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Australian Patent Cases Review 2021

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Introduction

Welcome to the inaugural Pearce IP Annual Patent Review for 2021.

Despite the challenges of the past year, patent litigation continued apace in Australia. With virtual hearings becoming the norm, it has been 'business as usual' at the Federal Court with just over twenty patent cases filed in the Court, seven substantive patent judgments delivered at first instance, and six Full Court appeal judgments. We review these judgments in the following pages, together with notable procedural decisions in patent matters and Australian Patent Office decisions.

Almost half of the substantive judgments reviewed relate to the life sciences industry. In that arena, we have observed a trend of expedition with a number of patent cases set down for trial in under a year. This has contributed to an average time from filing to first instance hearing of around 12 months for the cases we report on, and around 16 months from filing to judgment. While several cases involved discrete legal issues, no doubt shortening the length of the proceeding, the hearing of *Juno Pharmaceuticals Pty Ltd & Anor v Celgene Corporation* in 10 months from filing, including evidence from four expert witnesses on obviousness, is in our view an indicator of the willingness of the Court to expedite timetables where commercial realities dictate.

The legal issues traversed in the 2021 judgments are diverse. Patentability of computer implemented inventions has featured at all levels (see *Repipe* and *Aristocrat* in the Full Court, and *Amazon* and *Advanced New Technologies* in the Patents Office). Other patentability issues have also arisen in *Ariosa* (diagnostic methods), and *Thaler* in which the Australian Federal Court became the first in the world to endorse an AI system as an inventor. Two cases (*Ono* and *Merck*) have exposed problems with the Patent Office's approach to patent term extensions and are currently awaiting appeal decisions in the Full Court. Unusually, the Full Court has also delivered judgment on an ownership claim (*Vehicle Monitoring Systems*) clarifying the requirements for inventorship, an issue also dealt with by the Patent Office in *Sinnott v Aunex*.

We trust this review will be a useful snapshot of the year that has been, while we look forward to another busy year in patents in Australia ahead.

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Contents

Patent term extensions

Objections to patent grant

Patent amendments

Procedural issues

Legislative/policy update

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Quaker out of grace in the Full Court as the reasonable trial grace period is limited

***Fuchs Lubricants (Australasia) Pty Ltd v Quaker Chemical (Australasia) Pty Ltd* [2021] FCAFC 65**

Date: 05 May 2021
Court: Full Court of the Federal Court of Australia
Judges: Beach, Moshinsky and Thawley JJ

Background

Australian Patents AU2012304245 and AU2013100458 (**Patents**), owned by Quaker Chemical (Australasia) Pty Ltd (**Quaker**), relate to methods of detecting accidental high pressure fluid injection (**HPFI**) injuries, which can cause severe health consequences. HPFI injuries are known to be associated with hydraulic machinery used in mines and the invention involved the inclusion of fluorescent dye in hydraulic fluid, allowing UV detection of an HPFI in the human body.

In the first instance decision that preceded this appeal, Quaker was successful in establishing that Fuchs Lubricants Pty Ltd (**Fuchs**) had infringed the Patents pursuant to s117 of the *Patents Act 1990* (Cth). Fuchs unsuccessfully counterclaimed for revocation of the patents on numerous grounds, including that the invention had been disclosed by the inventor before the relevant priority date. While there was no dispute that there had been disclosures of all elements of the invention as claimed, they were deemed by the primary judge to be protected by the 'reasonable trial' grace period. Fuchs appealed.

Key Issues

Under Australian law, various statutory grace periods allow for certain public disclosures of an invention by a patent applicant to be disregarded for the purposes of determining whether the invention is novel and inventive. The most common grace period relied upon covers self disclosures made in the twelve months prior to the filing of a *complete* application.

However a further grace period extending twelve months prior to the *earliest claimed priority date* covers a working of the invention "for the purposes of reasonable trial" which is necessarily in public, for example, large machinery which must be trialled in a public place outdoors (**reasonable trial grace period**).

In the present case, two key disclosures by the inventor occurred more than twelve months prior to filing the complete application, but within twelve months prior to the filing of the relevant priority document, specifically a disclosure (in the absence of any confidentiality agreement) of the invention to a manager at Metropolitan mine and a demonstration of it to mine personnel with a simulator in the Metropolitan mine car park.

"The Full Court places limits on the 'reasonable trial' grace period, requiring there to be some 'direct or close connection' between the relevant disclosure and the working of the invention relied upon. Where disclosures could easily have been made subject to confidentiality restraints, it will not be reasonably necessary that they be in public."

At first instance, Robertson J concluded that, although these disclosures did not involve an actual working of the invention, they fell within the scope of the reasonable trial grace period as they were a necessary precursor for, and directed towards, the eventual working of the invention for the purposes of reasonable trial.

While the trials of the invention which subsequently took place may have satisfied the requirements of the reasonable trial grace period, Fuchs argued that the primary judge had cast the grace period too widely. Those disclosures did not involve a *working* of the invention *for the purpose of a reasonable trial*, and there was no necessity for the disclosures to be public.

Quaker argued that Fuchs' position led to potentially absurd and unjust consequences, since in the lead-up to any public trial, there would need to be disclosures for the purposes of health, safety and planning. It contended that the finding of the primary judge, that the three key disclosures "*were part of one course of conduct that involved, and arose in the circumstances of, the working in public of the invention of the relevant purposes*" was correct.

Outcome

The Full Court held that the reasonable trial grace period provisions were read too expansively by the primary judge. While accepting that the relevant grace period could encompass some necessary disclosures in advance of the trial, this did not extend as far as disclosures such as introducing the invention to a third party. There needed to be some 'direct or close connection' with the physical working.

Further, it was not reasonably necessary that the disclosures be public as they could have easily been the subject of confidentiality constraints. Indeed the inventor had given evidence at trial that he accepted this.

Accordingly, the appeal was allowed and all claims of the patents were invalidated as lacking novelty.

Implications

It is advisable that grace periods be relied upon only as a last resort, and that patent protection be considered and sought at an early stage to avoid issues such as those arising in this case. Where disclosure is necessary prior to filing of a patent, confidentiality agreements should always be put in place (preferably written), and if the owner of the invention becomes aware of a disclosure, patent protection should be sought as soon as possible.

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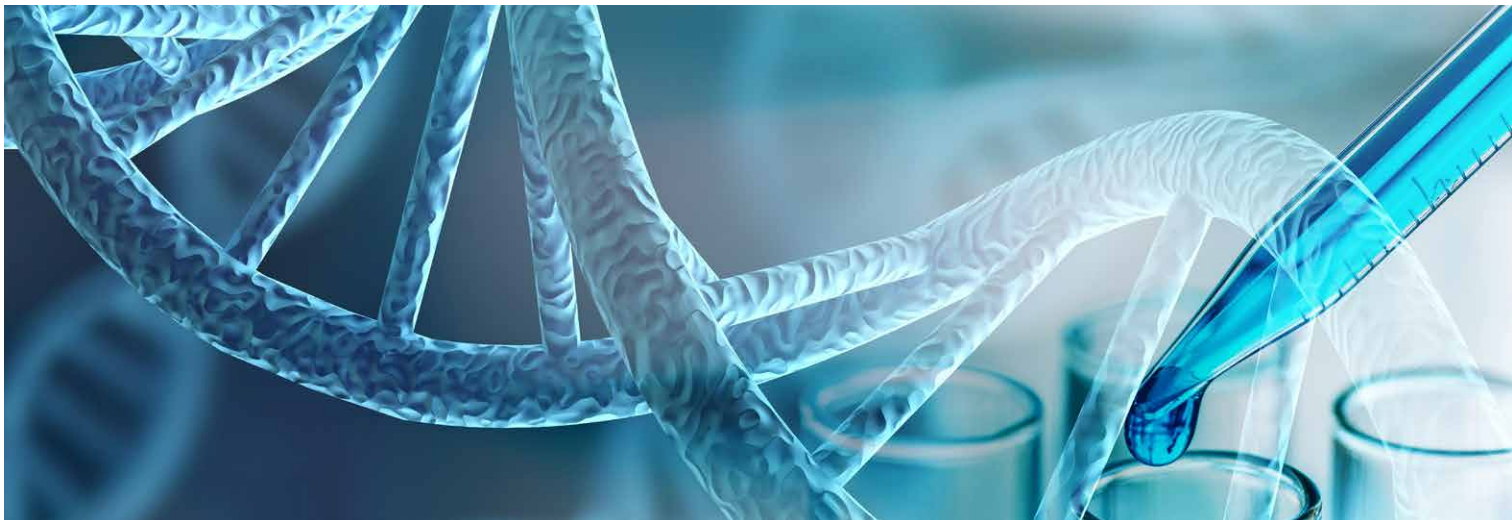

Diagnostic tests involving naturally occurring phenomena are patent eligible but circumventable

***Ariosa Diagnostics, Inc v Sequenom, Inc* [2021] FCAFC 101**

Date: 18 June 2021
Court: Full Court of the Federal Court of Australia
Judges: Middleton, Nicholas, Burley JJ

Background

Australian Patent 727919 (**Patent**) describes that the cell-free fractions of a pregnant woman's blood surprisingly contain high levels of cell-free foetal DNA (**cffDNA**). Conventionally, this portion of the plasma or serum was discarded as medical waste. This ground-breaking discovery led to the development of a non-invasive method for pre-natal diagnosis using maternal serum or plasma.

Ariosa Diagnostics Inc (**Ariosa**), conducts, and licenses others to conduct, the Harmony® blood test - a non-invasive pre-natal diagnosis test. Harmony® test samples are collected in Australia and exported to the United States for collation. The results are provided digitally to clinicians in Australia (**send out model**).

Sequenom alleged that Ariosa's "send out model" infringed the Patent. Ariosa sought revocation of the Patent. At first instance, the Federal Court found that Ariosa infringed all relevant claims but one, which was found to be invalid. Ariosa appealed to the Full Court.

Key Issues

Manner of Manufacture

Ariosa argued that the invention of the Patent does not result in any artificially created state of affairs because the end result of the claims involves the detection of something that is naturally occurring, and each of the relevant claims is to a mere discovery, which does not meet the manner of manufacture requirements for patent eligibility in s18(1)(a) of the *Patents Act 1990* (Cth) (**Act**). It submitted that although human action may be involved in the performance of the claimed methods, the end result is simply information, being the detection of cffDNA, which is nothing more than naturally occurring information.

Sequenom submitted that the claims were directed to an application of the discovery of the existence of cffDNA by the inventors. The invention resided in a new method of non-invasive detection of foetal DNA from a maternal blood sample and prenatal diagnosis.

Sufficiency

The Patent is governed by the pre-*Raising the Bar* sufficiency requirement, which required only that the specification allow the skilled person to make one thing falling within the scope of the claim.

"The Full Court has confirmed that Sequenom's claimed method of detecting cffDNA in pregnant woman permitting non-invasive prenatal diagnosis, is patent eligible subject matter in Australia, whereas in the US the same subject matter was found to be patent ineligible."

Ariosa submitted that three separate embodiments of the invention in substance comprised three separate "inventions", and argued that each embodiment must be fully described to satisfy the relevant test for sufficiency. The primary judge rejected these arguments, finding that the Patent claimed only one invention, and provided sufficient information to enable the skilled person to produce *something* within the scope of the claims without further prolonged study.

Infringement

The key issue was whether the send out model involved exploitation of the invention within the meaning in the Act, in Australia, given that the test results were collated outside of Australia.

Outcome

Manner of Manufacture

The Court held that the claims of the Patent encompassed an artificially created state of affairs of economic utility and so were to a 'manner of manufacture'. The Patent could be distinguished from the patent in suit in *Myriad*[1] in that the claims relate to a method rather than a product.

Sufficiency

The Court agreed with Sequenom that Ariosa's approach in dividing the Patent into three distinct "embodiments" artificially segregated the invention into parts. The Patent met the more limited pre-*Raising the Bar* sufficiency test.

Infringement

The Court held that Ariosa's send out model did not infringe the Patent. The term "product" (in the definition of "exploit") in the Act, does not cover "mere information" that is by itself unpatentable. To conclude otherwise would effectively extend Sequenom's monopoly into non-patentable subject matter. Importantly, the Patent did not include any product-by-process claims, which may have strengthened Sequenom's case for infringement.

Implications

This decision confirms that Australia and the US are at odds in relation to the patentability of diagnostic tests that rely on naturally occurring phenomena. Patent applicants can be confident that claims directed to diagnostic or prognostic tests that rely on a natural phenomenon will be considered as patent eligible subject matter in Australia.

However, the Court's decision in relation to non-infringement of Ariosa's send out model, means that a competitor can readily work around an Australian "diagnostic test" patent by conducting the tests outside Australia and providing the results to Australian subjects. It is prudent for "diagnostic test" patents to include product-by-process claims, to bolster the case for infringement against a send out model.

1. *D'Arcy v Myriad Genetics Inc* [2015] HCA 35

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Words matter: Specification guides claim construction

***Caffitaly System S.P.A. v One Collective Group Pty Ltd* [2021] FCAFC 118**

Date: 30 June 2021
Court: Full Court of the Federal Court of Australia
Judges: Yates, Moshinsky and Burley JJ

Background

The case concerns Australian Patents 2003200627 (**627 Patent**), 2010227121 (**121 Patent**), and 2008259388 (**388 Patent**), all of which relate to coffee capsule technology. Caffitaly Systems S.P.A. (**Caffitaly**) brought infringement proceedings against One Collective Group Pty Ltd and others regarding the importation and sale of coffee capsules.

The primary judge rejected the infringement claim, finding that the asserted claims of the first two patents (the 627 and 121 Patents) lacked inventive step, and the claims of the third (the 388 Patent) did not satisfy the sufficiency requirement under s40(2)(a) of the *Patents Act 1990* (Cth) to fully describe the claimed invention in the specification.

Caffitaly appealed all findings of infringement and invalidity.

Key Issues

A patent dispute will frequently turn on the construction of one or two phrases in a long claim. Here the meaning of the term "embossings" was a primary focus of claim construction.

Although the claims – and the term "embossings" – were to be read as understood by the notional person skilled in the art, and both sides presented expert opinion as to that meaning, the primary judge adopted neither of these constructions. Rather, the primary judge looked to the specification (which provided no specific meaning but did provide context for the term), drawings (which illustrated embodiments of the term), and to dictionary definitions.

The primary judge concluded that the claims of the 627 Patent lacked inventive step on the basis of evidence of an expert's approach to a hypothetical design task, which approach was said to be derived from common general knowledge. Critically, the primary judge found not all features of the claimed invention were present in the expert's design, but considered the missing feature of no great importance, finding that it would have been arrived at by well-known manufacturing techniques.

Outcome

The Full Court found that the primary judge erred in the inventive step analysis in relation to the 627 Patent, but the appeal otherwise failed.

In relation to construction of the term "embossings", the Full Court confirmed that the task of construction was a matter for the primary judge, and that he was not

"Construction is a matter for the Court, and the judge is not required to uncritically accept the views of the parties' experts on such matters. On obviousness, the failure of One Collective's expert to arrive at a design including all features of the claims was fatal to the obviousness case on such claims."

required to accept, uncritically, the views of the parties' experts on the term's meaning. The Full Court was satisfied that the context of the specification, which was the "*primary source of information available to the primary judge*", supported the meaning given by him to the term "embossings". They found no error in the primary judge's construction of the term.

The Full Court however found that the primary judge erred in his analysis of inventive step in relation to the 627 Patent. The expert's response to the hypothetical design task did not *actually* reach the claimed invention as it was missing a feature, the so called "fluid director member". According to the Full Court, this feature was simply missing from the expert's hypothetical design and nothing in the design could be viewed as an alternative to that claim feature. The Full Court distinguished this case from the evidence in cases such as *DSI Australia (Holdings) Pty Ltd v Garford Pty Ltd*[1] where the differences between the expert's design and the invention of the claims were "*mere design variants*". Here the feature was missing entirely.

Implications

On inventive step, this case confirms that to substantiate a lack of inventive step, it must be shown that the skilled person would be directly led to all the features in a claim from common general knowledge/ prior art.

On claim construction, the Full Court affirmed that construction of patent claims is the role of the judge, and that they may reject constructions proffered by experts, finding an alternative construction in the specification. As the primary source for interpreting patent claims is the specification, this is the inventor's opportunity to introduce and control the boundaries of claim terms and thereby the claim scope. A prudent patentee will ensure all key terms in the claims are defined/explained in the body of the specification to minimise room for debate around construction. Time spent carefully considering the terms of a claim and crafting their definitions is where the bulk of drafting time should be expended.

1. [2013] FCA 132; (2013) 100 IPR 19

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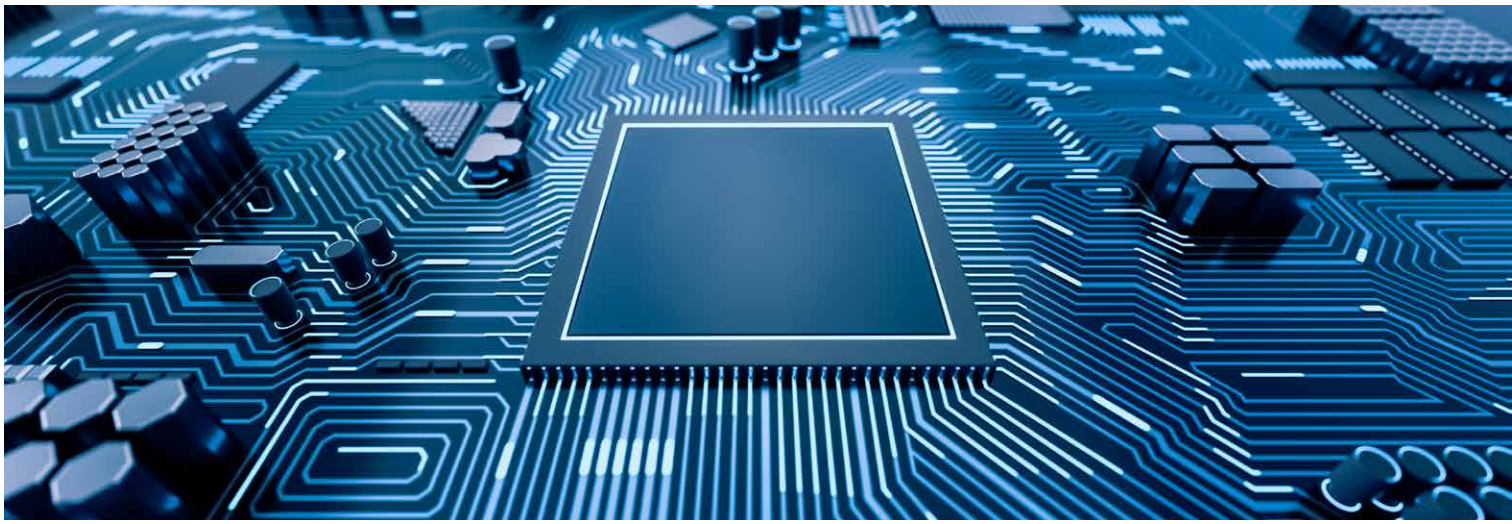

No jackpot for Aristocrat as Full Court finds electronic gaming machine claim unpatentable

***Commissioner of Patents v Aristocrat Technologies Australia Pty Ltd* [2021] FCAFC 202**

Date: 19 November 2021
Court: Full Court of the Federal Court of Australia
Judges: Middleton, Perram and Nicholas JJ

Background

In 2018 the Australian Patent Office refused to certify four innovation patents owned by Aristocrat Technologies Australia Pty Ltd (**Aristocrat**) on the ground that the claimed subject matter was not patent eligible.[1] The patents related to an electronic gaming machine (**EGM**), the modern form of a poker machine, the invention comprising steps for running a bonus "feature game" in addition to a usual "base game". The steps for the feature game were effectively rules enabling certain symbols to be selected and retained whilst other symbols were randomly changed, with any resultant prize depending on the combination of such symbols in the win line of the reel. The Patent Office found that this subject matter amounted to no more than a mere scheme or abstract idea and was therefore not patentable.

Aristocrat appealed to the Federal Court.[2] Burley J applied a two-step inquiry that asked whether the claimed invention was for a mere scheme or business method, and if so, whether there was something inventive about the manner in which it had been implemented in the computer. Burley J overturned the Patent Office decision finding that the invention claimed was to a mechanism of particular construction that involved a combination of physical parts and software (the EGM) to produce a particular outcome (i.e., a playable game), and was not a mere scheme. The Commissioner of Patents appealed.

Key Issues

As noted in the majority reasons, previous cases on computer implemented inventions heard by the Full Court, on which the primary judge relied involved inventions comprising methods which were undoubtably to be implemented in a computer.[3] However this case concerned a claim which included a physical object, containing, or of itself, a computer (the EGM). The Full Court considered the appropriate test in such circumstances.

Outcome

The majority, Middleton and Perram JJ, noted that the test applied by the primary judge did not incorporate an inquiry at the first stage as to whether the invention was a computer implemented one. This led to him conclude that because it was not a mere scheme, it was patentable. The majority proposed a different two-step test: (a) is the invention claimed a computer-implemented invention?; and (b) if so, can the

"The Full Court again weighs in on the issue of patent eligibility of computer-implemented inventions, finding that computer implementation of a set of rules for a feature game on an electronic gaming machine is not patent eligible. The majority proposed a two-step inquiry that asks whether the invention constitutes an "advance in computer technology".

invention claimed broadly be described as an advance in computer technology?

Their Honours answered the first question in the affirmative in this case. They considered that the EGM was undoubtedly a computer. However the inventive aspect of the claims was the feature game, and so the substance of the invention was the feature game implemented on the computer/EGM.

Turning to the second question, the majority noted that the claim did not specify the programming for the EGM to run the feature game. The nature of the invention therefore was a feature game defined by a set of rules (i.e., a scheme) on a computer, and that was not patentable.

Delivering separate reasons, Nicholas J agreed that the primary judge had fallen into error. Ultimately all three judges considered that the matter should be remitted to the primary judge for reconsideration in light of the Full Court's reasons.

Implications

The Full Court's approach dispels any notion that the physical hardware components of an EGM may place it in any different category in principle to other computers. However the majority explicitly noted that there are aspects of EGMs that relate to "human interaction" which may constitute an advance in computer technology and therefore be patentable. The Court's new two step test emphasises that patentability in such cases requires an "advance in computer technology", even where the invention is implemented in a physical object which incorporates the computer.

Aristocrat has since filed a Special Leave Application to the High Court to appeal the decision further. This application has now been granted, meaning the High Court will consider the case.

1. *Aristocrat Technologies Australia Pty Limited* [2018] APO 45
2. *Aristocrat Technologies Australia Pty Limited v Commissioner of Patents* [2020] FCA 778
3. *Encompass Corporation Pty Ltd v InfoTrack Pty Ltd* [2019] FCAFC 161; 372 ALR 646; *Commissioner of Patents v Rokt* [2020] FCAFC 86; *Commissioner of Patents v RPL Central Pty Ltd* [2015] FCAFC 177; 238 FCR 27

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Full Court finds another computer-implemented scheme unpatentable

***Repipe Pty Ltd v Commissioner of Patents (No 3)* [2021] FCA 31**

***Repipe Pty Ltd v Commissioner of Patents* [2021] FCAFC 223**

Date: 29 January 2021
Court: Federal Court of Australia
Judge: McKerracher J

Date: 08 December 2021
Court: Full Court of the Federal Court of Australia
Judges: Perram, Nicholas and Burley J

Background

Repipe Pty Ltd (**Repipe**)'s two innovation patents, Australian Patent 2017100560 and Australian Patent 2017100943 (**Patents**) were granted in 2017. Each patent claimed an invention relating to the sharing of workplace health and safety documents with staff in the field, and completion by the staff of such documents, using computer technology. The invention purported to be an advance over paper-based systems, with the additional advantages of real-time updates and location information.

No substantive examination is conducted of innovation patents before grant. However in order to enforce an innovation patent, examination must be requested. In this case, examination was requested at the time of filing. After a hearing, the Patents were revoked in 2018 by the Australian Patent Office on the basis that the inventions as claimed were not a manner of manufacture within the meaning of s18(1A)(a) of the *Patents Act 1990* (Cth) (**Act**).

Repipe appealed to the Federal Court. In that proceeding (***Repipe No 1***),[1] McKerracher J agreed that the inventions as claimed were not a manner of manufacture. His Honour however gave Repipe leave to amend the claims to overcome this deficiency, while expressing reservations as to whether this was possible.

Key Issues

In the current decision (***Repipe No 3***), McKerracher J considered lengthy claim amendments seeking to add significant detail to the configuration requirements of the server or smartphone used in the invention, and incorporating a GPS tracking feature. Repipe argued that the addition of this technical material overcame the manner of manufacture objections.

McKerracher J found that the amendments were insufficient to do so. In essence, his Honour's original reservations were borne out, as the amendments did not change the substance of the invention. Arguments by Repipe that the Full Court's application of a 'two-stage test' in *Commissioner of Patents v Rokt Pte Ltd*[2]

"The Full Court has found another computer-implemented invention to lack patentable subject matter, and confirmed that attempts to amend patent specifications claiming such inventions to overcome manner of manufacture objections are unlikely to succeed."

and/or Burley J's decision in *Aristocrat Technologies Australia Pty Limited v Commissioner of Patents*[3] (both handed down since *Repipe No 1*), should affect the outcome were rejected, as a matter of principle and because such arguments were properly a matter for appeal of the original decision. It was clear that McKerracher J agreed with the Commissioner's submissions that in truth, Repipe was seeking to re-open aspects of the original decision.

Outcome

In the Full Court, Perram J (Nicholas and Burley JJ concurring) upheld the first instance decision in *Repipe No 3*, finding that the invention did not constitute an advance in technology, but was rather '*deployment of existing technology for a useful purpose*'.

Repipe sought to draw an analogy with the *Aristocrat* case. By the time judgment was handed down in *Repipe No 3*, the Full Court had overturned Burley J's decision in *Aristocrat*.[4] However in any event, the Full Court in *Repipe No 3* concluded that there was no analogy with the facts of *Aristocrat*. Repipe's invention, being implemented via standard mobile devices and servers, comprised a mere use of existing technology rather than an advance on it.

As to the proposed amendments, Perram J concluded that the attempt to amend was "*inherently unsound*", since the assessment of the invention was a question of substance, not form. 'Tinkering' with the form of the patent could not solve the underlying issue since the amendments would need to transform the nature of the invention, and to achieve this, the amendments would fall foul of s102 of the *Patents Act 1990* (Cth).

Implications

Repipe No 3 joins an increasingly long line of Full Court decisions in which computer implemented inventions have been found unpatentable, and it is becoming clear that an advance in the field of computer technology is key to patentability.

Repipe has since filed an application for special leave to appeal to the High Court, as has Aristocrat in its case, with Aristocrat's application already granted. At least the *Aristocrat* case will therefore be heard by the High Court. We are hopeful that this will add further clarity in this area.

1. *Repipe Pty Ltd v Commissioner of Patents* [2019] FCA 1956
2. [2020] FCAFC 86
3. [2020] FCA 778
4. [2021] FCAFC 202. See our analysis of this case on pages 12-13.

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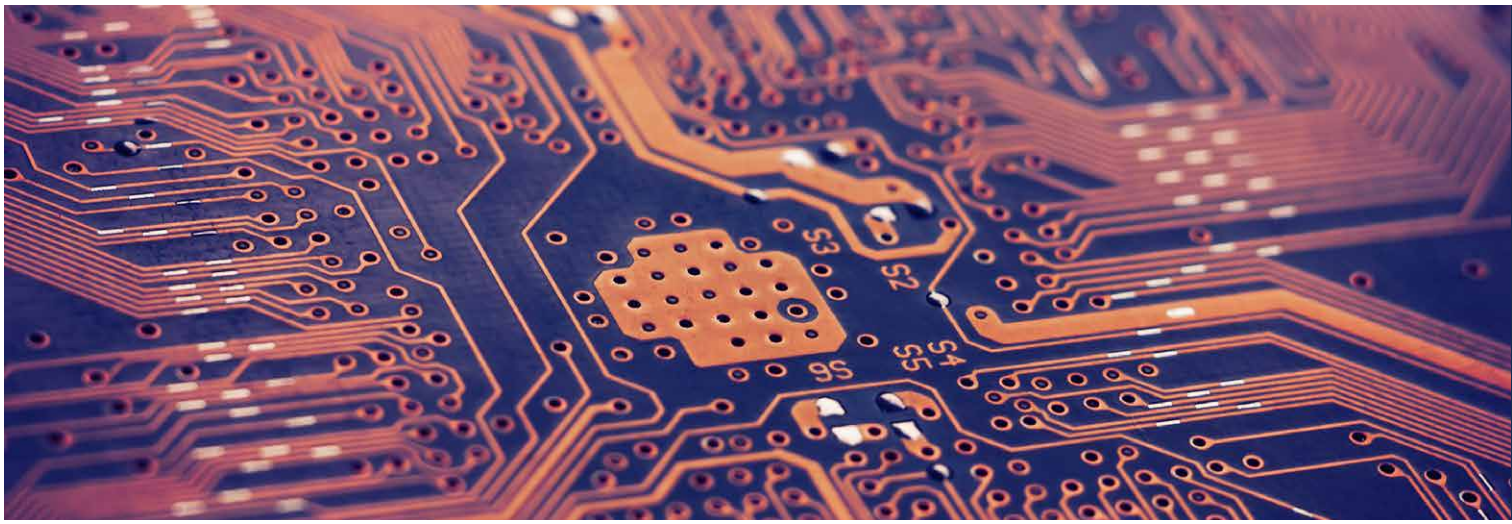

Amazon invention a mere business solution and not patentable

***Amazon Technologies, Inc.* [2021] APO 7**

Date: 16 February 2021
Forum: Australian Patent Office
Delegate: Kevin Restrick

Background

Under Australian law, business methods are not patent eligible because they are not considered to be a "manner of manufacture". However, inventions that may resemble business methods, but that rely on both a technical intervention and a technical innovation to solve a problem may meet the requirements for patentability. Australian Patent Application 2018204629 (**Application**), in the name of Amazon Technologies, was the subject of a hearing after the Application and its parent application, failed to reach acceptance following six examination reports in which objections for manner of manufacture had been raised.

The claimed invention of the Application related to the field of computer resource virtualization, and allowed various computing resources to be efficiently and securely shared by multiple customers. Prior to the hearing, the Examiner had maintained that the claimed invention did not involve any technical invention or ingenuity and that the technical aspects of the invention were achieved using generic computer functionalities.

Key Issues

In making his assessment, the Delegate carefully considered the substance of the invention based on the principles set out by the Delegate in *Aristocrat Technologies Australia Pty Ltd.*[1]

Specifically, the Delegate focused on identifying the problem to be solved, whether said problem was technical in nature, and whether the solution relied on a technical improvement to known computing technology.

The Delegate determined that the problem sought to be overcome was the efficient use of fixed computing resources when the client has unpredictable demands. The solution lay in the computing resources provider offering a level of service for the customer with what in essence was a 'payment plan' or a 'service level agreement', where the customer was provided with a guaranteed minimum level of service as well as "burst performance" should they have accumulated sufficient resource credits from previous time periods.

When considering any technical processes involved in the solution provided, the Delegate noted that the invention was not reliant on any optimised algorithm, artificial intelligence or advanced critical path analysis function and found that there was no improvement in

"A deep dive into the "substance" of the invention by the Patent Office leads to the conclusion that Amazon's invention was a mere business method wrapped up in technical language, rendering it unpatentable."

computing hardware or architecture.

In contrast, the applicant argued that the problem of "*how to*" provide the solution was actually a technical problem, and that the solution "*brought together a combination of new and known elements to form a working combination that had not previously been achieved, involving the use of computers in a way foreign to their normal use*".

Outcome

The Delegate considered that the problem to be solved by the invention was something that is a "core tenet" of business, namely, avoiding underutilised assets, reinforcing the notion that the problem to be solved was a business problem. He also found that the solution was defined by established business rules.

The Delegate also considered that the applicant's arguments with regard to the proposed technical effect of the invention would only apply in a very particular and niche situation, and he regarded most other scenarios where the invention might be applied as not achieving a useful result.

The Delegate added that on the rare occasions the useful result was achieved, this was largely dependent on a business decision being made by the customer.

As such the invention related to a business problem rather than a technical problem, and the substance of the invention amounted to "*nothing more than a scheme for scheduling work and is therefore not for a manner of manufacture*". In terms of how the work was scheduled, the Delegate stated that there is "*no technical innovation in how tasks are scheduled; they are scheduled based on business rules only*".

Implications

This decision is a reminder to patent applicants that it may not be sufficient to merely claim a technical effect achieved by an invention in limited scenarios, and that it is also important to establish that the problem to be solved is a technical one. While there may be cases where an invention is patentable by virtue of a business problem being solved with a technical solution,[2] it is preferable that both the problem and solution be technical in nature.

1. [2016] APO 49
2. See, for example, *Advanced New Technologies Co., Ltd* [2021] APO 29, discussed at pages 18-19

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Blockchain technology gets a nod as patentable subject matter

***Advanced New Technologies Co., Ltd.* [2021] APO 29**

Date: 21 July 2021
Forum: Australian Patent Office
Delegate: Ranganath Subbarayan

Background

Australian Patent Application 2018243625 (**Application**) in the name of Advanced New Technologies Co., Ltd relates to methods and systems for processing transaction requests in a blockchain network. Objections were raised to the Application by the Examiner on the basis of lack of manner of manufacture.

Key Issues

The invention sought to solve security issues associated with current transaction processes used in a blockchain system. Blockchain processes use 'nodes' (computer devices) to communicate and store data in a particular format that allows transactions to be verified and traced. The specification described the blockchain process as one in which a 'transaction node' broadcasts a transaction request to one or more 'consensus nodes' to verify a transaction. As part of the transaction request, data relating to the transaction is broadcast to all consensus nodes and is stored in the blockchain network.

However, the consensus nodes can synchronise with the blockchain to obtain transaction data stored on the blockchain, leading to privacy issues.

The invention solves this issue by converting the transaction data to a 'data abstract' which does not contain personal information. The data abstract is then broadcast for verification, and the transaction data cannot be obtained in reverse from the data abstract by the consensus nodes.

Outcome

The Delegate addressed a number of inquiries as relevant to the question of manner of manufacture:

1. *The substance of the invention* – the substance lay in a new method of processing a transaction request within an otherwise standard blockchain infrastructure wherein the transaction data is irreversibly converted into a non-recognisable form (data abstract), and using this data abstract to get approval and consensus validation for the transaction. When characterised in this way, the new method included elements that were technical, such as the conversion of the data using cryptographic techniques, and elements that might be considered an abstract scheme, such as the modified procedural rules for obtaining consensus

"The Patent Office has confirmed the patentability of technical improvements to blockchain technologies, despite doubt over the inventiveness of this particular invention."

validation.

2. *Whether the invention solves a technical problem* - the problem to be solved was the design of a method for verifying a transaction request, which avoided risk of privacy breach. A reading of the specification indicated that any such privacy breach would occur not because of any technological deficiencies but rather because of the administrative rules employed within a typical blockchain. This was more of a business problem than a technical one.

3. *Whether the invention provided a technical solution to the problem* - while not all steps of the claimed method were technical, the critical steps of converting the transaction data into an indecipherable data abstract and then generating a transaction abstract based on digitally signed approvals from the transaction nodes involved the application of information technology techniques. On balance, the claimed invention provided a technical solution to the problem of breach of privacy information

4. *Whether the claimed method required only generic computer implementation* – it was readily determined that the computer implementation was generic. However the focus of the invention was not the computer program to carry out the method and so the weight given to this factor was minimal.

5. *Whether there was a practical and useful result* - the invention yielded such a result in providing greater security for information stored in the blockchain.

6. *Whether the invention lay in the generation, presentation or arrangement of intellectual information* - each node was required to validate the transaction by doing consensus verification and storing the transaction abstract in the blockchain. The invention was not only in the generation and arrangement of intellectual information.

In balancing these considerations, the Delegate concluded that technical improvements to fundamental blockchain mechanisms were patentable even if not addressing technical problems.

However, the Delegate noted various prior art, leading to serious concerns about the inventiveness of the claimed invention. The Application was referred back to the Examiner to reassess inventiveness in light of that prior art and further searching.

Implications

This is the first Australian decision confirming the patentability in principle of technical improvements to blockchain technology. However the referral back to the Examiner for inventive step highlights the risk that the use of generic computer implementation in such cases may pose to establishing inventiveness.

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Vague proposals do not an inventor make

***Vehicle Monitoring Systems Pty Ltd v SARB Management Group Pty Ltd* [2021] FCAFC 224**

Date: 08 December 2021
Court: Full Court of the Federal Court of Australia
Judges: Nicholas, Yates and O'Bryan JJ

Background

Australian Patent Application 2013213708 (**708 Application**) relates to vehicle detection units in the field of parking compliance. The applicant, Vehicle Monitoring Systems Pty Ltd (**VMS**), opposed the grant of the 708 application before the Australian Patent Office, including on the basis that the respondent, SARB Management Group Pty Ltd (**SARB**), was not entitled to the grant of a patent on the invention, or was only entitled to a grant in conjunction with another person.

The entitlement objection was rejected by the Delegate and VMS' appeal to the Federal Court was dismissed on all grounds. VMS sought leave to appeal to the Full Court on the single issue of entitlement.

Key Issues

VMS contended that its managing director, Fraser Welch, was an inventor of the invention the subject of the 708 Application. Since SARB had not derived title to the invention from Mr Welch, it was not entitled to the Application, pursuant to s15 of the *Patents Act 1990* (Cth).

The parties agreed that the key issue was identification of the "inventive concept" of the application, and what Mr Welch's contribution to that inventive concept was (if any). The specification described a typical parking enforcement process as manual periodic inspection of restricted spaces, which is time consuming and inefficient, and the invention as an automated parking enforcement system. The claims were to a "vehicle detection unit" (**VDU**) which included a magnetic sensor and a processor determining the occupancy status of a vehicle space, which communicated any illegal parking to a supervisory device for pre-population into infringement issuing software. In short, the device detected variations in the earth's magnetic field caused by the presence of vehicles, to determine when a vehicle had overstayed in a parking place and allowed infringement notices to be automatically issued using this information.

VMS was the owner of the Parking Overstay Detection System (**POD system**), which used magnetic sensors in this way, but which required information regarding an infringement to be manually transcribed for a ticket to be issued. In 2005 Mr Welch had discussions with a SARB representative in which it was found he had suggested that the POD system could be integrated with SARB's ticket issuing device. VMS claimed on this basis that Mr Welch was an inventor of the invention. In the first instance appeal, the judge found that the inventive concept was focussed on a VDU configured

"The inventive concept of a patent is divined from the specification as a whole and a patent should be drafted with this in mind. Not all passing contributions or "vague proposals" will be sufficient to form the basis for inventorship."

and utilised in a particular way, and that Mr Welch had not contributed to the specific device.

Outcome

The Full Court noted that both parties agreed that the contested issue should be determined by reference to whether Mr Welch contributed to the "inventive concept" of the 708 Application. Notwithstanding, the Court queried whether the notion of "inventive concept" was apt or necessary as a tool for determining inventorship. That question was left unanswered.

As to the inventive concept in this case, the Court found that the primary judge had fallen into error by confining the inventive concept to the embodiments closely reflecting the claimed device. Rather, the inventive concept was to be derived from a reading of the specification as a whole, and included the idea of an integrated automated parking enforcement system in which magnetic sensors are able to output a sensor signal caused by the occupancy of a vehicle space by a vehicle and in which details pertaining to a notifiable event are pre-populated into infringement issuing software. Significant to this conclusion was the fact that the specification "seated" the invention as an automated parking enforcement system that provides advantages over a so-called manual parking enforcement system, and that only in "further preferred embodiments" the VDU would provide information to the supervisory device. In other words, the invention was not confined to devices having this capability.

However, the Court was not satisfied that Mr Welch's contributions made him an inventor of the invention. The Court particularly took into account that the information provided by Mr Welch to SARB about the POD system did not go beyond information that was already in the public domain, and found that his suggestion that "*it would obviously be much better*" if details from the POD system automatically populated in the infringement notice system was not of such significance as to amount to a material contribution to the inventive concept of the 708 application.

Implications

It is relatively rare for the Full Court to consider patent entitlement issues. This decision provides guidance in relation to the relevant principles. In particular, it is clear that the way in which the invention is described in a patent specification can be significant in determining its inventors. The decision also confirms that not all passing contributions or "vague proposals" will be sufficient to form the basis for inventorship. The importance of maintaining good written records of contribution to an invention is also highlighted. In this case the dispute played out some 15 years after relevant conversations had taken place, and oral evidence of precisely what was said in those conversations (which was critical to the issues at hand) was approached by the primary judge (and approved of by the Full Court) with considerable caution where not supported by documents.

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World-first decision: Artificial Intelligence recognised as a patent inventor under Australian law

***Thaler v Commissioner of Patents* [2021] FCA 879**

Date: 30 July 2021
Court: Federal Court of Australia
Judge: Beach J

Background

Australian Patent Application 2019363177 (**Application**) is directed to container products and methods for attracting enhanced attention, using convex and concave fractal elements. The inventor listed on the application was "DABUS",[1] an artificial intelligence system having artificial neural networks. The Australian Patent Office rejected the Application on the basis that DABUS could not be an inventor. The applicant, Dr Thaler, appealed.

Key Issues

S15(1) of the *Patents Act 1990* (Cth) (**Act**) provides that a patent may be granted to an inventor, an assignee of the inventor, or certain other persons, including a person who derives title from the inventor. There is no definition of "inventor" in the Act. The question that arose was whether an AI system can be an inventor for the purposes of the Act.

Outcome

Beach J concluded that an AI system can be an inventor of a patent.

In doing so he took a well-reasoned and progressive approach, the cornerstone of his reasoning being that "*there is no specific provision in the Act that expressly refutes the proposition that an artificial intelligence system can be an inventor*".

Whereas the Patent Office found that the term "inventor" was inherently human, Beach J considered that "inventor" is an "agent noun". The suffix "or" or "er" indicates that the noun describes the agent that does the act referred to by the verb to which the suffix is attached. Giving examples such as "computer" and "distributor" he concluded that the agent can be a person or a thing.

Beach J found further support for this approach in the comments of the High Court in *D'Arcy v Myriad Genetics Inc*[2] noting that a widening conception of "manner of manufacture" was a feature of current patent law as scientific discoveries inspire new technologies.

In his view there was "*no reason why the concept of 'inventor' should not also be seen in an analogously flexible and evolutionary way*".

Beach J also considered, in some detail, the potential of AI to generate innovations in, for example, the pharmaceutical industry and expressed a view that

"The Federal Court confirmed that an artificial intelligence system can be an inventor of a patent. However, the Court also held that a non-human inventor cannot be the owner of a patent. This landmark, world-first, decision goes against decisions of other key regions including the US and Europe, which have recently rejected AI inventorship of patents."

not permitting patents on such innovations because a legitimate inventor could not be listed would be the "antithesis" of the newly introduced object clause in the Act, the object being to promote "*economic wellbeing through technological innovation and the transfer and dissemination of technology*."

In arguing against AI inventorship, considerable reliance had been placed on s15(1) and the argument that since an AI system could not assign ownership of an invention, entitlement to a patent could not be established in such circumstances. Beach J confirmed that since an AI system is not a legal person, it cannot legally assign rights in an invention. However, he further noted that this does not preclude an applicant *deriving* rights in an invention from an AI inventor because the relevant provisions recognise that transfers of rights extend beyond assignments to encompass other means by which an interest may be conferred. He concluded that Dr Thaler, as the owner and controller of DABUS, would own any inventions made by it, when they came into his possession.

Implications

This decision signals a highly progressive approach by the Australian Federal Court, given that the same case brought in other jurisdictions has otherwise failed.

As expected, the controversial decision has been appealed and a decision by the Full Court of the Federal Court is keenly anticipated.

1. Device for the Autonomous Boot-strapping of Unified Sentience
2. (2015) 258 CLR 334

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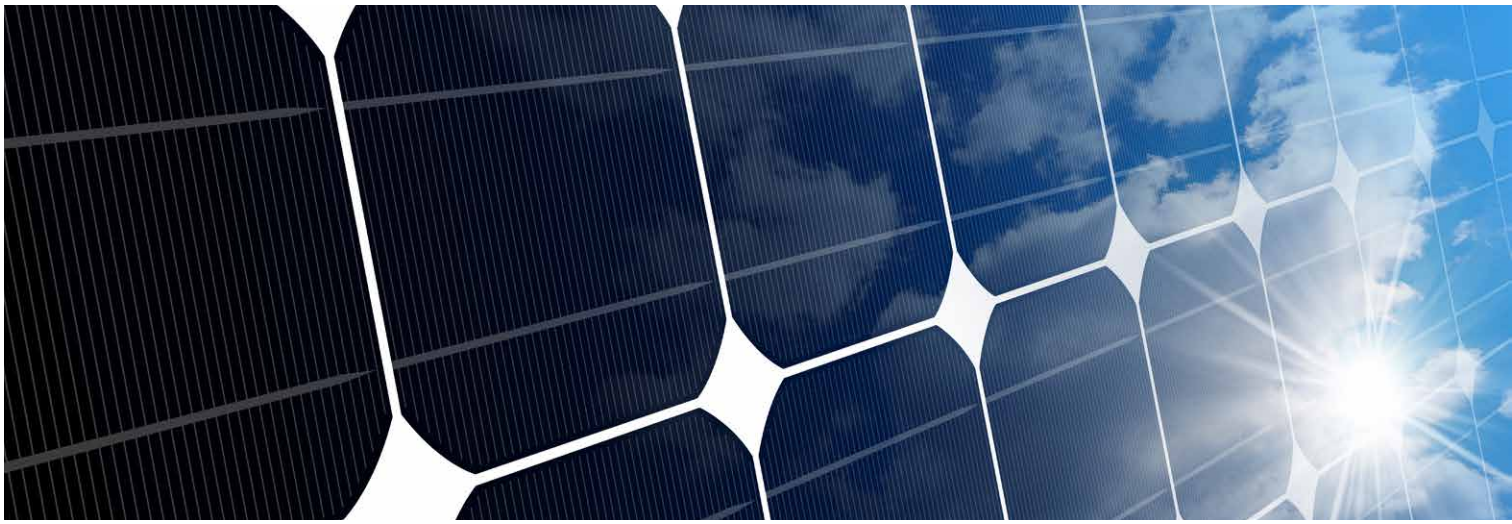

True inventor of a patent successfully opposes the patentee's attempt to surrender it

***Michael John Arieni v Sun-Wizard Holding Pty Ltd* [2021] APO 20**

Date: 11 May 2021
Forum: Australian Patent Office
Delegate: Ranganath Subbarayan

Background

Mr Arieni was a former colleague of one of the named inventors (Mr Fry) of Innovation Patent 2014100975 (**Patent**) to a rugged and weatherproof solar outdoor lighting device. Mr Arieni claimed to be the true inventor of the device and to have disclosed its inventive features to Mr Fry, after which Mr Fry had joined Sun-Wizard Holding Pty Ltd (**Sun-Wizard**), the patent owner.

Upon certification of the Patent, Mr Arieni challenged its validity, and Sun-Wizard applied to surrender the Patent in the face of the challenge. Mr Arieni withdrew his validity challenge and opposed the surrender on the basis that he was entitled to the Patent and so would be unfairly disadvantaged by its surrender. Mr Arieni also sought rectification of the Register of Patents to record himself as the inventor and patentee.

Key Issues

It is established law in Australia that the inventor of a patent is the person responsible for conceiving the inventive concept of an invention, rather than persons involved in reducing it to practice. However, the invention is only complete when it is sufficiently clearly defined that a person of ordinary skill can reduce it to practice without extensive further research or experimentation. The inventive concept is discerned from the whole of the specification of the patent, including the claims.

Based on consideration of the specification, the Delegate determined that three key features contributed to the invention achieving its objective as a rugged and weatherproof solar outdoor lighting device. These features represented the inventive concept, and it was irrelevant whether any of them were found in the prior art individually. In summary, the features were: a funnel-shaped reflector; providing LED lights around the periphery of the reflector pointing downwards; and the location of the solar panel above the reflector. The Delegate accordingly proceeded to consider who was responsible for the conception of these three key features.

Outcome

Mr Arieni's evidence included emails from a third party, Mr Gray, attaching drawings of a funnel-shaped reflector and a solar panel placed above the reflector. Mr Arieni explained that these were drawn by Mr Gray based on instructions provided by Mr Arieni.

Sun-Wizard argued that these two features were more

"The inventor of a patent is the person responsible for conception of the invention rather than its reduction to practice. This case highlights the difficulties that a patentee can face when a true inventor claims ownership."

likely developed by Mr Gray alone than by Mr Arieni. However, Sun-Wizard did not file any evidence to support this argument, such as from Mr Gray.

Mr Arieni's evidence also included a sketch made by him of LED lights around the periphery of a reflector pointing downwards. Sun-Wizard alleged that the sketch was undated and not authentic, but Mr Arieni provided an email verifying its date. Further, although Mr Fry claimed that there would be practical difficulties in implementing the sketch, the Delegate considered that these were part of the reduction to practice of the invention rather than its conception.

The Delegate noted that Sun-Wizard had said very little about how the named inventors contributed to the invention, focussing on engineering and tooling work, but these related to the invention's reduction to practice rather than its conception.

Accordingly, the Delegate decided that all three features constituting the inventive concept had been conceived by Mr Arieni, and the Register of Patents should be amended to record him as inventor. Sun-Wizard was not entitled to the Patent and did not have the right to surrender it.

Implications

This decision shows the importance in inventorship disputes of filing probative evidence of conception of the invention. Mr Arieni filed evidence from which the Delegate could conclude that he was an inventor, whereas Sun-Wizard and Mr Fry did not. The outcome of the case was an inevitable result of this disparity.

This decision can be contrasted with the outcome in the *Vehicle Management Systems v SARB Management Group*.[1] In that case, the Full Court considered the contributions of the person claiming inventorship to be insufficient and more in the nature of a 'vague proposal'. The applicant there had no drawings or similar materials such as those put into evidence by Mr Arieni here, highlighting the importance of good record keeping.

Mr Arieni's success in the case put Sun-Wizard in a difficult position. Sun-Wizard's application to surrender the patent appeared to be an attempt to avoid a scenario where it infringed a patent owned by Mr Arieni. However this was presumably the end result. Accordingly, where inventorship (and thus ownership) of a patent may potentially be in doubt, the prospective applicant would be well advised to consider the position (potentially seeking verification of inventorship from its employees) before filing a patent application, and to consider the possible outcomes if there is a risk of a competing claim of inventorship being made at a later date.

1. [2021] FCAFC 224. See our review of this case at pages 20-21.

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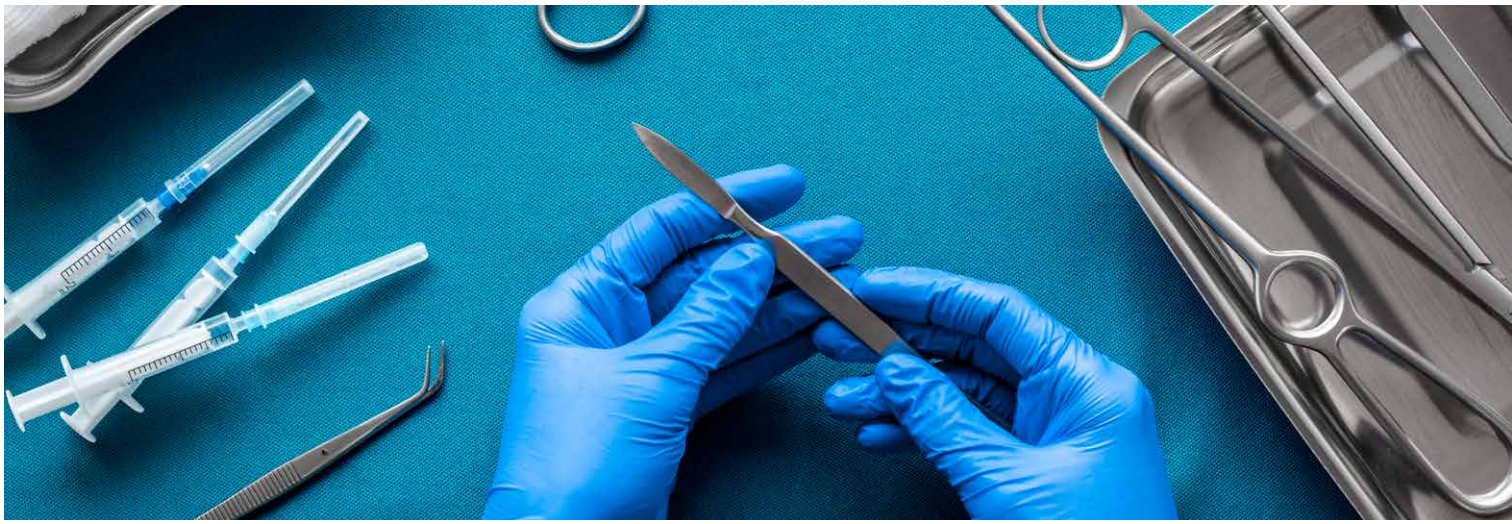

Sticking the knife in: owner of scalpel removal device patent survives entitlement attack

***Michael Sinnott v Aunex Pty Ltd* [2021] APO 23**

Date: 08 June 2021
Forum: Australian Patent Office
Delegate: Felix White

Background

This case concerned a dispute as to inventorship of an apparatus for detaching surgical blades, claimed in Australian Patent 2018203404 (**Patent**) granted to Aunex Pty Ltd (**Aunex**), with Mr Quek named as sole inventor. The case was initiated by the Managing Director of Qlicksmart Pty Ltd (**Qlicksmart**), Dr Michael Sinnott, who sought rectification of the Register of Patents to name his company as patentee and Qlicksmart's Research and Development Director, Dr Henry, as inventor. Mr Quek was a former employee of Qlicksmart and started up Aunex several months after ceasing employment at Qlicksmart.

Key Issues

The key issue for determination was whether the invention the subject of the Patent was truly conceived by Mr Quek and if so, when.

As set out by the Delegate, under Australian law, the determination of entitlement is assessed by considering the three-step approach adopted by the Full Court in *University of Western Australia v Gray*,[1] including:

1. identifying the "inventive concept" with reference to the specification as a whole, including the claims;

2. determining inventorship, being the conception or "formation in the mind" of the invention; and

3. determining any contractual or fiduciary relationships that give rise to rights in the invention.

Outcome

In relation to first step, the inventive concept in this case was deemed to relate to a particular arrangement of a rigid backing plate that constrained flexing of a blade detachment member such that surgical blades could be easily removed from blade holder handles when inserted into the claimed device. Rigidity of the backing plate was part of the inventive concept notwithstanding that the claims did not explicitly include such feature.

In relation to second step, the Delegate was satisfied that Mr Quek did conceive the invention himself.

Mr Quek's evidence set out the approach he took in identifying problems with other blade removal devices

"Evidence of actual conception of an invention by an ex-employee defeats an assertion of lack of entitlement raised by a former employer."

in the prior art and how he eventually realised that restraining the flexibility of the blade detachment member was critical to the success of the device. He also provided in his evidence photos of the prototype he manufactured, which were consistent with embodiments depicted in the Patent. On the other hand, evidence of Qlicksmart declarants was considered by the Delegate to be based on "assertions and opinions" and did not provide sufficient narrative from the alleged inventor, Dr Henry, about how or why he came up with the invention.

Finally, in relation to the third step of the test, the Delegate found that Mr Quek devised the invention after leaving the employ of Qlicksmart. Accordingly, as the invention was not made during the course of his employment, Mr Quek was not required to assign it to Qlicksmart. Further, to the extent that Qlicksmart asserted the invention might have *arisen* from Mr Quek's employment and therefore was required to be assigned, the Delegate dismissed this arugment, finding that Mr Quek used only publicly available information in devising the new invention.

Accordingly, Dr Sinnott's request to amend the Register of Patents was dismissed.

Implications

This decision affirms the importance to inventors and employers alike of keeping records in relation to the development of new inventions. If employee/employer relations do break down, or in cases where employees move to rival businesses, such evidence can be used to make or counter assertions of lack of entitlement to a patent.

1. *University of Western Australia v Gray* [2009] FCAFC 116

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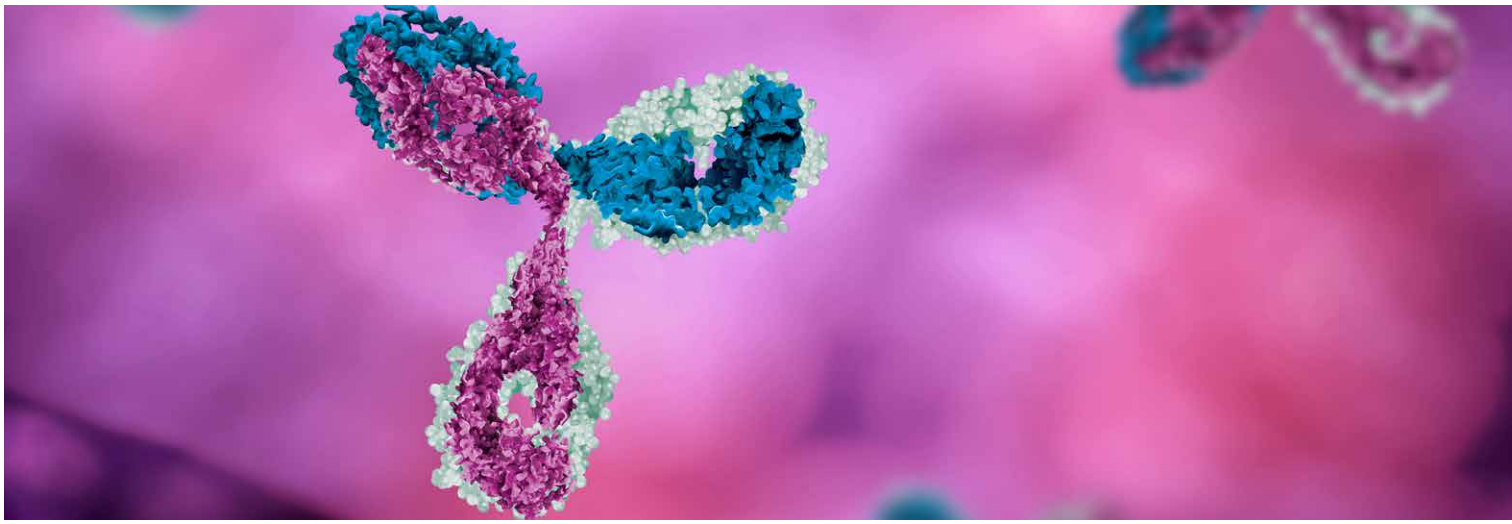

Common sense prevails in new interpretation of pharmaceutical extension of terms

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

Date: 11 June 2021
Court: Federal Court of Australia
Judge: Beach J

Background

Under Australian law, patents that cover certain pharmaceutical inventions are eligible for an extension of term (**PTE**) of up to five years. One of the requirements for obtaining a PTE is that the application must be lodged within six months of the later of the date the patent was granted and the date of the earliest regulatory approval (listing on the Australian Register of Therapeutic Goods (**ARTG**)) of a product containing or consisting of a pharmaceutical substance covered by the claims of the patent.

Australian Patent 2011203119 (**Patent**), in the name of Ono Pharmaceutical Co Ltd and another patentee (collectively **Ono**) covers antibodies that bind the immune checkpoint inhibitor PD-1 and includes claims which cover Opdivo® (Ono's product) and Keytruda® (competitor's product), both blockbuster cancer drugs. Regulatory approval for Opdivo® and Keytruda® was obtained in Australia on 11 January 2016 and 16 April 2015 respectively. On application made by Ono for a PTE based on approval of Opdivo®, the Australian Patent Office found that the pharmaceutical product with the earliest regulatory approval date covered by the claims of the patent was Keytruda®. The request based on Opdivo® was refused, and the six-month period for filing a PTE based on the Keytruda® approval had already expired. Ono appealed to the Federal Court.

Key Issues

Ono argued that the PTE provisions of the *Patents Act 1990* (Cth) recognise that there may be "one or more pharmaceutical substances" in substance disclosed in the complete specification and falling within the scope of the claims, and that relevant conditions must be satisfied "in relation to at least one of those pharmaceutical substances". Ono argued that the phrase "at least one" recognises that the relevant PTE requirements may be satisfied by any one of the pharmaceutical substances disclosed and claimed. It therefore submitted that the relevant "first regulatory approval date" is that of the product specified in the application for the PTE, which in the present case was Opdivo®, Ono's product.

The Commissioner of Patents argued that none of the relevant PTE provisions require a relationship between the patentee seeking the extension and the entity that holds the regulatory approval of the product, such that approval of a competitor product could form the basis of a PTE. Further, the Commissioner argued that the

"Regardless of whether the claims of a patent cover a competitor product with an earlier regulatory approval date, a patentee can validly apply for a patent term extension based on their first own pharmaceutical product covered by the claims."

relevant PTE provisions do not operate by reference to whichever substance an applicant nominates in an application form. Rather, the relevant provisions operate by reference to the "first inclusion" in the ARTG of goods that contain any of the pharmaceutical substances covered by the claims of the patent, which in this case was the inclusion of Keytruda®.

Outcome

Beach J anchored his analysis to the purpose of the PTE provisions, which were "*designed to remedy the mischief of a shortened period for an effective monopoly that has been caused by delays in obtaining regulatory approval.*" Accordingly, a liberal, rather than a literal, construction was to be preferred. A construction of the PTE provisions which required a patentee to seek a PTE on the basis of a competitor's product was not consistent with the legislative purpose and did not fit well with other relevant provisions. Consequently, Beach J ordered that the PTE for the relevant patent be granted based on Opdivo®, extending the term of the patent from 2 May 2026 to 11 January 2031.

The decision confirms that a patentee does not need to rely on a competitor's product for the purposes of a PTE application. However, it is unclear to what extent Beach J intended to comment on the ability of a patentee to choose between its own products for such purposes. As set out above, Ono's arguments appear to have been cast broadly, however Beach J noted that it was not Ono's position that a patentee should be permitted to "pick and choose" which of its products can be used for a PTE application. Nevertheless, some of Beach J's *obiter* comments could be construed as supporting such an approach. For this reason, there may be some tension between this decision and the subsequent decision of Jagot J in *Merck Sharp & Dohme Corp. v Sandoz Pty Ltd*,[1] which held that a patentee must base a PTE on its product with the earliest approval date covered by the claims. Both PTE decisions have been appealed and the Full Court's decisions will be eagerly awaited.

Implications

This Federal Court decision gives greater certainty to patentees in obtaining PTEs based on their own product, without the need to consider a competitor product having an earlier ARTG approval date which may fall within the patent claims. Accordingly, it is important for patentees to review their patent portfolios to identify any patents that might now be eligible for a PTE in light of the new interpretation of the legislation.

1. [2021] FCA 947. See our review of this case at pages 30-31.

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PTEs in Australia – hard lessons for patentees from the Federal Court

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

Date: 12 August 2021
Court: Federal Court of Australia
Judge: Jagot J

Background

Under Australian law, a patent term extension (**PTE**) must be based on the "first regulatory approval date" of a pharmaceutical substance covered by the patent, and at least five years must have elapsed between the effective filing date of the patent application and the first regulatory approval date. Once granted, a PTE will apply to all pharmaceutical substances covered by the patent claims.

Australian Patent 2002320303 (**Patent**), in the name of Merck Sharp & Dohme Corp (**Merck**), is directed to the treatment and prevention of diabetes. Its claims cover: sitagliptin, approved in Australia on 16 November 2006; and a composition containing a combination of sitagliptin and metformin, approved in Australia on 27 November 2008. A PTE application was submitted and ultimately granted based on the regulatory approval of the combination product of sitagliptin and metformin (the sitaglipin alone product was clearly not eligible for a PTE since less than five years elapsed between the patent date and regulatory approval). Sandoz Pty Ltd (**Sandoz**) challenged the PTE on the basis that it was not based on the pharmaceutical substance covered by the Patent with the *first regulatory approval date*

Key Issues

Merck put forward interpretations of the term "first regulatory approval date" as used in the relevant PTE provisions, which it said did not cover sitagliptin alone. Under its interpretation the first approval date could not relate to an approval obtained within five years of the date of the Patent. Therefore, Merck's position was that the regulatory approval of the combination product of sitagliptin and metformin qualified as the first approval date. In contrast, Sandoz submitted that the "first regulatory approval date" related to any pharmaceutical substances covered by the Patent regardless of whether such approval was eligible for a term extension in itself. Under this interpretation, the regulatory approval of sitagliptin would be considered the earliest first approval date, making the Patent ineligible for a term extension.

Outcome

Jagot J rejected Merck's interpretation of the PTE provisions on the basis that it required the Court to proceed as if there were a drafting error in the legislation, finding that there was no basis on which the court should assume that there were such an error. Furthermore, if Merck's interpretation was valid, it

"Where the claims of an Australian patent cover two pharmaceutical substances, a patent term extension (PTE) application must be based on the pharmaceutical substance having the earliest regulatory approval date."

could obtain "*a monopoly over sitagliptin for more than 20 years in circumstances where it never suffered an unacceptable delay in its capacity to exploit sitagliptin*".

For this reason, Jagot J found that the PTE on Merck's Patent was invalid.

Implications

As a result of Jagot J's interpretation of the PTE provisions, no PTE will be available on a patent, where any pharmaceutical substance falling within its claims is approved within five years of the relevant patent date. In some cases, this may mean that later pharmaceutical products covered by the patent cannot benefit from an extended patent term.

This decision has crucial practical implications for patentees of pharmaceutical patents, particularly in relation to the breadth of the claims and the timing of PTE applications. It is essential that patentees are aware of all the pharmaceutical substances covered by their claims and the relevant regulatory approval dates of these pharmaceutical substances. It is also critical that a PTE review be undertaken well before the PTE deadline to allow for appropriate amendment of the claims, if necessary, to exclude (generally by a narrow proviso) products that might jeopardise the request, and to pursue additional pharmaceutical substances in one or more divisional applications. This will ensure that PTE requests are based on the relevant pharmaceutical substance and that the PTE request is filed within the required time.

This decision is equally important for other stakeholders such as generics and biosimilars manufacturers, who should carefully consider the validity of PTE claims and possible strategies for early launch where such PTEs are not properly based.

This decision is now the subject of an appeal to the Full Court, which heard the appeal in November 2021. A decision is expected in coming months.

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Consider the Bar Raised for Sufficiency and Support: Nalco Patent Application Claiming Inhibitors of Silica Deposits Invalid

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

Date: 19 August 2021
Court: Federal Court of Australia
Judge: Burley J

Background

The 'Bayer process' has been used for over 130 years to extract alumina from bauxite to make aluminium. In this process, crushed bauxite is added to a caustic liquor at high temperature and circulated around tanks in a refinery. The alumina dissolves in the liquor, separating it from other minerals in the bauxite, which remain in a slurry. Those minerals include silica, which is deposited on tank surfaces as scale. Eventually, this scale must be removed from the tanks, which is costly.

Nalco Company (**Nalco**)'s Patent Application 2012220990 (**Application**) claimed methods for reducing such scale by adding to a Bayer process a mixture comprising at least one small molecule selected from a group of molecules, that mixture resulting from a reaction between specified compounds. Nalco's competitor Cytec Industries Inc. (**Cytec**) opposed the grant of the Application.

At first instance, the Delegate found all claims of the Application invalid on several grounds. Nalco appealed to the Federal Court and amended the claims of the Application to overcome the Delegate's objections.

Key Issues

During the appeal, the key issues raised were enablement, support and best method. An issue also arose as to the application of the grace period to 'whole of contents' prior art.

Outcome

Enablement and Support

Burley J considered that the amended claims included within their scope a reaction mixture containing only one of the small molecules recited in the claims. The expert witnesses agreed that the reaction would produce an extremely large variety of small molecules, including all of those in the group of molecules specified in the claims. It was a virtual impossibility that the reaction would result in only one member of the group (as one expert said, this would be "like trying to win the lottery in every country in the world with the same six numbers on the same weekend"). In consequence, the lower limit of the claims was not enabled and all of the claims were invalid.

In relation to the support requirement post-*Raising the*

"A Federal Court decision confirms that the bar for sufficiency and support has been raised by Australia's 2013 Raising the Bar law reforms. This is the second Federal Court decision invalidating a patent or patent application on these grounds."

Bar, Burley J referred to his own statement of the law in *Merck Sharp & Dohme v Wyeth (No 3)*,[1] including that the technical contribution to the art of the specification must justify the breadth of the monopoly claimed. He concluded that the Application did not disclose how to make a reaction mixture containing only one of the small molecules from the group of molecules recited in the claims. Therefore, for essentially the same reason as the claims were not enabled, all claims of the Application for lacked support.

Best Method

The experts agreed that the examples in the Application disclosed methods for making reaction mixtures in the laboratory but did not provide enough detail to enable the examples to be replicated at scale. Cytec submitted that the omitted details were part of the best method of practising the invention known to Nalco when it filed the Application.

Burley J was not persuaded, considering that the claimed invention was an industrial process and that the laboratory synthesis methods in question could only provide a rough starting point for developing the process on an industrial scale; they were not a proxy for it. The missing details of Nalco's laboratory method were not therefore part of the best method. Because Nalco had not in fact made reaction mixtures on an industrial scale, somewhat curiously, there was no best method for it to withhold in this respect.

Grace Period

Cytec contended that the claimed invention was anticipated by a related Nalco patent application as 'whole of contents' prior art i.e. prior art published after the priority date of the Application, but entitled to an earlier priority date. Nalco relied on the twelve month grace period for information made publicly available by the applicant; Cytec argued that the grace period did not apply to 'whole of contents' documents. Burley J held that the grace period applied in respect of the relevant prior art.

Implications

Where a claim includes a limitation of "at least" a particular parameter, it is essential that the invention works and is enabled when the parameter is set at that minimum.

Further, where a claimed invention can only be implemented on a larger scale (e.g., industrial or commercial scale) than is disclosed in a patent application, a failure to disclose the best method of practising the invention at a smaller scale (e.g., laboratory scale) may not be fatal to the validity of the application, unless the evidence indicates that the parameters used at the smaller scale can be scaled up for use at the larger scale.

Finally, it has been clarified that the grace period will apply to whole of contents novelty references where the other requirements are met.

1. [2020] FCA 1477

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CRISPR: the application of the wrong inventive step test by the Patent Office means a CRISPR patent application is upheld

***JH Corporate Services Pty Ltd v Sigma-Aldrich Co. LLC* [2021] APO 22**

Date: 02 June 2021
Forum: Australian Patent Office
Delegate: Damian Triffett

Background

In June 2021, the Australian Patent Office handed down a much-anticipated CRISPR decision, rejecting an opposition filed by JH Corporate Services[1] (**JHCS**) against Patent Application 2018229489 (**Application**) in the name of Sigma-Aldrich Co. LLC (**Sigma**) on the grounds of manner of manufacture, novelty, inventive step, utility, clear and complete enough disclosure, support, best method and clarity (post-*Raising the Bar*).

CRISPR-Cas9 gene editing technology (**CRISPR**) is one of the most important breakthroughs in molecular biology since the elucidation of the double helix structure of DNA. Since CRISPR can efficiently target and modify genes it has broad and game-changing applications in a wide range of research areas including drug discovery, cell development and differentiation, production of transgenic animals, improving crops, diagnosis of diseases, such as HIV and COVID-19, and curing genetic diseases.

Key Issues

A key aspect of the case was the inventive step argument. The test for inventive step in Australia involves consideration of both limbs of the 'modified Cripps question', namely:

- whether the prior art directly leads the skilled person as a matter of course to the invention; and
- whether the skilled person would have an expectation that the invention might well work.

It was agreed between the parties that the relevant prior art publication did "directly lead" the skilled person to the claimed invention. The only inventive step issue in dispute therefore was the second part of the test, whether the skilled person would have an expectation that performing the claimed invention might well produce the desired result.

Federal Court case law has emphasised that what is required in this respect is an expectation that the invention may well work, and that it is not necessary to *know* that steps will or would or even may well work. This was underscored by the Full Court's judgment in *Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd*,[2] suggesting that the threshold may be met by something which may be '*no better than fifty-fifty*'.

"In this highly anticipated decision on CRISPR technology, the Delegate appeared to artificially elevate the standard for invalidating a patent application on obviousness grounds, resulting in the patent application being upheld."

Sigma's submissions largely followed those made to the Opposition Division of the EPO in respect of the counterpart patent EP3138910 (rejected there), including that (our **emphasis**):

- "*it was not **known** whether such a bacterial system would function in eukaryotic cells*". and
- "*there is **no guarantee** that Cas9 **will work** effectively on a chromatin target*".

Outcome

The Application was upheld, conflicting with the outcome in Europe, where the counterpart patent was overturned for lack of inventive step.

Contrary to the case law referred to above, the Delegate appears to have set the benchmark for establishing obviousness as whether there was a reasonable expectation that the invention "***would** work*", stating (our emphasis) that he "*did not consider the steps to achieve targeted integration in eukaryotes would be a matter of routine, as **it is not clear whether there was a reasonable expectation that such steps would work***".

Implications

The test for obviousness was elevated in this case by the Delegate to a level that appears to be much higher than a Court would require. As the decision was not appealed, the application of the "***would work***" standard rather than the established "***may well work***" standard will not be redressed by the Federal Court in this instance.

The decision appears to leave room for patent applicants to argue during prosecution that unless an invention would be ***known*** to work before it was performed, there cannot be an expectation that it ***may well work***, taking the test closer to novelty than the established test for obviousness.

1. Pearce IP acted for JHCS in this case
2. [2020] FCAFC 116

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Disclaimer amendment allowed in mastitis patent

***Boehringer Ingelheim Animal Health USA Inc v Elanco New Zealand* [2021] FCA 1457**

Date: 25 November 2021
Court: Federal Court of Australia
Judge: Besanko J

Background

This appeal from a decision of the Australian Patent Office concerned the allowability of amendments to the claims of Australian Patent Application 2009304000 (**Application**) relating to an antiseptic formulation for treating mastitis in cattle. The key amendment to claim 1 was a disclaimer that the antiseptic is not an 'acridine', introduced by the patent applicant (**Elanco**) to avoid a novelty objection upheld in an opposition to the Application.

The opponent (**Boehringer**) opposed the amendment on the ground that amended claim 1 would claim matter not in substance disclosed in the specification. The Patent Office found that there was a real and reasonably clear disclosure in the specification of the matter claimed, i.e. the treatment of mastitis in cattle using an antiseptic that is not an acridine, and allowed the amendment. Boehringer appealed.

Key Issues

Besanko J's review of the case law showed that, although there is no automatic rule that amendments limiting the scope of a claim are allowable, this will usually be the case because the specification will usually provide a real and reasonably clear disclosure of what is left within the claim. However, the case law contemplated two potential exceptions to that rule, first, an amendment to narrow to a specific embodiment where the specification describes an invention only very generally, and second, an amendment to disclaim an embodiment which the specification recommends or prefers.

Boehringer's case was that, as a consequence of the first exception, the amendment could only be sustained if there was a positive disclosure that acridines were not to be used. Moreover, it argued that acridines were a preferred embodiment in the specification and therefore an amendment to disclaim them should not be allowed under the second exception. Although none of the antiseptics named in the specification (one of which, chlorhexidine, was clearly the most preferred) were acridines, Boehringer relied on a statement in the specification that the antiseptic preferably had one or more of six desirable properties. Two classes of antiseptics were exemplified as having one or more of these properties, ionised antiseptics (**IAs**) and quaternary ammonium compounds (**QACs**). Boehringer contended that acridines had one or more of the desirable properties, and that acridines were IAs or QACs. On either basis, acridines were preferred.

Outcome

Besanko J rejected the first argument as inconsistent

"Besanko J's analysis of the allowability of claim amendments will assist patentees to understand when they can amend to disclaim an embodiment."

with the authorities. Specifically, it is not necessary for the specification to disclose that a particular embodiment (in this case, acridines) is not to be used in the invention for an amendment to disclaim that embodiment to be allowable.

As to the second argument, of the six expert witnesses, two considered that the specification preferred only the four named antiseptics (**Interpretation 1**), two considered that it preferred any antiseptic with one or more of the desirable properties (including IAs and QACs) (**Interpretation 2**), and two considered both views reasonable but favoured Interpretation 1. The evidence established that a large number of antiseptics had the desired properties, and that some antiseptics with the desired properties would otherwise be unsuitable for use in the invention.

The evidence also established that IAs and QACs include acridines but that thousands of compounds other than acridines are IAs and QACs. Therefore, a reference to IAs or QACs could not be treated as a reference only to acridines or as a reference to all acridines. In other words, there was no correspondence between the terms. Further, the evidence demonstrated that it was not generally known amongst those skilled in the art that acridines were IAs or QACs. Therefore, even if the specification did prefer IAs or QACs, those skilled in the art would not have understood this as a preference for acridines.

For these reasons, the judge concluded that the specification did not express a preference for acridines, so the amendment to disclaim acridines from the scope of claim 1 was allowed.

Implications

The judgment confirms that amendments to disclaim certain embodiments from the scope of claims will only be considered unallowable in specific circumstances. Where an opponent to such an amendment contends that the specification prefers the embodiment so it cannot be disclaimed, they will need to identify a clear preference for that embodiment in the specification, for example, that the embodiment is one of a limited number identified by name. If the embodiment is not identified by name, it is unlikely to be considered to be preferred only on the basis that it is one of a large number of embodiments for which some preference is expressed. The embodiment is also unlikely to be preferred if it has properties which the specification states are undesirable in relation to the invention.

Federal Court Expedites Another Pharma Patent Trial

***Juno Pharmaceuticals Pty Ltd v Celgene Corporation* [2021] FCA 236**

Date: 19 March 2021
Court: Federal Court of Australia
Judge: Beach J

Background

Celgene Corporation (**Celgene**) markets lenalidomide for a number of blood cancers including multiple myeloma.

Juno Pharmaceuticals Pty Ltd and Natco Pharma Ltd[1] (collectively, **Juno**) filed revocation proceedings in respect of certain claims of Celgene's Australian Patent 715779 to various compounds including lenalidomide (**Compound Patent)**. Celgene filed a cross-claim for infringement not only of the Compound Patent, but of seven additional patents directed to the marketed indications and other methods of treatment (**MOT Patents**). The earliest of the MOT Patents was due to expire in April 2023, the latest in August 2027.

Juno applied to strike out the cross-claim in respect of the MOT Patents, and to schedule an expedited trial in respect of the Compound Patent. At the time of the decision, the Compound Patent term had slightly more than 16 months left to run before expiry on 24 July 2022.

Key Issues

Beach J considered the competing efficiencies of expedition in light of the cross-claim engaging seven additional patents. First, Beach J considered whether the inventive step issues in respect of the Compound Patent and the MOT Patents might overlap. He determined that they would not, given the different nature of the inventions, and the fact that six years had elapsed between the priority date of the Compound Patent and the earliest MOT Patent.

Second, he considered arguments by Celgene that, even if the Court found the relevant claims of the Compound Patent to be invalid, it would not be possible for Juno to take advantage of that decision by launching its generic product before 24 July 2022 without infringing at least one of the MOT Patents.

Marketing a generic pharmaceutical product requires prior approval by the Australian Therapeutic Goods Administration (**TGA**). Furthermore, many pharmaceutical products are not commercially viable unless they are listed on the PBS, thereby making them available to the public at a government-subsidised price. A generic product can only be granted TGA approval and PBS listing for indications already approved for the reference product (in this case Celgene's product). Celgene asserted that each of the on-label lenalidomide indications fell within the scope of at least one MOT Patent, so that removing one or more indication from the Juno product leaflet (and marketing the Juno product in accordance with that leaflet) could not avoid infringement entirely.

"This is one of several recent instances of the Federal Court expediting a patent trial (here within 10 months of commencement) in proceedings commenced to "clear the way" in advance of generic launch. Beach J granted expedition, despite the fact that the patentee's cross-claim for infringement engaged additional patents which would not be addressed by the expedited hearing."

Secondly, his Honour considered Juno's application to strike out parts of Celgene's cross-claim. He rejected Juno's strike out application because, while Juno could not launch without TGA approval, it was clear from the expedition application that it did intend to launch before expiry of the Compound Patent. Whilst Beach J considered the Celgene cross-claim to be "*in some respects hypothetical*", it was "*not sufficiently hypothetical to warrant summary disposition*". He noted that for the purposes of the strike out application before him he only needed to consider whether the parts of the cross-claim in question gave rise to a reasonable cause of action on their face. This contrasts with a summary dismissal application, which may require a determination that a party has no reasonable prospect of success.

Outcome

Beach J granted Juno's application for an expedited trial on the Compound Patent, with the infringement claim on the later expiring MOT Patents to be dealt with on a different schedule. To Celgene's argument that Juno should clear the way on all patents at the same time, his Honour pointed to the impracticality of doing this on an expedited basis, which would result in a lost opportunity for Juno to challenge the Compound Patent. In doing so, his Honour explicitly acknowledged that Juno's objective 'may not be fully met' even if successful with respect to the Compound Patent.

In the decision, his Honour indicated his intention to deliver judgment within one month of the expedited trial, "all being well".

Implications

The Federal Court is increasingly mindful of the commercial practicalities surrounding the timing of generic pharmaceutical launches, and the impact of regulatory frameworks affecting pharmaceutical approvals and reimbursement on the market. We observe a willingness by judges within the Court's IP practice area to expedite proceedings where appropriate, particularly in the pharmaceutical patent sphere. We consider this good news for litigants in general, and a positive sign of improvement to Australia's reputation for patent litigation. Of course, the *quid pro quo* for expedition is compressed timeframes, particularly in the evidentiary stages. Strategic planning, well before litigation is commenced, can be essential in making the most of the expedited timeframe and meeting the expectations of the Court.

1. Pearce IP acted for Juno and Natco in this matter.

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Discovering the boundaries of discovery: Otsuka denied additional application

***Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd (No 4)* [2021] FCA 416**

Date: 27 April 2021
Court: Federal Court of Australia
Judge: Yates J

Background

In March 2012, Otsuka Pharmaceutical Co., Ltd and Bristol Myer Squibb Company (together **Otsuka/BMS**) were granted an interlocutory injunction preventing Generic Health Pty Ltd (**GH**) from entering the market with generic aripiprazole products for treating schizophrenia. As a condition of the injunction, Otsuka/BMS were required to give the usual 'undertaking as to damages', that they would meet any damages suffered as a result of the injunction, if GH were ultimately found not to be infringing a valid claim. GH had originally applied to have its aripiprazole products listed on the Pharmaceutical Benefits Scheme (**PBS**) with effect from 1 April 2012, but withdrew its application as a result of the injunction. In June 2015, the Federal Court found the claims of the relevant patent invalid and revoked them,[1] and the invalidity findings were upheld by the Full Court.[2]

In mid-2017 and following the appeal decision, GH filed a claim for damages suffered as a result of the injunction, and specifically, its inability to obtain PBS listing of, or sell, its aripiprazole products. In mid-2018, the Commonwealth also filed an application for compensation in the order of $110 million for losses arising from the delay of the automatic price drop that entry of GH's PBS-listed aripiprazole products would have triggered, had GH not been injuncted.

Key Issues

This decision concerns an application for discovery of documents from the Commonwealth which Otsuka/BMS claimed were relevant to the question of whether GH would have launched its products, had the injunction not been granted. A first set of discovery orders against the Commonwealth was made in September 2019 and related to documents relevant to (i) whether GH had really intended to maintain its application to list aripiprazole products on the PBS, and (ii) whether GH's possible inability to supply aripiprazole products on the PBS listing date would have stopped the Government from approving its listing. This discovery over a period of many months had already come at a cost to the Commonwealth of over 1,300 personnel hours.

In its second discovery application, Otsuka/BMS sought to expand the categories of discovery to, among other things, documents evidencing the Government's approach when any supplier of a PBS-listed product triggering a price drop was unable to supply its product on the day of PBS listing, and information about the

"The Federal Court imposes limits on discovery as Otsuka and Bristol-Myers Squibb seek evidence that generic companies would not have launched generic pharmaceutical products even if not injuncted."

PBS expenditure effect of entry into the market of any non-aripiprazole treatments for schizophrenia.

Outcome

Yates J refused to make orders for all additional discovery categories sought.

In the first instance, his Honour observed that Otsuka/BMS should have requested the broader discovery categories in its initial application, to avoid overlap, costs and delays in the Commonwealth locating and producing relevant documents. Additionally, his Honour pointed to the several sets of discovery orders that were in force against GH, noting that some of the documents now requested by Otsuka/BMS from the Commonwealth would also be covered by those orders. His Honour took a dim view of the relevance of discovery in relation to the activities and behaviours of third parties, and also noted that Otsuka/BMS had failed to lay a factual foundation for the claim that market entry of other products indicated for treatment of schizophrenia would affect PBS expenditure on aripiprazole.

Implications

This ruling is a reminder of the importance of considering the breadth of a request for discovery as early as possible in proceedings, and certainly at the time that a first discovery request is made.

More generally, Otsuka/BMS' broadranging discovery requests are indicative of the intense scrutiny in previous damages inquiries of the likely commercial motivations and risk appetite of generic companies when faced with the prospect of launching a product 'at risk' (that is, in circumstances where damages will be payable if they are found to be infringing a patent), such as *Commonwealth v Sanofi (No 5)*.[3] It remains to be seen whether the discovery obtained in this case will help show that GH would not have launched, even if no injunction had been granted.

1. [2015] FCA 634
2. [2016] FCAFC 111
3. [2020] FCA 543

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Economy of court procedures primary factor in refusal to consider summary judgment application

***Deco Australia Pty Ltd v Aliwood Pty Ltd* [2021] FCA 1159**

Date: 22 September 2021
Court: Federal Court of Australia
Judge: Perram J

Background

Deco Australia Pty Ltd (**Deco**) alleged infringement by Aliwood Pty Ltd (**Aliwood**) of Innovation Patent 2019101244 (**Patent**). Aliwood asserted that the Patent was not entitled to its claimed priority date, and lacked novelty in light of an Deco publication dated after the claimed priority date but before the date Aliwood asserted was the true priority date. Aliwood contended that both parties' experts agreed that one specific embodiment of the claims of the patent was disclosed in a set of figures in the relevant Deco publication, and that the same set of figures also appeared in the priority document. It argued that this set of figures was not sufficient in the priority document to establish priority, but did deprive the claims of novelty when appearing in the Deco publication. According to Aliwood, the issue of the entitlement to priority was therefore case dispositive.

Aliwood had previously sought to have this issue decided as a separate question, which Perram J had refused to do. He had indicated on that occasion that he could not prevent Aliwood from filing a summary judgment application. Aliwood did so. By that stage, the evidence in the case was complete and all preparatory steps for trial had been taken other than the expert conclave and joint expert report.

Key Issues

The focus of the Court was primarily, and in the simplest terms, a consideration of whether the application would waste the Court's time. Perram J noted that the case was ready, and set down, for trial in April 2022, but that should summary judgment be granted, Deco would surely appeal. If the appeal were successful, the matter would come back before him for trial, and by his calculations, this would mean that the trial currently set down for early 2022 would likely not take place until 2023.

Aliwood's arguments that the summary judgment application would save costs were not persuasive since the issues were complex, particularly as they involved an application of s40 of the *Patents Act 1990* (Cth) that was "*new and not yet subject to appellate authority*", and the case was ready for trial but for the experts' conclave and the joint report. Accordingly, without delving into the merits of the summary judgment application, Perram J stood the hearing of the application over to the trial. In reality, this meant that the summary judgment application would not be dealt with separately from final determination.

"In this case, Perram J declined to even consider a summary judgment application, taking into account multiple factors most of which related to the effective use of the Court's time and the stage of the litigation. The application was stood over to trial, the practical effect being that the case would be finally determined at hearing, rather than the summary judgment application being heard."

Implications

Australian Courts are generally reluctant to decide discrete issues ahead of trial in intellectual property cases, as this case illustrates. There are numerous examples of refused applications for preliminary questions, and US-style Markman hearings on claim construction are rare. Generally, the Court has concluded that the splitting of issues tends to prolong, rather than facilitate early determination of, IP cases.

In patent cases, reliance on expert evidence to determine most issues is further considered to make such issues unsuitable for determination without oral evidence, and multiple hearings involving oral evidence are undesirable for many reasons.

In this case, the fact that the case was already well advanced also counted against Aliwood, even though it was the filed evidence which Aliwood relied upon as establishing the basis for summary judgment.

As a general rule, summary judgment applications are unlikely to succeed in patent cases, but in any event, should be made as soon as possible during proceedings to maximise the potential time and cost savings.

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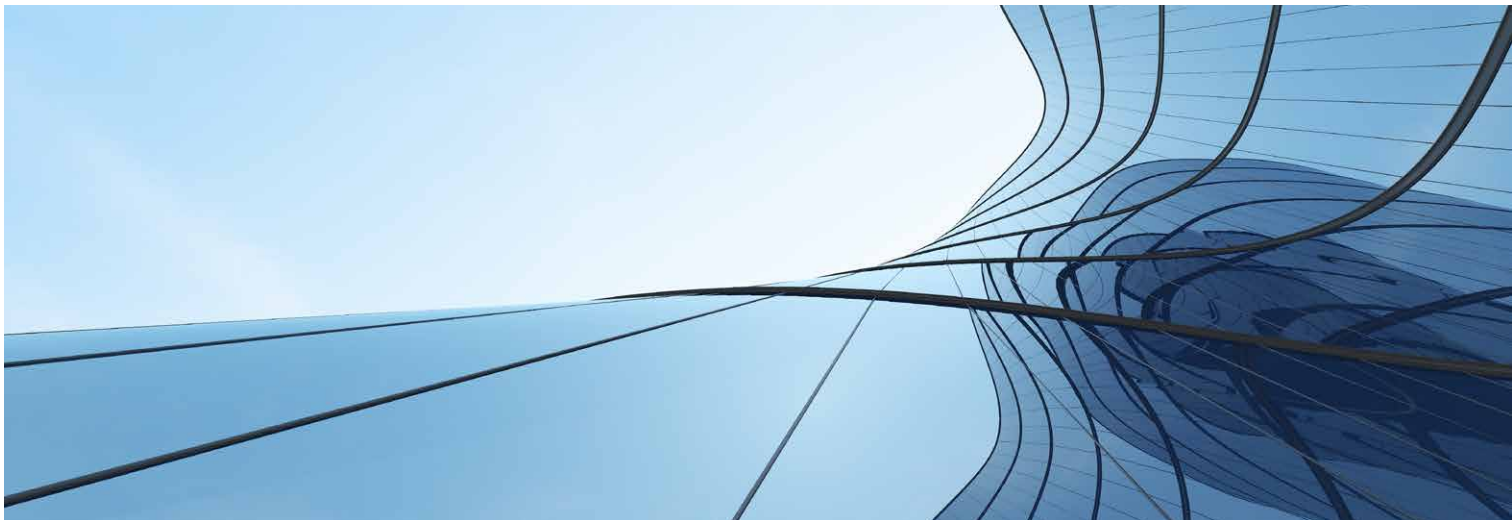

Taking a position on patent infringement: position statements where multiple products accused

***Surefoot IP Holdings Pty Ltd v All Footings Solutions Pty Ltd* [2021] FCA 1181**

Date: 30 September 2021
Court: Federal Court of Australia
Judge: Rofe J

Background

The patentee (**Surefoot**) alleged that seven of the respondents' (**All Footings**) products infringe Australian Patent 2012276281 (**Patent**), which relates to 'footing plates' to be placed at the base of posts, poles or upright beams to secure them in position. All Footings' seven impugned footing plates differ in their features, most significantly in that six of the footing plates are square and one is circular.

Key Issues

At the first directions hearing, Surefoot was ordered to serve particulars of infringement. It subsequently filed a position statement on infringement (**PSI**). PSIs are described in the Federal Court Intellectual Property Practice Note, and are intended to concisely state the facts and matters relied upon in support of infringement allegations, including by reference to the particular integers of any claim alleged to have been infringed. In this case, Surefoot's PSI addressed one of All Footings' products by way of example, only briefly addressing relevant differences between it and the other six products.

All Footings disputed the adequacy of the PSI, submitting that the PSI should address each footing plate individually to indicate how differences between the products were relevant to the integers of the claims. They further submitted that it was unclear from the PSI how three of the integers of the claims were satisfied by the exemplified product; in simple terms, how one part of the product "originated" from another part, how one part of the product was connected to and supported another part, and how one part of the product was "offset" from another part. All Footings therefore sought amendment of the PSI.

Surefoot submitted that All Footings were fully informed of the infringement case based on the PSI and that each of the alleged deficiencies in the PSI resulted from the parties' differing views on construction, which would be resolved at trial.

Outcome

Regarding All Footings' first submission, Rofe J held that, insofar as the six square footing plates were concerned, it was sufficient to use an example footing plate as the basis for identifying the features said to correspond to the claim integers. However, it was not sufficient in the case of the seventh, circular footing plate. This was because several of the claim integers referred to "edges" (plural), and there was room

"Position statements on infringement are a useful mechanism to clarify a patentee's construction of its claims and its basis for alleging infringement. Where multiple products are impugned, material differences between the products should be addressed in the PSI."

for confusion as to how Surefoot construed these integers to read onto the product features. Surefoot was ordered to amend its PSI to address the circular footing plate specifically.

As to All Footings' second submission, Rofe J applied established case law that the purpose of a PSI is to clarify the patentee's construction of the integers of each asserted claim, not to justify or explain that construction. In each case, Surefoot's construction of the relevant integer was clear from the PSI. All Footings were seeking an explanation or justification of that construction, which is a matter for trial. Surefoot was not required to amend its PSI to include such explanation or justification.

Implications

The judgment provides useful clarification on the use of a PSI and the level of detail required on points of construction. In the case of multiple allegedly infringing products, the PSI must adequately cover all features of each product to the extent that they materially differ from each other, but examples can be used where there are no such differences.

The judgment also highlights in a more general sense the utility of a PSI to force the patentee to adopt a specific construction of its claims and infringement position early on. By insisting that this is done precisely, a respondent can not only determine its response on infringement but also seek to prevent 'slippage' in construction arguments, particularly as an invalidity case takes shape.

Which Product Infringes? Kangatech Ordered to File Evidence Consistent with Pleadings Despite Later Workaround

***Vald Performance Pty Ltd v Kangatech Pty Ltd* [2021] FCA 539**

***Vald Performance Pty Ltd v Kangatech Pty Ltd (No 3)* [2021] FCA 1265**

Date: 20 May / 18th October 2021
Court: Federal Court of Australia
Judge: Greenwood J

Background

Australian Patent 2012388708 (**Patent**) relates to a device and its use in sports injury prevention and management, specifically by assessing a person's knee flexor muscle strength while that person performs certain movements of the legs and torso.

Vald Performance Pty Ltd (**Vald**) issued proceedings in July 2019 asserting that Kangatech Pty Ltd (**Kangatech**) had, and continued to, import, sell and otherwise exploit an infringing device (**Version 1**).

Kangatech denied infringement in respect of Version 1, but also claimed that since around December 2018 it had made several changes to its device, launching a new product (**Version 2**). In an Amended Defence filed in February 2020 it pleaded that as of July 2019 it had permanently disabled all but two units of Version 1. The basis for its denial of infringement (i.e. claimed features not present) in respect of Version 2 differed from that put forward in its original Defence in respect of Version 1.

In December 2020 Kangatech notified Vald that it had further modified Version 2 by installing controlling software that prevented it from performing certain functions (**modified Version 2**). It is unclear when these changes were made and how timely Kangatech's communication was. Importantly though, the communication occurred after the Amended Defence was filed and after Vald had filed its evidence in chief on infringement. The communication purported to rely on new bases of non-infringement in respect of modified Version 2, in addition to those pleaded by Kangatech in respect of both Version 1 and Version 2.

Key Issues

Kangatech asserted that Vald had failed to identify in its pleadings how each integer of the relevant claims of the Patent was present in each of the various versions of the Kangatech products. However Kangatech's Amended Defence had set out very specific bases for denying infringement on the basis of the absence of certain claim integers in Version 1 and Version 2, and Vald had filed its evidence on that basis. Vald also asserted that it did not have sufficient information to

"Implementing a workaround to a patent after infringement proceedings have commenced can leave the respondent without certainty as to whether the workaround is non-infringing."

assess modified Version 2, and to determine whether the software modifications in modified Version 2 were permanent, or could be reversed.

At a directions hearing in May 2021, Greenwood J canvassed these issues and ordered that Kangatech provide further details of the software changes incorporated in modified Version 2, and make that product available for examination by Vald.

In October 2021 the matter returned before the Court, and Kangatech maintained its position that Vald should plead each integer of the claims said to be infringed, after which Kangatech would respond to this pleading. Vald argued that Kangatech had denied infringement in its pleadings on a very specific basis and Vald had filed its evidence on infringement on the basis of those pleadings, so it should not now be required to re-plead.

Notably the Amended Defence did not refer to the software changes in modified Version 2. As the pleadings stood therefore, the question of whether modified Version 2 infringed the Patent was not in issue. Kangatech's position apparently sought to require Vald to put in issue infringement by modified Version 2.

Outcome

Greenwood J held that the proper course was for Kangatech to put on its evidence in the case in accordance with its Amended Defence, rather than the case being re-pleaded from scratch.

Implications

It appears that the likely effect of the orders made is that the case will be confined to Version 2 (pre-modification) and Version 1, and therefore no findings will be made as to whether modified Version 2 infringes the Patent. If Vald is successful in establishing infringement of the earlier versions, and a general injunction is granted as a consequence (i.e. an injunction prohibiting Kangatech in general terms from infringing the Patent), this will leave Kangatech in a difficult position: the Court will not decide in this case whether Kangatech's modified Version 2 product infringes the Patent, and Kangatech will be at risk of a finding of contempt of Court for breach of the injunction if it continues to sell modified Version 2 and that product is later found to infringe.

This procedural decision therefore highlights the careful consideration required when implementing a 'workaround' to avoid patent infringement once infringement proceedings are brought. Here Kangatech may have been better to apply to the Court to further amend its defence, although such an application is at the discretion of the Court and delay in applying, and the impact on the Court schedule, will be relevant considerations in relation to such an application.

Pfizer quest for Samsung Bioepis etanercept documents continues

***Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd (No 3)* [2021] FCA 1428**

Date: 18 November 2021
Court: Federal Court of Australia
Judge: Burley J

Background

In December 2016 Pfizer Ireland Pharmaceuticals (**Pfizer**) filed a preliminary discovery application against Samsung Bioepis AU Pty Ltd (**SBA**). The Full Court ultimately overturned Burley J's initial refusal of the application, allowing Pfizer access to SBA's confidential manufacturing information to ascertain whether SBA's products would infringe any of its three relevant patents. The exact scope of the discovery to be provided was the subject of further dispute, and discovery orders were not made until May 2019. Those orders expressly contemplated Pfizer making a further request for documents, if the documents discovered were insufficient to allow it to determine whether to commence patent infringement proceedings. In September 2020 Pfizer filed a further preliminary discovery application accordingly, and that application was the subject of this judgment.

Key Issues

In support of its new application, Pfizer put on evidence from its solicitor setting out various matters "on information and belief" from an independent expert engaged by Pfizer who had reviewed the discovery documents already provided. Pfizer's senior corporate counsel also gave evidence that, on the basis of a report provided to him by the independent expert, he believed that Pfizer did not have sufficient information to assess the patent infringement case and the potential costs and risks of the litigation. SBA's responding expert evidence was to the effect that the documents already discovered contained sufficient information to determine whether its process fell within the scope of the relevant patent claims.

In addition to seeking additional discovery from SBA, Pfizer:

- argued that there was an obligation of continuing discovery under the existing orders. Such an obligation arises in the course of standard discovery and requires the party subject to discovery to discover additional documents falling within relevant categories which are created or come into the party's possession after the date at which discovery is given. Pfizer argued that this duty applied in this case to capture documents relating to further batches of the relevant products produced after the original discovery was given;
- sought *Sabre* orders, so named after the *Sabre Corporation case*[1] in which the Court held that it had

"While Pfizer was successful in some of its efforts for further preliminary discovery, firm limits were placed on this exercise."

power to order a party to take steps to access and discover documents in the power or possession of another party, where there is a real likelihood that the first party would be given access to the documents. Such orders may be appropriate, for example, where documents are in the possession of another company within a corporate group which is not party to the litigation. Here, Pfizer sought an order that SBA seek documents from four other parties involved in the manufacture of SBA's Brenzys® products - SBA's parent company, Samsung Bioepis Co Ltd, Biogen MA Inc, and two companies within the Fujifilm group. SBA agreed to seek documents within the relevant categories from its parent company but resisted an order requiring it to seek the documents from the other companies.

Outcome

In line with the Full Court's decision in the first discovery application, Burley J accepted that it was sufficient that Pfizer's expert provide a reasonable basis for contending the relevance of the additional documents sought, notwithstanding that such relevance could ultimately be disproven. This requirement was satisfied in respect of some categories of documents. In other cases, he considered that the documents were not necessary, noting that it was not legitimate to seek documents in preliminary discovery "for additional comfort".

Burley J further rejected any duty of ongoing discovery in respect of preliminary discovery orders, noting the much more confined purpose of preliminary discovery. He held that no such continuing obligation arises unless expressly required in the orders, noting that such orders "would not be lightly made".

As to the *Sabre* orders sought, while Burley J accepted that the Court had power to make a *Sabre* order in the context of preliminary discovery, he refused to do so in this case. Noting again the distinction between preliminary discovery and standard discovery which "*serves to demonstrate that the Court would be slow to accept that mechanisms developed to aid discovery processes should be automatically be applied where there have been no pleadings and proceedings proper have not been commenced*", he was not persuaded that such orders were appropriate.

Implications

Burley J's application of the Full Court's test for preliminary discovery is perhaps uncontroversial. Of interest is the limited approach that he took to any duty of ongoing discovery and the availability of *Sabre* orders in the context of preliminary discovery, given that a claim that the applicant's legal rights have been infringed has necessarily not even been commenced in that context.

1. (1993) 46 FCR 428

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Correspondence lost to spam filter justifies extension of time

***QIP Nominees Pty Ltd v Delinia, Inc.* [2021] APO 24**

Date: 22 June 2021
Forum: Australian Patent Office
Delegate: Xavier Gisz

Background

As part of the *Raising the Bar* amendments introduced to the *Patents Act 1990* (Cth) in 2013, rigorous new requirements for extension of time applications in patent oppositions were brought in to expedite the (often protracted) proceedings.

The new requirements mandate that the Commissioner must be satisfied that (a) the requester made all reasonable efforts to comply with all relevant filing requirements and was unable to meet the evidence deadlines despite acting promptly and diligently at all times, or (b) there were exceptional circumstances that warranted the extension. Exceptional circumstances *include* a circumstance beyond the control of the party that prevents it carrying out the relevant act and certain other circumstances.

Since this new standard has been introduced, decisions from the Patent Office have indicated that satisfying the Commissioner that an extension should be granted is onerous. Difficulties identifying and/or engaging an appropriate expert and intervening holidays and competing priorities of either the expert or attorneys are generally not persuasive, as the Patent Office appears to expect parties in oppositions to have contingency plans to address these issues as they arise.

Key Issues

During opposition proceedings between the applicant, Delinia, Inc (**Delinia**), and the opponent, QIP Nominees (**QIP**), Delinia filed a request for an extension of time to serve evidence in answer. The extension request was based on the fact that email correspondence relating to the opposition from the Australian attorneys to Delinia's instructing US attorneys had been intercepted and destroyed by the US attorneys' spam filter. Accordingly, the US attorneys were unaware of the Notice of Opposition, the subsequent filing of the Statement of Grounds and Particulars, and the evidence in support filed by QIP, until one month before the deadline for filing of the evidence in answer. Indeed, the opposition had progressed for more than 8 months by the time a reminder email fortuitously made it through the US attorneys' spam filter, alerting the US attorneys and Delinia to the existence of the proceedings.

Initially, the request was refused by the Patent Office. While it could be accepted that the communication failure was unintended, in view of the Australian

"An attorney's failure to follow up unacknowledged emails to their client in order to obtain instructions is not necessarily fatal to an extension of time application."

attorneys' failure to follow up on the very important, unacknowledged emails, the Patent Office was not convinced that the "promptly and diligently" requirement had been met, nor that there were exceptional circumstances, since the email security issues were within the control of Delinia and those acting on its behalf. The Patent Office considered that "*the failure to do so, especially over an extended period of time and in view of the strict deadlines in opposition matters, is quite remarkable and failing to follow up on the lack of response does not appear to be commensurate with acting reasonably or promptly and diligently*". The Patent Office also questioned the actions of the US attorneys and Delinia for failing to enquire about the grant of the patent, and even queried whether the spam filter had been subjected to appropriate checks to ensure it was not intercepting legitimate emails.

Delinia requested a hearing, arguing that the initial refusal was based on the Senior Examiner's concept of a "counsel of perfection" formed in hindsight, and that it was reasonable to assume the emails had been safely received by the intended recipient.

Outcome

While noting that it could be envisaged that the circumstances could have been avoided with a follow up phone call, the Delegate considered that such speculation was beyond the realm of what was reasonably beyond the control of the parties. He concluded that the emails not being received (with no indication that the email was not delivered) was beyond the control of both the Australian attorneys and the US attorneys. Accordingly the circumstances were exceptional, and the extension of time was granted.

Implications

The Patent Office's recognition that, in a modern day patent practice, unexpected difficulties may arise, and in particular that there are practical limits to what can be considered to be "acting promptly and diligently at all times" will come as welcome news to Australian patent attorneys and their overseas instructors.

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Legislation and Policy Updates

Legislation and Regulation Amendments

In August 2021 the *Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2020* came into force. Crucially, the amendments contained in it triggered the phasing-out of innovation patents in Australia. Current innovation patents filed on or before 25 August 2021 will continue in force until their expiry, however applications for innovation patents will no longer be accepted.

The only change to the Patent Regulations 1991 coming into effect in 2021 was the *Intellectual Property Laws Amendment (Fee Amounts and Other Measures) Regulations 2020*.

Transparency Measures

In October 2020, the proposed Therapeutic Goods Agency "transparency notification regime" was scheduled for legislative implementation in early 2021. Under the new regime the first applicant to list a generic/biosimilar product on the Australian Register of Therapeutic Goods would be required to give notice of such application to the sponsor of the reference product. However the required legislative amendments have not yet been introduced to Parliament and no further timetable for such measures has been announced.

Federal Budget 2021

On 11 May 2021, the Federal Treasurer Josh Frydenberg announced that the 2021-2022 Australian Federal Budget would introduce a "Patent Box" tax incentive. This regime was designed to encourage domestic research and development and otherwise promote innovation in Australia, by providing for a lower tax rate on income from the commercialisation of patented technology. Whilst the proposal is a promising sign that the Australian Government is continuing to explore ways to increase domestic innovation, given the significantly greater tax breaks offered overseas, we do not foresee any significant change in local R&D investment to follow.

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