State of the Art

Key Australian IP developments

July 2020



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Foreword

Since it began, the COVID-19 pandemic has raised significant IP issues.

In this second edition of *State of the Art*, a publication by the Corrs IP team, we begin by outlining the key lessons from the GFC about IP rights management that businesses can apply throughout this humanitarian and financial crisis.

The rush to develop vaccines and treatments in the wake of the pandemic, and to ensure the provision of medical equipment and devices, has also raised a range of IP issues. We consider the rise of open source science, such as the Open COVID Pledge, including its risks and benefits, and look at the ability to access patented technology, by the Government or third parties, in the public interest.

We also focus on a number of other significant developments in the IP legal landscape this year. The Full Court of the Federal Court has clarified the patentability requirements for computer-implemented inventions, and the Federal Court has (again) highlighted the risks of using a generic and descriptive brand, having cancelled a trade mark for URBAN ALE on the basis that it was not capable of distinguishing the trade mark owner's beer.

Finally, Australia's Therapeutic Goods Administration has announced that from early 2021, innovative pharmaceutical companies will be notified when a generic or biosimilar application is made. This change will significantly impact the way pharmaceutical patent disputes play out, by bringing forward the starting line.

We hope you enjoy this edition of State of the Art. Please feel free to contact us if you have any questions.



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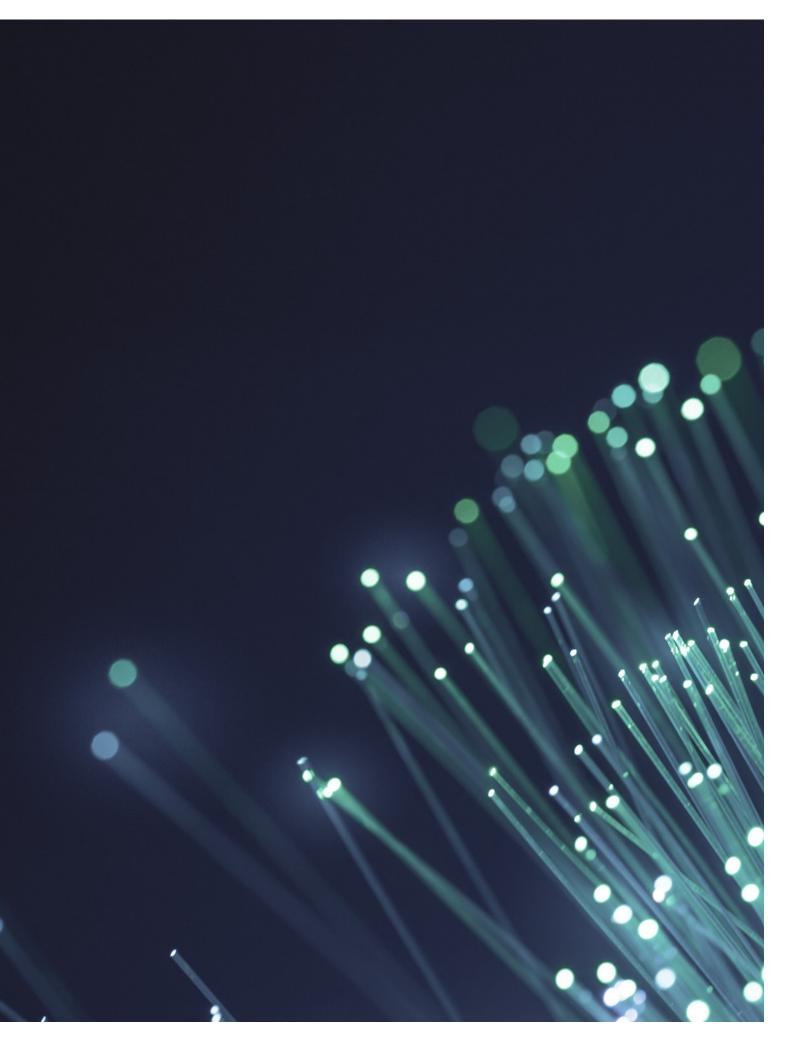
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Managing your intellectual property during crisis: lessons from the GFC

By Kate Hay, Head of Intellectual Property, Sandy Mak, Head of Corporate, Jürgen Bebber, Partner and Alex Dunlop, Special Counsel

COVID-19 is a global humanitarian and financial crisis that throws us into unchartered waters almost daily. The last time we saw this level of economy-wide pressure on businesses was during the 2007-8 Global Financial Crisis.

The effects of COVID-19 are already being keenly felt across all industries, with the logical consequence that businesses are looking for ways to evaluate their expenses and budget for future costs. Intellectual property will be one of those expenses for almost every business. IP rights are a critical asset that need to be managed cost effectively, but in a way that does not compromise rights and the financial viability of the business in the longer term.

In a crisis, scenario planning can help businesses respond with a forward focus – feeding in data and projections as they come to hand. However, there are lessons we can take from past crises like the GFC to avoid a re-run of past mistakes.

In this article, we set out the key lessons from the GFC about IP rights management that can be applied today.

The big picture – be strategic in managing your IP rights

The biggest take away from the GFC was the importance of approaching IP-related costs strategically.

Businesses that took this approach were able to reduce their costs, without compromising their position when the economy rebounded. On the other hand, businesses that treated their IP expenses as a balance sheet line item and made wholesale cost-cutting decisions were left compromised with unintended and long term consequences e.g. key innovation unprotected (or worse, snapped up by their competitors) and key personnel disaffected.

Taking a strategic approach to managing IP rights – both protection and enforcement – underpins the following five key lessons:

Lesson 1: Manage existing rights with an eye to the future

During the GFC, some businesses took the wholesale cost-saving measure of abandoning entire trade mark, domain name, design or patent portfolios, rather than paying renewal fees. This left them with no protection when the economy rebounded.

Businesses should certainly review their portfolios to identify cost savings, but should do so carefully and with an eye to the future. For example, are there any registrations for historic brands that are no longer being used or products that are no longer being made that can be safely allowed to lapse without jeopardising future revenue? On the other hand, what registrations are mission-critical and must remain protected – and does the existing portfolio provide sufficient protection?

Lesson 2: Registered trade marks – use them or risk losing them

The trade marks registration system in most countries, including Australia, incorporates a 'use it, or risk losing it' principle. In Australia, the general rule is that a registered mark that has not been used for three years can be removed on the basis of non-use.

Although the requirements to demonstrate ongoing use of a mark are not particularly onerous, this should be kept in mind if a business decides to temporarily shut down a product line with the intention of reviving it once economic conditions improve.



Lesson 3: Identify new rights as they are developed and consider appropriate protection now

Businesses should ensure any new rights which are capable of registration are identified internally as they are developed, and their revenue potential evaluated, so that the business's financial investments can be structured appropriately. Ideally, businesses should create an IP register which includes the chain of title (e.g. details on the inventors and their terms of engagement and written IP assignments).

During the GFC, we saw many businesses decide not to file new applications as a way of saving costs. In the case of patents and designs, applications cannot be filed after they have been publicly disclosed (with certain, limited exceptions). This meant that those businesses could not protect their designs and inventions later, leaving them with no protection from copycats and losing out on potentially lucrative licensing revenue streams.

In the case of trade marks and domain names, businesses that wait to file until later run the risk of opportunists 'beating them to the punch' and squatting on their rights, as we discuss below.

Where workforces contract (or expand as businesses pivot to meet unforeseen pandemic-driven demand), be careful to ensure trade secrets and IP ownership are not compromised. We've previously written on the key considerations for IP ownership and they apply with equal force in turbulent times. Look after the people who know your business and generate its IP (otherwise your competitors will).

Lesson 4: Watch out for opportunistic squatters

Opportunistic trade mark and domain name squatters are an unfortunate feature of the landscape and a scourge on many businesses.

We expect to see an increase in this activity in the coming months, as opportunists wait to see what trade mark and domain name registrations are abandoned. We saw an uptick in this activity during the GFC, with previously abandoned trade marks and domain names being offered back to their original owners at many multiples of the cost it would have taken to maintain them in the first place.

The same is true where a new brand is launched: without seeking appropriate protection, you become exposed to trade mark and domain name squatters who will to file applications with the sole purpose of extracting a premium price from the rightful owners.

For trade marks, the consequences of not filing are particularly severe in countries that have a 'first to file' trade mark system, like China. In those countries, rights are determined by the date on which an application was filed, disregarding any prior use the true owner may have made.

Even in countries like Australia that recognise 'first to use' rights, the cost of using the system to regain control of your brand will almost certainly be higher than the cost of filing a new application in the first place.

Lesson 5: Take appropriate, cost effective action against infringers

Even in difficult economic times, businesses should still monitor infringement of their rights.

Given the far reaching effects of COVID-19, it is in many respects an even playing field – this lends itself to quick and commercial resolution of matters. A letter of demand may be more forceful than ever when businesses have their eyes keenly on avoiding unnecessary expenses.

Game (not) over for computer-implemented inventions

By Kate Hay, Head of Intellectual Property, Colette Downie, Senior Associate and James Beavis, Associate

Appeals have been lodged in both these cases. A summary of significant developments is set out at the end of this piece and we will continue to report on these appeals as they progress.



Several recent Federal Court decisions concerning computer-implemented inventions have confirmed that the 'normal use' of a computer to implement (otherwise unpatentable) instructions, schemes or 'abstract ideas', will not confer patentability. Beyond abstraction being fatal, what are the lessons?

In a <u>previous article</u>, we discussed *Encompass Corporation Pty Ltd v Infotrack Pty Ltd* [2019] FCAFC 161, and expressed the hope that the then pending Full Court's decision in *Commissioner of Patents v Rokt Pte Ltd* [2020] FCAFC 86 (*Rokt*). would offer further clarity on the patentability of computer-implemented inventions.

To a degree, that hope has been realised. In finding that Rokt's digital advertising platform was not patentable, as it failed to disclose a 'manner of manufacture',¹ the Full Court has overturned an outlier decision in *Rokt Pte Ltd v Commissioner of Patents* [2018] FCA 1988, where Robertson J held that the platform was an 'improvement in computer technology' and therefore patentable.

Shortly after the *Rokt* decision was delivered, Justice Burley handed down *Aristocrat Technologies Australia Pty Limited v Commissioner of Patents* [2020] FCA 778 (*Aristocrat*). Referencing the *Rokt* decision, the Court in *Aristocrat* overturned a decision of the Commissioner of Patents that innovation patents concerning an electronic gaming machine (EGM), including a combination of physical parts and computer software to produce a particular gameplay outcome, were not a manner of manufacture.

These recent cases provide further guidance on how software-related inventions should be assessed, with *Rokt* offering some clarification on the role of expert evidence and prior art in such assessments. It remains to be seen how the Patent Office will apply the Court's remarks regarding the role of prior art in examining patentable subject matter.

Background to Rokt

Rokt's patent application

Rokt's patent was directed to digital advertising systems centred around an 'engagement offer', which would be relevant to the user (such as coupons, discounts, surveys, games and other 'click bait').² When the user clicked on the offer, they would then be presented with an offer which had been ranked as most relevant to them, based in part on their behavioural or demographic attributes.³ The specification disclosed the system comprising the invention at a very general level of abstraction.⁴

The application was rejected by the Patent Office as not concerning a manner of manufacture and Rokt appealed to the Federal Court.

- 1 Within the meaning of s 18(1)(a) of the Patents Act 1990 (Cth).
- 2 Commissioner of Patents v Rokt Pte Ltd [2020] FCAFC 86, [17].
- 3 Ibid, [18].
- 4 Ibid, [32].

Appeal to the Federal Court

Robertson J held that the invention claimed in the application was a manner of manufacture and that the application should proceed to grant.⁵

Based on the extensive evidence of Rokt's expert witness, Robertson J accepted that the substance of Rokt's invention was an 'improvement in computer technology' as it introduced a new software widget which determined the most effective engagement offers for a given user. This represented an alternative advertising technique to previous systems.

Further, the invention claimed to be a solution to:

- a business problem of attracting the attention of a consumer; and
- a technical problem of how to utilise computer technology to solve that business problem.⁸

The technical problem was solved by providing a platform in which user data could be used to provide personalised engagement offers ranked by likely attractiveness,⁹ and by providing those engagement offers and dynamically modifying the website the user was browsing to make those offers to the user.¹⁰ For these reasons, his Honour concluded that the invention was a manner of manufacture and therefore patentable subject matter.

Rokt on appeal to the Full Court

In a unanimous decision, the Full Court overturned Robertson J's decision, finding that the invention lacked patentable subject matter.

The Court held that his Honour had erred by treating the issue of how to construe and characterise the 'substance of the invention' as a matter of fact, rather than law. His Honour relied heavily on the evidence of Rokt's expert witness, treating it as (almost) determinative of whether the claimed invention was a manner of manufacture.

In rejecting this approach, their Honours emphasised that the construction of the specification and characterisation of the invention in issue remains fundamentally a matter for the Court, not an expert witness – the role of an expert witness is to place the Court in the position of the skilled addressee 'acquainted with the surrounding circumstances as to the state of the art and manufacture as at the priority date'. ¹¹ His Honour was also found to have fallen into error by premising his analysis of the technical problem solved by the invention on elements disclosed in the specification but not ultimately claimed. ¹²

The Court briefly discussed the extent to which prior art is relevant to whether a computer-implemented invention is a patentable manner of manufacture. The Court referred to statements in Myriad Genetics and RPL Central which call for an assessment of prior art, 13 but emphasised that this requirement does not extend beyond a review of the common general knowledge to the extent necessary to construe the specification. 14 The Court also considered the observations in Encompass that the unpatentable invention in that case involved 'generic software' required to be devised by the reader of the claims. 15 Contrary to Rokt's position that this represented a conflation of the requirements of s 40 with the question of manner of manufacture, the Court explained that this comment provided a 'litmus test' for whether the use of software in conjunction with hardware was simply a means of implementing an otherwise unpatentable scheme or business method.¹⁶

Further, a reference in past cases to the use of 'generic software' or to the use of computers for their 'well-known purpose' is not a finding as to common general knowledge but a determination, based on a careful review and construction of the specification, of the computer being used for its basic functions.¹⁷

- 5 Commissioner of Patents v Rokt Pte Ltd [2020] FCAFC 86, [2]. See Rokt Pte Ltd [2016] APO 66; Rokt Pte Ltd [2017] APO 34; Rokt Pte Ltd v Commissioner of Patents [2108] FCA 1988.
- 6 Commissioner of Patents v Rokt Pte Ltd [2020] FCAFC 86, [48].
- 7 Ibid, [49].
- 8 Ibid, [50].
- 9 Ibid, [50].
- 10 Ibid, [51].
- 11 Ibid, [71]–[73]. See also [96]-[110].
- 12 Ibid, [95]
- 13 Commissioner of Patents v Rokt Pte Ltd [2020] FCAFC 86, [67] (quoting D'Arcy v Myriad Genetics Inc (2015) 258 CLR 334, [12] ["That inquiry requires a definition of the allegedly patentable invention. That definition depends upon the construction of the impugned claims read in light of the specification as a whole and the relevant prior art"]), [84] (quoting Commissioner of Patents v RPL Central Pty Ltd [2015] FCAFC 177, [96] ["A claimed invention must be examined to ascertain whether it is in substance a scheme or plan or whether it can broadly be described as an improvement in computer technology ... It is not a patentable invention simply to "put" a business method "into" a computer to implement the business method using the computer for its well- known and understood functions"]).
- 14 Ibid, [85]
- 15 Ibid, [88]–[89] citing Encompass Corporation Pty Ltd v InfoTrack Pty Ltd [2019] FCAFC 161, [100].
- 16 Ibid, [90].
- 17 Ibid, [91].

In considering the patent application in suit, the Court held that the invention (as claimed in claim 1) amounted to an instruction to carry out a marketing scheme 'a list of steps to be implemented using computer technology for its well-known and understood functions'. 18

The relevant distinction for the Court was whether the computer was a mere tool in which the invention was performed or the invention lay in computerisation. ¹⁹ Here, neither the specification nor the claims suggested that computerisation was anything other than a vehicle for implementing the scheme through the ordinary use of computers. The specification described the hardware to be used in a very general sense and identified prior use of similar software, which suggests that neither the software nor the hardware required to achieve the desired outcome formed part of the invention. ²⁰

The claims did not contain any integer relating to computer technology beyond general and abstract references to desired functions and outcomes.²¹ Overall, the specification and claims amounted to little more than unpatentable abstract instructions to carry out a marketing scheme through the use of a computer.

Background to Aristocrat

The decision in *Aristocrat* concerned an appeal from the Commissioner of Patents' decision on the patentability of four innovation patents owned by Aristocrat. The Delegate for the Commissioner found that each invention claimed in all claims of the patents was not a manner of manufacture, as the substance of the inventions were mere schemes (being games and game rules of gaming machines).²²

Justice Burley overturned the delegate's decision, finding that the subject matter of the claims in each of the patents was not a mere scheme.²³ In doing so, his Honour applied the two-step approach to patentability recently confirmed in *Rokt*:

- First, to construe the specification and characterise the invention to determine whether or not the substance of what is claimed is a mere scheme, or business method.
- Second, (if a scheme or business method), whether or not there is nonetheless a manner of manufacture as invention lies not only in the scheme or plan, but also the means by which it was realised using computerisation.²⁴

As the EGM incorporated physical parts, it avoided being 'nothing more than a scheme or mere idea'. Importantly, the Court found that the skilled addressee would understand the invention as being a machine of a particular construction which implements a gaming function, rather than a generic computer-implemented invention. ²⁶

In doing so, his Honour observed that:

"It is difficult to see why the development of an implementation of an EGM that utilises the efficiencies of electronics technology would be disqualified from patent eligibility, when the old-fashioned mechanical technology was not. Such an approach would be antithetical to the encouragement of invention and innovation."

Key takeaways

When taken together, the *Encompass, Rokt* and *Aristocrat* decisions highlight that although the game isn't over for computer-implemented inventions, significant challenges in obtaining patent protection remain. Patent protection will not extend to inventions where the computer or software element is no more than the 'normal use of computers' or the 'computerisation' of a scheme or plan.

Although the court will apply a case-by-case approach, to establish patentability, it will remain important to demonstrate how the computerisation contributes to the claimed invention: is the computer integral to the claimed invention (thus patentable), or is it generic use of a computer in relation to a business method or mere scheme (thus unpatentable)? Detailing how specific computer technology achieves technical solutions or benefits (unlike in *Encompass* or *Rokt*), or how the physical features of hardware interact with software to achieve the desired outcome (such as in *Aristocrat*), will likely assist.

¹⁸ Ibid, [115].

¹⁹ Ibid, [106]-[108].

²⁰ Ibid, [110].

²¹ Ibid. [111]-[112].

²² Aristocrat Technologies Australia Pty Limited [2018] APO 45 at [67].

²³ Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents [2020] FCA 778, [3].

²⁴ Ibid, [86]-[91].

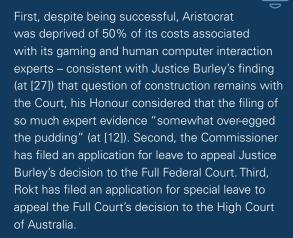
²⁵ Ibid, [94]-[95].

²⁶ Ibid, [97]-[98].

Core lessons

- Computer-implemented inventions still face significant barriers to being found patentable.
- The enquiry into the patentability of computerimplemented inventions is a two stage process:
 - Construe the specification and characterise the invention to determine whether or not the substance of what is claimed is a mere scheme, or business method.
 - If so, consider if there is a manner of manufacture as invention lies not only in the scheme or plan, but also the means by which it was realised using computerisation.
- Patent specifications should be drafted to highlight the 'technical problems' overcome, the 'technical benefits' achieved and how the 'computerisation' is 'beyond the normal use of a computer'.
- In the context of determining whether an invention is a manner of manufacture common general knowledge is to be used, "to the extent necessary, to construe the specification".
- Expert evidence does not displace the Court's role in determining what is patentable subject matter.

This article has been updated to address a number of significant developments.



We will continue to report on these appeals as they progress.



Distinctive to descriptive: trade mark considerations in the Australian beer industry

By Jürgen Bebber, Partner and Anoushka Tait, Lawyer

The Federal Court's judgments in *Urban*Alley Brewery Pty Ltd v La Sirene Pty
Ltd¹ and Stone & Wood Group Pty Ltd v
Intellectual Property Development
Corporation Pty Ltd² provides a warning
to craft brewers that fail to strike a
balance between descriptiveness and
distinctiveness in choosing sub-brands for
their beers.

The wide variety of craft beers available in Australia attests to the creativeness of its makers. A new range calls for a new name, often followed by a desire to monopolise it. But the creative energy used in mixing barley, hops and yeast with water does not always carry over into the name creation process.

Names often contain descriptive elements or emotive words that are chosen to reflect the origin or backstory of the brewery, often resulting in a name that is difficult to monopolise because it is insufficiently distinctive. The purpose of a trade mark is (or should be) to denote origin – the more distinctive a trade mark is, the easier it is for it to perform that function. At the other end of the spectrum, a more descriptive trade mark is less likely to easily perform the function of denoting origin because others may want to honestly describe products in the same or similar way.

Beyond the pale

In 2013, Coopers Brewery (Coopers) lodged an application to register the trade mark 'Original Pale Ale' for beer. This application followed Coopers' previous attempt in 2003 to register the same trade mark, 'Original Pale Ale' for beer (and other associated goods), which was ultimately not accepted by IP Australia.

Coopers' later application to register the Original Pale Ale mark resulted in a clash between some of Australia's biggest breweries, Carlton & United Breweries, Asahi, Lion and Thunder Road, as they each opposed Coopers' application to register the Original Pale Ale mark. Although the oppositions proceeded to a hearing before IP Australia in 2016 (with the exception of Thunder Road's opposition), Coopers' trade mark application was ultimately withdrawn before a decision was handed down.

Descriptive trade marks in a crowded market

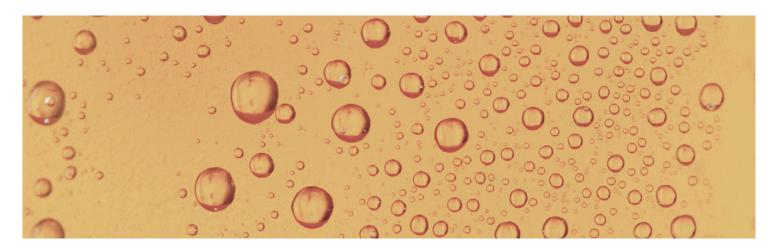
The trade mark application stage is not the only time at which distinctiveness is an issue. It may again become relevant at the enforcement stage. Trade mark registrations consisting of less distinctive marks are often inherently weak as they are open to attack on the basis that they are insufficiently distinctive.

The argument is that such a mark should therefore never have been registered to provide the monopoly its owner is seeking to enforce. It is also possible that an initially distinctive mark can become less distinctive as others adopt it in a descriptive manner. Rather than being able to seek relief against an alleged infringer, the trade mark owner may instead end up without the coveted trade mark registration.

Ales from the Pacific

In 2015, Stone & Wood commenced proceedings against Elixir, the producer of the 'Thunder Road Pacific Ale' beer (renamed 'Thunder Road Pacific' in 2015) for passing off, misleading or deceptive conduct, false or misleading representations and trade mark infringement of its 'Stone & Wood Pacific Ale' trade mark (Stone & Wood Mark).

- 1 [2020] FCA 82.
- 2 [2018] FCAFC 29.





Stone & Wood had been producing its Stone & Wood Pacific Ale displaying the Stone & Wood Mark since 2010. The word 'Pacific' had been chosen by Stone & Wood for the 'calming, cooling emotional response' it generates and for its relevance to the origin story of the Stone & Wood brewery.

The Court's findings

Stone & Wood's claims failed in the first instance. Furthermore, the primary judge found the 'Pacific Ale' element of the Stone & Wood Mark to be descriptive. His Honour stated that:

"by choosing a name for its product that has a descriptive aspect to it, Stone & Wood ran the risk that others in the trade would use it descriptively and that it would not distinguish its product."

As a result of the dominance of the 'Stone & Wood' branding on the labelling, packaging and marketing of its Pacific Ale products, His Honour found that:

"there is reason to think that some or many consumers will recognise or identify the name 'Stone & Wood' or the composite expression 'Stone & Wood Pacific Ale' rather than the words 'Pacific Ale' on their own. This makes it less likely that the words 'Pacific Ale' on their own would distinguish Stone & Wood's product from the products of others."

On appeal (after its claims were narrowed to the tort of passing off, false or misleading representations and misleading or deceptive conduct), Stone & Wood failed to make out that Thunder Road's use of 'Pacific Ale' or 'Pacific' represented to consumers that its beer was associated with Stone & Wood's Pacific Ale.

Stone & Wood's claim relied on a finding that Stone & Wood had a distinctive reputation in the words 'Pacific Ale' and 'Pacific' and that Elixir, therefore, intended to take advantage of the success of Stone & Wood's product to sell its own.

Although the word 'Pacific" had not been descriptive of a style of beer when Stone & Wood had launched its Pacific Ale product, by the time Stone & Wood brought its action in 2015, the words 'Pacific Ale' did not distinguish Stone & Wood's beer from the beers of other producers. The word 'Pacific' had come to 'serve a function of describing beers made from hops from Australia and New Zealand'. When 'Thunder Road Pacific Ale' came onto the Australian beer scene in 2015, it was soon to be one of a number of beers bearing the words 'Pacific' or 'Pacific Ale', such as Garage Project's Hapi Daze Pacific Ale, the Pacific Beverages Radler and Yeastie Boys' Stairdancer Pacific Ale.

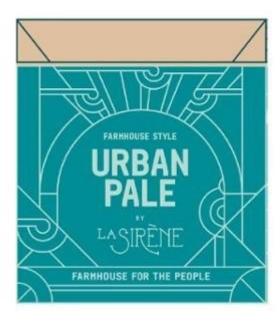
The Full Court agreed with the primary judge's finding that Stone & Wood's reputation lay in the phrase 'Stone & Wood Pacific Ale' brand, in which the words 'Pacific Ale' were being used as a descriptor. Stone & Wood therefore failed to prove that it had a substantial reputation in the phrase 'Pacific Ale' alone.

³ Full Federal Court at [38] citing the findings of Justice Moshinsky in *Stone & Wood Group Pty Ltd v Intellectual Property Development Corporation Pty Ltd* (2016) 120 IPR 478 at [134].

What Urban Ales you?

In the more recent case of *Urban Alley Brewery Pty Ltd v La Sirene Pty Ltd*, Urban Alley Brewery suffered a similar fate as Stone & Wood.

Urban Alley Brewery (**Urban Alley**) commenced proceedings against La Sirene for infringement of its 'Urban Ale' trade mark (amongst other claims). The complaint was levelled against La Sirene for its use of 'Urban Pale' in its 'Farmhouse Style Urban Pale by La Sirene' word mark and label mark (**Urban Pale Marks**). In response, La Sirene brought a number of claims and sought an order cancelling the Urban Ale mark,⁴ including on the basis that the Urban Ale trade mark was not capable of distinguishing Urban Alley's products (for which the mark was registered) from the goods of its rivals.⁵



At the time Urban Alley's Urban Ale mark was filed in June 2016, other beers bearing the name 'urban' were already on the market, namely Tiny Rebel Urban IPA and Belgian Urban IPA products (available since 2014) and Urban Crusader lager. Further, a number of breweries used the word 'urban' in their business names, including Urban Brewing Company and Hopworks Urban Brewery.

The Federal Court agreed with La Sirene's submission that Urban Alley's use of the word 'urban' in its trade mark was as a 'laudatory epithet to describe inner-city craft breweries, their beers and their target market'. The word 'urban' was found to have become associated with 'craft beer products and breweries'. The Court found that it:

"does not have any particular significance in terms of beer style or flavour characteristics; that it is a very generic term used to describe the location of a brewery or its target audience; that it communicates the aesthetic of an inner-city brewery or describes the inner-city beer movement; and that it is a generic term that brewers use to describe their location or ground their beer marketing as being relevant to an inner-city consumer."

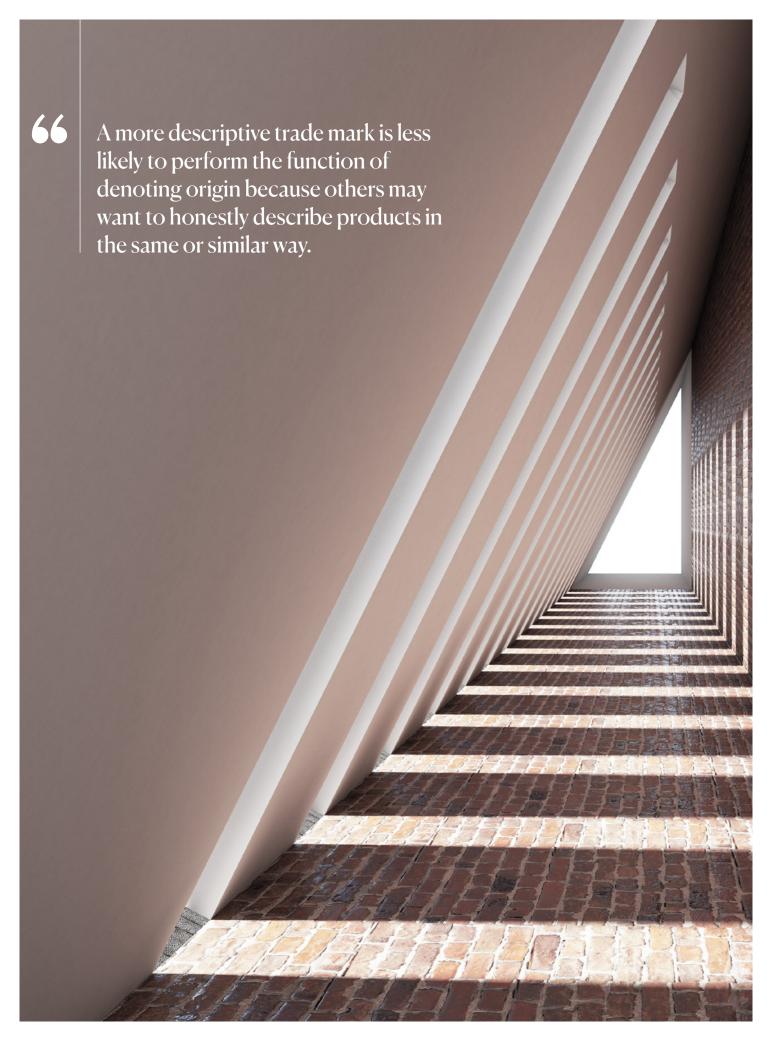
It upheld La Sirene's application (brought by cross-claim) to have the Urban Ale mark cancelled on the basis that the Urban Ale mark was not capable of distinguishing its owners goods. An order requiring the cancellation of the Urban Ale trade mark was subsequently made in *Urban Alley Brewery Pty Ltd v La Sirene Pty Ltd* (no 2), when Justice O'Bryan was again required to preside over this matter due to the parties' inability to establish agreed orders.

One for the road

Ultimately, the key take away from these recent proceedings was neatly summarised by Stephen J in Hornsby Building Information *Centre Pty Ltd v Sydney Building Information Centre Ltd*⁸ more than four decades ago:

"There is a price to be paid for the advantages flowing from the possession of an eloquently descriptive trade name. Because it is descriptive it is equally applicable to any business of a like kind, its very descriptiveness ensures that it is not distinctive of any particular business and hence its application to other like businesses will not ordinarily mislead the public. In cases of passing off, where it is the wrongful appropriation of the reputation of another or that of his goods that is in question, a plaintiff which uses descriptive words in its trade name will find that quite small differences in a competitor's trade name will render the latter immune from action."

- 4 Under section 88(1)(a) of the *Trade Marks Act 1995* (Cth).
- 5 Pursuant to section 41 of the Act. La Sirene also claimed that the Urban Ale mark could have been opposed under sections 44 and 58 of the Act.
- 6 The Federal Court found that La Sirene also established its ground under section 44 of the Act, which provided a further ground on which the Urban Ale mark could be cancelled.
- 7 [2020] FCA 351.
- 8 (1978) 18 ALR 639.
- 9 Hornsby Building Information Centre Pty Ltd v Sydney Building Information Centre Ltd (1978) 18 ALR 639 at [649], citing Lord Simmonds in Office Cleaning Services Ltd v Westminster Window and General Cleaners Ltd (1946) 63 RPC 39 at [42].



Shifting the starting line: regulatory changes to impact Australian pharma patent disputes

By David Fixler, Partner, Kate Hay, Head of Intellectual Property, Grant Fisher, Partner, Kate Donald, Senior Associate and Clancy Reid, Lawyer

Following a consultation process focused on increasing transparency in relation to medicines under evaluation, the Therapeutic Goods Administration (TGA) has announced that from June 2020, certain information about applications for new medicines will be published within one month after they have passed preliminary assessment. Also, from early 2021, innovative pharmaceutical companies will be notified when other companies make applications for generic or biosimilar versions of their pharmaceutical products.

This will bring forward the starting line for Australian pharmaceutical patent disputes and require innovators and generics / biosimilar companies to engage with each other at an early stage and develop their strategies in order to do so.

Current TGA regime and patent disputes

Typically, innovative pharmaceutical companies become aware of generic or biosimilar products when they receive regulatory approval (i.e. listing on the Australian Register of Therapeutic Goods (ARTG) maintained by the TGA). At that point, innovators must move quickly to prevent the imminent launch of generic or biosimilar products and the listing of those products under the Pharmaceutical Benefits Scheme (PBS) which would result in a 25% reduction in the subsidised price of the innovator's product. This means asserting the relevant patent and demanding assurances from the generic or biosimilar company not to launch or seek to list the product on the PBS.

If assurances are not forthcoming, the innovator must move quickly to obtain an urgent interlocutory injunction to restrain the generic or biosimilar launch and any PBS listing until the substantive patent infringement dispute can be heard and determined. The 'price' for obtaining an interlocutory injunction is an undertaking to compensate the respondent and any third parties adversely affected by the injunction (known as 'the usual undertaking as to damages').

Over the past ten years, innovative pharmaceutical companies have enjoyed success in obtaining interlocutory injunctions. As we have identified in a <u>previous article</u>, this was largely because the Court was persuaded of the difficulties for patentees to quantify any lost profits if the generic or biosimilar were permitted to launch – a view which is increasingly falling out of favour.

It is desirable to avoid the need for interlocutory injunctions and have disputes finally resolved before the proposed generic / biosimilar launch. Leaving to one side the time and cost involved in interlocutory injunction disputes, they delay the final determination of matters and expose each of the parties to significant risk. Innovators risk obtaining an interlocutory injunction, losing the case and having to face claims by the generic / biosimilar and third parties (including the Government) under the usual undertaking as to damages.

Generic / biosimilar companies face the risks of launching a product which is found later to be infringing or being prevented from launching a product that was ultimately non-infringing and having to make a complex claim for compensation under the usual undertaking.



TGA transparency reforms (February 2019)

In February 2019, the TGA published a consultation paper titled *Whether the TGA should publish that a prescription medicine is under evaluation*, and sought comments from interested parties on whether the TGA should disclose earlier that a prescription medicine is under evaluation.

These measures were said to be important from the patient's perspective as 'earlier knowledge about potential availability of treatments, should they be approved, may be considered as part of discussions about options for medical treatment and care with their healthcare practitioners'. In that context, the TGA raised the question as to whether proposed earlier publication should apply also to generic and biosimilar medicines. Although the consultation paper acknowledged that different public interest considerations applied, it did not consider the implications for patent disputes.

In April 2020, the TGA published the majority of the submissions received. There was overwhelming support for making all applications public, including generic or biosimilar applications. A number of these submissions, particularly those made by or on behalf of innovative pharmaceutical companies, identified that the increased transparency would allow additional time to resolve intellectual property disputes.

Enhanced measures and proposed options (April 2020)

On 8 April 2020, the Australian Government approved the implementation of enhanced transparency measures for prescription medicine, and the TGA has now published an <u>outline of measures</u> for earlier notification of both innovator and generic and biosimilar medicine applications.

In relation to generic and biosimilar applications, the TGA explained:

"Notification under the current system after entry of first generic medicines on the Register leaves little time for an innovator to appropriately consider whether its pharmaceutical patent is infringed by the generic medicine and consequently, to prepare for 'patent infringement'. The result has been that in certain cases an innovator applies to the Federal Court for an interlocutory injunction to restrain the marketing of the generic after entry onto the register, pending resolution of the dispute over the existence of a valid patent."

Accordingly, the TGA has proposed a non-public notification scheme whereby the generic/biosimilar applicant notifies the innovator of the existence of their application after an application for registration passes preliminary assessment (prior to the commencement of evaluation of the medicine).

The TGA has proposed two implementation options to give effect to this measure, one which requires notification only if the applicant identifies a relevant patent which has not expired, and one which requires notification in all circumstances. The TGA sought feedback on these options by 9 June 2020. Submissions have not yet been published and the TGA has not issued its response. It is proposed that the new notice scheme for generic and biosimilar applications would be implemented in early 2021.

Irrespective of which option is preferred, the proposed reform would fundamentally shift the starting line for pharmaceutical patent disputes.

Implications for innovators and generic / biosimilar pharma companies

Although the TGA's February 2019 consultation paper was not concerned with the implications of the proposed changes for pharmaceutical patent litigation, the following important considerations arise:

- Earlier notification will lead innovators to engage with generic / biosimilar companies before ARTG listing in order to:
 - obtain assurances that the generic / biosimilar will not launch / apply for PBS listing; or
 - obtain information to determine whether the generic / biosimilar product infringes.

If the generic / biosimilar does not provide the information sought, the innovator will have more time to pursue that information by way of a court application for preliminary discovery.

2. It is questionable whether the proposed changes will avoid interlocutory injunctions or undertakings. Generic / biosimilar companies may not have finalised their commercial plans with respect to the product in question and may not be willing to commence patent revocation proceedings at that early stage. It has always been open to generic / biosimilar companies who are ready to engage in revocation proceedings to commence proceedings to 'clear the way' before filing and obtaining regulatory approval.

- 3. Generic / biosimilar companies who are not ready and willing to commence revocation proceedings will likely offer innovators an undertaking to notify patentees before they decide to seek PBS listing and launch and not to rely on delay in the context of any interlocutory injunction application.
- 4. Innovators may accept undertakings of that kind and possibly use the time available to obtain information about the generic / biosimilar product so that they are well armed should they need to commence infringement proceedings further down the track.
- 5. As identified in a number of the submissions made to the TGA, the additional time may provide a greater opportunity for patent disputes to be resolved before litigation. It will, as usual, be necessary for parties to ensure that any agreements are not anticompetitive.
- 6. It remains unclear whether the new process will apply to existing applications or only new applications when it is introduced in early 2021. If it applies to existing applications, it appears likely that there will be a wave of notifications to innovators of forthcoming applications. If it only applies prospectively, there may be a rush by generic / biosimilar companies to file applications before it is introduced.





Open source science: balancing the benefits and risks

By Frances Wheelahan, Partner, James Cameron, Special Counsel and Emily McClelland, Law Graduate

Open source science involves an owner of intellectual property (IP) sharing their IP at no cost to the user, allowing IP owners to contribute to (usually) benevolent objectives while retaining ownership of their IP.

Open source science has the potential to be a great equaliser because it encourages access to IP and information without the financial barriers. It is particularly beneficial for developing countries where there may be gaps in research capabilities, and also has the potential to make IP more rapidly available than users seeking access to IP through a compulsory licensing procedure, if such a procedure is available in their country (see our previous commentary on the compulsory licensing rights under the *Australian Patents Act 1990* (Cth) here).

If an IP owner wants to make available certain IP on an open basis, it can make a public pledge to do so. Examples of this include the:

- Open COVID Pledge
- Tesla Patent Pledge
- Google's Open Patent Non-Assertion Pledge

The text of a pledge generally includes a licence grant, setting out the terms on which the IP owner is willing to license their IP.

The rise of open source science during COVID-19

As the world responds to the impact of COVID-19, international collaboration and the sharing of information has become much more important. Open source science is playing a key role in this collaboration, helping communities all over the world access life-saving IP rights such as research data, designs, patents and plans.'

The United Nations Educational, Scientific and Cultural Organisation supports the use of open source science. In March, UNESCO Director-General Audrey Azoulay called on governments to reinforce scientific cooperation and to integrate open science within their research programs.

Open source science has been crucial during the fight against COVID-19. For example, the research community has created open data resources such as the:

- Human Coronaviruses Data Initiative
- COVID-19 Open Source Dashboard
- Wikiproject COVID-19
- COVID Track Project

In January, a team of Australian researchers at the Peter Doherty Institute for Infection and Immunity provided the first genome of the SARS-CoV-2 virus to the World Health Organisation, which distributed the samples to research labs around the globe and published the genome. The genetic map was made freely available for access to all. This publication allowed the virus and its mutations to be sequenced over 3,000 times, contributing significantly to vaccine research.

Given the success of this initial use of open source science, an international coalition of scientists and lawyers called on organisations to make their patents freely available for the purpose of ending the COVID-19 pandemic by signing the Open COVID Pledge.

The Pledge is implemented through the <u>Open COVID</u> <u>License</u>, which details the terms and conditions under which intellectual property is made available. The licence allows for anyone to use the patent rights and copyrights of the pledgor for the purposes expressed in the licence up until a year after the World Health Organization declares COVID-19 is no longer a pandemic. In doing so, the IP owner grants a user a licence to make, use, sell and otherwise exploit any technologies that can be used in the fight against COVID-19.

The licence is non-exclusive, royalty-free, worldwide, fully paid-up, and non-sub licensable. Of interest, the Open COVID License does not contain audit rights for the IP owner, registration requirements for the licensee, or obligations on the licensee to make their learnings public. However, IP owners wishing to be involved with the Open COVID Pledge can customise its license terms or draft their own terms to include such protections.

Further examples of open source science

While open source science has gained more prominence during the COVID-19 pandemic, many organisations were already publishing their intellectual property on open source databases.

American electric vehicle and clean energy company, Tesla, Inc. made a patent pledge in 2014 to provide its intellectual property free of charge. The pledge states that Tesla 'will not initiate a lawsuit against any party for infringing a Tesla Patent through activity relating to electric vehicles or related equipment for so long as such party is acting in good faith'.

In a statement on 12 June 2014, CEO Elon Musk stated that the decision was made 'in the spirit of the open source movement, for the advancement of electric vehicle technology'. Tesla keeps a <u>patent register</u> of the available intellectual property on its website and sets out the terms of the licences. For example, it lists the definition of 'acting in good faith' and the limits of the licence.

In 2013, Google issued its 'Open Patent Non-Assertion Pledge' allowing 'the free use of certain of its patents in connection with Free or Open Source Software'. Google states that it made the commitment because it 'believes that Free or Open Source Software is a very important tool for fostering innovation'.

Both the Tesla and Google pledges include a term to the effect that any transferee of the patents will provide equal patent pledges.

More recently, Toyota announced it will grant royalty-free licences on nearly 24,000 of its patents for vehicle electrification-related technologies. In doing so, Toyota aims to further promote the widespread use of electrified vehicles, including hybrid vehicles, and contribute to the global efforts of addressing climate change. Toyota's provision of royalty-free licenses can be viewed as a variation on the open source model. Toyota retains more control over its IP in comparison to the Tesla or Google patent pledges because those who wish to use a patent must contact Toyota to negotiate the specific licensing terms and conditions.

Key legal issues and risks for IP owners

IP owners considering participation in the open source science movement need to ensure that their objectives (which may be benevolent, or otherwise may be directed at accelerating the uptake of a particular technology) are balanced with a sensible approach to managing legal risk.

In particular, IP owners should consider the following before engaging in open source science:

- ensuring the IP owner has the right and authority to license the particular IP;
- clearly defining the elements of the licence grant terms, including:
 - the particular IP being licensed
 - the licence period
 - the territory of the licence
 - the permitted purpose for which the IP may be used
 - whether the licence include sublicense rights
 - ownership of improvements to the licensed IP
 - whether there is an obligation on the licensee to make improvements and other results available to the IP owner (and perhaps also other licensees of the IP)
 - termination rights and what's required of the licensee on termination
- ensuring that liability, indemnity and insurance issues are carefully considered (including whether any warranties are given or excluded) and drafted appropriately in the licence;
- considering statutory obligations that may apply and how they may impact on the licence terms; and
- ensuring that the licence includes rights for the IP owner to monitor and audit the use of the intellectual property to ensure that it is being used within the terms of the licence.



COVID-19: when do private patent rights give way to the public interest?

By Kate Hay, Head of Intellectual Property, David Fixler, Partner, James Cameron, Special Counsel and Hilary MacDonald, Lawyer

With the COVID-19 pandemic rapidly depleting medical equipment and supplies and triggering a global race for a treatment or vaccine, there is growing concern to ensure that patent rights are not an obstacle. The Federal Opposition has already called upon the Government to invoke rarely used 'Crown use' patent provisions to help Australia respond to the health emergency.

Following a letter to the Industry Minister Karen Andrews in March 2020, Shadow Industry Minister Brendan O'Connor called on the Government to consider its ability to invoke Crown use to deal with the COVID-19 pandemic in Parliament:

"The government will need to detail how Crown use of patents may be invoked, particularly for use for repurposed manufacturing businesses, to address shortages of essential goods impacted by disrupted supply chains."

The Public Health Association of Australia's (**PHAA's**) 30 June 2020 submission to the Parliamentary inquiry into the implications of the pandemic was to a similar effect:

"Patents and other intellectual property protections can present barriers to procuring medicines, vaccines, diagnostic tests and medical devices...The Commonwealth Patents Act 1990 includes some important safeguards that enable patented inventions to be exploited without the consent of the patent owner... Australia should prepare to use them to prevent shortages of medical supplies."

COVID-19 and access to patented inventions

As foreshadowed in our <u>article</u> published last year, prescient amendments to the *Patents Act 1990* relating to Government and private third party access to patented inventions passed Parliament and became law only weeks ago. Access by the Government (and those authorised by the Government) is referred to as 'Crown use'. The 'compulsory licensing regime' enables access by third parties. These provisions are largely untested.

There are recent reports of offers by businesses and industries across a range of sectors to assist in the response to COVID-19 (some proactively offering their patented technology for free). There are also reports of businesses engaging cooperatively in research and development activities. These responses underscore the scale of the emergency we are facing.

Nevertheless, there are a number of considerations specific to the COVID-19 pandemic that make it particularly apt for the Crown use and/or compulsory licensing provisions to be engaged. They include:

- the potentially devastating economic consequences that could follow if the rate of infection does not abate in spite of social isolation / lockdown measures;
- the health emergency that may unfold if lifesaving medical equipment or medicines cannot meet demand;
- the immense pressure to restore depleted supplies of personal protective equipment;
- demand pressures if a vaccine is developed which would require expedited and super scaled production; and
- the general lack of a diverse range of local manufacturing businesses (Australia is a net importer of personal protective equipment, medications and medical equipment). In this regard it is noteworthy that on 18 March 2020, the Commonwealth Department of Industry, Science, Energy and Resources issued a request for information for the domestic production capability of medical personal protective equipment (PPE). The medical PPE listed in the request for information included surgical gowns, gloves and goggles.

Each of these considerations could very quickly lead to a situation where the public good could justify a Federal, State of Territory Government taking steps to authorise the exploitation of patented technology or drugs or requests for access by third parties.

It is noteworthy that corresponding provisions have already started to be invoked in other countries. For example, Israel has authorised the importation of generic version of AbbVie's HIV drug Kaletra (a drug that is being studied as a potential treatment for COVID-19).

Crown use, compulsory licences and the public interest

As outlined in our <u>previous article</u>, during emergencies the Crown Use provisions give the Government (Federal or State/Territory) powerful rights to immediately (and without consent of the patent owner) commence exploiting a patented invention for the provision of a service that the Government has the primary responsibility for providing or funding. It is hard to imagine an emergency more pressing than the COVID-19 pandemic.

The compulsory licensing regime enables the Court to allow a third party to use patented technology without the patent owner's consent where the demand for the technology is not being met on reasonable terms, the patentee has declined to authorise the third party to use the technology and it is in the public interest for the third party to have access to the patented technology.

For example, the Australian Government could authorise the production of COVID-19 diagnostic test kits that are the subject of an Australian patent owned by a third-party without having to consult with or obtain the consent of that third party.

As companies and universities undertake very significant research in the race to identify or develop a vaccine or treatments for COVID-19, we are likely to see attempts made to obtain patent protection. So far it has been reported that the Wuhan Institute of Virology filed a patent application in China in respect of the use of a known pharmaceutical product (used to treat Ebola) for the treatment of COVID-19. In the unlikely event that rights are asserted by a patent owner over a vaccine or treatment in a manner that is inconsistent with the public interest, the Crown Use provisions could be invoked.

Finally, if a patent owner sought to assert rights in a way that was inimical to the public interest by bringing patent infringement proceedings against the Government or a third party, the Court would consider the impact on the public in deciding whether to prevent any ongoing use of patented technology. It is important to emphasise that the public interest is (following the most recent amendments to the Act) recognised as one of the objects of the Act:

"The object of this Act is to provide a patent system in Australia that promotes economic wellbeing through technological innovation and the transfer and dissemination of technology. In doing so, the patent system balances over time the interests of producers, owners and users of technology and the public."

Key takeaways

The COVID-19 pandemic may well require governments and businesses to urgently access patented technology to avert either health or economic catastrophe. They should be aware of the avenues that are available to obtain access, including those available without the patent owner's consent.

Equally, patent owners will need to be mindful of the regimes that apply in these unusual circumstances and carefully consider how they will respond to both requests for access and any unauthorised use of patented technology by government or third parties.



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