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Best Patent Cases 2020 Australia and New Zealand

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Dear Reader

Welcome to Shelston IP's wrap-up of the most notable patent law decisions in Australia and New Zealand delivered during 2020.

- The High Court of Australia has endorsed the doctrine of exhaustion, but made clear the critical question remains whether the modifications made to a product in each case are properly characterised as permissible repair or impermissible re-making (***Calidad v Seiko Epson***).
- An enlarged Full Federal Court has confirmed that a protocol for a clinical trial can be novelty-defeating. The Full Court has also provided important guidance on the nature and scope of Swiss-style claims (***Mylan v Sun***).
- The Full Federal Court has found that a computer-implemented method that linked website users to online advertising was not patentable subject matter (***Commissioner of Patents v Rokt***). In separate decisions, a computer-implemented method relating to "sandboxing" (***Facebook***) and an invention relating to the hardware and software components of an electronic gaming machine (***Aristocrat v Commissioner of Patents***) were held to be patent-eligible, while a modified roulette table was found not to be (***Crown***).
- The Full Federal Court has confirmed that section 105(1A) of the *Patents Act 1990* (Cth), confers on the Federal Court the power to direct amendments to patent applications during the course of an opposition appeal hearing (***Meat and Livestock Australia v Branhaven***).
- In the long-running patent dispute relating to Lundbeck's antidepressant, Lexapro (escitalopram), the Full Court of the Federal Court overturned a decision that had found Sandoz liable for patent infringement during the extended term of a patent after it was restored, and awarded damages (***Sandoz v Lundbeck***).
- The Federal Court provided its first detailed analysis of the Raising the Bar reforms to Australian patent law concerning sufficiency and support. A subsequent judgment on final relief highlights the challenges facing a defendant who seeks to resist final injunctive relief on public interest grounds (***Merck Sharp & Dohme v Wyeth***). Those sufficiency and support requirements, as well as best method, were also considered in detail by the Australian Patent Office (***University of British Columbia, Gliknik v CSL***).
- In an unprecedented decision, the Federal Court of Australia has considered and dismissed a claim by the Commonwealth Government for compensation from sponsors of innovator pharmaceutical products, pursuant to undertakings as to damages given in exchange for an interlocutory (preliminary) injunction restraining the launch of the first generic product (***Commonwealth v Sanofi***).
- A party which gave undertakings not to launch an allegedly infringing biosimilar without first giving notice successfully resisted an application for preliminary discovery (***Pfizer v Sandoz***). Conversely preliminary discovery was granted against a former employee, but limited in scope due to financial circumstances (***Sovereign v Steynberg***).
- Extension of term applications were refused for pharmaceutical patents (***Pharma Mar, Ono***).
- An opposition to an Australian patent application based solely on a challenge to entitlement was successful (***Liquid Time v Smartpak***).
- The Federal Court considered the applicability of the Crown use defence to infringement, and the effect of prior disclosures by the Crown on validity (***Axent v Compusign***).
- The nature and detail of disclosures in prior art and the common general knowledge proved determinative of the validity in decisions concerning a combination pharmaceutical product (***Boehringer v Intervet***) and a parking management system (***Vehicle Monitoring Systems v SARB***).
- The construction of claims in the context of the entire specification proved determinative of infringement and validity in several oppositions (***Caffitaly v One Collective***, ***Nufarm v Dow***, ***CQMS v ESCO***).
- The Intellectual Property Office of New Zealand has delivered decisions demonstrating the difficulty of opposing an application under the "old" 1953 Act (***Lonza v Koppers***), the high burden for computer-implemented methods (***Thomson Reuters***) and the more onerous support requirements under the "new" 2013 Act (***Taiho Pharmaceutical***).

Please do not hesitate to take the opportunity to contact our authors, all subject-matter experts in their respective fields, for advice on the issues raised by these important decisions.

Editors

Duncan Longstaff (Principal, Lawyer)

Dr Roshan Evans (Lawyer)

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High Court endorses doctrine of exhaustion

***Calidad Pty Ltd and Others v Seiko Epson Corporation and Another* [2020] HCA 41 (12 November 2020)**

Read the Decision

Judges: Kiefel CJ, Bell, Gageler, Keane, Nettle, Gordon and Edelman JJ (in the High Court); Greenwood, Jagot, Yates JJ (in the Full Court); Burley J (at first instance)

| *mechanical* | *infringement* | *doctrine of exhaustion* |

Authors

Dr Roshan Evans
(Lawyer)

Duncan Longstaff
(Principal, Lawyer)

In brief

A majority of the High Court of Australia has endorsed the "exhaustion of rights" doctrine in preference to the "implied licence" doctrine, which has applied in Australia and the United Kingdom for over a century. In doing so, the High Court has indicated that a patentee's monopoly rights to a patented product are exhausted upon sale of the article, consistent with the approach taken in the United States and the European Union, and thereby limiting a patentee's ability to restrict post-market refurbishment or modification of patented articles. The decision should bring greater certainty to Australian patent law in relation to the boundaries of permissible repair, modification and refurbishment of patent products post-sale, which will be reflected only in contractual terms attending the sale of the patented article and not in any residual patent rights. However, it is important to recognise that the decision in this case, and the reasons of the majority and minority, turned entirely on the specific facts regarding whether the modifications in question constituted "repairing" (permissible) or "re-making" (impermissible) the patented article. Future cases will similarly turn on their own specific facts.

Background

Seiko Epson (**Seiko**) manufactures and sells Epson branded printer cartridges. These cartridges embody inventions claimed in two patents, of which Seiko is the registered owner. The Epson cartridges are designed as a single-use consumable product, and are intended to be discarded and replaced once the cartridge is spent. To restrict them to being single-use, the cartridges contain a memory chip programmed to recognise when the ink has been consumed, bringing the useful life of the cartridge to an end. Each cartridge is also configured to interface with only certain Epson printers.

After initial sale of the original Epson printer cartridges, a third party modified and refilled the used cartridges to enable them to be resold. Calidad acquired the refurbished printer cartridges and imported them into, and sold the cartridges within, Australia. No contractual conditions restricting the use of the cartridges were imposed at the point of sale.

Seiko alleged that Calidad had infringed its rights as patentee by importing and selling the refurbished cartridges, in competition with its original Epson cartridges. Calidad at first instance and in the Full Court argued, *inter alia*, that it had the benefit of an implied licence arising upon the sale of the cartridges, permitting the purchaser and subsequent owners to freely deal with the cartridges, including for the purposes of repair and modification.

The proceedings at first instance and in the Full Court were conducted on the basis that the implied licence doctrine, as applied by the Privy Council (on appeal from the High Court of Australia) in *National Phonograph Company of Australia Ltd v Menck* (1911) 12 CLR 15 (***Menck***), was the applicable law. However, in the Full Court Calidad reserved the right to argue on any appeal to the High Court that the doctrine of patent exhaustion was the correct approach to be taken in Australia.

At First Instance

At first instance, Burley J held that Calidad infringed the Seiko patents in relation to five of the nine categories of refurbished cartridges, where memory chips were replaced or the interface pattern had been altered. As we explained in our previous article on the first instance decision in *Seiko Epson Corporation v Calidad Pty Ltd* [2017] FCA 1403, available ***here***, Burley J's analysis turned on whether the implied licence, which was taken to have arisen validly and was terminated by the modifications carried out by the third party. This was to be determined, on his Honour's analysis, by whether the product was "materially altered" by the modifications.

Full Court Appeal

On appeal, the Full Court of the Federal Court (Greenwood, Jagot and Yates JJ, each in separate judgments) found entirely in favour of Seiko, extending the findings on infringement to all nine categories of refurbished printer cartridges. As we explained in our previous article on the Full Court decision in *Calidad Pty Ltd v Seiko Epson Corporation* [2019] FCAFC 115, available ***here***, each of the Full Court judges were of the view that the modifications brought into existence a new article, which could only be properly characterised as an impermissible "making" of the patented product, and unequivocally outside any implied licence.

Decision

The High Court of Australia, by a 4:3 majority (Kiefel CJ, Bell and Keane JJ, with Gageler J agreeing in a separate judgment; Nettle, Gordon and Edelman JJ dissenting) overturned the Full Federal Court's decision on infringement, finding that none of the refilled cartridges infringed Seiko's patents. The majority also expressly endorsed the doctrine that a patentee's rights with respect to a patented product will be exhausted at the first point of first sale – although this did not affect the outcome of the case as all parties and judges acknowledged the outcome in this case turned on the same question of fact under either the exhaustion or implied licence approach.

Exhaustion of rights rather than implied licence

The sale of a patented article gives rise to a conflict between a patentee's exclusive right to "exploit" the patented invention under the *Patent Act 1990* (Cth) (which includes the right to use and resell the product), and the rights of property ownership in a physical chattel at common law. Two contrasting approaches have developed to reconcile this tension between patent rights and the fundamental law of personal property, namely the doctrine of "patent exhaustion" (endorsed by the US Supreme Court in *Impression Products v Lexmark* (2017) 581 U.S. 1523), and the notion of an "implied licence" (adopted in the UK and Australia, most notably in the Privy Council decision in *Menck*).

Under the doctrine of exhaustion, upon the first authorised sale of a product by or with the consent of a patentee, all patent rights in the invention are exhausted with respect to the particular product sold. By contrast, the implied licence doctrine provides a legal fiction whereby the sale of a patented product confers on the purchaser a licence to use and resell that product without infringing the patent, subject to any conditions imposed by the patentee and brought to the purchaser's attention at the time of sale.

In endorsing the doctrine of exhaustion, the majority of the High Court observed that the doctrine of implied licences was complicated in its operation and inconsistent with the certainty demanded by trade and commerce and by consumers. Further, the maintenance of patent rights with respect of a product after sale was not conducive to the free flow of goods within a market. In this regard, the High Court observed that:

> *The exhaustion doctrine has the virtues of logic, simplicity and coherence with legal principle. It is comprehensible and consistent with the fundamental principle of the common law respecting chattels and an owner's rights respecting their use. At the same time, it does not prevent a patentee from imposing restrictions and conditions as to the use of a patented product after its sale but simply requires that they be obtained by negotiation in the usual way and enforced according to the law of contract or in equity. (at [76])*

While representing a significant departure from longstanding UK and Australian jurisprudence, the decision is consistent with the more pragmatic approach taken by courts in the United States and the European Union.

A new embodiment?

On the critical factual question upon which the question of infringement depended, the High Court reasoned that the right to make a new embodiment of a patented product is a separate and distinct right from the right to use or to sell the product, and therefore neither doctrine (implied licence, nor

patent exhaustion) has any part to play in the analysis of whether infringement has occurred. The majority observed that:

> *To establish infringement by making a new embodiment of the invention it is of course necessary for Seiko to show that the new product takes each of its essential features by reference to the description of the invention. (at [46])*

The majority found that Seiko's intention for the printer cartridges to be single-use only was not determinative of infringement. Infringement should be determined, as always, by reference to whether the new product takes each of the essential features or integers of the invention as claimed. On this occasion, the refilling of the original Epson printer cartridges with ink, reprogramming of memory chips and the removal of the interface patterns did not constitute the making of a new embodiment of the Seiko patents in suit – once the modifications were completed, what remained was the original Epson cartridges with some changes which enabled their reuse.

The majority decision provides little guidance on what forms of modifications will generally constitute "making" of a new embodiment of the invention and what forms of modifications will instead constitute permissible "repairs" (subject any applicable contractual terms). While in some ways disappointing, this is not surprising, given the Court's emphasis that the focus must always be on the specific facts of the patent claims and allegedly infringing products in issue.

Significance

For the first time, the High Court of Australia has endorsed the doctrine that a patentee's monopoly rights in a patented product are exhausted upon sale of the product. However, the significance of this aspect of the High Court's decision remains unclear given both the majority and minority judges acknowledged they did not strictly need to decide between the exhaustion and implied licence doctrines to decide patent infringement in this case.

A practical consequence of this decision is that patentees/Original Product Manufacturers must now rely on contractual provisions to impose conditions or restriction on the use of their patented products, giving them rights and remedies in contract (and equity) against a purchaser.

For remanufacturers, the question of whether modifications made to a patented product amount to the "making" a new embodiment of the invention must be determined by reference to each of the essential integers of the claims, and not the features of the original patented product.

Clinical trial protocols anticipate method of treatment claims, and further clarity provided on construction of Swiss-style claims

***Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd* [2020] FCAFC 116 (3 July 2020)**

Read the Decision

Judges: Middleton, Jagot, Yates, Beach and Moshinsky JJ (expanded Full Federal Court); Nicholas J (at first instance)

| pharmaceutical | novelty | inventive step | clinical trial protocols | Swiss-style claims |

Authors

Duncan Longstaff
(Principal, Lawyer)

Michael Christie PhD
(Principal, Patent Attorney)

In brief

An enlarged Full Federal Court has confirmed that a protocol for a clinical trial that is publicly available can be novelty defeating, provided the information disclosed is sufficiently specific and complete to disclose the invention that is later claimed. The Full Court has also provided important guidance on the nature and scope of Swiss-style claims, and the circumstances under which such claims may be infringed.

Background

The case concerned three patents relevant to Mylan's oral lipid-lowering agent, LIPIDIL (fenofibrate). An enlarged Full Court bench comprising 5 judges was appointed to hear and decide Mylan's appeal. This was because Mylan sought to clarify the Full Court's previous statement in *Merck & Co Inc v Arrow Pharmaceuticals Ltd* [2006] FCAFC 91; 154 FCR 31 that the characterisation of an alleged anticipation as a "suggestion" in relation to the invention, is "not necessarily fatal to a novelty argument". Mylan submitted this statement by the Full Court did not countenance "mere speculation" or "the presentation of no more than a reasoned hypothesis" as an anticipatory disclosure. On this basis, Mylan submitted to the Full Court (unsuccessfully, as explained below) that the trial judge had erred in finding that a hypothesis stated in a prior art document relating to a clinical study deprived methods of treatment claims of novelty.

The Full Court's decision also provides important guidance in relation to the approach taken by Australian courts in considering obviousness, the construction and infringement of Swiss-style claims under Australian patent law and the extent to which consistory clauses alone can provide fair basis for a claim.

Decision

Method of treatment and Swiss-Style claims lack novelty in light of clinical trial protocol

The Full Court considered whether method of treatment and Swiss-style claims could be anticipated by prior art comprising a protocol for a clinical trial of the claimed method. Mylan argued that such a protocol could not be novelty-defeating, because at most it identified a hypothesis that required testing, and could not be understood as teaching or recommending that the claimed method be put to clinical use. The Full Court rejected that analysis and upheld the trial judge's finding that Mylan's method of treatment and Swiss-style claims lacked novelty.

The Full Court held that, in assessing novelty, the key question is whether the information disclosed in the prior art is sufficiently specific and complete

to be equal to the invention that is later claimed. If so, then even a protocol for a trial to test the claimed method could be novelty-defeating. The Full Court acknowledged that, in this respect, Australia's law on novelty differs from the law applied by UK courts in cases such as *Regeneron Pharmaceuticals Inc v Genentech Inc* [2012] EWHC 657 (Pat) and *Hospira UK Limited v Genentech Inc* [2015] EWHC 1796 (Pat), which hold that the prior art must disclose actual achievement of the relevant therapeutic effect to be novelty-defeating.

This aspect of the Full Court's decision arguably fails to give due consideration to the proper meaning and importance of words such as "treat" and "prevent" in method of treatment and Swiss-style claims. As Mylan contended, at the stage of disclosing the protocol for a clinical trial, it is not known whether the product or method under consideration does in fact "treat" or "prevent" the particular condition or illness of interest, and there is a significant prospect that it will later prove ineffective or unsafe. The approach of the Full Court and the primary judge makes clear that the nature and extent of the prior-published clinical trial protocol or other document will be critical in each case. Those case-specific factual issues will be especially important in future cases, as it would seem a harsh outcome for patentees for statements of unproven hypotheses, theories, ideas or suggestions to anticipate and invalidate (for lack of novelty, putting aside considerations of obviousness which depend on the common general knowledge and availability of prior art) claims to a method that the patentee has subsequently proven effective and safe in "treating" or "preventing" the particular condition or illness.

Obviousness of formulation and method of treatment claims

Australian Courts generally assess obviousness by asking whether, before the priority date, a skilled person presented with the same problem as the patent owner would have been "directly led to try the claimed subject matter with a reasonable expectation of success" (referred to as the "modified Cripps question"). Historically, that test has been applied in a strict manner by Australian courts, leading a number of patents to be upheld in Australia that have been invalidated on obviousness grounds in other jurisdictions. Recently, however, Australian courts have adopted a more flexible interpretation of the Cripps test, and this case continues that trend. The trial judge held two of Mylan's patents (one relating to nanoparticulate formulations of fenofibrate, the other relating to methods of preventing or treating retinal damage associated with diabetes by administering fenofibrate) invalid on obviousness grounds, and the Full Court upheld those findings.

The following aspects of the Court's obviousness analysis are notable:

- Mylan's patent for a nanoparticle formulation of fenofibrate included claims which required the use of specified surface stablisers. The trial judge did not find that the skilled person would have been directly led to select those specific stabilisers with an expectation that they would be effective. Rather, he found that the claimed stabilisers were logical to try and that routine, trial-and-error testing would have demonstrated their suitability. The Full Court agreed this was sufficient to support an obviousness finding.
- In relation to Mylan's method of treatment patent, an expert gave evidence that, before the priority date, his expectation of success with the claimed method would have been less than 50%. The trial judge held that evidence was not inconsistent with a finding of obviousness, because the Cripps test does not require a numerical assessment. Again, the Full Court agreed with that analysis.

Defining the scope of Swiss-style claims

The claims asserted by Mylan included Swiss-style claims. Swiss-style claims are typically drafted in the form "Use of [active ingredient] in the manufacture of a medicament for the treatment of [disease or disorder]". They came about from the need to satisfy particular requirements for patentability which formerly applied under the European Patent Convention. Although these requirements do not exist in Australia, Swiss-style claims are routinely included in Australian patents as their scope is different from that of method of treatment claims, which are also permitted under Australian law. The Full Court in *Mylan* examined the interpretation of Mylan's Swiss-style claims, having regard to the decision of the UK Supreme Court in *Generics (UK) v Warner-Lambert* [2018] RPC 2, and provided guidance on determining the scope of such claims under Australian law.

One of the Swiss-style claims asserted by Mylan recites:

> *Use of fenofibrate or a derivative thereof for the manufacture of a medicament for the prevention and/or treatment of retinopathy, in particular diabetic retinopathy.*

The Full Court confirmed that the claim, if valid, conferred a monopoly in respect of the method or process of making the medicament, and that the

method or process is complete upon manufacture. The monopoly did not extend to a method of treatment – that being the province of method of treatment claims. The Full Court also confirmed that Swiss-style claims are purpose-limited in the sense that the medicament resulting from the method or process is characterised by the therapeutic purpose for which it is manufactured, as specified in the claim.

In the first instance decision, the primary judge said that thee crucial question concerning the infringement of a Swiss-style claim was whether the manufacturer had made or will make the medicament with the *intention* that it be used in the treatment of the designated condition. On this basis, to prove infringement of a Swiss-style claim, it would not be enough to show that it was "reasonably foreseeable" that a generic product would be put to the use referred to in those claims (although foreseeability could be relevant in the overall analysis). The trial judge held that, to prove infringement of Swiss-type claims, it would be necessary to show that the generic intended that its product be put to the use referred to in the Swiss-style claims.

The Full Court disagreed with this approach, instead finding that infringement of a Swiss-style claim is concerned with what the allegedly infringing manufacturer has done, not what it intended to do. That is, not what a generic manufacturer *intended*, but what the generic product is for. According to the Full Court, a single factual question arises when considering infringement: as the product of the claimed method or process, is the medicament for the specified therapeutic purpose? The question, the Full Court said, is answered having regard to "all the circumstances of the case", including the physical characteristics of the medicament as it emerges as a product of the manufacturing process (its formulation and dosage, packaging and labelling, and its patient information) and evidence of the manufacturer's actual intention in making the medicament, where such evidence is available. Both factors are relevant considerations, but neither is determinative. On the facts of this case (which included "skinny labelling" confining the approved indications of the generic product to indications outside the conditions within Mylan's method of treatment claims), the Full Court held that Mylan had not proved that Sun Pharma's fenofibrate products were "for" the second medical use covered by Mylan's Swiss-type claims. The Full Court also gave consideration to the reasonably foreseeable use or uses to which the medicament would be put after manufacture. But while a reasonably foreseeable use may be relevant in deciding the therapeutic purpose of a medicament, it is also not determinative: it might be reasonably foreseeable that a product might be

put to a particular use, but it does not necessarily follow that the product, as manufactured, is for that use. The Full Court agreed with the primary judge that mere suitability of a medicament for a claimed purpose cannot be determinative of the question of infringement of a Swiss-style claim. The fact that the patent has been granted on the basis of a second medical use means that there are multiple uses to which the medicament could be put. Evidence of suitability for use was therefore considered ambiguous and could not alone answer the question whether the medicament, as manufactured, is one for the specified therapeutic purpose.

Ultimately, the Full Court found that the Swiss-style claims, if valid, would not have been infringed by the manufacture of Sun Pharma's competing product. Of particular relevance to the Full Court's decision was the fact that the competing product could be used in a large number of diseases other than retinopathy.

Consistory clauses may not provide fair basis if too broad

Mylan's third patent, relating to an immediate-release micronized formulation of fenofibrate, was found by both the primary judge and the Full Court to be invalid for lack of fair basis. The Full Court endorsed the primary judge's reasoning that the disclosure elsewhere in Mylan's patent specification made clear that the invention was to the immediate release fenofibrate composition and a method for preparing it, whereas Mylan had advanced a construction of a consistory clause and corresponding claims to the effect that the invention extended to any composition of fenofibrate which satisfies the specified dissolution profile. The Full Court affirmed that, as Sun Pharma had submitted, this is "a paradigm example of claims which travel beyond the matter disclosed in the specification", amounting to invalidity for lack of fair basis.

Significance

The Full Federal Court (sitting as an expanded court) has confirmed that a protocol for a clinical trial containing what may be characterised as a "suggestion" may be novelty defeating, provided the information disclosed is sufficiently specific and complete to disclose the invention that is later claimed. This will depend on the nature and extent of the prior art disclosure, and thus will turn on the particular facts of each case.

This decision also confirms that the test for obviousness applied by Australian courts remains more demanding on the party seeking revocation than the approach taken by (for example) the European Patent Office or the UK courts. However this decision continues a trend in Australian patent cases towards a more flexible application of the Cripps question, serving to emphasise the importance of careful preparation of the obviousness defence in close collaboration with inventors and key expert witnesses.

The fair basis test considered in this case still applies to Australian patents for which examination was requested prior to 15 April 2013, when the "Raising the Bar" amendments came into effect. The 'fair basis' requirement is generally considered to be a lower standard for patentees than the 'support' requirement that replaced it from 15 April 2013, which Australian Parliament expressly intended to align more closely with requirements under European law. Therefore, if a consistory clause alone will not necessarily provide fair basis, that risk is likely to be even more significant for more recent patents and pending future patent applications required to meet the higher standard of support (such as an "enabling disclosure").

Finally, the decision validates the importance of including both Swiss-style claims and method of treatment claims when protecting a therapeutic use in Australia. Both types of claim are permitted in Australia, and although their scope is limited to the specified therapeutic use, each will directly capture a different infringer. In particular, Swiss-style claims provide a more direct avenue than method of treatment claims for pursuing manufacturers of competitive pharmaceutical products, rather than the medical practitioners who perform the treatment.

Rokt overturned in Full Federal Court decision on patentable subject matter

***Commissioner of Patents v Rokt Pte Ltd* [2020] FCAFC 86 (21 May 2020)**

Read the Decision

Judges: Rares, Nicholas and Burley JJ (in the Full Court); Robertson J (at first instance)

| *information technology* | *manner of manufacture* | *computer-implemented invention* |

Authors

Alana Gibson
(Associate, Patent Attorney)

Peter Treloar
(Principal, Patent Attorney)

In brief

The Full Court of the Federal Court has overturned the decision of a primary judge, finding that a method that linked website users to online advertising was not a "manner of manufacture" and therefore not patentable subject matter, consistent with the Full Court's decision in *Encompass Corporation Pty Ltd v InfoTrack Pty Ltd* [2019] FCAFC 161 (***Encompass***).

Background

The case involved a patent application entitled "A digital advertising system and method" in the name of tech company, Rokt Pte Ltd. (**Rokt**). The application related to a computer-implemented system and method that linked users to online advertising by presenting an "engagement offer" when a user accessed a website. It provided a context-based advertising system in which users who were more likely to engage with advertising were shown specific offers to increase engagement over traditional methods of digital advertising.

In 2017, an unsuccessful hearing decision issued in which the Delegate of the Commissioner of Patents decided that the application was not patentable on the basis that it was not a "manner of manufacture". In 2018, Rokt successfully appealed the outcome to the Federal Court, which ruled that the application was directed to patentable subject matter. Disagreeing with the Federal Court's judgement, the Commissioner of Patents appealed the Federal Court's decision to the Full Court. The judgement closely followed the guidance of the Full Court's earlier decision in *Encompass*, which we discuss in more detail ***here***.

Decision

The Full Court found that the primary judge erred in his analysis by focusing on the technical problem and solution identified in the specification, without addressing the question of whether the technical solution was actually claimed. The Full Court considered that the primary judge did not engage in any analysis of the central question of whether invention was found to lie in the implementation, or whether it amounted to simply *"an instruction to 'put' the scheme into computer technology."*

The decision emphasised that consideration of the common general knowledge should be used only for construing the specification, and not to provide characterisation or evidence of "'generic software' or the use of computers for their 'well known' purpose." Instead, they defined these terms as a reference to computer technology that is utilised for its basic, typical or well-known functions, rather than referring to common knowledge in the art.

Following the decision of *Encompass*, the Full Court considered the matter of whether the claimed method was implemented using generic software. In *Encompass*, the expanded Full Court observed that the claims of the invention did not define any particular software of programming to carry out the

invention, and so it was left up to those using the method to implement a suitable computer program for the purpose of carrying out the method. Agreeing with this approach, the problem addressed by the present invention was characterised as enhancing consumer engagement levels. The solution was thereby determined to be the provision of an intermediate "engagement offer" targeted to a user interacting with digital content.

In light of these observations, the invention was characterised as "a marketing scheme". This gave rise to a key consideration in assessing patentable subject matter: whether the computer is a mere tool in which the invention is performed, or whether the invention lies in the computerisation.

Following the approach laid out in *Encompass*, the Full Court came to the following conclusion:

> *...in our view nothing about the way that the specification describes the computer hardware or software indicates that either is any more than a vehicle for implementing the scheme, using computers for their ordinary purposes.* (at [109])
>
> *The specification does no more than describe the architecture of the hardware in a most general sense.* (at [110])
>
> *...the claim provides no content to suggest a different conclusion. Despite its length and detail, it contains no integer that serves to characterise the invention by reference to the implementation of the scheme beyond the most general application of computer technology utilised in an online environment.* (at [111])

Although it was determined that the specification represented a solution to problems in marketing, the lack of detailed description suggested that the scheme in which this solution was achieved did not involve the use of computer technology "other than as a vehicle to implement the scheme". In drawing a direct parallel to *Encompass*, the Full Court concluded that the claimed invention amounted to an instruction to carry out a marketing scheme, and that the invention provided no more than a list of steps which may be implemented using computer technology for its well-known functionality.

An application by Rokt for special leave to appeal to the High Court of Australia was dismissed with costs.

Significance

This decision is in line with recent decisions regarding computer-implemented inventions in the patentable subject matter arena, and leaves applicants with the often difficult task of determining whether the inventive concept lies in the idea, or in the implementation.

Full Court confirms the Federal Court's jurisdiction to direct amendments to patent applications on appeal

***Meat and Livestock Australia Ltd v Branhaven LLC* [2020] FCAFC 171 (8 October 2020)**

Read the Decision

Judges: Kenny, Nicholas and Burley JJ (in the Full Federal Court); Beach J (at first instance)

| biotechnology | patent application amendments | Court's power to direct amendments |

Author

Dr Roshan Evans
(Lawyer)

Katrina Crooks
(Principal, Lawyer)

In brief

The Full Court of the Federal Court has confirmed that section 105(1A) of the *Patents Act 1990* (Cth) (**Act**), introduced by the Raising the Bar reforms, confers on the Federal Court the power to direct amendments to patent applications during the course of an appeal hearing. This finding provides a measure of certainty for patentees when considering the strategy to be employed for patent application amendments.

Background

Meat and Livestock Australia Limited (**MLA**) opposed a patent application (**Application**) filed by Branhaven. The Application was directed to the use of genetic markers, known as single nucleotide polymorphisms (or SNPs), in the selective breeding of cattle. In the Patent Office, the opposition failed, other than a finding that claim 13 of the Application suffered "a minor issue of clarity … which can be rectified by amendment".

MLA appealed the decision to the Federal Court, re-agitating all of its unsuccessful grounds raised in the Patent Office. Justice Beach upheld the appeal to the extent that he found that both claims 1 and 13 lacked clarity, but otherwise dismissed the appeal. His Honour's reasons, *Meat & Livestock Australia Ltd v Cargill, Inc* (2018) 354 ALR 95 (**first set of reasons**), noted that these issues of clarity could be rectified by amendment and he indicated that he would not make final orders until Branhaven was given an opportunity to amend the claims of the Application to overcome the deficiencies identified.

MLA applied to make amendments to existing claims, to introduce additional dependent claims, and to delete claim 13.

Subsequently, in a separate judgment, *Meat & Livestock Australia Ltd v Cargill, Inc* (No 2) (2019) 139 IPR 47 (**second set of reasons**), Beach J allowed the amendments proposed by MLA pursuant to section 102 of the Act, and held that the amendments were sufficient to overcome the objections to the impugned claims.

Decision

MLA submitted that the primary judge's decision with respect to both the Court's power under section 105(1A) of the Act to direct a party to amend a patent application, and the allowability of the relevant amendments more generally, were sufficiently doubtful to warrant reconsideration by the Full Court.

Power to consider amendments to a patent application

MLA first appealed to the Full Court on grounds that the Court lacked the power to direct a party to amend a patent application, after it had made findings on the validity of that same application. MLA's submission was that when the Court handed down its first set of reasons, the proceedings effectively came to an end. On MLA's construction of section 105(1A), the provision did not contemplate the making of amendments after reasons finding a claim invalid had been given.

The Full Court dismissed MLA's arguments, finding that neither the publication of his Honour's first set of reasons nor the making of the order requiring the parties to file and serve proposed orders in relation to any application to amend the claims of the Application, had brought the proceedings to an end. The Full Court held that any such position was untenable. No order had been made by the Court to dispose of the proceedings. Rather the Court had made clear that it would not bring the proceedings to an end until such time as the question of any amendment to the Application had been dealt with.

Until the introduction of the Raising the Bar reforms in 2013, the Federal Court did not have the power to direct amendments to a patent application in an appeal brought in respect of a decision of the Commissioner of Patents. Section 105(1A) now provides that:

> *If an appeal is made to the Federal Court against a decision or direction of the Commissioner in relation, the Federal Court may, on the application of the applicant for the patent, by order direct the amendment of the patent request or the complete specification in the manner specified in the order.*

The Full Court considered that the language of section 105(1A) was clear and unambiguous in conferring on the Court the power to deal with amendments to patent applications under appeal.

The Full Court nonetheless also referred to the explanatory memorandum to the *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011* (Cth), confirming that the intended purpose of section 105(1A) was to provide the Court with the jurisdiction to deal with and decide on proposed amendments while an appeal remained on foot.

Permissibility of amendments

MLA also argued, in the alternative, that the amendments to the Application were not allowable under section 102 of the Act, as the amendments were not in substance disclosed in the specification (under the pre-Raising the Bar provisions). Claim 1 of the Application in its unamended form did not expressly include the requirement for linkage disequilibrium of SNP genetic markers, and did not specify the degree of linkage disequilibrium required, nor the means by which this should be measured. MLA argued that the amendments, in effect, introduced new matter into the claim which was not present in the specification. At first instance Beach J allowed the amendments as 'limiting' or 'narrowing' in nature, and in substance disclosed in the specification. The Full Court agreed with his Honour's findings, deciding that while the requisite degree of linkage disequilibrium, and means of measurement, were not expressly disclosed in the specification, this would have been known to the skilled addressee at the priority date.

As MLA failed to demonstrate a clear *prima facie* case of error in the Court's judgment the subject of the proposed appeal, the Full Court dismissed the application for leave to appeal.

Significance

The ability to amend a patent application that is the subject of an appeal to the Federal Court after a judgment is given provides substantial flexibility to a patentee to seek to defend its claims, and amend them if it is not successful in doing so.

The Full Court's confirmation that section 105(1A) is, in fact, intended to allow just such a mechanism for amendment provides a measure of certainty for patentees when considering their strategy for patent application amendments.

Long-running patent dispute relating to Lundbeck's Lexapro reaches High Court for a third time

***Sandoz Pty Ltd v H Lundbeck A/S* [2020] FCAFC 133 (4 August 2020)**

Read the Decision

Judges: Nicholas, Yates and Beach JJ

| *pharmaceutical* | *escitalopram* | *construction of contractual term* | *damages* |

Authors

Andrew Rankine
(Special Counsel, Lawyer)

Duncan Longstaff
(Principal, Lawyer)

In brief

In the long-running patent dispute relating to Lundbeck's blockbuster antidepressant, Lexapro® (escitalopram), the Full Court of Australia's Federal Court overturned a decision of Jagot J, who had found Sandoz liable for infringement of the Lexapro patent and awarded Lundbeck more than AU$16 million in damages. Lundbeck has recently been granted special leave to appeal to the High Court of Australia, which for the third time will hear an appeal regarding an aspect of this litigation.

Background

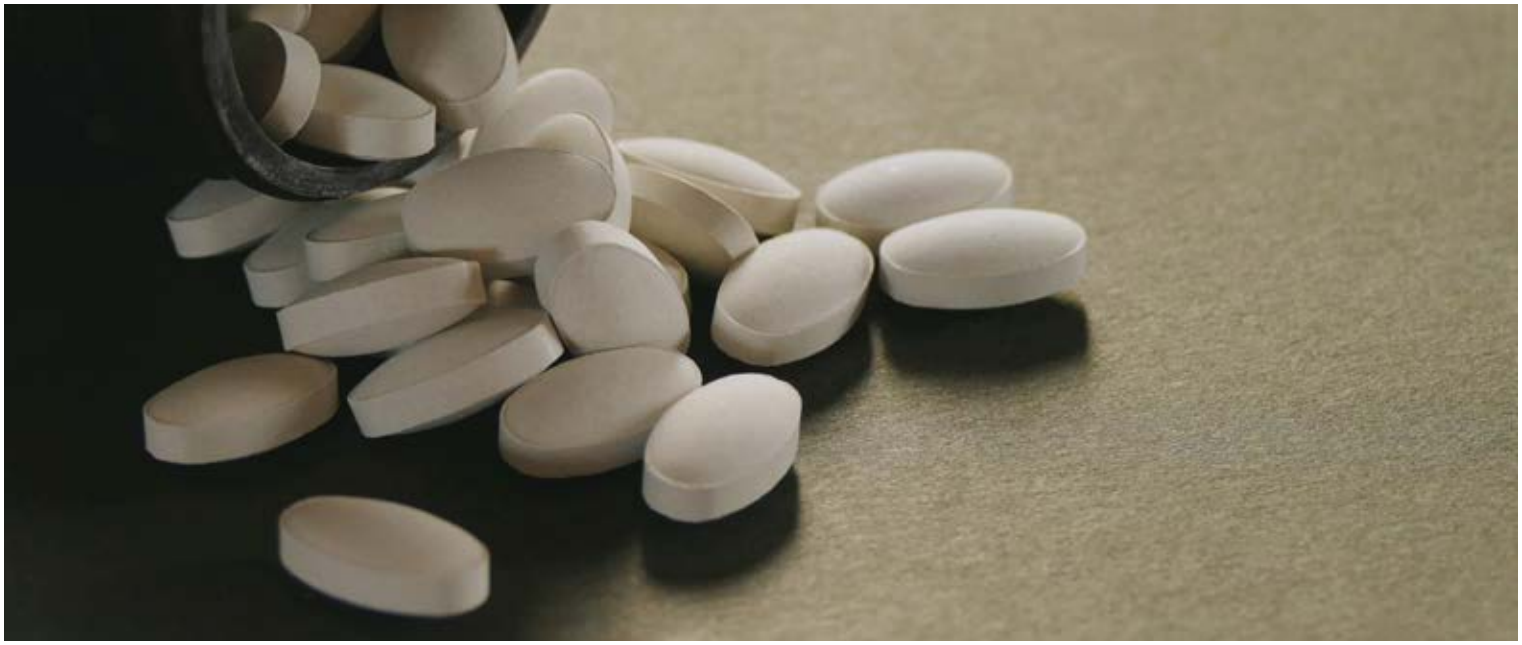
The original 20-year term of the Lexapro patent (AU 623144) was due to expire in June 2009. In April 2004, the Commissioner of Patents granted a 5-year extension of the patent term, calculated by reference to the first regulatory approval date for Lexapro. The active ingredient of Lexapro is escitalopram, the S-enantiomer of citalopram. A racemic form of citalopram (a mixture of the S- and R-enantiomers) was earlier marketed in Australia by Lundbeck under the trade name Cipramil.

In subsequent Federal Court proceedings, that extension of term was held invalid (*Alphapharm Pty Ltd v H Lundbeck A/S* (2008) 76 IPR 618; upheld on appeal: *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151). The Court found that any extension of term application needed to be made by reference to Cipramil, being the first approved therapeutic goods that "contain" the S-enantiomer of citalopram within the meaning of the *Patents Act 1990* (Cth) (**Act**). It followed that such application was required to be made within six months of the first regulatory approval date for Cipramil. Lundbeck's application was therefore submitted out of time.

In consequence, the Lexapro patent expired on 13 June 2009, at the end of its original term. Three days later, Sandoz and other generics launched generic escitalopram products. In doing so, they appeared to be taking a risk. On 12 June 2009, Lundbeck had sought an extension of time to submit a new extension of term application, based on the first regulatory approval date for Cipramil.

Given that the time limit for submitting such an application expired in mid-1998, Lundbeck required a 10-year extension of time. Nevertheless, that extension was granted, on the basis that the applicable time limit had been unclear until determined by the Federal Court in June 2009 (*Alphapharm Pty Ltd v H Lundbeck A/S* (2011) 92 IPR 628; upheld on appeal: *Aspen Pharma Pty Ltd v Commissioner of Patents* (2012) 132 ALD 648; *Aspen Pharma Pty Ltd v H Lundbeck A/S* (2013) 216 FCR 508; *Alphapharm Pty Ltd v H Lundbeck A/S* (2014) 254 CLR 247).

Armed with this extension of time, Lundbeck submitted a new application to extend the term of its Lexapro patent. In June 2014, some 5 years after the patent had expired, that extension was granted (*Alphapharm Pty Ltd v H Lundbeck A/S* (2014) 109 IPR 323; upheld on appeal: *Alphapharm Pty Ltd v H Lundbeck A/S* (2014) 110 IPR 59; *Alphapharm Pty Ltd v H Lundbeck A/S* (2015) 234 FCR 306; *Alphapharm Pty Ltd v H Lundbeck A/S* [2016] HCATrans 52).



The newly extended term of the Lexapro patent expired in December 2012. By that time, Sandoz and other generics had been marketing escitalopram products in Australia for over three years. Lundbeck sought damages for infringement of the Lexapro patent during that period.

In defence of such damages claim, Sandoz relied on a settlement agreement it had reached with Lundbeck in February 2007 (**Settlement Agreement**). In return for Sandoz discontinuing its revocation case against the Lexapro patent, Lundbeck agreed to grant Sandoz an irrevocable licence to the patent, effective from a date two-weeks prior to its expiry (the **Early-entry licence**).

At the time that agreement was reached, the expiry date of the Lexapro patent remained uncertain – litigation concerning the validity of the original extension of term was ongoing. The agreement recorded several alternative dates on which the Early-entry licence might commence. However, it did not address the possibility that the term of the Lexapro patent might expire and, sometime later, be extended. That is, of course, what transpired.

In defence of Lundbeck's damages claim, Sandoz submitted that, on a correct construction of the Settlement Agreement, the Early-entry licence commenced in May 2009, two-weeks before expiry of the Lexapro patent, and remained in force thereafter. By contrast, Lundbeck submitted that, because the term of the patent was extended to December 2012, the early-entry licence did not commence until November 2012, leaving Sandoz liable for infringement in the intervening period.

First instance decision

Lundbeck was successful before the primary judge (*H Lundbeck A/S v Sandoz* [2018] FCA 1797). However, Jagot J did not accept either party's construction of the Settlement Agreement.

Her Honour found that, under the terms of the Settlement Agreement, the Early-entry licence commenced in May 2009, two weeks before the Lexapro patent expired. In reaching that conclusion, Jagot J held that the operation of the agreement ought not be tested by reference to the fact that, 5 years later, a new extension of term was granted, because this could not have been predicted by the parties in February 2007, when they entered into the Settlement Agreement.

However, in Jagot J's view, this was not the end of the matter. Noting that Sandoz would not require a licence after the Lexapro patent had expired, her Honour found that the effect of the Settlement Agreement was to confer on Sandoz a licence which commenced in May 2009 and ceased to operate two weeks later, upon the expiry of the patent's original term.

It followed, in Jagot J's view, that Sandoz did not have the benefit of a licence when the term of the Lexapro patent was subsequently extended. Based on these findings, Jagot J held Sandoz liable for infringing the patent between June 2009 and December 2012, awarding Lundbeck in excess of AU$16 million in damages.

Decision

An appeal by Sandoz to the Full Court was successful. The critical issue on appeal concerned the construction of the Settlement Agreement, in particular, whether the Early-entry licence ceased to operate on expiry of the original term of the Lexapro patent in June 2009, or continued thereafter.

In approaching that question, the Full Federal Court reiterated well-established principles of contract construction. The terms of a contract are to be construed objectively. The question is what the language used would convey to a reasonable business person, in light of the surrounding circumstances known to both parties at the date of their agreement, including the objects of the contract, and assuming that the parties intended to achieve a commercial result. A court will be slow to adopt a construction that would give a contract an effect that is commercially nonsensical.

On the other hand, the Full Court emphasised that commercial common sense and surrounding circumstances may not be invoked to discount the language in which a contract is expressed. The fact that a contractual provision may operate to disadvantage one party to an agreement is not a reason to depart from the ordinary meaning of the language in which that provision is expressed.

In the view of the Full Court, the language of the Settlement Agreement was sufficiently clear. It granted Sandoz an irrevocable licence that commenced in May 2009, two weeks before expiry of the Lexapro patent, and remained in force thereafter. The Full Court held that, objectively ascertained, it was the parties' intention to stipulate a start date for the licence, but not an end-date.

Notably, the Full Court agreed with Jagot J that it appeared neither party had, at the time of concluding the Settlement Agreement in February 2007, turned their mind to the possibility that the Lexapro patent might expire and only subsequently have its term extended. That is unsurprising, given unprecedented course of the Lexapro proceedings. As the Full Court observed, had the parties been able to foresee the course those proceedings would take, it is likely that express provision would have been made for such eventualities in the Settlement Agreement.

Significance

The Full Federal Court's decision highlights the complexity of the extension of time and extension of term provisions under Australia's patent legislation which, together or separately, can significantly affect the course of the litigation and the negotiation of commercial settlement terms.

The decision of the Full Federal Court does not yet bring to a close one of the most complex patent disputes in Australian legal history, as Lundbeck was recently granted special leave to appeal to the High Court of Australia (*H. Lundbeck A-S & Anor v Sandoz Pty Ltd*; *CNS Pharma Pty Ltd v Sandoz Pty Ltd* [2021] HCATrans 13 (11 February 2021)). That will be the third time this litigation has reached the High Court for a substantive appeal, with Lundbeck previously succeeding in both its application for an extension of time to apply for an extension of term and then the extension of term application itself. Over its long course, the Lexapro litigation has made a number of significant contributions to Australian patent law, including in relation to the validity of enantiomer claims and the operation of the provisions of the Act which govern extensions of term and extensions of time, and now it appears set to contribute to Australia's contract law as well.

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Danger in amending patent claims to remove integers asserted to be optional

***Pilkin v Sony Australia Limited* [2020] FCAFC 51 (6 April 2020)**

Read the Decision

Judge: Greenwood, McKerracher and Yates JJ (in the Full Federal Court); Rares J (at first instance)

| electronic | novelty | summary dismissal | service out of jurisdiction |

Authors

Andrew Lowe
(Senior Associate, Patent Attorney)

Mark Vincent
(Principal, Lawyer)

In brief

Mr Vitaly Pilkin appealed from a Federal Court decision summarily dismissing his patent infringement proceedings against Sony Australia and refusing leave to serve Sony entities out of jurisdiction in the US and the UK (see our discussion of that earlier decision in *Best Patent Cases 2019*). The Full Federal Court refused Mr Pilkin's application for leave to appeal the decision, upholding the primary judge's findings that due to a deferral in the patent priority date to the date of key amendments, the claimed invention could not be novel in light of prior art products. The Full Court observed that Mr Pilkin had a substantial and contestable case in response to prior US patent publication considered by the primary judge to deprive the claimed invention of novelty, but noted that was to no avail because the appeal failed, and his infringement case should be summarily dismissed, on other grounds.

Background

Mr Pilkin sued Sony Australia for infringing his innovation patent AU 2010101517 (**517 Patent**), by its sale of the PS Vita, PS3 and PS4 consoles (the **Consoles**) in Australia since 22 February 2012. Mr Pilkin also sought to serve proceedings on US and UK based Sony entities. In response, Sony Australia and the Sony entities (the **Sony parties**) conceded that their consoles fell within the scope of the claim of the 517 Patent but sought summary dismissal because the Patent had a later priority date than its claimed priority date, meaning that the sales of the Consoles anticipated the 517 Patent, and that the 517 Patent also lacked novelty over a US patent publication (the **Case patent**).

The 517 Patent

The 517 Patent converted from a national phase patent application of a PCT application, had a priority date of 5 October 2009. The PCT application described the invention as an electronic device, with various options for the location of a touch pad and/or a joystick on the device. The claims corresponded to this description, listing the possible locations of the touch pad and the joystick as alternatives. The Patent was amended on 11 July 2014 to state only one claim, an electronic device having, inter alia, a front touch screen visual display, a rear touch pad and a joystick. The possible locations of the joystick on the electronic device were omitted from the claim.

First instance decision

(a) Priority date

Justice Rares found that on a reading of the PCT application, he agreed with the Sony parties that the amendment was beyond the original disclosure in the PCT application. It was clear that the location of the joystick on the device other than on the front surface was essential to the invention. Hence, the omission of any particular location of the joystick in the claim of the 517 Patent meant that the amendment was a broadening amendment, deferring the priority date of the 517 Patent to 11 July 2014.

(b) Novelty

The effect of the deferred priority date for the 517 Patent meant that the sales of the Consoles anticipated the claim of the 517 Patent as the sales occurred earlier, since at least 2012. It was also held that the Case patent anticipated the claim of the 517 Patent, as it described that a folded over laptop could include a joystick to control a cursor on the front screen display.

(c) Summary dismissal

As there were no reasonable prospects of success in Mr Pilkin's causes of action, in light of the novelty issues created by the deferred priority date of the patent, the patent infringement proceedings were dismissed.

Service out of jurisdiction

Justice Rares held that the facts pleaded by Mr Pilkin did not establish a prima facie case for relief to warrant service on the Sony entities in the US and the UK. The US Sony entity was only incorporated in April 2016, and so did not exist at the time of first sales of the Consoles in 2012. Also, the press release relied upon by Mr Pilkin did not establish that the US Sony entity had taken over manufacturing of the Consoles. The failure of Mr Pilkin's infringement claims also meant that there was no prima facie case against the UK based Sony entities.

Decision

Mr Pilkin sought leave to appeal on all grounds, repeating his submissions made in the first instance decision – that the amendment to the 517 Patent only removed various alternatives listed in the PCT claims, and that the location of the joystick was not an essential integer to the invention. Mr Pilkin further argued that the Case patent did not provide clear and unmistakable directions to all the features of the claim. In a unanimous decision, the Full Federal Court refused Mr Pilkin leave to appeal, agreeing with Rares J's reasons and findings on the deferred priority date for the Patent, its invalidity due to the sales of the Consoles and the lack of a *prima facie* case to warrant service out of jurisdiction.

However, the Full Federal Court considered that Mr Pilkin's submissions on the Case patent were sufficiently reasonable to make that issue contestable. The Full Court also noted that the central reason for the primary judge's finding of lack of novelty was that a skilled person would have been able to produce the claimed device through routine trial and error. This central reason was not supported by evidence and related more to inventive step issues. However, Mr Pilkin's failure on his other grounds meant the issues relating to the Case patent were immaterial, because his application for leave to appeal was to be dismissed, and his infringement case was to be summarily dismissed, on the other grounds described above.

Significance

The decision illustrates the dangers in amending patent claims to remove integers asserted to be optional. While the removal of optional integers may appear to narrow the scope of a claim, there could be an argument that this in effect broadens the scope of the claim beyond its original disclosure. Patent applicants and patentees should exercise caution in amending the claims or drafting claims with too many alternative integers to avoid a potential loss of priority date and thus lose validity by reason of a later amendment.

The decision also highlights the need to clearly separate the criteria for novelty from the criteria for inventive step. The basis for the finding on lack of novelty for the Case patent relied on matters relating to inventive step and unsupported by evidence.

Finally, the case emphasises the importance of accurately pleading consistent facts. The contradiction between the dates of the alleged infringing conduct and the existence of the US Sony entity led to refusal of the application to serve out of jurisdiction.

Prevnar vaccine case demonstrates the impact of Australia's "Raising The Bar" patent law reforms

***Merck Sharp & Dohme Corporation v Wyeth LLC (No 3)* [2020] FCA 1477 (14 October 2020)**

Read the Decision

***Merck Sharp & Dohme Corporation v Wyeth LLC (No 4)* [2020] FCA 1719 (30 November 2020)**

Read the Decision

Judge: Burley J

| biotechnology | construction of "comprising" | support | sufficiency |

Authors

Andrew Rankine
(Special Counsel, Lawyer)

Charles Tansey PhD
(Principal, Patent Attorney)

Duncan Longstaff
(Principal, Lawyer)

In brief

In October 2020, Australia's Federal Court delivered judgment in a patent dispute concerning vaccines against *Streptococcus pneumoniae*, a leading cause of serious infections in children. The trial judgment provides the first detailed analysis by a Federal Court judge of the *Raising the Bar* reforms to Australian patent law concerning sufficiency and support. A subsequent judgment on final relief, delivered in November 2020, highlights the challenges facing a defendant who seeks to resist final injunctive relief on public interest grounds.

Background

A polysaccharide-protein conjugate vaccine against pneumococcus developed by Wyeth, known as Prevnar 7, was in clinical use before the priority date of the patents at issue in this case. That product comprises capsular polysaccharides from 7 different pneumococcal serotypes, in each case conjugated to a single carrier protein (known as CRM_{197}). Evidence led in the case indicated that, before the priority date, steps had been taken to develop polysaccharide-protein conjugate vaccines consisting of 9 and 11 pneumococcal serotypes, but no such products had yet been licensed or launched.

Three patents were at issue in this proceeding. Two of them, referred to by Burley J as the "Composition Patents", were related members of the same patent family. The more senior family member (the **Parent Composition Patent**) was subject to the provisions of Australia's *Patents Act 1990* (Cth) (**Act**) as they stood prior to the *Raising the Bar* amendments. The more junior family member (the **Child Composition Patent**) was subject to the post-*Raising the Bar* Act. The body of the specification was substantially the same in the parent and child patents. It described multivalent immunogenic compositions comprising 13 distinct polysaccharide-protein conjugates, thereby providing increased coverage of pneumococcal serotypes compared to the Prevnar 7 vaccine in use before the priority date.

Decision

Merck Sharp & Dohme (**MSD**) sought revocation of Wyeth's Composition Patents on a variety of grounds, including lack of novelty, lack of inventive step, false suggestion, lack of clarity, lack of fair basis (in relation to the pre-*Raising the Bar* Parent patent) and lack of support (in relation to the post-*Raising the Bar* Child patent). By a cross-claim, Wyeth alleged that a pneumococcal vaccine comprising 15 pneumococcal serotypes which MSD proposed to launch and market in Australia would infringe selected claims of the asserted patents.

The construction issue

Wyeth's allegation that the Composition Patents would be infringed by marketing of MSD's vaccine in Australia gave rise to a critical issue of claim construction in the proceeding, namely, whether the claims of those patents were *limited* to vaccines covering 13 serotypes (as MSD contended) or extended to vaccines covering 13 or *more* serotypes (as Wyeth submitted).

The specification of each of the Composition Patents included text indicating that "comprising" is used in an inclusive sense ("including") rather than an exhaustive sense ("consisting of"). That text provided the basis for Wyeth's submission that, because MSD's vaccine *included* the 13 serotypes identified in the claims of the Composition Patents, it fell within those claims. On Wyeth's construction, the presence of two additional serotypes in MSD's vaccine was irrelevant to infringement. On this key issue, Burley J preferred Wyeth's construction. In his Honour's analysis, the inclusive definition of "comprising" was decisive. Provided that a vaccine included each integer of Wyeth's claims, it would infringe – a conclusion not altered by the presence in the infringing product of additional serotypes.

What is notable for present purposes is the very substantial breadth given to Wyeth's claims on the construction adopted by Burley J. On that construction, the range of valences covered by Wyeth's claim would appear to have no upper bound. Unsurprisingly, in view of this broad construction, a question arose as to whether the claims were fairly based on, or supported by, the disclosure contained in the body of the Composition Patent specification.

Raising the Bar reforms

The *Raising the Bar* reforms were introduced to address concerns that Australia's patent standards were lower than those of its major trading partners, causing Australia's innovation landscape to become cluttered with unduly broad patents. The amendments were expressly directed at aligning key aspects of Australian patent law, including on sufficiency of disclosure and support for claims, with the standards applied by UK courts and the European Patent Office (**EPO**) Boards of Appeal. Although the *Raising the Bar* amendments were enacted in April 2012, lengthy transitional provisions mean that many of the key reforms, including those concerning sufficiency and support, are only now coming before the courts for interpretation and application.

(a) The law pre-Raising the Bar

Prior to the *Raising the Bar* reforms, the relationship between the disclosure in the body of a patent specification and the breadth of the claims was governed by the legal requirement for "fair basis", – that is, whether each claim corresponds textually with what the patentee has described as their invention in the body of the patent specification. The equally permissive standard for sufficiency is that a patent specification will have adequately described the invention if it would enable a person skilled in the relevant art to produce "something" falling within each claim. That body of law is of continuing relevance for Australian standard and innovation patents for which examination was requested before 15 April 2013. In the present case, that "old" body of law applied to the Parent Composition Patent.

Applying those authorities, Burley J found little difficulty in concluding that, notwithstanding his Honour's broad interpretation of the claims of the Parent Composition Patent, those claims were fairly based. Reflecting the essentially textual nature of the pre-*Raising the Bar* test for fair basis, that conclusion followed from the fact that the description of the invention in the body of the Parent Composition Patent employed the same inclusive language ("comprising") as appeared in the claims.

(b) The law post-Raising the Bar

Following the *Raising the Bar* amendments, the provisions of the Act dealing with sufficiency and support are in substantially the same terms as the corresponding provisions of the European Patent Convention and the United Kingdom's *Patents Act 1977*. Parliamentary records make clear that those provisions were intended to have substantially the same effect as their European and UK counterparts, and that Australia courts are expected to have regard to decisions of the EPO Boards of Appeal and of UK courts in interpreting those provisions.

Burley J reviewed a number of EPO and UK authorities, including the recent decision of the UK Supreme Court in *Regeneron Pharmaceuticals Inc v Kymab Ltd* [2020] UKSC 27, to interpret the post-Raising the Bar requirement that the claims be "supported by matter disclosed in the specification". Referring to the landmark decision of the House of Lords in *Biogen Inc v Medeva Plc* [1997] RPC 1, Burley J observed that the claim support obligation has come to be understood as falling "under the umbrella of the requirement that the patent specification contain an *enabling disclosure*" (emphasis added). His Honour noted that, although the requirement for sufficient description is directed to the specification as a whole, while the requirement for support is directed specifically to

the claims, both requirements serve to ensure that a person skilled in the relevant art, armed with the patentee's specification, is enabled to perform the invention over the whole area claimed without undue burden. Referring to the decision of the EPO Board of Appeal in *Exxon/Fuel Oils (*T 409/91) [1994] EPOR 149, Burley J noted that the requirement for enablement across the full claim scope has been recognised as reflecting the general legal principle that the scope of a patent monopoly, as defined by the claims, should correspond to the patentee's technical contribution to the art, as disclosed in their specification.

Applying those authorities, Burley J concluded that the claims of the Child Composition Patent were not supported by the matter disclosed in the specification. On the construction advanced by Wyeth and accepted by His Honour, those claims encompassed any polysaccharide-protein conjugate pneumococcal vaccine comprising 13 *or more* serotypes. While there was no dispute that the specification of the Composition Patents would enable a skilled person to make and use a 13-valent vaccine, uncontested evidence established that the disclosure of the specification could not be extrapolated to vaccines containing other, additional serotypes. Manufacture of polysaccharide-protein conjugate vaccines comprising more than 13 serotypes was not enabled. In the result, the asserted claims of the Parent Composition Patent were held to be valid and infringed, while the asserted claims of the Child Composition Patent were held invalid for lack of support.

Final relief and the public interest

In a separate judgment delivered in late November 2020, Burley J addressed the question of final relief for infringement of Wyeth's Parent Composition Patent.

MSD argued that no final injunction should be granted, or alternatively that the question of injunctive relief should be deferred until after the determination of any appeal. MSD based those arguments on the public interest in accessing its 15-valent vaccine. MSD asked Burley J to convene a separate hearing on these issues. Justice Burley refused MSD's request for a separate hearing and determined that it was appropriate that Wyeth be granted a final injunction.

On the one hand, Burley J pointed to a number of factors suggesting it was premature to determine the public interest question. MSD has not yet obtained regulatory approval to market its 15-valent vaccine in Australia and its intended launch date remains unclear. Wyeth's counsel indicated that Pfizer (the parent company of Wyeth) intends launching a 20-valent pneumococcal vaccine in Australia, which may come to market before the MSD product is approved. Justice Burley observed that the timeline of these events would be expected to have a significant bearing on the assessment of the public interest arguments raised by MSD. On the other hand, Burley J found that the question of whether a final injunction should be refused on public interest grounds had been raised on the pleadings for the infringement case and his Honour was not persuaded that MSD should be permitted to, in effect, re-open its case on this issue, after judgment.

It is possible that MSD may seek to test those conclusions before the Full Federal Court. A notice of appeal against Burley J's judgment on issues of validity and infringement was filed by MSD in late January 2021.

Significance

The disparate conclusions reached in this case concerning the Parent and Child Composition Patents serve to illustrate the profound changes to Australian law brought about by the R*aising the Bar* reforms. Such disparate outcomes are likely to remain a feature of Australian patent disputes for some years to come. Australian patents subject to the pre-Raising the Bar law are expected to remain in force until at least 2033.

This decision also demonstrates that the post-Raising the Bar incarnations of Australia's written disclosure requirements in section 40 of the Act can be a much more powerful weapon in the arsenal of a party seeking to revoke an Australian patent. Historically, the low thresholds for fair basis and sufficiency have provided relatively wide scope for Australian patentees in advancing positions on claim construction to capture alleged infringements. The main constraint for patentees in advancing a claim construction under the pre-*Raising the Bar* body of law has been (and will remain) potential novelty and inventive step consequences arising from constructions being so broad as to capture prior art or common general knowledge. The onerous post-*Raising the Bar* support and sufficiency requirements will add an extra dimension to these construction "squeezes" and another powerful validity ground which must be fended off.

On the issue of final injunctive relief, defendants who wish to preserve the ability to oppose such relief on public interest grounds may need to apply, at an early stage in the proceeding, to have that question deferred for separate determination, after the main trial on infringement and validity, with the parties granted leave to file fresh evidence on the public interest considerations which apply at that time.

Federal Court dismisses first Commonwealth damages claim against an unsuccessful pharmaceutical patentee

***Commonwealth of Australia v Sanofi (No 5)* [2020] FCA 543 (28 April 2020)**

Read the Decision

Judge: Nicholas J

| *pharmaceutical* | *damages* | *voluntary undertakings* | *Commonwealth claim* | *remoteness* |

Authors

Dr Roshan Evans
(Lawyer)

Duncan Longstaff
(Principal, Lawyer)

In brief

In an unprecedented decision, the Federal Court of Australia has considered and dismissed a claim by the Commonwealth Government for compensation from sponsors of innovator pharmaceutical products, pursuant to undertakings as to damages given in exchange for an interlocutory (preliminary) injunction restraining the launch of the first generic product.

While in principle the Commonwealth was not precluded from claiming compensation under a patentee's usual undertaking as to damages, the Court found that the Commonwealth's losses were not a direct consequence of the interlocutory injunction granted in this case which, although restraining infringement of Sanofi's patent generally, did not explicitly restrain listing on the Commonwealth's Pharmaceutical Benefits Scheme (**PBS**). This finding calls into question future Commonwealth damages claims based on interlocutory injunctions that do not explicitly restrain PBS listing.

You can read our detailed analysis of this decision ***here***.

Background

The case concerned the blockbuster blood-thinner, clopidogrel, sold in Australia by Sanofi as PLAVIX and by Bristol-Myers Squibb (**BMS**) as ISCOVER, under a global co-marketing arrangement. Apotex proactively commenced proceedings in August 2007 against Sanofi seeking revocation of Sanofi's Australian Patent No. 597784 (**784 Patent**). An interlocutory injunction was granted in late September 2007, the trial on validity was conducted in April 2008 and a first-instance decision upholding the validity of some claims of the 784 Patent was delivered in August 2008. A Full Court appeal decision, revoking all claims of the 784 Patent, was delivered in late September 2009 and an application by Sanofi for special leave to appeal to the High Court was refused in March 2010. Apotex's clopidogrel products were listed on the PBS from 1 May 2010. In 2010, Apotex and other generic companies commenced damages proceedings, seeking compensation from Sanofi and BMS pursuant to the undertaking as to damages. Those claims were settled in 2014. The Commonwealth brought its claim for damages in 2013.

The interlocutory injunction obtained by Sanofi in September 2007 restrained Apotex from infringing the Patent, including by importation and sale of pharmaceutical products which had clopidogrel as their active ingredient. Sanofi gave the usual undertaking as to damages in connection with the interlocutory injunction. Importantly, the interlocutory injunction did not expressly prevent Apotex from applying for inclusion of its products on the PBS. However, on the same date (and noted in the same set of orders as gave effect to the interlocutory injunction) Apotex gave the Court a voluntary undertaking (the **Apotex Undertaking**) that it would not apply to list its clopidogrel products on the PBS until the determination of the patent proceeding. Sanofi did not provide any cross-undertaking as to damages for the Apotex Undertaking.

The Commonwealth's claim

The Commonwealth claimed losses in respect of the supply of clopidogrel products under the PBS, said to result from the delay in the Commonwealth's ability to reduce the subsidised price for those products via statutory price reductions triggered by first generic entry and subsequent price disclosure-related

reductions. The various components that made up the claimed price difference amounted to a sum of approximately AU$325 million, excluding interest.

This is the first case in which judgment has been given on a Commonwealth claim for damages pursuant to a pharmaceutical patentee's undertaking as to damages given in connection with grant of an interlocutory injunction. The Commonwealth has previously settled claims for compensation, relating to extended release formulations of the antidepressant venlafaxine (a decision in that case concerning damages claims by generic suppliers), and to rosuvastatin (in that case, both the Commonwealth and the generic parties reached a settlement with the innovator). A Commonwealth claim for damages pursuant to undertakings given in relation to the antipsychotic aripiprazole is continuing.

Decision

Commonwealth entitlement to damages

The Court found that the Commonwealth was, in principle, entitled to seek compensation, as its circumstances were not different from those of a natural person, notwithstanding that it had control over the PBS regime.

However, on the question of causation and remoteness of loss, Nicholas J found that the Apotex Undertaking had been given voluntarily and was not a necessary or natural consequence of the interlocutory injunction issued by the Court. While his Honour did accept the Commonwealth's position that the Apotex Undertaking would not have been proffered but for the interlocutory injunction, and that the interlocutory injunction had the *practical (indirect) effect* of preventing Apotex from applying for PBS listing of its generic clopidogrel products (including providing a guarantee of supply to the Therapeutic Goods Administration), nevertheless it did not directly restrain Apotex from PBS-listing.

As Sanofi's undertaking as to damages did not extend to the Apotex Undertaking, his Honour considered that there was strong contextual support for the view that the undertaking as to damages should not be interpreted as extending to loss suffered by the Commonwealth due to Apotex being prevented from applying for PBS listing as a result of its voluntary undertaking.

PBS price reduction reversal

The Court considered that it was more likely than not that the Commonwealth would have been prepared to reverse the 12.5% statutory price reduction for Sanofi's products triggered by the generic listing on the PBS, if sale of the generic product was subsequently restrained by a permanent injunction. In coming to this conclusion, Nicholas J was strongly influenced by evidence of two previous examples of discretionary PBS price reductions for other products having been reversed and lamented the lack of evidence from the senior Commonwealth decision-maker to support its contentions that it would not have reversed the 12.5% price reduction.

Significance

This decision is consistent with the view that loss incurred by the Commonwealth as a result of delayed PBS-listing of generic products due to patent litigation is compensable, in principle, where the necessary elements for the award of damages are established. Patentees seeking interlocutory injunctions must therefore continue to take into account a possible Commonwealth claim as an incident of obtaining an interlocutory injunction.

However the Court's findings on the question of whether the connection between the interlocutory injunction and the alleged loss is sufficiently direct may present an impediment to future Commonwealth claims for compensation based on interlocutory injunctions that do not expressly restrain PBS-listing of generic products. It will be of interest to see how the Full Court views this question.

Whether the Commonwealth becomes more actively involved in the hearing of interlocutory injunction applications and presses for the issue of PBS listing to be addressed in the terms of any interlocutory injunction granted and the associated cross-undertaking as to damages also remains to be seen.

The decision also sounds a warning to generic parties to carefully consider any voluntary undertakings they may provide to the Court, where such undertakings are not supported by any cross-undertaking as to damages given by the innovator. In those circumstances, the generic party is may not be compensated for losses flowing from its undertakings, even if ultimately successful in the patent proceedings.

Finally, the Court's finding that it was likely that any statutory reduction in the PBS-price for Sanofi's products would have been reversed had an interlocutory injunction been refused and final judgment subsequently delivered in Sanofi's favour, may have implications for future interlocutory injunction applications in pharmaceutical patent cases. It has previously been suggested that such price reductions would be effectively irreversible, even if the innovator was ultimately successful in obtaining a final injunction. This finding of Nicholas J, to the contrary, has the potential to contribute to the trend away from the routine granting of interlocutory injunctions in pharmaceutical patent disputes, observable in a number of recent judicial decisions.

The matter with added matter in patent specifications – allowability of amendments under post 'Raising the Bar' test

Commonwealth Scientific and Industrial Research Organisation v BASF Plant Science GmbH
[2020] FCA 328 (12 March 2020)

Read the Decision

Judge: Beach J

| biotechnology | support | added subject matter | intermediate generalisations |

Authors

Michael Christie PhD
(Principal, Lawyer)

Katrina Crooks
(Principal, Lawyer)

In brief

In this decision the Federal Court of Australia considered the allowability of amendments to patent specifications under section 102(1) of the *Patents Act 1990* (Cth) (**Act**), as amended by the Intellectual *Property Laws Amendment (Raising the Bar) Act 2012* (Cth) (**Raising the Bar Act**). In overturning a decision of the Commissioner of Patents, Beach J decided that BASF's proposed amendments were impermissible because they claimed and disclosed matter that extended beyond the specification as filed. In so doing, the Court decided that the same strict test used by UK Courts should also be applied in relation to added matter in Australia.

Background

BASF Plant Sciences GmbH (**BASF**) filed a patent application entitled "Process for the production of polyunsaturated fatty acids in transgenic organisms", which relates to genes from a species of unicellular algae that code for enzymes which can be employed for the recombinant production of polyunsaturated fatty acids in plants.

CSIRO opposed BASF's accepted application, and during the opposition proceedings BASF applied to amend its application and introduce new dependent claims. The Australian Patent Office initially refused the proposed amendments on the basis that, as a result of the proposed amendments, the specification would not comply with the requirements of section 40(3) of the Act. However, a second set of proposed amendments was submitted, which a Delegate of the Commissioner of Patents subsequently allowed. CSIRO then lodged an appeal to the Federal Court against that decision under section 104(7) of the Act.

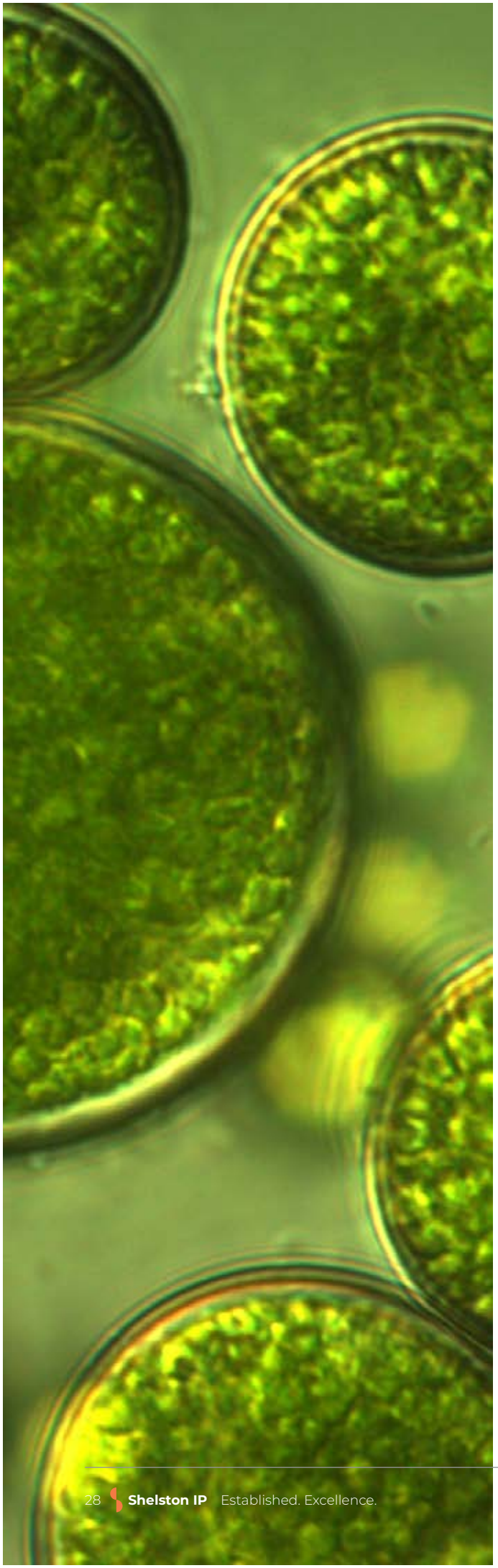
The amendments

In a passage referred to by the parties as the "bridging paragraph", the specification as filed stated that:

> *The invention, the subject of the present application, is directed to the following:*
>
> - *a CoA-dependent delta-6 desaturase having the substrate specificity of the delta-6 desaturase shown in SEQ ID NO:14 [referred to by Beach J as* **Feature A***], **and***
> - ***the above** CoA-dependent delta-6 desaturase which has a preference for conversion of alpha linolenic acid compared to linoleic acid* [referred to by Beach J as **Feature B**]. (emphasis added)

The experts agreed that the words "the above" in the statement meant that this statement must be read together with the statement in the first bullet point of the bridging paragraph. The bridging paragraph is the only place in which a conversion preference is disclosed in the body of the specification of the application as filed. The invention described in each bullet point of the bridging paragraph is claimed in claims 1 and 2 respectively of the application as filed.

BASF removed the bridging paragraph and deleted corresponding claims 1 and 2 by amendment during prosecution and replaced it with a description that defines the invention as:



- *a process for the production of a substance of general formula I … wherein the process comprises the cultivation of (i) a host cell … or (ii) a transgenic non-human organism comprising … "an isolated polynucleotide comprising a nucleic acid sequence coding for a CoA-dependent delta-6 desaturase having at least 75% identity to a nucleotide sequence which codes for a polypeptide as shown in SEQ ID NO: 14"* [referred to by Beach J as "**Feature C**"]; *and*

- *use of an isolated polynucleotide … (or vector, host cell, or transgenic non-human organism comprising said nucleic acid sequence) … for the production of an oil, lipid or fatty acid composition.*

In light of the amendments to the bridging paragraph and the deletion of the corresponding claims, the application as accepted did not refer to Feature A, Feature B or Feature A combined with Feature B. As Beach J noted, Feature C captures a broader range of polypeptides than Feature A. In a further round of post-acceptance amendments BASF sought to insert new dependent claims, to a process for production of, and use of, a CoA-dependent delta-6-desaturase:

> *a) having at least 75% identity to a nucleotide sequence which codes for a polypeptide as shown in SEQ ID NO:14* [**Feature C**]*; and*
>
> *b) that preferentially converts alpha linolenic acid compared to linoleic acid* [**Feature B**].

The amendments also sought to introduce the following description after the consistory clause:

> *According to an embodiment of the abovementioned process and use, the CoA-dependent desaturase preferentially converts alpha-linolenic acid compared to linoleic acid.* [**Feature B**]

CSIRO argued that the post acceptance amendments were not allowable as they would introduce a claim combining Feature C with Feature B, when the only disclosure of Feature B in the specification as filed was in the context of Feature A.

Decision

Justice Beach noted that that the Raising the Bar provisions were intended to mirror other jurisdictions, such as the UK and Europe, and that it was intended that Australian courts would have regard to the developments of case law in those jurisdictions when interpreting the Raising the Bar provisions. More specifically, he noted the intention disclosed in the explanatory memorandum to the Raising the Bar amendments that the operation of sections 40(2) and (3) of the Act as amended (which deal with sufficiency and support) be as close as practicable to that given to the corresponding provisions in the UK Patents Act and the European Patent Convention.

Justice Beach therefore commenced a review of the UK authorities and in coming to his decision, noted two "conceptual themes permeate the UK authorities", namely "added matter" and "intermediate generalisation". In terms of the former, and with reference to several landmark UK decisions on added matter (including *Bonzel v Intervention Ltd (No 3)* [1991] RPC 553; *Richardson-Vicks Inc's Patent* [1995] RPC 568; *European Central Bank v Document Security Systems Inc* [2007] EWHC 600). It was noted that subject matter will be impermissible added matter "unless it is clearly and unambiguously disclosed in the application as filed", having reference to what has been disclosed both explicitly and implicitly.

As to intermediate generalisations, it is useful to consider the EPO guidelines, which explain:

> *...the content of the application as filed must not be considered to be a reservoir from which individual features pertaining to separate embodiments can be combined in order to artificially create a particular combination.*
>
> *When a feature is taken from a particular embodiment and added to the claim, it has to be established that*
>
> - *the feature is not related or inextricably linked to the other features of that embodiment and*
> - *the overall disclosure justifies the generalising isolation of the feature and its introduction into the claim.*

In other words, the concept of "intermediate generalisation" requires that an amendment is not allowable if it takes a feature which is only disclosed in a particular context and seeks to introduce it into a claim deprived of that context. Justice Beach found that there was "no good reason not to follow the UK authorities" to apply these analogous concepts for the purposes of construing the present form of section 102(1) of the Act. BASF argued that the relevant amendments were narrowing amendments. Justice Beach accepted this insofar as the comparison was with the accepted claims, however he noted that this did not resolve the issue of whether the amended specification would claim or disclose matter extending beyond that disclosed in the specification as *filed*. BASF further argued that there was disclosure of Feature C in a particular paragraph of the specification as filed. However, Beach J decided that this paragraph could only be read in the context of the description of 'the invention' in the bridging paragraph. In this regard, Beach J considered that the bridging paragraph did not provide disclosure of a delta-6 desaturase with Feature B in the absence of Feature A. Justice Beach concluded that BASF's amendment sought to remove Feature B from the context in which it was disclosed in the application as filed and introduce it into the specification and the claims deprived of that context. The amendments generalised the originally disclosed technical information, thereby introducing subject-matter extending beyond the content of the application as filed.

As a result, BASF's amendment was refused, and CSIRO's appeal was upheld.

Significance

This decision confirms that the test in Australia for added matter is strict, and that subject matter will be impermissibly added "unless it is clearly and unambiguously disclosed in the application as filed". Importantly, until now it has not been clear whether the prohibition on "intermediate generalisation", a familiar concept in European patent law, would be adopted in Australia. Justice Beach has confirmed that an intermediate generalisation is not permissible, where a feature which is only disclosed in a particular context is introduced into a claim deprived of that context.

At the time of filing a patent application, it is important to provide a full disclosure of your invention as adding subject matter later will not be allowable. It is also important to ensure that your patent application discloses your invention in terms that encompass all variants of the invention that you may later wish to claim. Such limitations should also be borne in mind if seeking to limit granted claims in pre-litigation or litigation to avoid prior art brought to the attention of the patentee.

Pfizer preliminary discovery attempt on Erelzi fails

***Pfizer Ireland Pharmaceuticals v Sandoz Pty Ltd* [2020] FCA 1648 (13 November 2020)**

Read the Decision

Judge: Burley J

| biotechnology | biosimilars | preliminary discovery | undertakings |

Authors

Katrina Crooks
(Principal, Lawyer)

In brief

In this Federal Court case, Pfizer's attempt to obtain documentation from Sandoz regarding its ERELZI etanercept product failed, Burley J finding that undertakings provided by Sandoz to give notice prior to exploiting ERELZI products in Australia removed any reasonable belief that Pfizer might have the right to obtain relief *as at the time of the application*. The circumstances illustrate the significance of the form of undertakings given by potential generic/biosimilar entrants when patent disputes erupt.

Background

Pfizer markets the highly successful etanercept therapy under the name BRENZYS in Australia, for conditions including rheumatoid and psoriatic arthritis. In October 2017 Sandoz obtained registration on the Australian Register of Therapeutic Goods (**ARTG**) for its biosimilar, ERELZI. The Department of Health's Pharmaceutical Board Advisory Committee recommended that the products be listed in March 2018, subject to certain further information being provided. In April 2018 Sandoz informed the Department of Health that it had decided not to proceed to the next step "at this point in time".

Sandoz has taken no further steps with respect to launch of ERELZI in Australia since that time. In December 2019, Pfizer sought preliminary discovery from Sandoz for documents relating to the manufacture of ERELZI, on the basis that it may have a right to relief for infringement of three of its patents.

Decision

The test for obtaining preliminary discovery has recently been clarified by the Full Court of the Federal Court in a case brought by Pfizer against Samsung Bioepsis (*Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd* [2017] FCAFC 193 (***Samsung***), which we discussed ***here***) in respect of its biosimilar etanercept product. The Full Court confirmed that as long as there are reasonable grounds for a belief that there may be a right to relief, it is not necessary to show, for example via expert evidence, that such a claim would succeed. Indeed the purpose of obtaining preliminary discovery is to determine whether a right to relief in fact exists.

In light of the *Samsung* decision, it would likely have been difficult for Sandoz to show in this case that Pfizer did not have the requisite level of belief that ERELZI may fall within the scope of the claims of its patents, and indeed Sandoz accepted that Pfizer had such belief for the purposes of the application.

However, Sandoz relied on undertakings offered to Pfizer, pursuant to which it undertook not to exploit any ERELZI products in Australia or take steps to proceed with PBS listing, for the duration of the patent, without first giving Pfizer certain notice. The length of the notice offered is not recorded in the judgment for confidentiality reasons, however the judgment notes that in earlier correspondence Sandoz had offered to give Pfizer 150 days' prior written notice. It is assumed therefore that the notice period offered is relatively substantial. Sandoz also agreed to provide certain discovery within a period of time after giving any such notice (the details of this undertaking were also confidential).

In these circumstances, Pfizer contended that the notice period offered was insufficient to allow it to obtain relief in time if Sandoz did in fact give notice of an intention to launch. It sought an order that Sandoz give preliminary discovery of specified schedules of documents within 7 days of giving the relevant notice and a 'Sabre order' requiring it to seek production of any such documents held by related companies. The issues were therefore quite confined.

Justice Burley refused the orders sought by Pfizer. Based on the language of the relevant Federal Court Rules governing preliminary discovery, his Honour

concluded that Pfizer needed to show a reasonable belief that its rights may be infringed as at the date when the application is being assessed. Calling in aid notions of *quia timet* relief, Pfizer argued that the relevant question was whether it held a reasonable belief that the notice offered by Sandoz was likely to afford Pfizer sufficient time to protect itself from material harm. However, Burley J held that the circumstances of the case did not warrant a reading of the Rules which would in effect provide an exception to the reluctance of the Court to answer questions based on hypothetical facts, as was the case here where Sandoz had not yet made a decision to launch. He gave examples of difficulties which could arise, in particular, the appropriate scope of any preliminary discovery could be affected by admissions which Sandoz might make with respect to infringement.

Significance

While the outcome in this case is highly dependent on the specific facts, it does highlight the potential effectiveness of appropriately crafted undertakings in resisting legal action, where a product has been listed on the ARTG and steps have been taken to list on the PBS, circumstances which would generally amount to a threat of patent infringement, in the absence of any undertakings.

Preliminary discovery applications are set to become a more common weapon in the patent litigation arsenal in years to come, particularly given the increasing significance in Australia (as elsewhere) of biosimilar patent litigation, where patents covering manufacturing processes are likely to assume greater importance given the additional complexities at play in claiming active biological molecules per se, and the significance of specific manufacturing processes in the production of biologics. Given the likely lack of available information as to a competitor's manufacturing processes, preliminary discovery may be an essential prelude to patent infringement claims in such cases, assisted by the planned Therapeutic Goods Administration "transparency measures" which will introduce an earlier notification scheme for generic and biosimilar medicines. Equally we expect to see the strategies to resist such applications develop providing more case law in this area.

Intervet parries a challenge to its combination injectable anthelmintic formulation patent application

***Boehringer Ingelheim Animal Health USA Inc. v Intervet International B.V.* [2020] FCA 1333 (17 September 2020)**

Read the Decision

***Boehringer Ingelheim Animal Health USA Inc. v Intervet International B.V. (No 2)* [2020] FCA 1433 (5 October 2020)**

Read the Decision

Judge: Moshinsky J

| *pharmaceutical* | *animal vaccines* | *Patent Office opposition appeal* | *validity* | *costs* |

Authors

Ean Blackwell
(Senior Associate, Patent Attorney)

Katrina Crooks
(Principal, Lawyer)

In brief

An appeal from a decision of the Delegate of the Commissioner of Patents was denied, with the the patent application in dispute held to be novel, inventive and not lacking utility. In particular the invention was a "substantial departure" from known formulations, and addressed a long-standing need for a combination parasitic treatment, and was thus not obvious.

In a subsequent decision on costs for two interlocutory amendment applications, each party was required to bear its own costs, particularly in circumstances where the amendments sought were in the nature of an "indulgence", and there had been no adjudication on the merits of either application as the amendments were ultimately consented to.

Background

Merial Inc, now Boehringer Ingelheim Animal Health USA Inc (**Boehringer**), appealed from an opposition decision in respect of Australian patent application AU 2011268899 (**899 Application**). The invention described in the 899 Application related to injectable formulations comprising a macrocyclic lactone and levamisole for controlling parasites in animals, and the use of such formulations in the preparation of a medicament for controlling parasites. The problem addressed by the 899 Application was that some parasites develop a resistance to anti-parasitic drugs. Combinations of known drugs had been used in the art to overcome this resistance, but it was desirable to develop an injectable formulation for a combination of a macrocyclic lactone and levamisole, two of the most widely used and effective antiparasitic drugs.

However, such combinations have been difficult to formulate, for three main reasons. First, levamisole and macrocyclic lactones are chemically incompatible and tend to react with each other when combined. Secondly, levamisole and macrocyclic lactones are stable under different pH conditions. Finally, levamisole salts are soluble in water, whereas macrocyclic lactones are not water soluble but are soluble in organic solvents, and are commonly formulated in oils and organic solvents. The invention in the 899 Application addressed these issues by adopting a non-aqueous solvent system comprising oil and an organic solvent, in which the macrocyclic lactone is in *solution*, and the levamisole is a salt in particulate form (that is, in *suspension*). This type of formulation achieves a separation of the macrocyclic lactone and the levamisole, thus addressing the issue of chemical incompatibility.

Claim 1 of the 899 Application is as follows:

> *An injectable formulation of a macrocyclic lactone and levamisole in a non-aqueous solvent system comprising oil and an organic solvent, wherein the macrocyclic lactone is in solution and the levamisole is a salt in a particulate form, and wherein the levamisole salt is present in the range of between 10-35% w/v.*

Decision

Boehringer was unsuccessful in its opposition in the Patent Office and appealed on various grounds.

Novelty

Boehringer contended that various claims were not novel in light of Chinese patent application CN 1375291A (**CN 291**). Example 3 of CN291 set out an oil injection containing a combination of ivermectin (a macrocyclic lactone) and levamisole hydrochloride. However, it was clear that the concentration of levamisole HCl in Example 3 at 5% w/v did not fall within the scope of claim 1 of the 899 Application, which specified 10-35% w/v. Further, Example 3 did not set out any manufacturing steps, or any description of what was intended to be made. Moreover, it did not describe the levamisole HCl as being in particulate form (or in a suspension).

Boehringer submitted that Example 3 of CN 291 was to be read in conjunction with claim 3 of CN 291, which discloses levamisole HCl in the amount of 10-20% w/v, and with the specification, which discloses that preferably the levamisole HCl is present in the amount of 10-20% w/v. Further, Boehringer submitted that a skilled person reading CN 291 as a whole would understand that CN 291 contained a direction, recommendation or suggestion to make the Example 3 formulation using 10-20% w/v levamisole HCl, because they would consider the 5% w/v concentration of levamisole HCl stated in Example 3 to be far too low for cattle, particularly in light of the other teaching in CN 291.

Based upon expert evidence, Boehringer further argued that the skilled person would expect the levamisole HCl in Example 3 to be suspended in the solvent system and to be present in particulate form, because the skilled person would expect that levamisole HCl will not dissolve in the solvent system of Example 3. However, Moshinsky J was not convinced, finding that there was no sufficiently clear and unambiguous direction to modify Example 3 by applying the higher concentration level described elsewhere. Further, the Court emphasised that Example 3 did not describe the intended formulation as one in which the levamisole HCl is in particulate form.

Inventive step

Boehringer contended that that it would have been obvious to the notional skilled person or team, based on the common general knowledge alone, or in light of the common general knowledge together with CN 291, to make a suspension formulation using an oil or organic carrier as a base and a co-solvent such as benzyl alcohol, in which the macrocyclic lactone was in solution and the levamisole salt was in suspension. It submitted that the skilled person would appreciate that, in such a composition, the levamisole salt would be in particulate form, and that they would know to use a concentration of levamisole salt sufficient to achieve the desired dose.

However, the Court found that an oily formulation with levamisole present as a particulate was a substantial departure from known formulations, particularly in respect of levamisole. The expert evidence had also shown that, in order to be effective, levamisole needed to reach a high peak concentration in the animal's gut rapidly, and preferably underwent similarly rapid clearance from the animal to meet regulatory requirements. As there were no existing formulations of levamisole as a particulate in oil, a carrier often used to slow down absorption of a drug, it was not clear in the common general knowledge whether an effective peak concentration of levamisole could be reached in the animal using such a formulation. Based upon the evidence, it was held that a solution appeared to be preferable to a suspension for an injectable formulation, and that the above uncertainties as to efficacy, as well as others, would point away from the adoption of such an approach.

Lack of utility

Boehringer submitted that the stability data in Intervet's patent application WO 2017/108954 A1 demonstrates that not all formulations falling within the scope of the claims of the 899 Application achieve the promise of being physically and chemically stable. In particular, Boehringer relied on data demonstrating loss of stability at 2 months. However, the figures for *3 months* – this being the relevant period for the purposes of the promise – did not show such a loss of stability. Accordingly, it was held that the data did not establish that the invention failed

to meet the promise of stability (that is, stability for 3 months under accelerated conditions). Moreover, it was found that the data was inherently unreliable, and, even if it *had* shown a loss of stability as at 3 months, the Court would not have been satisfied that the invention failed the promise of stability.

Costs of amendment applications

In a subsequent judgment (*Boehringer Ingelheim Animal Health USA Inc. v Intervet International B.V.* (No 2) [2020] FCA 1433), the Court dealt with the costs of two interlocutory amendment applications. In respect of each interlocutory application to amend, the Court found that "Intervet sought something in the nature of an indulgence". The Court held that in such cases, the patentee may be ordered to pay the costs of the amendment application, regardless of the outcome. Accordingly, Boehringer's request that each party bear its own costs was appropriate, particularly in circumstances where there was no adjudication on the merits of either application because Boehringer had ultimately consented to the amendments.

Significance

In this case, an expected change to the gut absorption rate of levamisole salt was an obvious reason not to formulate the combination injectable with the levamisole salt in a suspension, meaning that the solution arrived at by the 899 Application (in which the macrocyclic lactone is in solution, and the levamisole salt is in suspension) was inventive.

Crown use defence to infringement and the effect of disclosure by the Crown on validity

***Axent Holdings Pty Ltd t/a Axent Global v Compusign Australia Pty Ltd* [2020] FCA 1373 (25 September 2020)**

Read the Decision

Judge: Kenny J

| mechanical | Crown use defence | Crown disclosure | extension of prescribed period |

Authors

Tam Huynh
(Principal, Patent Attorney)

Dean Bradley
(Patent Engineer)

In brief

This decision of Kenny J of the Federal Court of Australia considers many issues including the Crown use defence; whether information published by the Crown (and made available to them by a patentee) can be novelty defeating; and the effect that requesting an extension of time to renew a patent outside of the grace period has on the relevant period the patent is taken to have ceased.

Background

Axent Holdings Pty Ltd, trading as Axent Global, (**Axent**) commenced proceedings against Compusign Australia Pty Ltd and Compusign Systems Pty Ltd (together **Compusign**) as well as Hi-Lux Technical Services Pty Ltd (**Hi-Lux**) (the respondents) for infringing Australian Patent No. 2003252764 titled "Changing Sign System" **764 Patent**). The 764 Patent claimed an earliest priority date of 4 October 2002 and was granted on 26 June 2008. The respondents filed a cross claim asserting the Patent was invalid.

The invention related to a changing sign system for use as a variable speed limit sign (**VSLS**) on roadways. The VSLS could be used to display a lower hazard speed limit instead of the normal maximum safe speed when a certain condition is detected. In September 2001, Mr Fontaine, the director of Axent and named inventor of the Patent, met with Mr Bean, who worked for VicRoads, to view a demonstration of Axent's variable speed limit sign. Mr Fontaine stated that he subsequently received tender documents which included a VicRoads specification (the **September 2001 specification**) which contained a requirement that part of the inner diameter of the annulus should be capable of flashing on and off.

Decision

Crown use defence

Hi-Lux submitted that each of VicRoads, the South Australian Department of Planning, Transport and Infrastructure, and the City of Greater Geelong was an authority of a State for the purposes of section 163 of the *Patents Act 1990* (Cth) (**Act**) which provides that exploitation of an invention by or for the services of the Commonwealth, or a State is not an infringement of any patent rights.

Her Honour considered that each of the organisations were an Authority of the state and that the exploitation of the sign was for the services of each Authority. However, this was subject to section 163(3) which required that the exploitation of the invention was necessary for the proper provision of the services within Australia. Her honour considered it may be that exploitation was not strictly necessary in the sense contemplated by section 163(3) because alternative signage was available and widely used. However, this was not considered further, in any event, as Hi-Lux failed to satisfy her Honour that it were authorised in writing by an authority of the State.

The contract for the supply and installation of variable speed limit signs between the Commissioner of Highways and Hi-Lux included a specification which set out the requirements for the variable speed limit signs. There was a possibility this contract may have required a product that infringed the 764 Patent and thus, the infringing acts may well have been authorised for the purposes of section 163. However, in the absence of submissions or evidence to this effect, her Honour was not satisfied that the contract with the Commissioner required Hi-Lux to supply goods that necessarily infringed the patent in suit. Accordingly, Hi-Lux's defence under section 163 of the Act did not succeed.

Lapse of patent

Axent did not pay the renewal fees for the Patent by the due date 6 October 2015; nor did it pay the fees by 6 April 2016, within the 6 month grace period. Axent applied for an extension of time which was granted on 1 September 2016 and the renewal fees were then applied to the 764 Patent. The 764 Patent therefore ceased to be registered for a period for the non-payment of fees.

The respondents submitted that the period for which infringement cannot be asserted was from the day after that on which the renewal fee for the 764 Patent was due, 7 October 2015, to the day on which an application to extend the time to pay the renewal fee was granted, 1 September 2016. Axent submitted the relevant period began on 5 April 2016 (that is, approximately 6 months after the 7 October 2015) and concluded on 1 September 2016. The commencement of the relevant period turns on the construction of reg 13.6 of the *Patents Regulationsection 1991* (Cth), which relevantly provides that the period in which the renewal fee must be paid is the period ending at the last moment of the anniversary, however, if the renewal fee is paid within 6 months after the end of the relevant anniversary the period is taken to be extended until the fee is paid. The respondents submitted, and her Honour accepted, that the period is only "taken to be" extended if the condition of the renewal fee being paid within the 6 month grace period is satisfied. Had Axent paid the renewal fee at any time before the end of the 6 month grace period, the patent would never have ceased as the prescribed period would have been extended by reg 13.6(2)(a) to end on the day Axent paid the fee. However, Axent did not pay the renewal fee before 5 April 2016, and in consequence reg 13.6(2)(a) had no application.

Invalidity of the Patent

The respondents submitted the claims were not novel because the invention was disclosed by the September 2001 specification and as part of the installation process for the Western Ring Road Project. Axent submitted that the September 2001 specification was merely a "wish list" that provided insufficiently direct disclosure and in any event was excluded from being considered for the purposes of novelty because of section 24(1)(b) and/or section 24(2). Axent contended that it had disclosed its invention to VicRoads confidentially and never consented to VicRoads on-disclosing it in the September 2001 specification. The respondents contended, and her Honour agreed, that section 24(2) did not apply because the September 2001 specification was a disclosure made by, and not to, the Crown and the language of section 24(2) did not support the "reach-through effect" that Axent had argued.

There was still the further question as to whether section 24(1)(b) operated. A central issue was whether the information was made publicly available without the consent of Axent. Whilst there was no evidence that Axent expressly stated consent, having regard to the circumstances and the evidence, her Honour was satisfied that Axent positively consented to the inclusion of the claimed invention in the September 2001 specification. Accordingly, section 24(1)(b) did not apply.

Justice Kenny rejected that the September 2001 specification was part of the common general knowledge or that it could be combined with the common general knowledge. Accordingly, the critical question was, whether each of the claims lacked inventive step by reference to common general knowledge alone. The evidence was clear that, apart from the flashing annulus feature, the other features of the claims were obvious as at the priority date. However, there was clear evidence that that the skilled worker was aware of a flashing annulus feature well before the priority date.

Her Honour considered that no problem was overcome or barrier crossed by the adoption of the flashing annulus feature and that the evidence indicated a person skilled in the art would have taken the steps leading from the prior art to the claimed invention as a matter of routine. The Patent was found invalid for lack of inventive step by reference to the common general knowledge alone, and claims 1, 9, 10, 14, 15, 17, 20 and 27 were invalid for want of novelty in light of the disclosure of September 2001 specification.

Significance

The decision clarified that the prescribed period to pay a renewal fee to prevent a patent ceasing is only taken to be extended until the fee is paid if the fee is paid within the 6 month grace period. Accordingly, when the renewal fee is paid after the 6 month grace period by relying on an extension of time, the patent is taken to have ceased from the point after the last moment of the anniversary of the patent.

Regarding the Crown Use defence, the decision indicated that written authorisation by the Crown to exploit an invention may be explicit or implied, but the authorisation must be specific such that the necessary exploitation of the invention is authorised and that alternatives are not possible.

For information made available to the Crown by a patentee and subsequently published by the Crown, the decision indicated section 24(2) did not provide a "reach-through effect" to exclude such a publication from the prior art when considering novelty and inventive step.

Patent litigation is a (long) black art

***Caffitaly System S.p.A v One Collective Group Pty Ltd* [2020] FCA 803 (19 June 2020)**

Read the Decision

Judge: Nicholas J

| mechanical | infringement | novelty | inventive step |

Authors

Connie Land
(Patent Engineer)

Paul Harrison
(Principal, Patent Attorney)

In brief

This decision explores the construction of claims and the interpretation of a specification as a whole during infringement proceedings.

Background

Caffitaly System S.p.A (**Caffitaly**) manufacture and sell coffee machines and coffee capsules worldwide. Caffitaly commenced infringement proceedings against its competitor, One Collective Group Pty Ltd (**OCG**) for infringement of the Caffitaly coffee capsules embodied in Australian patent 2003200627 (**627 Patent**), 2010227121 (**121 Patent**) and 2008259388 (**388 Patent**). OCG issued cross-claims seeking to invalidate and revoke Caffitaly's three patents.

Caffitaly alleged OCG's version 5 coffee capsule infringed the 627 Patent which principally comprised of a fluid director member with a plurality of openings and a plurality of embossings. OCG challenged the novelty and inventive step of the 627 Patent alleging the feature of a cover member, adapted to be sealingly attached to the main body of the capsule was anticipated by US patent 4,921,712 (**712 Patent**) either alone or in combination with common general knowledge. To aid their argument, OCG set mechanical engineer, Mr Karl Winkler, a hypothetical design task to establish the coffee capsule of the 627 Patent was obvious.

Caffitaly alleged versions 1 to 4 of OCG's coffee capsules infringed claims of the 121 Patent which principally comprised a coffee capsule with an annular groove that was designed to engage with a peripheral edge of a filter to clampingly fix the filter to the capsule. OCG submitted claims of the 121 Patent were not novel in light of the application for the 627 Patent (**627 Application**) and the application of a European Patent (**EPA605**). OCG further submitted that the 121 Patent lacked an inventive step in light of common general knowledge and the 627 Application or EPA605. Caffitaly opposed OCG's arguments stating the skilled addressee would not seek to modify the collar arrangements of EPA605 in preference of a groove due to the clear advantages of the collar arrangement. Caffitaly further submitted the 627 Application does not provide motivation or suggestion that would directly lead the skilled addressee to adopt the arrangement of the coffee capsule in the 121 Patent.

Caffitaly alleged the physical characteristics of versions 1 to 3 of OCG's coffee capsules infringed the 388 Patent. In support of their claim, Caffitaly presented several tests carried out by mechanical engineer, Mr William Hunter on OCG's coffee capsules. OCG asserted the 388 Patent was invalid due to lack of sufficiency and utility.

Decision

627 Patent

The Court ruled that OCG's version 5 capsule did not infringe the claims of the 627 Patent on the basis that the raised portions on OCG's capsule were not "embossings". Rather, the raised portions were intended to be used as piercers.

Justice Nicholas found the sealing sheet of the 712 Patent was not "adapted to be sealingly attached" to the main body portion of the cartridge. As such, Nicholas J was not satisfied the 712 Patent contained a clear disclosure of the invention in the 627 Patent. Therefore, the 627 Patent was found to be novel over the 712 Patent.

Justice Nicholas contemplated the design of an Espresso coffee capsule in relation to the common general knowledge and Mr Winkler's design task. His Honour conceded the design of an Expresso coffee capsule which included the features of the 627 Patent would not require inventive ingenuity or any

contribution to the art that was "beyond the skill of the calling". Accordingly, Nicholas J deemed the 627 Patent to be invalid due to the lack of an inventive step in light of the common general knowledge.

121 Patent

Justice Nicholas noted corresponding features in versions 1 to 4 of OCG's coffee capsules and the 121 Patent did not perform the same function or engage in the same way. As such, Nicholas J concluded that versions 1 to 4 of OCG's coffee capsules did not infringe the 121 Patent.

Justice Nicholas concluded the claims did not lack novelty over the 627 Application or EPA605 on the basis there was no clear feature of an annular groove in either of the prior art documents. With respect to inventive step, Nicholas J noted it was likely the skilled addressee would try other fixing arrangements such as the groove of the 627 Application. In turn, Nicholas J concluded that claims 1 to 5 and 14 of the 121 Patent were invalid for lack of inventive step in light of the common general knowledge when combined with either the 627 Application or EPA605.

In making his decision, Nicholas J also considered freedom to operate searches and whether the cited art constituted information the skilled addressee could be reasonably expected to have ascertained, understood and regarded as relevant from the search. In this case, it was concluded that a routine patent search would have identified EPA605 as relevant art, and therefore, the skilled addressee should be aware of EPA605. Accordingly, the Court found EPA605 could be used, alongside common general knowledge, to determine whether the invention as claimed involved an inventive step.

388 Patent

Justice Nicholas was not persuaded by Mr Hunter's experiments as his evidence considered infringement at "a level of abstraction" rather than addressing the question of how OCG's capsules would behave in a compatible coffee machine. In turn, on the balance of probabilities, Nicholas J stated OCG's coffee capsules would not infringe 388 Patent by sale, use or otherwise.

Justice Nicholas considered the steps a person skilled in the art would be required to take to make a capsule disclosed in the 388 Patent and noted it "would be neither readily apparent nor standard or routine in character". The Court also stated the coffee capsule of the 388 Patent would not fulfil the promise of the invention as the capsule did not provide any opportunity for pre-infusion. As such, Nicholas J found claims of the 388 Patent lacked sufficiency and utility, and therefore were invalid.

Significance

This decision highlights the importance of modelling the alleged infringing product in relevant circumstances (i.e. in everyday use of the product). Specifically, Nicholas J grounded the infringement evidence of the 388 Patent as it "sought to deal with the infringement issues at a level of abstraction that ignores the effect that the operation of the coffee machine in which the capsule is used will have on the behaviour of the capsule".

Not quite déjà vu: Anshun Estoppel and permanent stay arguments rejected

***Vehicle Monitoring Systems Pty Limited v SARB Management Group Pty Ltd trading as Database Consultants Australia* [2020] FCA 6 (10 January 2020)**

Read the Decision

Judge: Yates J

| *electronic* | *infringement* | *Anshun estoppel* |

Authors

Onur Saygin
(Lawyer)

Mark Vincent
(Principal, Lawyer)

In brief

This decision of the Federal Court dealt with an interlocutory application in proceedings brought by a respondent on the basis that the applicant's case should be precluded as it was seeking to litigate questions so connected with earlier proceedings between the same parties that it was unreasonable not to have made the claim in the earlier litigation, so that "all relevant issues could be determined at once" (**Anshun Estoppel**) and separately that the case should be permanently stayed as an abuse of court process. The Court ultimately rejected the respondent's arguments, providing insight into factors which an Australian Court will consider determinative when Anshun Estoppel and abuse of process are alleged by a litigant in the process.

Background

In 2019, Vehicle Monitoring Systems Pty Limited (**VMS**) commenced Federal Court litigation against SARB Management Group Pty Limited (**SARB**) and the City of Melbourne (**COM**) for infringement of its Australian Patents numbered 2005243110 filed on 9 May 2005 (**110 Patent**) and 2011204924 filed on 2 December 2010 (**924 Patent**). These patents are both entitled "Method, apparatus and system for parking overstay detection". The 924 Patent is a divisional of a divisional of the 110 Patent.

VMS's patents encapsulate a vehicle detection system (**PinForce Systems**) and a vehicle detection unit (**PinForce Sensors**), which VMS alleges have been exploited by SARB since October 2007. VMS also alleged that since at least 2009, SARB has used, offered to use and authorised others (including COM) to use these inventions *in methods for identifying overstay of a vehicle in a parking space* (the **PinForce Methods**). VMS also alleged that COM *has used, and kept for the purpose of using, the PinForce Sensors and the PinForce Systems, and used them in the corresponding PinForce Method.*

Earlier related litigation between VMS and SARB focused on a separate VMS Innovation patent 2010101354 (**354 Patent**), also being a divisional of a divisional of the 110 Patent. That litigation generated the 2013 decision of *Vehicle Monitoring Systems Pty Limited v SARB Management Group Pty Ltd trading as Database Consultants Australia* [2013] FCA 395, which found that SARB had infringed claims of the 354 Patent prior to its expiry by exploiting a product and authorising COM to use the method encapsulated by the 354 Patent. The 2013 first instance decision was appealed by SARB but in 2014 settlement was reached and a deed of release concluded prior to a judgment being issued, with the proceeding discontinued (not dismissed).

On payment of a sum of money by SARB, the 2014 deed of release between the parties (**Settlement Deed**) came into effect. It referred only to the 354 Patent and infringements which occurred prior to its expiry, setting particular restraints on what VMS could do, including restricting it from suing parties to which SARB had supplied the PinForce Sentinel vehicle detection unit. It also explicitly identified that the deed did not release SARB or other third parties *"from any Claims for infringement and/or exploitation of any other patents or patent applications, including any patents or patent applications that may be related to"* the 354 Patent.

Decision

The 2019 litigation commenced following correspondence between SARB and VMS in which VMS sought assurances about the activities of SARB in supplying products it suspected of infringing its patents, similarly to those the subject of the 2013 litigation. VMS included in its statement of claim certain allegations that related to a "second version" of the Pinforce Sensors and Pinforce Systems.

Other important facts to note about the patents are that there is a close correlation between some of the claims of the 110 Patent, 924 Patent and the 354 Patent and that during the first proceeding, the 110 Patent was in force but the 924 Patent was not granted until 4 February 2016.

In its application for a permanent stay, SARB's main arguments were that:

- *the 110 patent is so connected with the subject matter of the first proceeding, that it was unreasonable for VMS not to have made that claim in that proceeding, so that "all relevant issues could be determined at once",*
- that due to this close connection, the bringing of the claim relating to the 110 Patent and the 924 Patent was additionally an abuse of the Court's Process,
- to the extent VMS's claims encapsulated sale or supply of PinForce Sensors and PinForce Systems before 9 May 2013 which VMS had already been compensated for, they were an abuse of the Courts process by reason of double compensation, and
- statute of limitations bars any recourse with respect to sale or supply of patented products before the relevant statutory cut off, which was 15 February 2013.

Anshun Estoppel

The Court found that VMS ought not be prevented (estopped) from continuing its litigation in relation to the 110 Patent on the following bases:

- As legal conceptions, the rights which subsist in each of the 354 and 110 Patent are discrete from one another, notwithstanding the relation between the patents. For this reason, a judgment in relation to the 110 Patent could not be said to *"contradict or impeach the judgment on liability given in respect of the 354 patent"*.
- VMS could not have sued in relation to the 924 Patent in the 2013 proceedings as that patent was granted on 4 February 2016, years later.
- Whilst VMS could have sued in relation to the 110 Patent which was live when the first proceeding commenced in April 2011, this would have increased the complexity of that case and hence the duration and costs involved, whilst it had been reasonable to expect that suing on the 354 Patent alone could achieve cessation of the respondent's infringing conduct. Hence at the time of the 2013 proceeding, it was not inevitable that VMS would need to sue SARB in relation to the 110 Patent – there was a *real prospect* that it would not.
- SARB's assertion in correspondence that the PinForce Product it supplies, the subject of the present litigation, differ from the products the subject of the 2011 litigation. The Court considered that: (1) this validated the proposition that suing only on the 354 Patent in 2011 achieved SARB ceasing the impugned conduct in relation to the product, and (2) exploitation of the current products could not have been litigated in 2011 as they did not exist at that time.
- The terms of the Settlement Deed made it clear that VMS was free to sue in respect of rights other than the 354 Patent, including related patents. Whilst the deed did not explicitly bar an action by SARB claiming Anshun Estoppel or abuse of process, its terms made clear that part of the bargain was that SARB be free to sue in respect of other patents for the same acts the subject of the 2011 litigation.

The Court agreed with the argument raised by SARB that Anshun Estoppel served, in addition to private interests, public interests and should not be limited by acts of parties or agreements reached by parties. However the Court did not consider the facts in this case to diminish the public policy objectives. The Court also pointed out that in the 2011 proceedings, it had been open to SARB, which knew of the 110 Patent, to cross-claim for a non-infringement declaration for that patent or seek revocation of that patent.

Abuse of process

The Court outlined the two bases under which the Court may find there has been an abuse of process, being:

A. *the use of the court's procedures occasions unjustifiable oppression to a party;* and

B. *the use serves to bring the administration of justice into disrepute.*

The Court cited authorities which acknowledge that litigating issues which could have been raised during prior litigation can in some circumstances be classified as an abuse of process.

SARB argued that the proceedings should be stayed permanently as an abuse of process, based on same reasons it sought Anshun Estoppel and also because: (1) to do so would advance public policy considerations, by counteracting the *perception that the administration of justice is inefficient, careless of costs and profligate in its application of public moneys;* (2) part of VMS's claim was barred by the limitation period stated in the *Patents Act 1990* (Cth); and (3) overlap in the alleged infringing conduct with the 2013 proceedings would result in VMS being compensated for the same infringing conduct twice.

Emphasising again that SARB's Settlement Deed with VMS and SARB's assertion that its current products were different weighed against a finding of an abuse of process, the Court was unpersuaded that it should enliven a finding of abuse of process in this case for largely the same reasons as its dismissal of the Anshun Estoppel arguments. In terms of arguments (2) and (3), the Court considered these were matters better suited for consideration at trial.

The Court dismissed SARB's argument that the extension of VMS's case to the 924 Patent was also an abuse of process. SARB's argument suggested that if the 110 Patent infringement pleading was an abuse of process, that ought also apply to the 924 Patent on the basis it would "subvert the protection" that SARB had in relation to the 110 Patent. In rejecting SARB's argument, the Court highlighted that the 924 Patent did not exist at the time of the first proceeding and that SARB was asserting that the products in question in the hearing differed from those considered in the earlier proceeding.

Other issues

The Court also considered an argument by SARB that VMS's statement of claim contained particulars of the infringement which were vague, general and failed to identify examples of infringement and that the allegations in relation to the second version of SARB's products and ought be struck out. The Court rejected this argument, suggesting that the appropriate course was that VMS provide appropriate particulars at some appropriate time, unless VMS demonstrated this was not warranted.

Significance

While Anshun Estoppel or abuse of process may sometimes offer swift respite to a respondent in otherwise lengthy litigation, this case is illustrative of some of the obstacles for respondents to contemplate when considering these procedural options.

The Court in this decision was significantly persuaded by the wording, including caveats in the Settlement Deed. That the deed made it clear that VMS reserved its rights outside of the narrow agreement to agree not to sue in relation to past infringement, was also highly persuasive.

Any settlement of a patent infringement dispute must be carefully considered from the perspective of the patentee's rights to immediately commence fresh proceedings for infringement of any other claim in any other patent in its portfolio. If an understanding is sought as to a period in which no new litigation will be commenced, then a covenant not to sue on particular patents, for particular periods or in particular jurisdictions should be negotiated.

Furthermore, a patent in a current lawsuit which was not yet granted during past litigation is indicative of the fact that the litigation relates to a distinct instance of intellectual property. Notably, a significant overlap in claims does not necessarily mean there are identical patent rights.

Finally, as findings of patent infringement originate from specific conduct of a responded, litigants in Patent proceedings running Anshun Estoppel or abuse of process arguments and alleging relitigating of issues previously put before the Court should take great care to ensure that any suggestion that their present conduct does not infringe because it differs from former conduct is weighed up against the reality that if true, this undermines their prospects of success.

A non-obvious solution for issuing parking infringement notices

***Vehicle Monitoring Systems Pty Ltd v SARB Management Group Pty Ltd* [2020] FCA 408 (30 March 2020)**

Read the Decision

Judges: Burley J

| electronic | post-raising the bar provisions | claim construction | inventive step |

Authors

Dean Bradley
(Patent Engineer)

Greg Whitehead
(Principal, Patent Attorney)

In brief

This decision forms part of an ongoing battle between two Australian companies over patented technology for improving the efficiency by which authorities monitor and manage access to public parking. In this decision, the Federal Court of Australia provides some helpful guidance on the approach to assessing whether or not a claimed invention involves an inventive step (i.e. is not obvious) under the current provisions of Australian patent law.

Background

Vehicle Monitoring Systems Pty Ltd (**VMS**) developed a Parking Overstay Detection System (**the POD system**), which uses in-ground sensors to detect changes in the earth's magnetic field when a vehicle enters a parking space bay. A message is sent wirelessly to a device carried by a parking officer who can then issue an infringement notice, as required.

VMS sought to collaborate with SARB Management Group Pty Ltd (**SARB**) to advance the POD system technology. SARB is the designer and distributor of software popularly used with generic handheld PDAs for issuing parking infringement notices by council officers. However, no collaboration eventuated from these discussions. Instead, SARB developed its own vehicle detection system which was also based on the use of a sensor to detect changes in the earth's magnetic field when a vehicle enters a parking space. More specifically, SARB's system incorporated a vehicle detection unit (**VDU**) using a magnetic sensor capable of detecting occupancy of a vehicle space by a vehicle; a storage device carrying parameters which define notifiable vehicle space occupancy events; and a processor operable to initiate a communication from the VDU to a supervisory device (such as a PDA) upon occurrence of a notifiable event (such as a parking violation), wherein the communication includes data items pertaining to the notifiable event and is communicated in a format suitable for pre-population into infringement issuing software.

SARB's system became the subject of Australian Patent Application No. 2013213708, entitled 'Vehicle Detection' (**SARB application**). Relevantly, VMS opposed the SARB application on the grounds that the claimed invention lacked an inventive step and that SARB was not entitled to the grant of a patent for this invention under the *Patents Act 1990* (Cth). An opposition hearing was conducted before the Australian Patent Office (*Vehicle Monitoring Systems Pty Ltd v SARB Management Group Pty Ltd* [2017] APO 63). The Patent Office rejected each of the grounds advanced by VMS, determining that claims 1-24 should proceed to grant (but claims 25-28 should not be granted). VMS appealed this decision to the Federal Court of Australia and the present decision concerns the outcome of this appeal.

Decision

VMS submitted that claims 1-24 of the SARB application lacked an inventive step in light of the common general knowledge and five sources of prior art information, including: a published PCT application (filed by VMS); a published Australian patent, a published journal article; slides of a presentation given at an industry conference in 2005; and details of an oral presentation given at an industry conference in 2006.

Claim construction

For ease of reference, claim 1 is reproduced below:

> ***A vehicle detection unit (VDU)*** *comprising:*
>
> 1. *a* ***magnetic sensor*** *able to sense variations in magnetic field and for outputting a sensor signal caused by occupancy of a vehicle space by a vehicle;*
> 2. *a* ***storage device*** *carrying parameters which define notifiable vehicle space occupancy events;*
> 3. *a* ***processor*** *(a) operable to process the sensor signal to determine occupancy status of the vehicle space, and (b) operable to compare the occupancy status of the vehicle space with the parameters in order to determine whether a notifiable event has occurred, and (c) operable to initiate a communication from the vehicle detection unit to a supervisory device upon occurrence of a notifiable event, wherein the communication includes (i) data items pertaining to the notifiable event and (ii) communicated in a format suitable for pre-population into infringement issuing software.*

There were contentions over the construction of the scope of claim 1, particularly as to whether the VDU initiates a communication only upon the occurrence of a notifiable event or whether the claim includes that the VDU is operable (i.e. able) to initiate a communication at a time other than when a notifiable event has occurred. The Court preferred the latter construction, as to do otherwise would inappropriately add a limitation to the claim that is not present – that is, inserting the word 'only' before 'operable'. Additionally, the Court considered that data items pertaining to the notifiable event did not include all data items as the plain language of the claim simply refers to "data items".

Furthermore, there was consideration of the feature "communicated in a format suitable for pre-population into infringement issuing software". VMS submitted that this required the data communicated from the VDU to the supervisory device to be able to be pre-populated into the data fields in the infringement issuing software without further data processing by the supervisory device. SARB largely accepted this construction but submitted that the language of claim 1 does not preclude additional necessary processing at the supervisory device; for example to receive and organise the data packets. The Court agreed with VMS's construction and SARB's qualification.

Inventive step

Section 7(3)(a) of the *Patents Act 1990* (Cth) enables any publicly available single item of prior art information to be added to the common general knowledge for the purpose of considering whether or not an invention involves an inventive step. Section 7(3)(b) facilitates the addition of a combination of two or more (publicly available) pieces of prior art information to supplement the common general knowledge for the consideration of invention step, subject to the condition that the skilled person could be reasonably expected to have combined them. The requirement that the prior information merely be publicly available for it to be available for the consideration of inventive step represents a significant departure from the more rigorous requirements that existed before the changes to Australian patent law introduced by the *Raising the Bar Act*.

There was some dispute between the parties as to the proper approach to be taken when seeking to combine two or more pieces of prior art information under s 7(3)(b). The Court reviewed the submissions from each party and summarised the relevant law before stating:

> *It follows that I do not accept that it is necessary for VMS to demonstrate any more for the purpose of s 7(3)(a) than that the prior art information has been made publicly available. Once it has done so, such information is notionally supplied to the person skilled in the art within s 7(2). For combining two or more pieces of prior art information, s 7(3)(b) deems that if those pieces of information are 'publicly available', they are be made available to the person skilled in the art. It will be a question of fact whether or not they may be reasonably be expected to be combined.*

The Court considered that the broad working of the POD system formed part of the common general knowledge in the art but did not accept that the common general knowledge would include a detailed understanding of the mechanisms of the POD system, or experience of using the POD system. VMS first relied on the combination of the PCT application with information contained in an article on the POD system entitled "PODS – the Next Big Thing". However, the article did not consider pre-population of data items into infringement issuing software, which was a crucial item of detail absent from the disclosure of the PCT application. VMS also cited a PowerPoint presentation, by Mr Gladwin, only as a publication of the slides. The meaning of the slides, shorn of detail provided during the presentation, was opaque and the information in them was not considered to be of any practical use in the implementation of the PCT application. Additionally, VMS cited a presentation given by Mr Welch at a conference in November 2006. However, VMS faced insurmountable hurdles in proving the content of the presentation was made publicly available.

In considering inventive step, the Court was conscious that the question is whether the combination, not each integer, is obvious. On this basis, the Court identified four points of uncertainty for the skilled team seeking to implement a system or method as disclosed in the PCT application. Referring to the four identified points of uncertainty, the Court considered that each point required decisions on how to proceed which would involve prototype testing and evaluation.

The Court noted the following:

> *In my view, whilst the number of alternative solutions is relatively limited, there is no single line of logic that leads to the invention as claimed such that it can be concluded that the combination arrived at was 'very plain', or obvious. In my view the qualitative evaluation weighs sufficiently in favour of SARB to arrive at this conclusion.*

Accordingly, the Court held that VMS had not discharged its onus of demonstrating that the invention claimed in claim 1 lacked an inventive step in view of the prior art information relied on.

Significance

This decision provides some helpful clarification that publicly available prior art information can be readily added to the common general knowledge when assessing whether or not a claimed invention possesses an inventive step, following changes made to Australian patent law under the *Raising the Bar Act*. This decision also highlights the practical difficulties that can arise when relying on non-documentary publications such as presentations and lectures, particularly the difficulty in determining precisely what information was made publicly available by such events over time.

Aristocrat hits the jackpot as electronic gaming machine found patentable

***Aristocrat Technologies Australia Pty Limited v Commissioner of Patents* [2020] FCA 778 (5 June 2020)**

Read the Decision

Judge: Burley J

| mechanical | manner of manufacture | computer-implemented invention | hardware |

Authors

Andrew Lowe
(Senior Associate, Patent Attorney)

Duncan Longstaff
(Principal, Lawyer)

In brief

Aristocrat Technologies Australia Pty Limited (**ATA**) appealed to the Federal Court from an Australian Patent Office decision that four of its innovation patents (the **Patents**) for electronic gaming machines (**EGMs**) should be revoked to failing to define patentable subject matter. The Federal Court allowed the appeal, finding that the EGMs were patentable subject matter.

Background

EGMs, also called "slot machines", are a combination of hardware and software components. The hardware includes cabinets with video display screens, a "slot" or other vending device to receive money or other forms of credit, and various internal electronics, including an internal computer to operate software to operate the EGM. The internal computer, commonly called a "game controller", runs software to visually display reels with symbols on the screen and simulate movement of the reels, in order to play a game based on the displayed symbols. Typically, a person makes a wager or monetary bet via the vending device to play the game on the EGM. In this case, the novel and innovative features of the Patents lay in the aspects of the game played on the EGM, as controlled by the computer, and not in any aspect of the hardware (which was essentially generic for EGMs).

ATA had filed the Patents and requested examination of each one before the Australian Patent Office. The Patents each defined in their respective independent claims an EGM comprising various hardware components and the steps performed by the game controller to execute the game. During examination, the Patents were each objected to for failing to define patentable subject matter (known as "manner of manufacture" under the *Patents Act 1990* (Cth)). The basis of the objection was that the substance of the invention was in the rules or procedure for playing the game, and so was a mere scheme that was unpatentable. ATA requested a hearing before a Delegate of the Commissioner of Patents to decide the issue. The Delegate agreed with the examiner and held that the Patents did not define patentable subject matter, finding that the hardware components of the claimed EGM did not add anything of substance to the "inventive concept", being the game. ATA appealed the Delegate's decision regarding each of the Patents to the Federal Court.

Decision

In the Federal Court appeal, Burley J reviewed the authorities on patentable subject matter and found that in determining whether a patent defined patentable subject matter, there was a two-step test. The first step was to consider whether the invention related to a mere scheme or business method. If so, the second step was to consider whether the invention is in the computerisation of the scheme or business method.

Expert evidence

In deciding the issue, Burley J followed the recent Full Federal Court decision in *Commissioner of Patents v Rokt Pte Ltd* [2020] FCAFC 86 (discussed earlier in this publication), where it was held that expert evidence on patentable subject matter was of limited use. As such, the extensive expert evidence filed by both parties during trial before the Rokt decision issued was mostly ignored. However, Burley J did rely on

expert evidence as to the highly regulated nature of EGMs in Australia as an indication that EGMs must have a particular construction and are built for a specific (and limited) purpose.

Are inventions relating to EGMs a mere scheme?

In applying the two-step approach, Burley J found that the invention claimed by each of the Patents was not simply a mere scheme or business method. Rather, Burley J construed each of the claimed inventions as a "mechanism of a particular construction, the operation of which involves a combination of physical parts and software to produce a particular outcome in the form of an EGM that functions in a particular way". As the initial question was answered in favour of patentability (ie, not a mere scheme), it was not necessary to answer the second question (ie, whether the invention lay in the computerisation).

In support of his finding, Burley J pointed out specific hardware components of an EGM, including the display for virtual reels, credit input mechanism (vending device), game play mechanism (buttons) and the game controller that are characteristic of EGMs. Due to the highly regulated environment in Australia in which EGMs can be operated, these factors demonstrated that the invention is a machine specifically designed to provide a specific gaming function. Accordingly, the combination of the physical hardware components and the virtual software components (being the virtual reels and displayed symbols) produced the "invention". Thus, the invention had a specific character and a single purpose – to enable a person to play a game.

The fact that the hardware components were agreed by both ATA and the Commissioner to be part of the common general knowledge in the art did not detract from this finding.

Mechanical equivalent

It was also noted by Burley J that the Commissioner of Patents had conceded that a traditional gaming machine comprised solely of hardware and mechanical components that implemented the same game without any software would have been patentable subject matter. To Burley J, this concession was inconsistent with the Commissioner's position that effectively separated the game rules or procedure from the hardware in an EGM only because of its electronic nature.

Overall comment

It seems that the particular construction of EGMs and their highly regulated nature influenced Burley J's assessment of whether the claims of the Patents defined patentable subject matter. Despite the agreement of both parties that the hardware components were conventional in the art of gaming machines, the specific function and purpose of those hardware components, compared to generic computer or processor parts typically found in other computer-implemented inventions, led to the finding that the invention was not simply a scheme or business method, and so was decisive.

While this reasoning seems logical to some extent, the test for when hardware forms part of the invention appears to remain somewhat arbitrary. It could be said that hardware components of EGMs are just as "generic" or "conventional" within the EGM field as general computer elements, like a processor or memory.

Significance

The decision provides some guidance on the patentability of computer-implemented inventions that employ specific and not generic hardware. Where a computer-implemented invention employs hardware components that are specific to the invention or purpose-built, then the invention will be patentable, even if those hardware components are well-known in the technical field. However the decision appears to have limited application to the patentability of computer-implemented inventions in general, such as those found to be unpatentable in previous Federal Court decisions. In particular, many computer-implemented inventions are specifically, and advantageously, designed to be "hardware-neutral" so they can efficiently leverage a wide variety of computer technologies (such as personal computers, smartphones, physical and wireless internet networks, satellites, etc). This recent decision does not provide any additional hope for companies seeking patent protection in Australia for such inventions.

Accordingly, in the appropriate circumstances, patent applicants should carefully draft their patent applications to emphasise the combination of hardware and software in achieving a computer-implemented invention, and especially whether the hardware components are specific to a particular technical field or serve a particular purpose, and are not simply generic computer components applicable to all fields of computer technology.

Injecting preliminary discovery into patent infringement proceedings

***Sovereign Hydroseal Pty Ltd v Steynberg* [2020] FCA 1084 (30 July 2020)**

Read the Decision

Judge: McKerracher J

| mechanical | preliminary discovery | reasonable belief | ex-employee | confidential information |

Authors

Chris Byrnes
(Patent Engineer)

Duncan Longstaff
(Principal, Lawyer)

In brief

An application for preliminary discovery of documents relating to the constituents of a 'sealing composition' and methods of using it to seal passages was granted in circumstances where an exclusive licensee of the asserted patent suspected infringement by a third party based on past employment, access to confidential information, information from a private investigator, and the similarities of the processes being carried out by both parties. The scope of the discovery order was limited due to the financial circumstances of the respondent.

Background

Sovereign Hydroseal Pty Ltd (**Sovereign**) is the exclusive licensee of Australian Patent No. 2012216392 (**392 Patent**) which relates to a method and composition for sealing passages such as cracks, joints and voids in concrete structures and geological formations using a sealing composition. The sealing composition, which includes a mix of latex and additional components, is delivered into a passage under pressure in order to seal the structure from water ingress.

Together with the joint patentee, Relborgn Pty Ltd and Triomviri Pty Ltd, Sovereign sought an order for preliminary discovery of documents to be produced by Mr Johannes Steynberg (**Steynberg**), a former employee of Sovereign, and now operating a business called 'H2O Seal', pursuant to which a process was being used for sealing cracks and joints involving a 'liquid rubbery substance' injected by pumps. Sovereign contended that it required production of these documents on the basis that it did not have sufficient information to decide whether to start a proceeding against Steynberg for patent infringement, breach of confidence, breach of contract, and contempt.

During the period July 2008 to June 2009, when Steynberg was employed by Sovereign, he had received training on how to seal a passage in a body such as a geological formation with a seal composition, including insight into types of equipment as well as details of the materials and compositions used. For the purposes of his work, Steynberg had access to Sovereign's confidential information including details of product specifications and formulations, processes involving those products, customer records and customer information.

In September 2019, Sovereign became aware of Steynberg's involvement in H2O Seal by way of a flyer on the H2O Seal business, internet-based searches, and enquiries made by a private investigator. The investigator obtained information that indicated Steynberg was using a product called "N-LICS", and that H2O Seal used a natural nano-technology rubber grout injected under pressure into the voids sealing cracks and joints. Concerned that Steynberg was using at least one method of sealing cracks and joints that infringed the method claimed in the 392 Patent, Sovereign applied for preliminary discovery under rule 7.23 of the *Federal Court Rules 2011* (Cth).

Steynberg did not contest that Sovereign subjectively believed that it may have a right to obtain relief, but argued that the belief was not reasonably held. Steynberg argued against Sovereign's allegations as follows:

- The photos on the flyer did not reveal any confidential information and it would be difficult to conclude that Sovereign had a reasonable belief based on them.
- The material filed by Sovereign included evidence of Steynberg employing a blend of rubber emulsions injected under pressure into a passage, which converted from liquid to solid via coagulation, but did not reveal whether Steynberg was using the same formula as Sovereign. Accordingly, the evidence was insufficient to ground a reasonable belief.
- Finally, Steynberg pressed the point that Sovereign's right to discovery under Rule 7.23 needed to be weighed against Steynberg's interest in protecting his own intellectual property rights with respect to the methods he had developed and was using from disclosure to Sovereign (his competitor).

Decision

In considering subrule 7.23(1)(a) and (c), the Court found that the evidence established that even though none of the information provided by Sovereign proved that Steynberg was employing the same method or chemical compositions, the processes being carried out by both parties appeared on their face to be very similar, and Steynberg held documents regarding the methods and chemical compositions he used to seal passages which were directly relevant and could help Sovereign in deciding whether to seek relief.

Justice McKerracher concluded that Sovereign had established an adequate foundation for a 'reasonable belief' that it may have had the right to obtain relief from Steynberg, and that Steynberg may have had documents directly relevant to that question. Considering the requirements for an order to be fulfilled, McKerracher J allowed Sovereign's application for preliminary discovery subject to the provision of security for the costs of compliance. The order to provide security for costs was made in response to the expansive terms of discovery sought by Sovereign, taking into account concerns regarding Steynberg's financial capacity to comply.

Significance

This case highlights how preliminary discovery applications can be used by a patentee or exclusive licensee to inform its decision-making in relation to whether to commence a proceeding in respect of potential patent infringement. The case also confirms the observations made by the Full Court in *Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd* (2017) 257 FCR 62 (which we previously analysed ***here***).

In terms of subrule 7.23(1)(a), the main point of consideration when granting preliminary discovery orders is not whether the belief in the applicant's rights to relief is based on speculation, but rather whether the belief resulting from that speculation is a reasonable one. Potential applicants should bear in mind, however, that the scope of discovery sought can be restricted as a result of factors such as the financial capacity of the third party to comply with the order.

This decision is another illustration of the relatively low thresholds for obtaining preliminary discovery in Australia, particularly for patents that claim compositions or manufacturing processes that cannot otherwise be readily discerned from public information or inspection of product samples (even if such samples can be obtained).

“Obtained” or “obtainable”?

***Nufarm Australia Limited v Dow AgroSciences, LLC* [2020] APO 10 (31 January 2020)**

Read the Decision

Patent Office Delegate: Dr S J Smith

| *chemical* | *examination* | *product by process claims* | *obtained* | *obtainable* |

Author

Jon Wright PhD
(Senior Associate, Patent Attorney)

In brief

Nufarm Australia Limited (**Nufarm**) opposed the grant of Australian patent applications 2016202508 (**508 Application**) and 2016203677 (**677 Application**), filed in the name of Dow AgroSciences, LLC (Dow) on the grounds of novelty, inventive step, utility and support. The decision provides useful guidance in relation to the use of *product-by-process* claims in Australia, and, to the type of claim language that would be acceptable in Australia for these particular claims.

Background

The 508 Application and **677** Application were filed on 20 April 2016 and 2 June 2016, respectively, by Dow. The applications are third generation divisional applications each descended from parent application 2015200368, grandparent application 2013203406 and great-grandparent application 2008219657 (**657 Application**), entitled “Compounds derived from herbicidal carboxylic acids and tetraalkylammonium or (arylalkyl) trialkylammonium hydroxides”.

Of particular note was the fact that the acceptance of the 657 Application and the subsequent post-acceptance claim amendments submitted with respect to this application had previously been opposed by Nufarm some years earlier, but Dow had elected to withdraw the 657 Application just prior to a hearing taking place to determine the allowability of the proposed post-acceptance claim amendments. Interestingly, the 508 divisional application was subsequently filed a few weeks later with substantially the same claims as the proposed claim amendments submitted with respect to the withdrawn 657 great-grandparent application.

Decision

On 14 August 2019, a hearing took place to determine the allowability of the claims of each of the 508 and 677 divisional applications.

While Nufarm was only successful in establishing that certain claims of the 677 Application lacked novelty, it was of particular note that the findings in both cases hinged on the construction of the claims, and more particularly, on whether the language used in the product-by-process claims associated with each of the two divisional applications fell under the guise of (1) “obtained by” or (2) “obtainable by”.

508 Application

Each of the independent claims of the 508 Application are product-by-process claims that recite the following language: a “reaction product produced by the process…”.

In construing these product-by-process claims, the Delegate looked to the leading authority on this matter, *Hospira UK Limited v Genentech Inc.* [2014] EWHC 3857, in which the judge overseeing the case, Birss J, referred to such claims as:

> *…a claim “which straddles the boundary between products and processes” and said: “As a matter of language there are two kinds: (1) a product ‘obtained by’ a process, and (2) a product ‘obtainable by’ a process…*

During the proceedings, Nufarm submitted that the product-by-process claims in the 508 Application are of the second category referred to by Birss J, that being) a product ‘obtainable by’ a process, thereby effectively defining a product per se, and not limited by its process of production. Nufarm reasoned that if the intention was that the claims be limited to the process by which they are produced clearer wording (e.g. “the reaction product when produced” such as in claim 8 of the 508 Application) could have been used.

In their counterargument, Dow submitted that the words of the claim are of the first category, that being, (1) a product ‘obtained by’ a process, as the words most naturally describe a compound *actually* produced by the defined process, and

that there would be no utility in drafting the claims as an "obtainable by" claim as the skilled person would understand what the product of the reaction described is.

The Delegate agreed with Dow that a "reaction product produced by the process..." requires, as a matter of ordinary English, that the reaction product actually be produced by the defined process, and therefore surmised that this wording clearly falls within the guise of the "obtained by" category of claim referred to by Birss J.

While none of the grounds were successfully made out in respect of invalidating the claims of the 508 Application, the Delegate's construction of the product-by-process claims clearly provides some useful guidance as to acceptable claim language for filing applications in Australia.

677 Application

The preamble to the one independent claim of the 677 Application recites "a method for preventing a herbicidal composition that has been administered to a locus of unwanted vegetation from injuring a crop that neighbours the locus, and to which the herbicidal composition has not been administered". The product-by-process aspect of the claim recites that the herbicidal composition comprises the "reaction product of a herbicidal carboxylic acid and a (tetraalkyl) ammonium hydroxide".

The Delegate noted from the evidence provided by both parties that the specification discloses three preparative methods for producing the reaction product, each of which was declared by one of the inventors acting for Dow as a declarant, would provide the defined reaction product.

Weighing up the evidence, the Delegate took the view that since all three preparative methods could be employed to produce the defined reaction product, the claim would most likely support the "obtainable by" construction rather than the "obtained by" construction.

Ordinarily, after establishing that a product-by-process claim has the "obtainable by" construction, it is then appropriate to consider whether the claimed invention could have been reasonably claimed using an alternative process. If an alternative is not possible, then the "obtainable by" construction is considered an allowable construction.

In this instance, however, the Delegate did not have to consider this question, as the independent claim was ultimately found to be lacking novelty.

Significance

In Australia, product-by-process claims are allowable if the claims are directed towards a product "obtained by" a specific process. If, however, the claims are directed to products "obtainable" by a specified process then such claims are generally not allowable, unless the claimed invention is such that it cannot be otherwise reasonably claimed.

Applicants should be aware that product-by-process claims can be difficult to prosecute in Australia, because the novel features usually reside in the process rather than in the product and are therefore difficult to enforce against potential infringers who produce products by different processes.

That said, it can be difficult to determine whether a potentially infringing product falls within the scope of a product-by-process claim. Thus, the uncertainty surrounding such claims may deter competitors from engaging in a potentially infringing action.

Patent term extension for a kit of parts?

Pharma Mar SA (2020)
[2020] APO 8 (31 January 2020)

Read the Decision

Patent Office Delegate: S J Smith

| pharmaceutical | patent term extension | kit or combination | pharmaceutical substance per se |

Author

Charles W Tansey PhD
(Principal, Patent Attorney)

In brief

The Patent Office has determined that a patent term extension is not available to a kit or combination of two vials, one consisting of the active ingredient of the product and the other its diluent, intended for reconstitution prior to use. Preparation of the reconstituted solution was found to be part of the directions for use of the product, and not the product itself.

Background

Pharma Mar obtained a patent for a didemnin formulation in 2003, based on a 1999 Application. Didemnins are a family of cyclic depsipeptides which have cytotoxic and antiviral activity. Although didemnins themselves were a known class of compounds prior to the filing of the Pharma Mar patent, they had proved to be challenging to use therapeutically. Didemnins are not generally stable in solution and Pharma Mar patent addressed this problem by way of a dosage form consisting of two separate vials. The first vial contained the active didemnin compound in lyophilised form along with a bulking agent, typically mannitol, which was required for proper reconstitution. The other vial contained a mixed solvent system for reconstitution that included water to dissolve the bulking agent and a solvent for the didemnin compound. Upon mixing the contents of the two vials, a suitable solution of the didemnin compound was obtained that could be administered satisfactorily in a short but useful timeframe.

Pharma Mar apparently had no commercial product approved for use at the time the patent was granted and obtained regulatory approval for a didemnin formulation only in December 2018, very shortly before the normal term of expiry of the patent in February 2019. Because of the lengthy delay between the filing of its patent application and the date of obtaining regulatory approval, Pharma Mar was in a position to secure the maximum five year extension of term for its patent, provided they could meet the other requirements necessary to qualify for a pharmaceutical extension of term, being:

- one or more pharmaceutical substances per se must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification (section 70(2)(a) of the *Patents Act 1990* (Cth) (**Act**)); and
- goods containing, or consisting of, the substance must be included in the Australian Register of Therapeutic Goods (**ARTG**) (section 70(3)(a) of the Act).

Pharma Mar's main claim read:

> *A pharmaceutical composition of a didemnin compound, comprising firstly a lyophilised didemnin preparation including water-soluble material and secondly a reconstitution solution of mixed solvents.*

There did not seem to be any dispute that the specification lacked adequate disclosure of the didemnin preparation, the reconstitution solution or the reconstitution process itself.

The Pharma Mar product that was approved and included in the ARTG was "APLIDIN". This was identified as APLIDIN powder (in a vial) and solution for infusion (in an ampoule) provided as a composite pack. The active ingredient was a specific didemnin compound.

The Extension Request

Pharma Mar applied for an extension of term in good time, shortly before the expiry of its patent. Its request was refused and in the course of arguing with the Patent Office, they received three deficiency notices based on an alleged failure to meet the requirements of sections 70(2)(a) and 70(3)(a). The matter was set down for a hearing before a Delegate of the Commissioner of Patents.

Decision

The Delegate considered it quite clear that the ARTG registration was for a kit or combination product comprising the didemnin compound and a reconstitution solvent. The Delegate stated that in determining what goods are included on the ARTG, the goods themselves must be distinguished from directions or indications for their use, as set out in *Celgene Corporation and Commissioner of Patents and Children's Medical Center Corporation* [2013] AATA 55 (***Celgene***). In *Celgene*, the patent was directed to the combinations of thalidomide and a steroid in the treatment of cancer, with the unsuccessful extension request being based on an ARTG approval of thalidomide for use in combination with steroids for the treatment of multiple myeloma.

Pharma Mar tried to draw a distinction between *Celgene*, where two actives were administered, and its own case, which was a new formulation of a single active, however, this was found unpersuasive. The Delegate did not consider that the goods included in the ARTG extend beyond the (two-part) product associated with the ARTG registration to include the reconstituted solution. The Delegate considered that reconstitution of the didemnin compound with the reconstitution solvent to form a solution was found to be a direction for use of the product. Thus, the goods included on the ARTG were limited to the co-pack and did not extend to the reconstituted solution. The Delegate thus arrived at the conclusion that the goods listed on the ARTG reflect the claimed mixture of separate parts and further, that that mixture was in substance disclosed in the specification as filed and in substance falls within the scope of the claims. This then led the Delegate to the critical decision of whether the kit of integers can be considered a pharmaceutical substance per se.

Is a "kit" or "co-pack" a pharmaceutical substance per se?

Having arrived at that key question, the Delegate then concluded, consistent with other Federal Court decisions that a pharmaceutical substance per se must be a single entity, and cannot be in the form of separated components, i.e. a kit or co-pack. The Delegate summed up her position, stating "[i]n this case, what is relevantly claimed, a two-part combination, is, to my mind, more in the nature of a substance in combination with a separate (excipient) integer, than a "substance" as such or taken alone – I am not persuaded that a pharmaceutical substance per se can be understood to encompass a "deconstructed" formulation intended for later reconstitution".

The patentee had argued that the particular nature of the problem its invention addressed, should not disadvantage it insofar as an extension of term is concerned. Pharmaceutical extensions exist to compensate patentees for the unusually long regulatory barriers in that industry and Pharma Mar had certainly been impacted by that. As submitted by the patentee: "It would be entirely perverse if a claim to a new formulation of a known stable and soluble drug that does not require reconstitution prior to administration […] could form the basis of a term extension, but not a claim to a new formulation of a drug that has stability and/or solubility issues and which formulation overcomes difficulties arising from those issues".

Although the Delegate was not unsympathetic to the patentee's situation, she remained unconvinced that section 70 allows for a pharmaceutical substance per se to encompass the claimed 'composition' comprising physically separated components, stating "the consideration with respect to section 70(2) is not one of the merits of the invention, or what difficulties the patentee has overcome in arriving at a formulation, but simply whether a pharmaceutical substance per se in substance falls within the scope of the claims".

Significance

As reiterated in *Celgene*, it is clear from all of these decisions that the term pharmaceutical substance *per se* is intended to be a pharmaceutical that is presented as a single entity, and not in the form of a kit or as separate dosage forms. It is tempting to speculate exactly how Pharma Mar could have framed its patent claims to secure an extension based upon its registration. The Delegate did note in an aside that the type of "kit" claim granted to Pharma Mar would not usually proceed to acceptance, as it merely defined two integers without a necessary working interrelationship specified.

Facebook wins on patentable subject matter despite generic computer implementation

***Facebook, Inc.* [2020] APO 19 (21 April 2020)**

Read the Decision

Patent Office Delegate: K. Wagg

| *information technology* | *manner of manufacture* | *computer-implemented invention* |

Authors

Alana Gibson
(Associate, Patent Attorney)

Peter Treloar
(Principal, Patent Attorney)

In brief

The Australian Patent Office has found that claims to a method that helps applications share information are directed to patentable subject matter based on the technical improvement provided, despite concluding that the claims only required generic computer implementation.

This decision considers the key question of how to determine the substance of the invention. Whilst the invention was found not to be technical in nature, and only to require generic computer implementation, it was considered that the invention addressed a technical limitation and provided a technical improvement. In the end, the invention was found to constitute patentable subject matter under Australian law.

Background

Facebook, Inc. (**Facebook**) requested a hearing back in August 2018, reaching an impasse with the Examiner after a fourth Examination Report was issued. The only matter under consideration was the outstanding manner of manufacture objection.

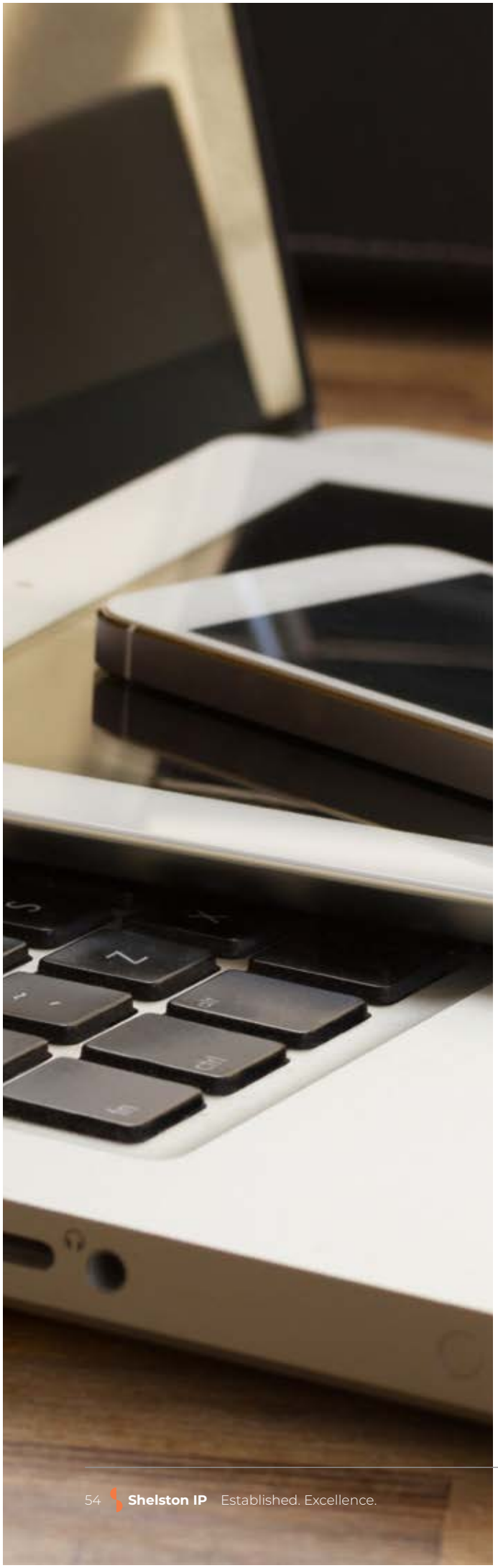
The Australian patent application no. 2014209546 (**Application**) titled "Conversion tracking for installation of applications on mobile devices" in the name of Facebook, provides a method which enables app to communicate with each other by accessing a shared memory. Most apps, when installed on a mobile device, are "sandboxed", which means that data and code execution are isolated from other apps. As such, the apps do not have the ability to communicate with each other. This can make it difficult for advertisers to track whether their advertisement is successful in getting a user to download a new app.

Facebook's invention enabled data to be written to a shared memory location that is outside of the app's sandbox, allowing them to share information with each other. Using an example from Facebook's hearing submissions, when a user sees an advertisement for Uber while browsing Facebook, and then downloads the Uber application by clicking on the advertisement link, Facebook can know that the Uber application has been installed and pass this information back to Uber.

Decision

The decision of the Delegate of the Commissioner of Patents relied upon 5 key questions in assessing whether the invention was a manner of manufacture. There were taken from the considerations discussed in *Aristocrat Technologies Australia Pty Limited* [2016] APO 49 (Aristocrat):

- *Is the contribution to the claimed invention technical in nature?*
- *Is the computer merely the intermediary, configured to carry out the method, but adding nothing of the substance of the idea?*
- *Does the claimed invention merely require generic computer implementation?*
- *Does the invention result in an improvement in the functioning of the mobile device?*
- *Does the claimed invention solve a technical problem in the functioning of the computer?*



The Delegate concluded that the claims allow for advertising attribution and conversion tracking, but considered that this was not technical in nature. Although accepting that the use of the computer was intrinsic to the claimed method, he was not convinced that the steps of the claim (including executing data and installing an application) were more than generic computer implementation.

However, upon consideration of whether the invention resulted in an improvement, the Delegate agreed that the method performed something new. There was enough detail to show that the device was now able to do something it could not do previously, and provided a technical improvement. There was also agreement that the inability for some applications to communicate information was a technical limitation faced by application developers. Interestingly, the Delegate recognised that the "sandboxing" (or isolating) of applications still exists in light of the method being utilised, but that the invention works around the existing system. In light of the clear technical limitation along with the ability to perform something new, there was found to be a technical improvement in the device.

Significance

Although the claims in this instance were not considered to be technical in nature, this does not mean that they did not address a specific technical problem. The key, in this case, was including enough information in the claims to specify that the method concerned a specific type of application (the type that could not communicate with each other). This addition made it clear to the Delegate that the invention solved, or worked around, a precise technical limitation.

Further, the decision provides a bona fide example that satisfying all the points outlined in Aristocrat is not necessary to show that the invention is patentable subject matter. The fact that the computer was intrinsic to the method and that there was a clear technical improvement provided by the method was enough to establish that the invention was patentable subject matter. This reiterates the importance of providing specific technical details when drafting a patent specification to ensure that the technical improvements provided by the invention are clear and unambiguous.

ESCO applications opposed in the Patent Office

***CQMS Pty Ltd v ESCO Group LLC* [2020] APO 14 (16 March 2020)**

Read the Decision

***CQMS Pty Ltd v ESCO Group LLC* [2020] APO 24 (22 May 2020)**

Read the Decision

***CQMS Pty Ltd v ESCO Group LLC* [2020] APO 53 (16 December 2020)**

Read the Decision

***CQMS Pty Ltd v ESCO Group LLC* [2020] APO 54 (16 December 2020)**

Read the Decision

Patent Office Delegate: Xavier Gisz

| *mechanical* | *Patent Office opposition* | *support* | *novelty* | *inventive step* |

Author

Rodney Dabboussy
(Senior Associate, Patent Attorney)

In brief

The following four opposition decisions relate to three patent applications in the name of ESCO Group LLC. In each case the application was opposed by CQMS Pty Ltd. The applications are all in the competitive field of earth moving equipment used in mining and, in particular, to bucket and associated wear members. The decisions deal with matters of support, novelty and inventive step. Our comments below focus on the main points of each decision.

Background (640 Application)

Australian patent application No. 2016253640 (**640 Application**) in the name of ESCO Group LLC (Applicant) was filed on 3 November 2016. The 640 Application, entitled "Wear Assembly", relates to the wear parts commonly provided along the digging edge of excavating equipment used in mining such as buckets for dragline machines, and the like.

Decisions (640 Application)

After submissions were made by both sides, the Delegate found the claims to be novel and inventive in light of the prior art identified by the Opponent. The claimed invention was also found to meet the requirement of utility and useful. However, the Delegate was of the view that the claims did not pass the support test, in that, claims 1 to 6 and 8 were found to extend beyond the disclosure and thus lacked support.

Claim 1 as accepted is directed to a wear member for attachment to earth working equipment including the feature of:

> *...a holding component movable in the mounting component in both inward and outward directions between a release position where the wear member can be installed on and removed from the base and a locked position where the wear member is secured to the base.*

In the description, a device is described that mechanically retains the holding component in either the release position or locked position. However, in the claims there is no limitation of the holding component being mechanically held in either the release or locked position. As such, the claims extend beyond what is described in the description because they could encompass any means that indicate the release or locked position. Examples provided by the Delegate included things *such as a visual indicator (for example alignment markings) of the release position and the locked positions .... an electronic sensor system measuring for identifying pre-determined positions of the holding component.* Claims 1 to 6 and 8 were therefore found to extend beyond the disclosure and thus lack support.

The Applicant was given two months to propose suitable amendments to overcome the Delegate's finding.

In response to the Delegate's decision, the Applicant filed amendments to claims 1, 5, and 6 on 17 April 2020. These amendments were then allowed on 17

September 2020. On 22 September 2020, CQMS Pty Ltd again requested to be heard in relation to the final determination of the matter on the basis that that the amended claims continued to lack support.

In order to rectify the claims after the first decision, the Applicant added the following underlined limitation to claim 1:

> *...a holding component movable in the mounting component in both inward and outward directions between a release position where the wear member can be installed on and removed from the base and a locked position where the wear member is secured to the base, wherein the holding component is mechanically secured in the release and locked positions."*

The Opponent was of the view that claims as amended merely require any form of mechanical securement. This is contrary to the specification which stipulate that the mechanical means provide feedback to the user of the two positions. The Applicant disagreed in that due to being mechanically secured, movement to either the release or the locked positions for inherently provide feedback to a user.

Upon review, the Delegate agreed with the Opponent. The claims as amended state that the holding component is secured in the release and locked positions and do not define (explicitly or implicitly) that the holding component moving into the release and locked positions is noticeably differently than when the holding company moves to any other position. The Delegate found that the amendments therefore did not address the lack of support deficiency identified in the first decision.

The Delegate allowed the Applicant a further six weeks in which to file further amendment to the claims in order to address the lack of support in the claims.

Background (371 Application)

Australian patent Application No. 2014240371 (**371 Application**), entitled 'Wear assembly removal and Installation', is directed to a process and a tool for installing and removing various kinds of wear members used with earth working equipment.

A notice of opposition was filed by CQMS Pty Ltd (**Opponent**) on 11 October 2018 on the grounds that the claims lacked novelty, inventive step, amongst other grounds.

Decision (371 Application)

The Opponent identified prior art documents EP 1 522 636 "Dietens" and US 2013/0045055 "Derycke" as being relevant to the novelty of the independent claims. Prior art documents Dietens, Derycke, US 3,927,778 "Zrostlik" and DE 29902127 "Demmler" were identified as being relevant to the inventive step of all the claims, in addition to the common general knowledge. After submissions were made by both sides, the Delegate found claims 1 and 21 to lack novelty and inventive step in light of Derycke (US 2013/0045055) and claims 1, 4-12, 16, 17, 20-23, 25-30, 32 and 33 found to lack an inventive step in light of Dietens (EP 1 522 636).

Looking at novelty aspect of the Delegate's decision, claim 1 is recited below in the integer format used by the opponent:

> *1.1 A tool for replacing a wear member secured to earth working equipment operating in a mine*
>
> *1.2 the earth working equipment including a base, a wear member mounted on the base, and a retainer to hold the wear member to the base, the tool comprising:*
>
> *1.3 at least one auxiliary tool to hold the wear member mounted on the earth working equipment, and to release the retainer*
>
> *1.4 a single manipulator movably supporting the at least one auxiliary tool*
>
> *1.5 wherein the manipulator and the at least one auxiliary tool cooperate to release the retainer and remove the wear member from the base of the earth working equipment*
>
> *1.6 and cooperate to install a second wear member on the base and secure a second retainer to hold the second wear member to the base*
>
> *1.7 a controller to direct the movements of the at least one auxiliary tool and the manipulator*
>
> *1.8 a mobile base to support and move the at least one auxiliary tool and the manipulator from a first location to the earth moving equipment with the wear member.*

Derycke refers to a method for replacing a disk cutter attached to the head of a tunnel boring machine. The disk cutter is mounted in a casing attached to the cutting head of a tunnel boring machine. The disk cutter is also attached to an element for locking into a housing. The method of replacing the disk cutter

taught by *Derycke* involves the first step of removing a worn disk cutter from housing by: clamping a disk cutter handling device onto the housing; taking hold of the disk cutter, unlocking, extracting the disk cutter and, unclamping the device. The second step is fitting a replacement disk cutter in the reverse order of the first step. In these respects, both the Applicant and Opponent agreed that *Derycke* disclosed features 1.2-1.7 of claim 1. The only features in dispute were 1.1 and 1.8. That is, whether *Derycke* discloses: a) earth working equipment operating in a mine, and b) a mobile base.

Whilst not a common use, after considering the submissions, Delegate was satisfied that a tunnel boring machine as taught in *Derycke* could be considered as an "earth working machine operating in a mine" and therefore it discloses feature 1.1. The Delegate was also satisfied that the term "mobile base" of feature 1.8, simply required the base to be moveable with respect to the earth moving equipment and therefore also disclosed in *Derycke*.

The Applicant was given two months to propose suitable amendments.

Background (221 Application)

Australian patent Application No. 2014262221 (**221 Application**), entitled 'Wear part monitoring', is directed to a system of monitoring the bucket used with earth working equipment.

This decision is a follow on from *CQMS Pty Ltd v ESCO Group LLC [*2020] APO 5, where the Delegate found claims 1, 6, 7, 15 and 18 to lack inventive step in light of prior art Japanese Patent Application Publication No. 07-042201A (**D14**). In reply, the Applicant filed amendments and the Opponent, CQMS Pty Ltd, requested to be heard in relation to the amendments filed.

Decision (221 Application)

Claim 1 as amended:

> *A monitoring system comprising an excavating bucket having walls defining a containment portion for gathering earthen materials, and a digging edge, at least one wear part secured to the digging edge, at least one electronic sensor secured to one of the walls, and a programmable logic device receiving information from the at least one electronic sensor and making a determination of at least one of presence, health, wear, impact, fill, and performance of the bucket and/or the at least one wear part.*

As can be noted, claim 1 was amended such that the monitoring system no longer included making a determination of the "fill" of an excavating bucket and/or at least one wear part.

The Opponent claimed that the removal of the fill limitation made no change to the scope of the claims because "performance of the bucket" includes fill level within its scope. According to the Delegate, the claim still encompassed the monitoring of the fill level of the bucket and, therefore, the claims remained obvious in light of D14. The Delegate agreed with the Opponent that "performance of the bucket" is a phrase of broad scope which included, amongst other things, the presence of health, wear, impact and fill of the bucket within its scope. Consequently, the amended claims do not overcome the inventive step objection.

Given the genuine attempts to overcome the deficiencies identified in the first decision, the Delegate provided the Applicant an additional 6 weeks to file further amendments to rectify the claims.

Significance

Amongst other aspects, these decisions highlight the need for patent descriptions to be more robust by providing possible variations to support the claims.

Pharmaceutical patent term extensions: broader is not always better

***Ono Pharmaceutical Co., Ltd. et al* [2020] APO 43 (16 September 2020)**

Read the Decision

Patent Office Delegate: G. Powell

| *pharmaceutical* | *extension of term* |

Authors

Ean Blackwell
(Senior Associate, Patent Attorney)

Katrina Crooks
(Principal, Lawyer)

In brief

This decision of the Patent Office reinforces that an application for a patent term extension (**PTE**) must be based on the earliest inclusion on the Australian Register of Therapeutic Goods (**ARTG**) of a pharmaceutical substance falling within the scope of the claims, irrespective of the sponsor of the goods. It is not open to the Commissioner to calculate the term of the extension only on the basis of goods sponsored by the patentee.

Background

Australia's *Patents Act 1990* (Cth) (**Act**) provides a PTE to account for the delays that can occur when obtaining regulatory approval for a pharmaceutical substance. The extension can last for up to five years and is available when the following requirements are met:

- the patent, in substance, discloses and claims a pharmaceutical substance per se, or a pharmaceutical substance when produced by recombinant DNA technology;
- goods containing or consisting of the pharmaceutical substance are included in the ARTG; and
- the first regulatory approval for the pharmaceutical substance occurred more than five years after the filing date of the patent.

The length of a patent term extension is equal to the period between the filing date of the patent and the date of the earliest first regulatory approval, reduced by five years.

Decision

This decision concerned a request to extend the term of a patent covering anti-PD-1 antibodies. The patent included claims covering the patentee's OPDIVO. However Merck Sharp & Dohme's KEYTRUDA was also considered to fall within the scope of the claims of the patent because it was a monoclonal antibody that cross-competed with the antibody as defined in claim 3. Both OPDIVO and KEYTRUDA had received regulatory approval in Australia, but on different dates. The question at issue, then, was which regulatory approval date was relevant for deciding the patentee's PTE request.

The patentee hedged its bets, filing two PTE requests; one based on KEYTRUDA, which received regulatory approval on 16 April 2015, and another based on OPDIVO, which received regulatory approval on 11 January 2016. From the patentee's perspective, the request based on OPDIVO was preferred as it would result in a longer extended term (an additional 8 months, 26 days). However, the Patent Office refused that request, finding that KEYTRUDA was included on the ARTG first and therefore should form the basis of the request. The patentee disagreed and requested to be heard.

At the hearing, the patentee submitted that the "first regulatory approval date" should be the approval date of their own product, OPDIVO. This, they argued, was consistent with the purpose of the extension

of term provisions, that being to restore the time lost by patentees in gaining marketing approval, and to compensate the patentee for the additional time, expense and difficulty in developing and commercialising a new drug.

The patentee argued that the reference to "first" regulatory approval in the Act was only important when multiple regulatory approval dates existed for the same substance, such as for different delivery forms (e.g. capsules, tablets, slow-release, different strengths) that manifested in different ARTG registrations. According to the patentee, it was only logical, given that the regime is intended to be beneficial and remedial, that it can only be about rewarding patentees for their work and, by implication, not the work of others. If not, the patentee would not receive the full extension of term for *its* product.

The Delegate accepted that the PTE regime was designed to encourage the development of new drugs, but rejected the patentee's broader purposive construction of the Act. Such a construction, the Delegate noted, would encourage companies to develop a substance that is not new and seek regulatory approval as late as possible, secure in the knowledge that a PTE will be granted for the (not new) substance. According to the Delegate, this type of scheme would not incentivise new drugs. Rather, it would incentivise new extension applications.

The Delegate acknowledged that there is some ambiguity in the words of the Act insofar as they do not say one way or the other whether the relevant pharmaceutical substance is only that belonging to the patentee, or whether it includes other, equivalent substances owned by third parties. But the Delegate also noted that this ambiguity had been dealt with previously by the Patent Office in *G.D. Searle LLC* [2008] APO 31. In that case, the Patent Office held that an application for PTE must be based on the earliest inclusion on the ARTG of a pharmaceutical substance falling within the scope of the claims, irrespective of the sponsor of the goods. Moreover, in *Pfizer Corp v Commissioner of Patents (No 2)* [2006] FCA 1176, the Federal Court held that "the term of the extension is based on the earliest inclusion, regardless of the identity of the sponsor. It is not open to the Commissioner to calculate the term of the extension only on the basis of goods sponsored by the Patentee."

The Delegate therefore found that the substance with the earliest regulatory approval date for the purpose of the PTE request was KEYTRUDA, not OPDIVO. As such, the patentee's request for a PTE based on OPDIVO was refused.

Significance

In circumstances where a patent claims more than one registered pharmaceutical substance, this decision confirms that the earliest registered substance will be used to determine eligibility for a PTE and to calculate the length of the extension, irrespective of whether the registered substance is sponsored by the patentee or by a third party. Patentees should therefore be aware of all possible ARTG registrations encompassed by their claims. If a patent covers more than one pharmaceutical substance, an applicant may be well-advised to file one or more divisional applications to ensure that its own registered pharmaceutical substance is quarantined within separate patent claims, thus enabling a maximum extension to be sought for that registration.

The high bar for patentable subject matter in Australia for games and related apparatus

***Crown Melbourne Limited* [2020] APO 47 (16 October 2020)**

Read the Decision

Patent Office Delegate: R Subbarayan

| mechanical | manner of manufacture | gaming apparatus |

Author

Andrew Lowe
(Senior Associate, Patent Attorney)

In brief

The Australian Patent Office has refused a patent application by Crown Melbourne Limited (**Crown**) for a modified roulette table layout and roulette wheel on the grounds that the claims do not define patentable subject matter, known as "manner of manufacture" in Australia. The decision demonstrates that inventions relying on game rules, even though they result in a modification to a physical apparatus, may still be unpatentable.

Background

Crown filed standard patent application AU 2018219972 for a roulette apparatus (**972 Application**), which was a grandchild of application AU 2008203384. There was also a related innovation patent that was certified but whose term had expired. The invention of the 972 Application related to providing a modified table layout and wheel for a roulette table that incorporated an additional "00" number in both the table and wheel. This allowed two different versions of roulette to be played; "Single Zero" roulette popular in Europe and Australia and "Double Zero" roulette popular in the United States. The effect of the modified table layout and wheel was to allow Double Zero roulette to be played while still being able to make the same types of wagers used in Single Zero roulette that was previously not possible in Double Zero roulette.

Independent claim 1 of the 972 Application essentially defined a roulette apparatus having a table layout with an additional "00" square that is only adjacent the "0" square and not any other squares with numbers. Independent claim 2 of the 972 Application essentially defined a roulette apparatus having the same table layout as claim 1 but with a roulette wheel having the "00" and "0" squares adjacent each other. Independent claims 4 and 5 of the 972 Application defined methods of playing roulette using the apparatuses of claims 1 and 2, respectively.

During examination, the Examiner raised only one objection – that the claims did not define manner of manufacture. The Examiner's reasons were that the invention was characterised solely by the arrangement of information (i.e. the arrangement of numbers including the "00") and this arrangement was abstract. The arrangement also enabled a scheme of wagering. Neither the arrangement nor the wagering scheme were considered to be of "material advantage" in the sense of conferring any practical utility. In response, Crown sought a hearing before a Delegate of the Commissioner of Patents to overcome the manner of manufacture objection.

Decision

Crown initially argued that the Examiner's objection was unclear – how could the arrangement of information be abstract when they resulted in a practical activity like wagering or be physically present on the table layout and wheel? Crown also made the following key submissions in support of its argument that the invention was not an abstract idea, scheme or plan:

- the invention was not related to the presentation of information per se, but involved physical and positional means to realise a game, resulting in an artificial state of affairs;
- the information is in a particular location on a physical apparatus (table layout or wheel) and functionality is derived from this positional location that improves the apparatus;
- the claims related to a physical table layout that had a new functionality not previously possible with conventional Single Zero or Double Zero roulette table layouts;

- the claims defined physical components that went to the "heart" of the improvement offered by the invention to produce a modified roulette game with material advantages over the conventional Single Zero or Double Zero roulette games;
- the positional location of the "00" on the table layout had a mechanical result or served a mechanical function in enabling betting options not previously available to be made;
- the invention was directed to a physical apparatus and method using that physical apparatus involving physical process steps that can only be carried out using the physical apparatus on a physical product; and
- there was not any attempt to monopolise the presentation of information or numeric value of information.

After considering the specification, the Delegate concluded that in his opinion the substance of the invention was a modified Double Zero roulette game in which the layout of the numbered wagering spaces on the betting table had been rearranged so that it more closely resembled that of a Single Zero game layout so it could offer the same betting options as a Single Zero game in addition to the standard Double Zero game betting options. On this basis, the Delegate held that the substance of the invention was merely a scheme or strategy to popularise the Double Zero game in Single Zero game markets by providing a similar visual appearance and similar betting options. Consequently, the invention was not a manner of manufacture.

In arriving at his decision, the Delegate distinguished previous cases where inventions related to the presentation of information were found to be a manner of manufacture because in those cases the presentation of information served a mechanical purpose and provided some advantage, which was material in the field of economic endeavour. For example, in *I.T.S Rubber's Application* (1979) 96 RPC 318 the blue coloured squash ball provided increased visibility against the white background of the court.

The Delegate also distinguished *Aristocrat Technologies Australia Pty Ltd* [2016] APO 49. In that case, the touch interface enabled selection of a game and bet denomination with a single touch by a player. The electronic gaming machine responded to this single touch by performing consequential actions to identify and display the selected game and bet denomination. In contrast, the roulette apparatus in the Application did not perform any physical or mechanical actions in response to the player placing a bet on one of the numbered squares.

Significance

The decision illustrates the high bar for patentable subject matter in Australia for games and related game apparatus as a consequence of the line of Federal Court decisions on the patentability of computer-implemented inventions. Despite the claims in the 972 Application clearly defining a physical apparatus and the physical components of a table and wheel, these were insufficient to confer patentability where the "substance" of the invention was tied to the presentation of information on those physical components. Instead, it is necessary to demonstrate that the presentation of information confers some physical or mechanical effect or some technical benefit beyond simple economic benefit or commercial advantage.

Australian Patent Office considers Raised Bar written description requirements

***The University of British Columbia* [2020] APO 15 (20 March 2020)**

Read the Decision

Patent Office Delegate: Dr S.D. Barker

| biotechnology | examination hearing | sufficiency | support | best method |

Author

Duncan Longstaff
(Principal, Lawyer)

In brief

This decision considered how the "raised bar" requirements of support (section 40(3), *Patent Act 1990* (Cth) (**Act**)), enablement (section 40(2)(a)) and best method (section 40(2)(aa)) are to be assessed. The decision is a reminder that these requirements are now more onerous than they were previously in Australia, and (with respect to the best method requirement) in other major jurisdictions. When drafting specifications intended for prosecution in Australia, especially in biotechnology and pharmaceutical areas which are often struck by unpredictability, inventors should provide, and attorneys must include, not only as much detail as possible on the experimental methods for producing, evaluating and testing but also the best method known to perform the claimed invention.

Background

The claimed invention related to antibodies exhibiting selectivity for the 'eta' isoform of a protein over other isoforms of that protein. The ability of the antibodies to discriminate between the isoforms has utility in the diagnosis of inflammatory conditions such as arthritis. The claims, as proposed to be amended, were directed to methods of determining the presence of the eta isoform of the protein in a sample using the antibodies.

The applicant (The University of British Columbia) requested a hearing after receiving a third adverse examination report for its patent application (No. 2015202689), which maintained objections raised under section 40 of the Act with respect to the requirements for clear enough and complete enough disclosure, support and best method of performance. The Examiner reserved his opinion on novelty and inventive step pending resolution of the section 40 issues. The applicant submitted a declaration from the inventor, Dr Marotta, during prosecution.

Decision

In relation to enablement, the Delegate cited the approach taken in the earlier Patent Office decision *Evolva SA* [2017] APO 57 (***Evolva***), which confirmed that enablement of a claim should be determined according to a 2-step approach involving "plausibility" and "undue burden". Applying the approach from *Evolva* and on the basis of Dr Marotta's declaration, the Delegate was satisfied that the specification provided a general method of producing hybridomas and sufficient description of how to distinguish hybridomas that produce the desired antibodies. He accepted that the required testing is routine in the art and is not onerous.

As to the second issue, support, the Delegate cited *CSR Building Products Limited v United States Gypsum Company* [2015] APO 72 (***CSR***), which suggested that to meet the (relatively) new Australian requirement of support, the claims should correspond to the technical contribution to the art. The Delegate referred to the indication in CSR at [113] that: "[a]n important question will often be whether the technical contribution to the art is a general principle or the specific examples in the specification".

The Delegate found that both the specification and information provided by Dr Marotta indicated that the technical contribution was the use of select epitopes to produce antibodies selective to the eta isoform. Accordingly, the Delegate decided there was

a principle of general application and thus the claims, although broader than the examples disclosed in the specification, were supported.

For the final issue, best method, which is not a major consideration in jurisdictions outside of Australia, the Delegate referred to *Kineta, Inc* [2017] APO 45 (***Kineta***) at [18]:

> *...it is necessary to determine what method is disclosed in the specification, and then to ask whether there is any evidence that the applicant was aware of a better method of performing the invention.*

The Delegate explained that the specification identified four immunogens and their use in preparing hybridomas for producing the antibodies of interest, and that there was no evidence that the applicant was aware of a better method.

Significance

This decision highlights some of the leading Patent Office decisions in Australia regarding enablement (*Evolva*), support (*CSR*) and best method (*Kineta*). While assessment of these requirements will continue to be required on a case-by-case basis, the findings here are informative as to how the Patent Office is likely to assess section 40 provisions. However these findings must now be considered in the light of the Federal Court's subsequent decision in *Merck Sharp & Dohme Corporation v Wyeth LLC (No 3)* [2020] FCA 1477 (***MSD***), which considered for the first time the requirements for sufficiency of description and support for claims, as a result of the Raising the Bar amendments to the Act. You can read our analysis of the decision in *MSD* earlier in this publication.

When drafting specifications in the areas of biotechnology and pharmaceuticals, it is important that the applicant include, not only as much detail as possible on the experimental methods for producing, evaluating and testing but also the best method known to perform the claimed invention. The decision is also a good reminder that a declaration from the inventor (in some cases more preferably from an independent expert) can assist in showing that a skilled person can perform the claimed invention on the basis of the disclosure in the specification. Further, the ability to request a hearing is worth considering, to address an Examiner's maintenance of objections in Australia. This effectively "stops the clock" on the acceptance deadline and provides an opportunity for the matter to be heard by a hearing officer who may take a different view to the primary and/or supervisory Examiner.

Entitlement: a tidal wave in patent opposition

***Liquid Time Pty Ltd v Smartpark Technologies LLC* [2020] APO 48 (19 November 2020)**

Read the Decision

Patent Office Delegate: R Subbarayan

| *mechanical* | *Patent Office opposition* | *inventorship* | *entitlement* |

Authors

Connie Land
(Patent Engineer)

Allira Hudson-Gofers
(Principal, Patent Attorney)

In brief

This decision provides guidance on proving entitlement to an invention through previous employment of an inventor. In this case, it was found that the inventive concept of the opposed patent was conceived during the inventor's previous employment. Accordingly, the current employer of the inventor is not an "eligible person" in relation to the invention and therefore, not entitled to the opposed patent.

Background

The applicant, Smartpark Technologies LLC (**Smartpark**) filed patent application no. 2017251684 (**684 Patent**) on 23 October 2017 titled "Surfing wave pool using ship waves" with Mr Steven Schmied listed as the sole inventor. The invention related to a wave pool for surfing using ship waves generated by one or more constant beam wavedozers. The opponent, Liquid Time Pty Ltd (**Liquid Time**), specialising in the development and commercialisation of wave pool technologies, filed a notice of opposition to the grant of the 684 Patent under section 59 of the *Patents Act 1990* (Cth) (**Act**). Liquid Time's sole ground for opposition was that the nominated entity, Smartpark, was not entitled to the grant of a patent for the invention, instead stating the rights to the patent and claimed invention should lie with Liquid Time.

Decision

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

(a) is the inventor; or

(b) would, on the grant of a patent for the invention, be entitled to have the patent assigned to the person; or

(c) derives title to the invention from the inventor or a person mentioned in paragraph (b); or

(d) is the legal representative of a deceased person mentioned in paragraph (a), (b) or (c).

In other words, a patent may only be granted to the inventor of an invention or someone who derives title to the invention from the inventor, known as an "eligible person".

In order to determine who was entitled to the 684 Patent, the Patent Office drew upon principles set forth by *University of Western Australia v Gray* [2009] FCAFC 116 (***UWA***) and *Polwood Pty Ltd v Foxworth Pty Ltd* [2008] FCAFC 9 (***Polwood***). UWA sets of the following steps for determining who is an eligible person:

- identify the *"inventive concept"* of the invention as defined in the claims;
- determine inventorship including the person responsible for the inventive concept and the time of conception as distinct from its verification and reduction into practice; and
- determine whether any contractual or fiduciary relationships give rise to proprietary rights in the invention.

Contractual relationships

Typically, the inventor is the owner of the invention unless the invention is transferred to another person or entity. Liquid Time submitted the present invention was conceived when Mr Schmied was an employee of Liquid time and therefore as per Mr Schmied's employee agreement, Liquid Time has proprietary rights to any intellectual property that was created by Mr Schmied during his employment.

Liquid Time also referred to a number of projects Mr Schmied was involved in as part of a joint research program with the University of Tasmania and the Technical University of Delft. Liquid Time referred to an agreement between the parties of the joint research program and stated that all intellectual property generated during the program belonged to Liquid Time as they were a major sponsor of the program. The Patent Office concluded that Liquid Time was entitled to any intellectual property relating to wave pools created by Mr Schmied during his tenure of employment with Liquid Time.

Inventorship and conception

The Patent Office was satisfied that Mr Schmied was the sole inventor of the 684 Patent. Liquid Time submitted that all of the key inventive features of the wavedozer and wave pool of the 684 Patent (which the Patent Office considered to be the movable hull with the constant beam and angled hull surface) had been conceived by Mr Schmied when he was an employee of Liquid Time. Liquid time referred to numerous papers Mr Schmied co-authored as a part of the joint research project.

One of the papers disclosed a wave pool with a deep area and a shallow area with a sloping bathymetry and a movable pressure source in the deep part of the pool capable of generating waves in the pool. Liquid Time specifically referred to model 3 of the pressure source which was in the form of a wedged shaped wavedozer. The Patent Office concluded that model 3 of the wavedozer had a constant beam or width along its length and a hull surface that was angled to the horizontal plane and therefore, contained aspects of the inventive concept of the 684 Patent. Liquid Time also referred to other documents said to disclose the inventive concept of the 684 Patent.

The Patent Office concluded it was clear that the inventive concept was developed by Mr Schmied during his employment at Liquid Time. As a result of contractual obligations between Mr Schmied and Liquid Time, the Patent Office found that Liquid Time was solely entitled to any intellectual property relating to wave pools created by Mr Schmied during his employment with Liquid Time. As such the Patent Office found that the eligible person for the invention of the 684 Patent was Liquid Time and not Smartpark Technologies LLC.

Significance

This decision is interesting as lack of entitlement was successfully used as the sole ground of opposition. It highlights the importance of determining the time of conception of the inventive concept as distinct from its verification or reduction into practice. This decision also reinforces the importance of utilising clear and concise written agreements with employees and commercial partners that address intellectual property and invention ownership.

Australian Patent Office considers the plausibility of Swiss-style claims

***Gliknik, Inc. v CSL Behring Lengnau AG* [2020] APO 46 (12 October 2020)**

Read the Decision

Patent Office Delegate: F White

| biotechnology | Patent Office opposition | Swiss-style claims | support | plausibility |

Author

Michael Christie PhD
(Principal, Patent Attorney)

In brief

For the first time the Patent Office has considered the plausibility of Swiss-style claims, finding that such claims must have plausible efficacy across the full scope of the indications claimed, in line with the test for plausibility of method of treatment claims (an aspect of the "support" requirement).

Background

This case concerned a patent application for engineered proteins intended for use as replacements for intravenous immunoglobulin. The application included claims directed to methods of treating autoimmune or inflammatory diseases as well as a Swiss-style claim directed to the same diseases. Gliknik, Inc. opposed the application on several grounds including that the specification did not sufficiently disclose the invention as claimed.

The standard for "sufficient" disclosure was raised in Australia following the commencement of the *Intellectual Property Laws Amendments (Raising the Bar) Act 2012* (Cth) and its assessment has been approached by the Australian Patent Office with the following two-step enquiry:

1. Is it *plausible* that the invention can be worked across the full scope of the claim?
2. Can the invention be performed across the full scope of the claim without *undue burden*?

Decision

The Patent Office considered for the first time the plausibility of a Swiss-style claim. Following the principles recently set out by the Full Federal Court in *Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd* [2020] FCAFC 116 (***Mylan***) (discussed earlier in this publication), the Delegate observed that Swiss-style claims confer a monopoly in respect of a method of making a medicament. They are not product claims, nor are they method of treatment claims – the monopoly extends to the point where the medicament is made. Nevertheless, Swiss-style claims are purpose-limited in the sense that the medicament resulting from the method is characterised by the therapeutic purpose for which it is manufactured, as specified in the claim. Unlike method of treatment claims, however, a Swiss-style claim does not require that the therapeutic effect be achieved.

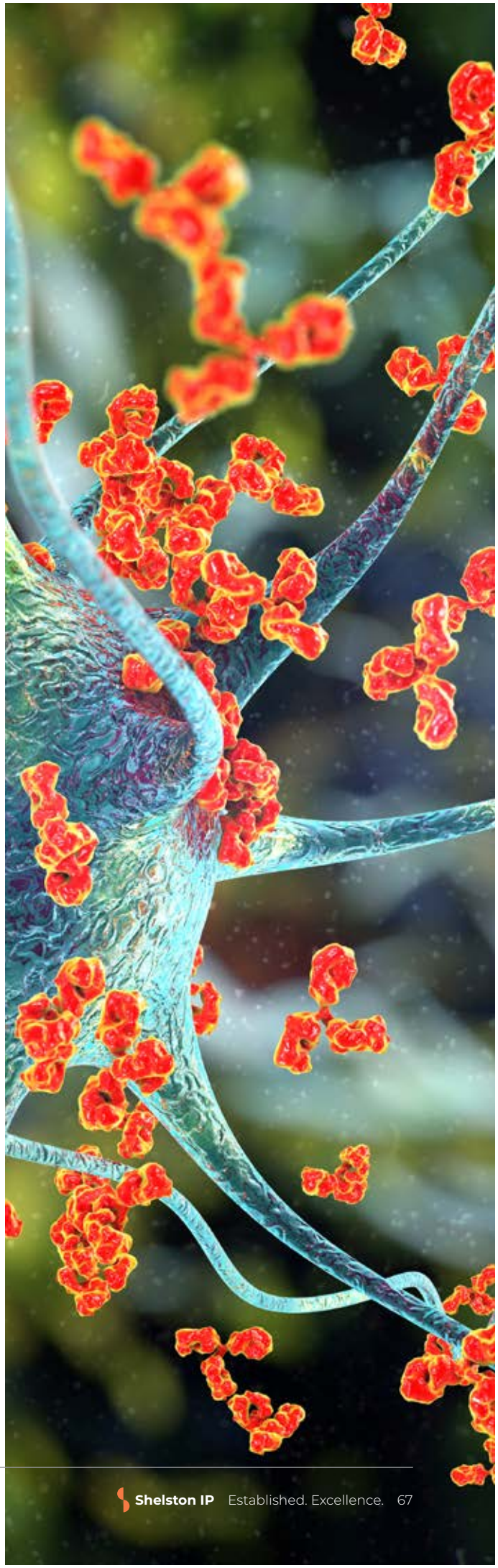
Having construed the claims, the Delegate then considered whether the plausibility standard of therapeutic effectiveness (for method of treatment claims) differed from that of therapeutic purpose (for Swiss-style claims). In the absence of Australian jurisprudence, the Delegate turned to UK authorities, and in particular, the principles set out by Sumption LJ in *Warner-Lambert Company LLC v Generics (UK) Ltd* [2018] UKSC 56. Although that case concerned the plausibility of *efficacy* rather than *purpose,* the Delegate reasoned that, if the efficacy of a product is

not plausible, then it would follow that an intention to treat would not be plausible. The Delegate concluded that substituting the word “efficacy” for “purpose” in Sumption LJ’s comments would not provide any substantial difference to the plausibility analysis.

Turning then to the disclosure of the specification, and the evidence of the common general knowledge in the field, the Delegate found it plausible that the engineered proteins of the invention could effectively treat some, but not all, conditions specified in the claims. For certain conditions, the specification provided no more than a speculative assertion and so the claims were found to be insufficiently enabled.

Significance

This decision shows that the Australian Patent Office will apply a similar standard of plausibility to method of treatment claims as it will to Swiss-style claims. For each type of claim, the disclosure of the specification, supplemented by the common general knowledge, must make the efficacy of the treatment plausible.



Opponent looks to "squeeze" in all the wrong places

***Lonza NZ Limited v Koppers Performance Chemicals New Zealand* [2020] NZIPOPAT 4 (22 October 2020)**

Read the Decision

NZ Patent Office Delegate: M D Luiten

| chemical | IPONZ | opposition proceeding | inventive step | sufficiency |

Author

Gareth Dixon PhD
(Principal, Patent Attorney)

In brief

A classical invalidity "squeeze" advanced by the Opponent (i.e., if the Delegate finds the claims novel and inventive then s/he must also find them insufficient) failed on all three grounds for reasons not accounted for in the Opponent's submissions. This opposition, decided under the now superseded *Patents Act 1953 (*NZ) (**1953 Act**), follows the strict wording of the legislation and precedent case law in confirming that even small differences between the claimed invention and the prior art can confer patentability. The Opponent's squeeze, based upon a tangential argument, failed as a result and the claims were held novel, inventive and sufficiently described in the specification as filed.

Whereas the legal aftermath of this decision suggests the Opponent may have had better (even if only partial) success employing a slightly different strategy, the commercial reality is that the Applicant has a marketable product sitting comfortably distinct from the prior art. For this reason, the Opponent appeared to adapt a "knockout" strategy which, of course, came at considerably higher risk.

Background

New Zealand patent application 704395, to Lonza NZ Limited (the **Applicant**), was filed on 3 February 2015, accepted on 20 October 2015 and opposed by Koppers Performance Chemicals New Zealand (the **Opponent**) on 28 January 2016. Because the opposed application is a divisional from NZ 604053, filed before the *Patents Act 2013* (NZ) took effect, it is correctly considered under the opposition criteria provided in the 1953 Act, which include novelty, inventive step and sufficiency.

The opposed application is entitled "Broad spectrum synergistic fungicidal compositions and methods of use". The application relates to a fungicidal composition including known fungicides triadimefon and cyproconazole as active ingredients, for use in the glue-line treatment of wood and engineered wood products. The claimed ratio of triadimefon to cyproconazole is 6:1 to 20:1 by weight, which was narrowed from the originally-claimed 1:1 to 20:1 during prosecution.

The claimed composition is added to glue in amounts that maintain the adhesive properties of the glue but impart upon it fungicidal efficacy against a broad spectrum of fungi that may infest the wood within the glued end-product.

A single prior art document (US 2006/0252847, "D1", having a NZ family member for local novelty purposes) was relied upon by the Opponent in contending the grounds of novelty and inventive step. D1 generally discloses triadimefon and cyproconazole in a molar ratio from 5:1 to 1:3. The Opponent alleged that the opposed application lacked novelty and an inventive step in light of D1 – and failing that, the opposed specification was insufficient such that it did not provide enough information to allow a skilled person to determine which of the ratios within the claimed range of 20:1 to 6:1 were in fact "synergistic".

Decision

As noted above, the Opponent pressed three grounds of opposition available under the 1953 Act: lack of novelty over D1, lack of inventive step over D1, and insufficient disclosure of the claimed invention. Considering each in turn:

First, the Delegate noted that any difference between molar ratios (as taught in D1) and weight ratios (as claimed) was negligible such that triadimefon (293.75 g/mol) and cyproconazole (291.77 g/mol) have similar molecular weights. This appeared to fall in the Opponent's favour, who then argued that any difference between the 5:1 ratio of D1 and the 6:1 ratio of the claimed invention was inconsequential. However, the Delegate considered otherwise. Applying the test for anticipation in *General Tire & Rubber Company v Firestone Tyre and Rubber Company Limited* [1972] RPC 457 (***General Tire***), i.e.,

whether in following D1 (upper limit of 5:1), the skilled person would inevitably produce a composition within the claimed weight ratios (lower limit 6:1), it was held that the skilled person would not deviate from the prior art as they would be seeking a composition with known fungicidal properties. No evidence was adduced as to normal tolerances in the art and on this basis, it is unsurprising that the Delegate took D1 on its face and held the opposed claims novel over D1.

The Opponent then argued that the apparent closeness of the ratios meant that the opposed claims were obvious over D1. However, the Delegate noted that one does not necessarily beget the other and that the respective tests for novelty and inventive step still need to be satisfied. Rephrased, being "nearly not novel" does not imply that the claims are obvious.

Working through the evidence, the Delegate found that obviousness had not been established. The Opponent had argued that there was no material difference between a 5:1 ratio (D1) and a 6:1 ratio (as claimed) as the specification disclosed no difference in synergy across those ratios. The Delegate held that this was not drawn out in the Opponent's evidence and as such, it would not be obvious for the skilled person to investigate "close by" ratios such as 6:1.

The Opponent further asserted that the skilled person would test azole pair combinations for fungicidal efficacy across a range of ratios from 20:1 to 1:20. The Applicant countered with evidence that an increasing synergistic effect as the ratio increased from 6:1 to 20:1 was unexpected. In apportioning any benefit of the doubt (as is a requirement of the 1953 Act), the Delegate sided with the Applicant for what appear to be three sound reasons.

First, the Delegate questioned whether the testing regime advanced by the Opponent was indeed common practice or more akin to confidentially-held company information. Secondly, the Opponent's evidence covered only a 1:1 ratio with the asserted range extrapolated from this. Thirdly, the Opponent's expert was considered to lack requisite glue-line experience. Rather, the Delegate accepted the evidence of the Applicant's experts who asserted that common practice was to test azole pair combinations for fungicidal efficacy across a relatively narrow range of 3:1 to 1:3. The Delegate also accepted that cyproconazole was known to be a better fungicide than triadimefon and as such, it would be counterintuitive for the skilled person to suspect that further diluting cyproconazole with triadimefon may give improved results. Given these doubts the Delegate held that obviousness had not been established.

Finally, the Opponent's insufficiency "squeeze" required the Delegate to form the opinion that the formulations described in D1 were not "synergistic fungicidal compositions". Thus, the Opponent contended that if the claimed invention was considered novel and non-obvious "on [this] basis", then the specification would be insufficient because it does not provide enough information to allow a skilled person to determine which of the triadimefon to cyproconazole ratios within the claimed 20:1 to 6:1 range of ratios were in fact "synergistic".

However, as related above, the Delegate's findings in relation to novelty and inventive step did not require the Opponent's specific construction of D1. The claims were held novel and inventive without requiring the Delegate's consideration as to whether D1 indeed taught "synergistic fungicidal compositions". The insufficiency squeeze necessarily failed as a consequence.

Significance

New Zealand patent oppositions, especially those conducted under the 1953 Act, are an efficient vehicle for the disposal of plainly bad patent applications. It is a relatively quick, pre-grant, *inter partes* procedure that attempts to balance expediency, cost, the public interest and the respective interests of the adverse parties. Given that a Delegate's findings can be appealed to the New Zealand court system, and that any benefit of the doubt is apportioned in favour of an applicant, then one will appreciate it is a somewhat "high bar" for an opponent to have to satisfy before the Office.

Further, the grounds of novelty and obviousness are not easily made out. As we have seen in this case, the *General Tire* precedent does not allow much deviation from the literal disclosure of a prior art document. Moreover, in respect of obviousness, section 21(e) imports the additional requirement that a claim *clearly* does not involve an inventive step. Considered against the Delegate's comments in relation to the Opponent's evidence and the benefit of the doubt, it is hardly surprising that the ground of obviousness was not made out.

The Opponent's final ground was the insufficiency squeeze reliant upon the Delegate adopting a particular construction of D1. When this construction was not followed, the squeeze necessarily failed.

The implications of this case are unremarkable. It is very much a case of "steady as she goes" - manifestly untenable applications will continue to be struck off at this point whereas those having patentable merit at least worthy of consideration before a Court can be appealed to this forum if commercial interest justifies the expenditure. That said, from a commercial perspective, the most significant aspect of this case may be that even if the Opponent had established the obviousness of 6:1, the Applicant could presumably have amended its claims without affecting its monopoly over an existing commercial product having a ratio of 10:1. In large measure, this may explain the Opponent's "all or nothing" reliance upon the failed squeeze argument.

A computer program “as such” is not an invention

***Thomson Reuters Enterprise Centre GmbH* [2020] NZIPOPAT 7 (17 December 2020)**

Read the Decision

NZ Patent Office Delegate: M. Luiten

| information technology | IPONZ | manner of manufacture | computer-implemented methods |

Author

Gareth Dixon PhD
(Principal, Patent Attorney)

In brief

This is the first hearings decision issued by the Intellectual Property Office of New Zealand (**IPONZ**) regarding section 11 of the *Patents Act 2013* (**2013 Act**). Section 11 excludes computer programs “as such” from patentability on the basis that they are neither an invention nor a manner of manufacture.

Leading up to, and during passage of the 2013 Act, section 11 was unquestionably the most dynamic and controversial of the new provisions. Software was originally going to be patentable subject matter. However, a very well-organised anti-software lobby was successful in swaying Government’s position during the Select Committee stage, leaving section 11 as a slightly awkward exclusion provision when considered against New Zealand’s obligations under the Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreement.

Perhaps unsurprisingly, given the very clear policy decision that computer programs should be excluded, IPONZ adopted a hard line in this decision. All claims 1-20 were held to be excluded under subsection 11(5), with claims 1-6 further excluded under subsection 14(a) for defining merely a scheme or plan.

Background

New Zealand patent application 746441, to Thomson Reuters Enterprise Centre GmbH (the **Applicant**), relates to a computer-implemented method for classifying data. With examination having reached an impasse, and with the section 71 (acceptance) deadline fast approaching, the applicant filed an amended set of 20 claims and requested to be heard before a Delegate of the Commissioner.

According to subsection 11(3) “the actual contribution made by the alleged invention” must be read as the actual contribution made by the alleged invention as claimed. Subsection 11(5) emphasises the intended effect of subsection 11(1) and in conjunction with subsections 14(a) and 65(1) clarifies that whether a claim relates to a computer program as such must be decided in the first instance during examination by the Commissioner, prior to grant.

Claim 1 is rather long. However, its preamble recites “[a] computer-implemented method for classifying data..”. On the face of it, therefore, it is unsurprising that such a claim met resistance from IPONZ during examination. The substance of claim 1 involves presenting areas on a touchscreen at respective locations around the perimeter of a screen and presenting the data items as tiles on the touchscreen. When the user swipes a data item tile onto or into a category area this gesture including the identity of the tile swiped and the category into which it was swiped is recognised by the operating system and the category assigned to the data item is recorded and stored in the memory. According to the specification, the data item is not permanently moved into the category area by the user’s swipe, but rather stays at its original position on the screen. However, once a data item or tile has been assigned to a category by the swipe, the appearance of the item or tile is modified to indicate the category to which it has been assigned.

On its face, the alleged invention must involve or make use of a computer program. To this end, the amended claims 7-11 actually provide a list of such computer programs. However, the 2013 Act does not define what is meant by a “computer” or “computer program” or equivalently, a “program for a computer”. These terms must be taken to mean what persons skilled in the art would understand them to mean in the broadest sense.

Decision

The Delegate found that all claims 1-20 related to a computer program as such and were thereby excluded under subsection 11(5). The Delegate further held that claims 1-6 also related to a mere scheme or plan, thereby falling foul of subsection 14(a).

The applicant argued that the actual contribution of the invention resided in a new and improved way in which a computer works to provide an improved interface and therefore provide an improved visible and physical outcome with an effect on the physical and visual interaction of the end user with the interface of the touch-sensitive device. The applicant suggested that by eliminating the user's need for peripheral devices to interact with the classification system, they had made an advancement in the art beyond merely another computer "app".

The Delegate thought otherwise, finding that "when the user classifies the data items into the categories by using the touchscreen interface as claimed, no process outside of the computer system is affected by the classification. In other words, the method is simply a method implemented via the touchscreen interface and servers to classify data items into categories and gather information regarding the classification of the data items. What happens in the computer is entirely dependent on the data being processed and the user's input to the interface, and the application being used".

The Delegate thereby concluded that the actual contribution made by the alleged invention resided solely in it being a computer program. Therefore, the claims related to a computer program as such, and did not define an invention and were not for a manner of manufacture.

Significance

Given the specific technology and the legislative history, it is difficult to see how this case could have been decided otherwise. It appears a rather straightforward decision. That said, as the first hearings decision regarding section 11, it does set a deliberately high bar for future applicants looking to obtain a patent within the software space.

The text of section 11 was introduced by way of a Supplementary Order Paper (**SOP**) by the Commerce Select Committee following consideration of submissions on the original content of the *Patents Bill* (which, as noted, had purported to allow software patents). The explanatory note to the SOP explains that a computer program as such is not an invention and is not a manner of manufacture, and that where the actual contribution of an invention lies solely in it being a computer program, it is ineligible for patent protection. The net effect is that it is not possible to obtain a patent for an invention that involves or makes use of the computer program if the sole inventive feature is that it is a computer program. It is, however, possible to obtain a patent for an invention that makes use of or comprises a computer program (including embedded computer programs) if the actual contribution lies outside the computer or which, if it affects the computer itself is not dependent on the type of data being processed or the particular application being used. The provision does not include any consideration of whether the claim has a technical character or effect.

The decision also purports to distance section 11 from Article 52 of the European Patent Convention. Article 52 stipulates that a computer program as such is not an invention that is patentable whereas section 11 goes further in that a computer program as such is also not a manner of manufacture. In Article 52 computer programs as such are just one of a list of "intellectual inventions" that are not patentable, whereas section 11 is a specific singular exclusion. Further, Article 52(3) refers to "a European patent application or European patent relates to such subject-matter or activities as such" whereas subsections 11(2) and 11(3) refer specifically and explicitly to "a claim in a patent or patent application". As such, section 11 is rather claim-focussed by comparison with the more nebulous "subject matter or activities" of Article 52(3). Future applicants purporting to rely upon Article 52 precedents can expect to find themselves distinguished on these bases.

Claims to "synergy" found to lack support

Taiho Pharmaceutical Co., Ltd.
[2020] NZIPOPAT 5
(6 November 2020)

Read the Decision

NZ Patent Office Delegate: M D Luiten

| pharmaceutical | IPONZ |
Swiss-style claims | support |

Author

Gareth Dixon PhD
(Principal, Patent Attorney)

In brief

To date, the Intellectual Property Office of New Zealand (**IPONZ**) has issued only a handful of hearings decisions on matters pertaining to the *Patents Act 2013* (NZ) (**2013 Act**). The present decision is notable insofar as it brings together two of the more interesting aspects of life under the 2013 Act: the examination of Swiss-style claims and the heightened descriptive support requirements.

With the section 71 (acceptance) deadline approaching, the Applicant sought to safeguard its position via the classical route of a) requesting a hearing (which allows one last chance to contest any residual examination issues) and b) filing a divisional application.

In the decision, the Applicant actually went backwards (all previous rejections were maintained, and new rejections were raised). The application is now voided, but the Applicant lives to fight another day by virtue of its divisional application. The decision does, however, confirm that the "support" threshold under the 2013 Act is perceptibly higher than the "fair basis" standard as existed under the *Patents Act 1953* (NZ) (**1953 Act**).

Background

New Zealand patent application no. 718662, to Taiho Pharmaceutical Co., Ltd., describes the use of a combination drug (trifluridine (**FTD**) and tipiracil hydrochloride (**TPI**) at a molar ratio of 1:0.5) co-administered with an antibody (one of bevacizumab, cetuximab or panitumumab). The patent claims are presented in Swiss-style format.

The application was facing a section 71 (acceptance) deadline of 11 March 2019. Four days prior, the Applicant filed an examination response, an amendment, a request to be heard – and filed a divisional application (NZ 750260) in order to safeguard its position in the event of a further adverse finding by IPONZ. Under New Zealand practice, this amounts to a classical defensive strategy on the part of the Applicant's attorney.

A further examination report (the **Fifth report**) was issued on 12 April 2019 (which was after expiry of the section 71 deadline). The Fifth report, which was to form the basis of matters contested at the hearing, maintained two rejections. Firstly, that all of claims 1-5 were considered obvious, and secondly, that independent claim 3 lacked descriptive support. The two independent claims (1 and 3) recited:

1. *Use of a combination drug comprising trifluridine (FTD) and tipiracil hydrochloride (TPI) at a molar ratio of 1:0.5 for the manufacture of a medicament for the prevention or treatment of cancer in a subject, wherein the medicament comprises the combination drug comprising trifluridine and tipiracil hydrochloride in a molar ratio of 1:0.5 which is formulated for co-administration at a dose of from 35 to 70 mg/m2/day as FTD with an antibody selected from the group consisting of bevacizumab, cetuximab and panitumumab at a dose of: from 1.10 to 10 mg/kg/day bevacizumab, from 44 to 400 mg/m2/day cetuximab, or from 0.67 to 6 mg/kg/day panitumumab; and wherein the cancer is colorectal cancer or breast cancer.*

3. *Use of a combination drug comprising trifluridine (FTD) and tipiracil hydrochloride (TPI) at a molar ratio of 1:0.5 for the manufacture of an antitumor effect enhancer to enhance the antitumor effect of an antibody in a cancer patient, wherein the antitumor effect enhancer comprises the combination drug which is formulated for co-administration at a dose of from 35 to 70 mg/m2/day as FTD with an antibody selected from the group*

consisting of bevacizumab, cetuximab and panitumumab at a dose of: from 1.10 to 10 mg/kg/day bevacizumab, from 44 to 400 mg/m2/day cetuximab, or from 0.67 to 6 mg/kg/day panitumumab; and wherein the cancer is colorectal cancer or breast cancer.

In advance of the hearing, the Applicant filed a written submission and a further amendment. The amendment was refused because it was filed out of time. The hearing was therefore decided on the basis of the examined claims 1-5 (dated 7 March 2020) and the Applicant's written submission.

Decision

This decision is notable insofar as it brings together two of the more interesting aspects of patent practice before IPONZ: the examination of Swiss-style claims (which is currently undergoing Government review and is likely to feature in this year's *IP Omnibus Bill*) and the heightened descriptive support requirement for cases examined under the 2013 Act. Other aspects of the decision (i.e., the novelty and inventive step assessments) are specific to this case and are unremarkable.

First, claim 1 was found to lack descriptive support. The Applicant taught that breast and colorectal cancers were treatable by co-administering the FTD/TPI combination drug and a bevacizumab, cetuximab or panitumumab antibody to a patient suffering one of those diseases. It was known to treat these diseases with one or the other of the combination drug or the antibody at the same dosages as claimed. Thus, it was the co-administration that was essentially at the nub of the invention. Accordingly, a Swiss-style claim commensurate with the disclosed therapy should have defined the use of both drugs (the combination drug and the antibody) in the manufacture of medicaments for the treatment of breast and colorectal cancers by way of co-administration. As drafted, the independent claim 1 was not directed to this use and was thereby found to lack support.

Applying a slightly different rationale, independent claim 3 was also found to lack descriptive support. This claim recited the same compositions, antibodies, and dosages as did claim 1, but rather than being for the prevention or treatment of colorectal or breast cancer, the therapeutic purpose of the medicament was for enhancing the anti-tumour effect of an antibody in a cancer patient suffering from colorectal cancer or breast cancer – that is, an alleged "synergistic" therapy result with reduced harm effects.

By the Delegate's prior reasoning, a Swiss-style claim that is not commensurate with the method disclosed cannot be adequately supported by the matter disclosed in the complete specification.

With the inventive contribution alleged to reside in the synergy of action of the FTD/TPI/antibody co-administration at particular dosages, the Delegate opined that synergistic interactions between drugs can be critically dose-dependent and are not easily predicted. He noted that across the three co-administrations, the specification establishes only one instance of synergy (FTD/TPI/bevacizumab co-administration, with the FTD/TPI dosage less than 70mg/m^2/day and bevacizumab). From this, it followed that claim 3 was not properly supported across its entire scope.

Significance

The decision does nothing to dampen expectation that Swiss-style claims can be both valid and enforceable under New Zealand law. There appears no reason in principle that a Swiss-style claim directed to the use of more than one compound in the manufacture of medicaments for specified therapies or the treatment of specified diseases should not be allowable on the condition that such a claim is commensurate with the invented therapy (and of course, both novel and inventive).

The finding in respect of claim 3 is likely the more interesting of the two. Whereas claim 1 "missed the mark" in terms of not being drafted to cover its disclosed use, claim 3 was drafted more correctly. It fell down in that it claimed synergy across a range of co-administrations whilst demonstrating only a single instance of such synergy. Notably, had claim 3 been subjected to the lower "fair basis" criteria of the *Patents Act 1953* (i.e., the Mond-Nickel Rules), it is entirely likely that it would have passed muster (only to then have failed for the want of an inventive step).

The decision in respect of claim 3 is in keeping with an earlier decision issued by IPONZ in respect of [2017] NZIPOPAT 16 and is unlikely to be too controversial. It confirms that "support" under the 2013 Act is a higher bar than "fair basis" under the 1953 Act.

SHELSTON
INTELLECTUAL PROPERTY

Level 9, 60 Margaret Street
Sydney NSW 2000 Australia

T. +61 2 9777 1111
F. +61 2 9241 4666

email@ShelstonIP.com
ShelstonIP.com