices cannot generally be supplied in Australia unless they are included on the Australian Register of Therapeutic Goods (**ARTG**). Inclusion on the ARTG requires considerations that span the life of a medical device requiring adoption of a total product life cycle approach to risk and quality management.

The period of clinical use of a medical device can be considerably longer than the expected lifespan of the technology that allows its operation. This was flagged in the Therapeutic Goods Administration's (**TGA**) 2021 publication 'Medical device cyber security guidance for industry', wherein the TGA, noting the rapidly evolving threats to the cyber security, provides that manufacturers and sponsors of medical devices must undertake constant monitoring and appropriate corrective and preventative action, cooperating and coordinating with medical device users.[2] Adverse medical device cybersecurity events can result in patients or users suffering physical harm, among other unintended consequences such as psychological impacts, incorrect diagnosis, breaches of privacy through the disclosure of personal information and financial consequences.

TGA regulations

Wearable medical devices are regulated under the *Therapeutic Goods Act 1989* (Cth) (**Act**) and the *Therapeutic Good (Medical Devices) Regulations 2002* (Cth) (**Regulations**), which set out the essential principles against which a medical device is assessed at every stage of the medical device's life (**Essential Principles**). Consideration and minimisation of safety concerns are therefore also imperative to compliance with many of the Essential Principles.

1 Medical Device Recall, USA Food and Drug Administration, 'Medtronic Recalls Remote Controllers Used with Paradigm and 508 MiniMed Insulin Pumps for Potential Cybersecurity Risks', 10 May 2021.

2 Therapeutic Goods Administration, Department of Health (Cth), 'Medical device cyber security guidance for industry', March 2021.

Adverse cybersecurity incidents have the potential to breach many of the Essential Principles, prominently Essential Principle 12.1, which requires that programmable medical devices or medical devices containing software be designed, produced and maintained with regard to best practice in relation to software, security and engineering to provide cybersecurity of the device. This includes:

- protection against unauthorised access, unauthorised influence or unauthorised manipulation;
- minimisation of risks associated with known cybersecurity vulnerabilities;
- facilitation of the application of updates, patches, compensating controls and other improvements;
- disclosure of known vulnerabilities in the device or its components and associated mitigations; and
- making available sufficient information for a user to make decisions with respect to the safety of applying, or not applying, updates, patches, compensating controls and other improvements.

Other Essential Principles include the obligation to ensure that medical devices are designed and produced so that any risks associated with the use of the medical device are acceptable when weighed against the intended benefit to the patient, and that devices are compatible with a high level of protection of health and safety.

Under the regulations, manufacturers and sponsors also have a duty to identify associated risks with both the intended purpose and foreseeable misuse of the device, and to eliminate and reduce the risks as far as possible, adopting a policy of safe design and safe construction. If cybersecurity risks are identified by the TGA such that they amount to a breach of the Essential Principles, the TGA may recall the medical device or take non-recall actions such as safety alerts, product notifications, suspension of future supply pending investigations by the TGA and product withdrawal. Other regulatory actions that could be taken against the manufacturer or sponsor of that medical device may include:

- the issue of a warning and imposition of conditions on manufacturers;
- suspension and other enforcement actions, such as enforceable undertakings or the issuing of an infringement notice; and
- cancellation of the medical device from the ARTG (breaches of the Act or Medical Device regulations may also result in the TGA initiating civil or criminal proceedings).

TGA recommendations and other considerations

In addressing the rising risk of cybersecurity incidents in medical devices, the TGA recommends a comprehensive approach by reviewing, addressing and remediating the following situations which could amount to non-compliance with the Essential Principles, depending on the type of device:

- off-label use of devices by clinicians in certain situations;
- malicious and unauthorised access to or modification of a device;
- exploitation of known vulnerabilities in the device software or hardware;
- unsupported user modification of devices to customise a device to perceived needs or preferences; and
- use of devices in operating environments that are not or may not be secure.[3]

Alongside the TGA's regulatory requirements for device safety, performance and quality, organisations could also attract scrutiny for serious data breaches under the Office of the Australian Information Commissioner's Notifiable Data Breach Scheme under the *Privacy Act 1988* (Cth).

Copyright considerations are also a relevant factor. The unauthorised copying or modification of data from a device by unauthorised persons, or by individuals hacking their device for improved personal use, may also infringe the copyright of manufacturers or breach the terms of the licence agreement to which the user is subject.

In the US, a group of patients and researches were granted an exemption to a rule under the *Digital Millennium Copyright Act*, 17 USC (1998), which prohibits circumvention of technological measures that control access to copyrighted works. The group sought the exemption on implanted medical devices and associated personal monitoring systems in order to research into their safety, security and efficacy and to allow patients access to information generated by their own devices.

No such exemption has been granted under Australian copyright law, but this brings into question whether a uniform approach is the most appropriate avenue for the regulation of medical device cybersecurity.

3 Therapeutic Goods Administration, Department of Health (Cth) (n 2).

Contacts

Eugenia Kolivos

Partner and
Head of Intellectual Property

+61 2 9210 6316
+61 407 787 992
eugenia.kolivos@corrs.com.au

David Fixler

Partner and
Editor, *State of the Art*

+61 3 9672 3173
+61 407 086 955
david.fixler@corrs.com.au

Jürgen Bebber

Partner

+61 3 9672 3260
+61 412 082 114
jurgen.bebber@corrs.com.au

Jodie Burger

Partner

+61 7 3228 9720
+61 458 201 947
jodie.burger@corrs.com.au

Philip Catania

Partner

+61 3 9672 3333
+61 419 320 815
philip.catania@corrs.com.au

Arvind Dixit

Partner

+61 3 9672 3032
+61 438 278 463
arvind.dixit@corrs.com.au

Grant Fisher

Partner

+61 3 9672 3465
+61 407 430 940
grant.fisher@corrs.com.au

Odette Gourley

Partner

+61 2 9210 6066
+61 413 186 947
odette.gourley@corrs.com.au

Eddie Scuderi

Partner

+61 7 3228 9319
+61 419 731 560
eddie.scuderi@corrs.com.au

Stephen Stern

Partner

+61 3 9672 3148
+61 419 346 680
stephen.stern@corrs.com.au

Frances Wheelahan

Partner

+61 3 9672 3380
+61 419 517 506
frances.wheelahan@corrs.com.au

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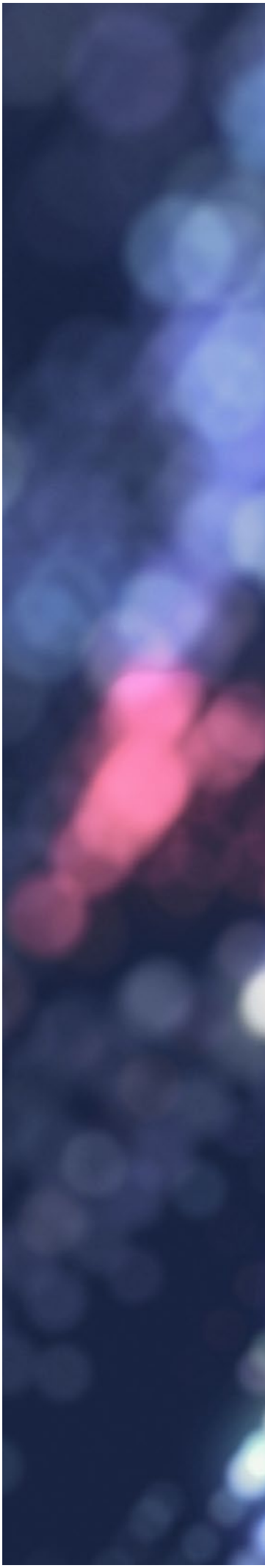

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