Best Patent Cases 2017
Australia
Welcome to Shelston IP’s round-up of the best patent cases from Australia delivered during 2017.

The year saw some interesting decisions delivered in relation to various issues that had not been judicially considered for quite some time.

The Full Federal Court delivered important decisions clarifying the basis on which damages should be awarded in connection with unjustified threats of patent infringement proceedings, the requirements for a successful preliminary discovery application in connection with a biosimilar medicine, the patentee’s obligation to disclose the best method of performing an invention known at the time of filing and the difficulties of overturning factual findings in a complex biotechnology case.

The Federal Court delivered its first damages award (AU$30 million) in a patent infringement matter for decades and also ordered the infringer to pay indemnity costs from the time it refused the patentee’s Calderbank offer, and also provided long-awaited guidance on when modifications to a patented article will and will not enable a patentee to maintain control post-sale (the “repair v rebuild” dichotomy). Three pharmaceutical patentees sought and obtained interlocutory injunctions late in the year, following a long period in which pharmaceutical patentees had seemingly held back due to the uncertainty arising from the claims the Australian Government is pursuing for alleged “overpayments” of PBS reimbursements. Incidentally, there was also an interlocutory decision issued in the Australian Government’s favour in the first of those proceedings. The Federal Court also provided guidance on the high level of transparency required if a patentee wishes to amend its patent during litigation, confirmed that mere offers of supply constitute patent infringement and highlighted the importance of securing an assignment of rights when engaging an independent contractor to perform work in relation to a potential innovation.

The Australian Patent Office issued important decisions relating to the grace period applicable to “whole of contents” novelty citations, the enablement and best method requirements in the context of biotechnology inventions and the strict approach to manner of manufacture for computer-implemented inventions.

The Snapshots section on the next page is designed to assist readers in navigating this publication and identifying cases of particular interest. Please do not hesitate to contact any of our authors if you are interested in learning more.

We hope this provides a useful resource.

Duncan Longstaff,
Senior Associate, Lawyer

Natasha Faigenbaum,
Lawyer
Snapshots of Best Patent Cases (2017)

Full Federal Court Appeal Decisions

**Australian Mud Company Pty Ltd v Coretell Pty Ltd [2017] FCAFC 44**

**Coretell Pty Ltd v Australian Mud Company Pty Ltd [2017] FCAFC 54**

**Unjustified threats Damages Mechanical**

In two significant decisions in the same proceeding, the Full Federal Court has reversed an award of substantial damages for an unjustified threat in long-running litigation and also determined that infringement cannot occur until grant of the innovation patent. See page 8

**Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd [2017] FCA 285**

**Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd [2017] FCAFC 193**

**Preliminary discovery Biosimilar**

At first instance, Burley J of the Federal Court of Australia has delivered an important decision dismissing an application for preliminary discovery of documents relevant to determining whether a registered biosimilar product might infringe one or more patents claiming manufacturing processes. On 29 November 2017, the Full Court of the Federal Court of Australia (Allsop CJ, Perram and Nicholas JJ) delivered its decision upholding Pfizer’s appeal. Accordingly, the Samsung Bioepis parties (SBA and SBK) will now be required to give preliminary discovery, although the matter has been remitted to Burley J for determination of the final form of the orders, including any questions of confidentiality, and the question of the costs of the application at first instance. See page 11

**Sandvik Intellectual Property AB v Quarry Mining & Construction Equipment Pty Ltd [2017] FCAFC 138**

**Best method Prior use novelty Inventive step Mechanical**

This decision illustrates that applicants should include the best method(s) of performing the invention known at the time of filing a patent application, as withholding better or superior embodiments or features can result in invalidity of the granted patent. Novelty destroying prior use does not always need to be corroborated by contemporaneous documentary evidence. Experts need to be carefully selected as an unsuitable expert will be less persuasive on inventive step issues. Claims are invalid for inutility where they include embodiments that are not useful. See page 15

**Idenix Pharmaceuticals LLC v Gilead Sciences Pty Ltd [2017] FCAFC 196**

**Insufficiency Inutility Appeal of factual findings Pharmaceutical**

This decision is an appeal from the Federal Court of Australia decision, which had found the patent at issue invalid for reasons of insufficiency and inutility. The appeal against the finding of invalidity was dismissed and the grounds of contention were deemed not made out. See page 17
Snapshots of Best Patent Cases (2017)

Federal Court Trial Decisions

**Bayer Pharma Aktiengesellschaft v Generic Health Pty Ltd [2017] FCA 250**

**Bayer Pharma Aktiengesellschaft v Generic Health Pty Ltd [2017] FCA 428**

Infringement Damages Calderbank costs award Pharmaceutical

In a landmark Federal Court of Australia decision, Bayer was awarded $30m ($25.7m in damages plus interest) to compensate for lost revenue caused by generic product sales infringing its patent covering the oral contraceptive Yasmin (ethinylestradiol/drospirenone). This sets a new benchmark in Australia for future damages claims against generic manufacturers. The Court’s willingness to adequately compensate the patent holder enhances Australia’s already very attractive “value proposition” for patentees. The Court also penalised Generic Health for its failure to accept Bayer’s reasonable settlement offer during the litigation, ordering it to pay Bayer’s costs on an indemnity basis from the day that offer expired. See page 20

**Seiko Epson Corporation v Calidad Pty Ltd [2017] FCA 1403**

Infringement Repair v rebuild Implied licence Mechanical Electrical

In this first instance Federal Court of Australia decision, Burley J considered the tension between the rights of the purchaser of a patented product, and the rights of the patentee to maintain control of the product in order to determine under what circumstances the importation and sale of a refilled or refurbished printer cartridge will infringe patent rights applicable to the original cartridge. Ultimately his Honour confirmed the “implied licence” approach applied in National Phonograph Co of Australia Ltd v Menck (1911) 12 CLR 15 and cast a new test to determine whether the repair or refurbishment of a patent product will extinguish the implied licence. See page 23

**Dincel Construction System Pty Limited v AFS Systems Pty Ltd [2017] FCA 262**

**Dincel Construction System Pty Limited v AFS Systems Pty Ltd (No 2) [2017] FCA 791**

**Dincel Construction System Pty Limited v AFS Systems Pty Ltd (No 3) [2017] FCA 919**

Interlocutory injunction Infringement Mechanical

In these Federal Court of Australia decisions, Dincel Construction System Pty Ltd sued AFS Systems Pty Ltd for infringement of a patent to which it was the exclusive licensee. After establishing that the circumstances warranted an interlocutory injunction, the Court focused on the key issues of claim construction arising from use of the non-technical term “ramp surface”. See page 26

**Doric Products Pty Limited v Asia Pacific Trading (Aust) Pty Ltd [2017] FCA 849**

Innovation patent Novelty Innovative step Mechanical

In this first instance Federal Court of Australia decision, Doric Products Pty Limited sued Asia Pacific Trading (Aust) Pty Ltd for infringement of the claims of two innovation patents relating to window winders. Asia Pacific Trading (Aust) Pty Ltd advanced a cross-claim asserting that those claims of the innovation patents are invalid on the grounds of lack of novelty and lack of innovative step. The key issues in the case were the correct construction of identified terms within the claims, whether the alleged infringement falls within the claims of the innovation patents, and whether the claims of the innovation patents are novel and innovative. See page 28
Snapshots of Best Patent Cases (2017)

Federal Court Interlocutory Injunction Decisions

**Janssen Sciences Ireland UC v Alphapharm Pty Ltd [2017] FCA 1399**

**Interlocutory injunction Pharmaceutical**

Janssen was granted interim injunctive relief to avoid Pharmaceutical Benefit Scheme (PBS) listing of generic pharmaceutical products for treating HIV infection. In addition to restraining the generic, Alphapharm, from making, selling, offering to sell, using or otherwise exploiting generic products, Yates J of the Federal Court of Australia ordered the respondent to discontinue assurance of supply of generic products for the purpose of obtaining PBS listing and to withdraw the assurance of supply it has already given, pending the determination of the final hearing. The judgment was delivered on 27 November 2017, just three days before the threatened PBS listing and launch of generic products on 1 December 2017. See page 30

---

**InterPharma Pty Ltd v Hospira, Inc (No 3) [2017] FCA 1536**

**Interlocutory injunction Pharmaceutical**

The Federal Court of Australia (Kenny J) has granted Pfizer companies Hospira and Orion an interlocutory injunction precluding InterPharma from marketing generic dexmedetomidine products despite InterPharma raising triable issues under several grounds of patent invalidity. See page 33

---

**Apotex Pty Ltd v Cipla Limited [2017] FCA 1627**

**Interlocutory injunction Pharmaceutical**

The Federal Court of Australia (Beach J) has granted Cipla and its exclusive licensee an interlocutory injunction restraining Apotex from infringing its patent by launching a nasal spray combining an antihistamine and a corticosteroid. Although Apotex raised assertions of invalidity with some merit (particularly regarding manner of manufacture), Beach J considered that Cipla had an undoubtedly strong *prima facie* case on infringement and the balance of convenience also favoured the grant of the interlocutory injunction. See page 36

---

Federal Court Interlocutory Decisions (Other)

**Apotex Pty Ltd v ICOS Corporation [2017] FCA 466**

**Post-grant amendments Amendments during litigation Pharmaceutical**

The Federal Court has provided guidance regarding the level of disclosure required by a patentee in order for a court to exercise its discretion to allow amendments to the specification during court proceedings. See page 39

---

**Apotex Pty Ltd v Warner-Lambert Company LLC (No 3) [2017] FCA 94**

**Infringement Mere offer Pharmaceutical**

In this decision, the Federal Court of Australia (Nicholas J) delivered a significant judgment in confirming that an Australian patent will be infringed by offers made during the term of the patent, without the patentee’s consent, to supply infringing products after the patent has expired. The decision also highlights the importance of including Swiss-style claims in Australian pharmaceutical patents. See page 42
Snapshots of Best Patent Cases (2017)

Merial, Inc. v Intervet International BV (No. 3) [2017] FCA 21

Merial, Inc. v Intervet International BV (No. 4) [2017] FCA 223

Entitlement Patent Office appeal Veterinary medicine

The first of these decisions (No. 3) concerned an appeal by Merial, Inc. from an Australian Patent Office opposition proceeding in which Intervet International BV successfully defended its patent application relating to an anti-parasitic soft chew formulation. The Federal Court appeal was based on two grounds, inventive step and lack of entitlement, the latter of which was raised for the first time before the Court. The key issue was whether Intervet was entitled to grant of a patent from named inventor Mark Pieloch, an independent contractor whom Intervet Inc. had engaged to assist with formulating and producing the soft chews. Having found that Intervet was not entitled to grant of a patent, the second of these decisions (No. 4) concerned whether Intervet could remedy the entitlement defect by amendment before the Commissioner of Patents.

See page 44

--------------------------------

Electronic Tax-Free Shopping Ltd v Fexco Merchant Services (No 3) [2017] FCA 569

Post-acceptance amendments Appeal from Patent Office opposition Computer-implemented

This case considered the allowability of amendments to a patent specification sought under s105(1A) of the Patents Act, which allows for amendments to be granted by the Court in an appeal from a decision of the Patent Office. The Court considered whether the requirements of s102 of the Patents Act were met and the way in which the discretionary exercise of the power of the Court to direct amendments should be approached in relation to patent applications not yet granted. The Court directed that the amendments be made. See page 46

--------------------------------

Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis) [2017] FCA 382

Damages Interlocutory injunction Undertaking Pharmaceutical

The Australian Government has had another small victory in the most recent interlocutory decision in the clopidogrel damages enquiry, which is likely to be the test case for its claims for reimbursement of PBS “over-payments” for the patentee’s listed pharmaceutical products during the period of an interlocutory injunction restraining generic entry (and consequent price drops), where the patent was ultimately revoked. The Court held provisions of a settlement deed between the patentee Sanofi and alleged infringer (and party restrained by interlocutory injunction) Apotex, prohibiting Apotex employees from assisting other parties such as the Government in pursuing claims against Sanofi under its usual undertaking as to damages, to be unenforceable as they were contrary to the public interest and would interfere with the administration of justice.

See page 48

--------------------------------

Mizzi Family Holdings Pty Ltd v Morellini (No 3) [2017] FCA 870

Unjustified threats Damages Mechanical

The Federal Court has declined to award damages in a successful claim for relief from unjustified threats on the basis that no damages as a result of the threats were proved to be suffered by the threatened party. See page 50

--------------------------------
Snapshots of Best Patent Cases (2017)

Australian Patent Office Decisions

**Rozenberg & Co Pty Ltd v Velin-Pharma A/S [2017] APO 61**

**Patent Office Grace period Whole of contents novelty Pharmaceutical**

The Australian Patent Office has issued an opposition decision notable for the Hearing Officer’s interpretation of the grace period provisions, which were held to extend to “whole of contents” novelty citations (earlier-filed patent applications). See page 52

**Evolva SA [2017] APO 57**

**Patent Office Support Enablement Biotechnology**

Australia has relatively recently implemented support laws (as part of the “Raising the Bar” amendments applicable to applications where examination was requested after 15 April 2013) that require a specification to provide sufficient information to enable the skilled person to perform an invention over the entire scope of the claims without undue burden or the need for further invention. These new support laws have been stringently applied by the Australian Patent Office, in particular in relation to claims defining chemical compounds, such as proteins where, in many cases, the only claims considered to be enabled are ones directed to embodiments exemplified in the specification. See page 55

**Kineta, Inc. [2017] APO 45 (31 August 2017)**

**Patent Office Best method**

In this decision, the Patent Office has followed the Full Court’s decision in *Les Laboratoires Servier v Apotex Pty Ltd* [2016] FCAFC 27 (8 March 2016) and rejected an application for failure to disclose the best method of performing the invention. Given the facts of the case, a single sentence included in the specification would have satisfied the best method requirement. Accordingly, it is crucial that patent attorneys, when drafting specifications intended for prosecution in Australia, understand Australia’s best method requirements. See page 57

**Rokt Pte Ltd [2017] APO 34**

**Patent Office Manner of manufacture Computer-implemented**

In this case, a method and system for linking a computer user to an advertising message by way of an intermediate engagement offer was held not to be eligible subject matter resulting in refusal of the patent application. The decision has been appealed to the Federal Court and is set to be heard in July 2018. See page 59

**Todd Martin [2017] APO 33**

**Patent Office Manner of manufacture Computer-implemented**

In this case, a system and method for tracking usage of athletic equipment of an athlete using a computer web-based training log server and a GPS-enabled mobile device was found not to be eligible subject matter. The innovation patent was revoked. The decision in the case was one of a number of Australian Patent Office decisions in 2017 that applied a controversial four step approach from a UK Court decision in *Aerotel*. See page 61
Background

An innovation patent is a short-term patent available under Australian patent law. It has a lower patentability threshold, as there is no requirement for an inventive step. Rather the invention need only involve an “innovative step” – that it varies from the prior art in a way which makes a substantial contribution to the working of the invention. Other usual requirements for patentability such as novelty, support, clarity etc. still apply.

An innovation patent is granted without substantive examination. However to assert it against an infringer it must be certified, which requires examination. An innovation patent runs for 8 years from the “date of the patent”. The date of the patent is the filing date, other than in the case of a divisional application where the date of the patent is the filing date of the parent, grandparent or earlier generation patent.

Innovation patents are commonly sought in Australia in conjunction with a standard patent application, often a national phase PCT filing. This is achieved by entering PCT national phase and filing a divisional innovation patent application within 3 months of the date of advertised acceptance of the standard patent. Innovation patents can generally be granted and certified within 6 months, providing a useful weapon against infringers in the short term while the standard application is still under examination and awaits the opposition period.

In Britax Childcare Pty Ltd v Infa-Secure Pty Ltd (No 3) [2012] FCA 1019 (Britax), the Federal Court considered alleged infringement of a number of divisional innovation patents filed in these circumstances. The question arose as to the date from which infringement of the innovation patents could occur. The alleged infringer argued that liability for infringement could not arise before certification of an innovation patent. However the judge concluded that infringement could run from the “date of the patent” (being the date of filing of the parent application).

This decision substantially increased the value of innovation patents, particularly when filed as a divisional application, as they could be infringed before the divisional application was even filed, let alone its claims published. In Britax, this resulted in potential infringement from June 2005.
notwithstanding that the latest innovation patents had only been filed as recently as 2009. It should be noted, however, that the Australian Government recently indicated it would follow the Productivity Commission’s recommendation to abolish the innovation patent in the near future.

In this proceeding, the primary judge had held that the respondents (Coretell) had not infringed the patent of Australian Mud Company (AMC) and therefore Coretell was awarded substantial damages ($1,506,859) in respect of the cross-claim for unjustified threats and lost revenues from consequent non-supply of its allegedly infringing Camteq tool. However, the Full Court held that the primary judge failed to determine the key question of causation in accordance with section 128(1)(c) of the Patents Act 1990 (Cth).

AMC appealed the decision on the basis that evidence suggested that at the time the threats were made, the Camteq tool was still being developed and tested (meaning it was not ready for commercial supply) and that problems with the Camteq tool ultimately led Coretell to develop and market a different tool and to abandon further development of the Camteq tool. Accordingly, AMC submitted that Coretell did not sustain any lost sales caused by the threats.

Issues and decision

The Full Court confirmed that in hypothesising what would have happened but for the threats, the Court is not entitled to engage in estimation, speculation and guesswork. Causation must be determined as a question of fact on the balance of probabilities. Further, the Full Court disagreed with the primary judge in stating that the difference between sales lost as a result of the threats and sales lost as a result of the proceedings is ‘semantical’. The Full Court confirmed that only sales lost as a result of a threat are those that inflict damages encompassed by section 128.

The Full Court accepted that a logical problem with the primary judge’s reasoning was that there was no evidence to support a finding that development of the Camteq tool ceased after the threat letter. The evidence only suggested that marketing and hiring ceased. Moreover, at the time the threats were made, the evidence also demonstrated that Coretell was working hard to perfect the tools. First, this suggests that the tools were still in the development stage demonstrating that Coretell did not suffer any loss of revenue as they did not have a tool ready for commercial supply. Secondly, the evidence demonstrates that Coretell were not impeded by the threat letters suggesting that any damage suffered was not caused by the threat letters. Further, the conclusion at trial that the Camteq tool would have been ready for commercial supply within six months of the first threat was “glaringly improbable” and “contrary to compelling inferences”.

The Full Court therefore held that the only conclusion available is that what occurred would have occurred in any event. The appeal was allowed and Coretell ordered to pay AMC’s costs.

On the topic of the date from which an innovation patent can be infringed, the key respect in which Burley J (with whom the other two judges agreed) differed from Britax was in finding that whilst the “date of the patent” (the filing date or in the case of a divisional application, the filing date of the parent/grandparent etc.) determines the term of a patent, infringement is determined by reference to the date of grant. In reaching this conclusion, Burley J referred to the infringement provisions of the Patents Act 1990 (Cth), noting that they refer to infringement of “a patent”, inferring a granted patent. Further, section 57(1), which provides that an applicant for a standard patent has the same rights from the date of publication as if a patent had been granted, does not ‘move forward’ the date from which infringement would otherwise run from the filing date, but rather ‘moves backwards’ the relevant date from the date of grant. As section 57 does not apply to innovation patents (and nor is there any equivalent provision for innovation patents), infringement can only occur from grant. Burley J also noted the central significance of the claims in determining infringement. He confirmed that there is no infringement of an invention as such, there can only be infringement of the claims.

In that context, publication of a specification forms a necessary part of allowing rivals to understand the scope of the monopoly, and it is out of keeping with this scheme to allow infringement before the claims are published.
Implications

This decision provides useful clarification and guidance regarding what an alleged infringer of a patent (or, likely by extension, copyright or a registered trade mark) must establish to receive a damages award in a claim for unjustified or groundless threats of infringement proceedings. In particular, the bar for causation between the threat (as distinct from any subsequent proceedings commenced) and the loss or harm has been set higher by the Full Court than by the primary judge, such that it must be clear that there is no other plausible explanation for sales or profits of products or services not being made following the threat and, effectively, before proceedings were subsequently commenced. It may practically be hard to show substantial damage as a result of a threat where actual proceedings for infringement follow soon afterward.

In its recent Inquiry Report on Intellectual Property Arrangements, the Productivity Commission commented on the fact that divisional innovation patents could be infringed before they were made public, in context of its recommendation to abolish the innovation patent system entirely. The Coretell decision alleviates at least that concern with respect to the innovation patent system, providing a common sense interpretation in line with the framework of the Patents Act generally, and in particular, the provisions relevant to infringement. It also provides certainty to businesses, which can at least be assured that they will not be liable for patent infringement damages in respect of a patent which has not yet been filed.
Pfizer succeeds in Full Federal Court appeal and will now receive preliminary discovery regarding possible infringement of biological medicine process patents

*Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd [2017] FCA 285 (21 March 2017)*

*Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd [2017] FCAFC 193*

**Preliminary discovery Biosimilar**

**Allsop CJ, Perram, Nicholas JJ and Burley J**

At first instance, Burley J delivered an important decision dismissing an application for preliminary discovery of documents relevant to determining whether a registered biosimilar product might infringe one or more patents claiming manufacturing processes. The Full Court (Allsop CJ, Perram and Nicholas JJ) upheld Pfizer’s appeal, and the Samsung Bioepis parties (SBA and SBK) will now be required to give preliminary discovery, although the matter has been remitted to Burley J for determination of the final form of the orders, including any questions of confidentiality and costs.

**Authors:**

Duncan Longstaff  
Senior Associate, Lawyer

Natasha Faigenbaum  
Lawyer

Jacinta Flattery-O’Brien PhD  
Principal, Patent Attorney

Katrina Crooks  
Principal, Lawyer

---

**Background**

The Pfizer parties (collectively, **Pfizer**) were concerned that Samsung Bioepis Co Ltd Korea (**SBK**) and Samsung Bioepis AU Pty Ltd (**SBA**) were infringing one or more of their registered patents claiming a process for making a biological medicine, etanercept. Etanercept is the active ingredient in ENBREL, a biological medicine used in the treatment of autoimmune diseases sponsored in Australia by Pfizer Australia Pty Ltd. Until recently, it has been the only product containing etanercept registered on the Australian Register of Therapeutic Goods. In 2016, SBA sponsored the registration of two pharmaceutical products containing etanercept as their active ingredient and both have been registered on the ARTG under the name of BRENZYS. The parties agreed that BRENZYS were developed as a biosimilar to ENBREL, meaning that it is almost an identical copy of an original product that is manufactured by a different company. The TGA guidelines require that biosimilars must satisfy an extensive comparability exercise with the chosen reference medicinal product to ensure similar quality, safety and efficacy. However, Burley J noted that simply because BRENZYS and ENBREL were biosimilars does not conclusively determine that the process used to manufacture the products is the same.

**Issues and first instance decision**

Pfizer sought orders pursuant to Rule 7.23 of the *Federal Court Rules 2011* (Cth) for preliminary discovery of confidential documents lodged with the Therapeutic Goods Administration (**TGA**) in order to determine whether to commence proceedings against SBK and SBA for patent infringement.

At first instance, Burley J accepted that through a chain of correspondence with the respondents, Pfizer had made reasonable inquiries and did not have sufficient information to decide whether to commence proceedings, as required by Rule 7.23(1)(b). On this note Burley J confirmed that it is sufficient for a prospective applicant to broadly provide the basis on which it forms the views that it holds and makes inquiries of parties from whom it might reasonably be expected that relevant information may be obtained. Burley J specifically observed that Pfizer’s offer of a
confidentiality regime confining access to the requested documents assisted it in establishing the reasonableness of its inquiries.

The main issue for determination was whether Pfizer had the requisite subjective and objective reasonable belief that it had the right to obtain relief for patent infringement from SBA in accordance with Rule 7.23(1)(a). There was no dispute that Pfizer had demonstrated the requisite subjective belief. However, the substantive debate was whether there was an objective basis. Pfizer reasoned that BRENZYS had a peculiar level of similarity to ENBREL and that because of the complexity of the products the similarity inferred that the process to make each product must be similar. Further, because Pfizer contended (without adducing direct evidence) that the process by which it manufactures ENBREL falls within the scope of the claims in question, the process by which SBK manufactures BRENZYS must therefore also fall within the scope of the claims. Nonetheless, Burley J held that this chain of reasoning did not rise above speculation. Accordingly, Pfizer failed to demonstrate a reasonable objective belief that they have the right to obtain relief for patent infringement from SBA in accordance with Rule 7.23(1)(a).

Further, Burley J found that even if Pfizer had established the requisite reasonable belief, he would have exercised the judicial discretion conferred by Rule 7.32(2) against granting the preliminary discovery order sought. Burley J noted in particular the scope of the documents sought and the fact that Pfizer did not adduce evidence of its own manufacturing process for ENBREL.

Issues and appeal decision

The key issues in Pfizer’s appeal were:

- the standard of proof and belief that Pfizer, as prospective applicant, had to demonstrate to obtain preliminary discovery orders under Rule 7.23 of the Federal Court Rules 2011 (Cth); and

- whether the opinion evidence of Pfizer’s in-house scientific expert that Pfizer’s own ENBREL product was produced by processes falling within Pfizer’s patents should have been admitted into evidence in circumstances where the primary documents relating to Pfizer’s own manufacturing processes had not been produced to support the expert’s opinion.

The parties’ competing positions were neatly summarised by Allsop CJ at [22]-[23]:

“Simply put, Pfizer submitted that the evidence revealed that the biosimilarity of ENBREL and BRENZYS and the close similarity of the glycosylation profiles of the two products led [Pfizer’s internal scientific expert] Dr Ibarra (and so, [Pfizer’s Assistant General Counsel] Mr Silvestri) reasonably to believe that SBA may be using the same process in phase (b) as Pfizer and so may be using the patents. Crucial to this belief were three considerations: first, the close similarity of the two glycosylation profiles; secondly, the likelihood of that close similarity deriving from the similarity of process used by both companies in phase (b); and thirdly, the fact that Dr Ibarra’s view (which she conveyed to Mr Silvestri) was that Pfizer’s process was in accordance with the patents (or one or more of them).

SBA in answer, simply put, contended [with support from experts, particularly a Professor Gray] that the close similarity in the glycosylation profile of the two products was a feature of biosimilarity which could have been brought about by matters concerned with phase (a) or phase (c) or phase (b) or a combination of them all and that it was insufficient to lead one reasonably to believe that SBA may be infringing the patents.”

As can be seen from this passage, the manufacturing process for etanercept involved three phases: (a), (b) and (c). Pfizer’s patents covered only phase (b). Dr Ibarra’s evidence attributed the glycosylation profile of BRENZYS, and its similarity to the glycosylation profile of ENBREL, to a manufacturing process which included Pfizer’s patented “phase (b)”. SBA contended that the similarity could equally arise from similarities in phases (a) and/or (c) of the product process, or any combination of the various phases. A key aspect of Burley J’s decision was that, having considered the competing expert evidence, Dr Ibarra’s opinion was “not persuasive”. The Full Court identified this aspect of Burley J’s approach as involving error.
The Full Court emphasised the summary nature of a preliminary discovery application, as provided by words of Rule 7.23, and the need to act accordingly. As Allsop CJ put it at [69], “[t]here appears to be a real scientific contest about that in the particular circumstances here…[t]here has been no trial of the issue, no cross-examination and the presentation of competing views…Dr Ibarra may be wrong, but it is difficult to see how her views can be put to one side as unreasonable or untenable in a hearing such as took place”.

As articulated by Allsop CJ at [70], “[t]he correct question was not who was more persuasive or to be preferred, but whether Dr Ibarra’s views so lacked foundation that reliance on them by Mr Silvestri did not demonstrate that he reasonably believed that Pfizer may have a right to obtain relief” (emphasis added). Similarly, Perram J explained at [134] that “[t]he question was not whether Professor Gray was right and Dr Ibarra was wrong [but] whether the belief held by Mr Silvestri, the Assistant General Counsel and directing mind of Pfizer, was reasonable (either on what was before him or subsequently, the Court)”.

Each judge of the Full Court was satisfied that Mr Silvestri, informed by the evidence of Dr Ibarra, held the requisite reasonable belief that Pfizer’s process patents may have been infringed by SBA and SBK in the manufacture of BRENZYS.

SBA also objected to the admission of Dr Ibarra’s evidence that Pfizer’s own ENBREL product was produced by processes falling within Pfizer’s patents, arguing that there was a failure to lay a foundation for the evidence because Pfizer had not produced its primary documents relating to its own manufacturing processes. Clearly, Pfizer did not want to disclose its manufacturing processes to a competitor, even under a confidentiality regime. The Full Court was satisfied that the evidence was admissible to prove that Pfizer in fact believed it may have a right to relief, as Mr Silvestri had read and relied upon the affidavit of Dr Ibarra, knowing her technical expertise and particular familiarity with Pfizer’s patents. The Full Court was also satisfied that, once it had been admitted into evidence (without any restriction as to how it could be relied upon), the Court was entitled to consider Dr Ibarra’s evidence in evaluating the reasonableness of Pfizer’s belief. Because the only issues were whether Pfizer held the requisite belief and that belief was reasonable, the Court did not need to consider whether Dr Ibarra’s evidence in fact proved that ENBREL was made using Pfizer’s patented process, and therefore any lack of foundation was not relevant.

Implications

Although each judge delivered separate reasons, this Full Court decision provides clarity as to the requirements for prospective applicants seeking preliminary discovery of documents bearing on whether they may have a claim for patent infringement, as well as to prospective respondents resisting such preliminary discovery applications. The following summary by Perram J at [120]-[121] is particularly instructive (emphasis in original judgment):

“The following propositions about preliminary discovery applications should be accepted:

(i) the prospective applicant must prove that it has a belief that it may (not does) have a right to relief;

(ii) it must demonstrate that the belief is reasonable, either by reference to material known to the person holding the belief or by other material subsequently placed before the Court;

(iii) the person deposing to the belief need not give evidence of the belief a second time to the extent that additional material is placed before the Court on the issue of the reasonableness of the belief. That belief may be inferred;

(iv) the question of whether the belief is reasonable requires one to ask whether a person apprised of all of the material before the person holding the belief (or subsequently the Court) could reasonably believe that they may have a right to obtain relief; and

(v) it is useful to ask whether the material inclines the mind to that proposition but very important to keep at the forefront of the inclining mind the subjunctive nature of the proposition. One may believe that a person may have a case on certain material without one’s mind being in any way inclined to the notion that they do have such a case.

In practice, to defeat a claim for preliminary discovery it will be necessary either to show that the subjectively held belief does not exist or, if it does, that there is no reasonable basis for thinking...
that there may be (not is) such a case. Showing that some aspect of the material on which the belief is based is contestable, or even arguably wrong, will rarely come close to making good such a contention”.

It is clear, therefore, that the threshold for patentees seeking preliminary discovery regarding suspected infringements is lower than that imposed by Burley J – which begged the question of how the patentee of a patent claiming a process or method of producing a product, rather than the product itself or a method of using it after it has been made and entered the market (eg, in a method of treatment), can obtain the information necessary to elevate suspicions of infringement to the requisite level of belief to commence court proceedings. The issue is particularly stark in the context of biosimilars and generic pharmaceuticals, where associated regulatory requirements mean the allegedly infringing products are relevantly equivalent (and possibly identical) to at least the patentee’s own approved products (which patentees will contend embody the inventions of one or more of their patents). The confidential nature of regulatory applications such as those made to the TGA mean the only parties with access to documents which set out the manufacturing processes for the subject products are the product sponsor and the TGA itself. The likely futility of seeking the information or documents from the TGA under the Freedom of Information Act 1982 (Cth) (see: Secretary Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Limited [2010] FCA 1442) means that a patentee’s only practical option is to seek the information required to form a view on infringement of its patents from the alleged infringer itself – either voluntarily through correspondence, or under the compulsion of a court order for preliminary discovery.

The critical aspect underpinning Burley J’s decision appears to have been that Pfizer needed to, but did not, adduce evidence regarding the processes by which its own products were produced, which would have established whether or not those processes embodied the inventions of one or more of its three patents. That is, Pfizer effectively needed to provide quid pro quo by giving the Court and SBA’s external lawyers confidential access to details of its own production processes, as this could have resolved many of the uncertainties and assumptions underpinning its objective reason to believe BRENZYS was manufactured using Pfizer’s patented processes. Although such an approach by Pfizer may not have led to a different outcome on its preliminary discovery application, it does appear that any patentee seeking such an order to establish infringement of patents claiming production processes should be prepared to adduce evidence of its own production processes, at least to the Court and the other party’s external solicitors.

The approach expounded by the Full Court is consistent with the wording of Rule 7.23, the summary nature of a preliminary discovery application and steps that a patentee might reasonably be expected to take to show a reasonable belief that there may be an infringement. Patentees, particularly for process patents, can be encouraged by this decision when considering potential preliminary discovery applications in future.

Many will see this important decision as not only correcting (by pulling back) the standard of proof and belief required of prospective applicants for preliminary discovery, but also as a statement by the Full Court that parties should not, to paraphrase Allsop CJ at [84], “over-refine” their evidence and arguments in contesting preliminary or interlocutory disputes. In particular, Allsop CJ sought at [2] to “…highlight the way the existing authorities appear to have been influencing these applications into a form of mini-trial here a form of fact finding takes place, well beyond the mandate of the words of the rule”, that “…the words of the rule are the framework of analysis for deciding applications under the rule” and that “…these are summary applications not mini-trials”. This is consistent with the approach to litigation his Honour has championed in recent years since becoming Chief Justice, including by establishing specialised national practice areas and issuing a suite of pragmatic new practice notes to guide the conduct of different types of disputes as efficiently as possible.
Always give your best (method)

Sandvik Intellectual Property AB v Quarry Mining & Construction Equipment Pty Ltd [2017] FCAFC 138

Best method Prior use novelty Inventive step Mechanical

Greenwood, Rares and Moshinsky JJ

This decision illustrates that applicants should include the best method(s) of performing the invention known at the time of filing a patent application, as withholding better or superior embodiments or features can result in invalidity of the granted patent. Novelty-destroying prior use does not always need to be corroborated by contemporaneous documentary evidence. Experts need to be carefully selected as an unsuitable expert will be less persuasive on inventive step issues. Claims are invalid for inutility where they include embodiments that are not useful.

Background

This is a decision of the Full Federal Court of Australia (FFC) on an appeal from a judgment at first instance on the validity of Australian Patent No. 744870 (the Patent) in the name of Sandvik Intellectual Property AB (Sandvik) and its alleged infringement by Quarry Mining & Construction Equipment Pty Ltd (Quarry). The Patent and claims were directed to an extension drilling system for drilling holes to insert cable bolts in underground mines.

At first instance, it was held that claims 1 to 4, 6 and 7 of the Patent were not infringed and were invalid on the grounds of failing to describe a best method of performing the invention, lack of novelty, lack of inventive step and inutility. Sandvik appealed on all grounds.

Issues and decision

In respect of best method, the claims of the Patent did not define a water seal. However, evidence indicated that a water seal was a “real issue that needed to be overcome” for the invention to work. The Patent had only described a horizontal type seal member, whereas at the time of filing of the Patent, Sandvik had developed a superior seal member having upper and lower sections.

Sandvik submitted that the best method requirement should be assessed against the claimed invention or having regard to the “promise” of the invention relative to the problem to be solved. The FFC disagreed with both submissions, holding that the best method relates to the invention as described in the Patent. On this basis, the embodiments of the invention as described (not as claimed) omitted the superior seal member. Thus, the Patent was invalid for not meeting the best method requirement.

On novelty, three witnesses for Quarry provided evidence of invalidating prior use based on their personal recollection of a system 25 years before the priority date. No supporting evidence was provided, such as drawings, photographs, samples or documents. The FFC held that the absence of supporting evidence did not render the prior use evidence unreliable and referred to the trial judge’s opinion that the witnesses were credible under

Authors:

Andrew Lowe
Senior Associate, Patent Attorney

Russell Davies
Principal, Patent Attorney
examination and cross-examination. Thus, the claims of the Patent in suit were also invalid for lack of novelty.

Sandvik was successful on the inventive step ground. The FFC held that the trial judge gave too much weight to one of Quarry’s experts, where that expert was shown not to be aware of information the parties had agreed was common general knowledge in the art and had mischaracterised other information as being common general knowledge when in fact it was not.

Dependent claim 4 recited that an extension rod could have a hexagonal or round cross-section that is driven by a chuck or an adaptor. However, evidence showed that if the extension rod had a round cross-section, it could not be driven either way to make the invention work. Accordingly, the trial judge held it lacked utility. On appeal, Sandvik sought to rely on a person skilled in the art construing the claim using the principle of purposive construction in order to exclude this non-working embodiment. The FFC held that the proposed purposive construction could not overcome the plain and unambiguous meaning of the words in the claim. Thus, claim 4 was invalid for inutility.

Implications

This case provides a warning to applicants to ensure that the description of embodiments in a patent specification is updated prior to filing, especially when the application is claiming priority to an earlier patent application. Sandvik’s failure to include the superior sealing member rendered the Patent invalid even though the sealing member was not claimed.

The case also demonstrates the importance of witnesses and experts. A credible witness can enable prior use evidence to invalidate a patent even where it is not corroborated by other contemporaneous documentary evidence. Similarly, an expert shown not to be a suitable person skilled in the art will undermine any inventive step arguments relying on that expert’s evidence.

The finding of inutility of claim 4 demonstrates that applicants should be careful in drafting claims that include within their scope embodiments that do not work; otherwise the entire claim will be rendered invalid.
Idenix v Gilead: Full Court confirms the first instance decision

_idenix Pharmaceuticals LLC v Gilead Sciences Pty. Ltd [2017] FCAFC 196_

**Insufficiency Inutility Appeal of factual findings Pharmaceutical**

Nicholas, Beach and Burley JJ

This decision is an appeal from the Federal Court of Australia decision, which had found the patent at issue invalid for reasons of insufficiency and inutility. The appeal against the finding of invalidity was dismissed and the grounds of contention were deemed not made out.

**Background**

The patent in suit was Australian Patent No. 2003247084, entitled “Modified 2’ and 3’-nucleoside prodrugs for treating flaviridae infections” (084 Patent).

Previously, at the Federal Court of Australia, Idenix Pharmaceuticals LLC, Università degli studi di Cagliari, Centre national de la recherche scientifique and Université De Montpellier (collectively referred to as Idenix) contended that a new drug, sofosbuvir, infringed its Australian patent and Gilead Sciences Pty Ltd (Gilead) asserted that Idenix’s patent was invalid.

At the first instance, Gilead conceded on infringement. The primary judge considered the issues of novelty, internal fair basis, insufficiency, lack of utility, manner of manufacture and false suggestion. Insufficiency and lack of utility led to a finding of invalidity.

Idenix appealed against the finding of invalidity whilst Gilead contended that the patent was also invalid on other grounds in addition to insufficiency and lack of utility.

**Issues and decision**

This decision mainly concentrates on insufficiency.

At first instance, insufficiency was addressed as two separate issues: the synthesis issue and the treatment issue:

Regarding the synthesis issue, at first instance it was common ground that the 084 Patent did not describe any synthesis of a compound within claim 7 but said that “[t]he nucleosides of the present invention can be synthesized by any means known in the art”. However, Idenix’s own documents recorded its consistent failures to make a compound within claim 7 of the 084 Patent. Idenix argued that these documents were irrelevant because they did not establish that the routes tried or contemplated by Idenix were routes which would have been taken by the skilled person armed only with common general knowledge and the 084 Patent. Idenix argued that its own team fell below the standard of a person skilled in the art or, in the alternative, that its team was “too clever” and possessed so much knowledge that the team did...
not do what the skilled person would do. However, the primary judge did not accept these arguments. Her Honour weighed up the Idenix documents with the other available evidence including written evidence and cross-examination of numerous experts. Her Honour was of the opinion that the experts’ proposed synthetic routes were the result of something other than the common general knowledge and the 084 Patent because additional literature, not forming part of the common general knowledge, was relied upon.

On appeal, Idenix maintained that synthesis of the compounds could be achieved using common general knowledge. Referring to the text of the patent “[t]he nucleosides of the present invention can be synthesized by any means known in the art”, Idenix argued that there is no statement in the patent that making the nucleosides would present any difficulty or that the skilled person would have to employ anything other than a known method to make a compound within the claim.

Idenix also argued that the primary judge had erred in treating Gilead’s experts as representatives of the skilled person and in accepting their knowledge both constituted common general knowledge and represented its outer bounds whilst finding the Idenix experts possessed additional knowledge beyond common general knowledge and rejecting their evidence.

Idenix further contended that the primary judge placed “determinative weight” on the Idenix documents in finding insufficiency and that Gilead had failed to demonstrate that the work of the Idenix team was representative of the skilled person armed with only common general knowledge.

Turning to the treatment issue, the primary judge noted that the 084 Patent did not disclose any biological data and it did not provide any guidance by which a skilled person would select one compound over another in order to make a compound with the relevant antiviral activity. On appeal, Idenix argued that Gilead failed to prove that any compound within the relevant claims were not effective in the treatment of at least one of the flaviviridae infections in at least one of a human or an animal and therefore failed to prove insufficiency.

On lack of inutility, the primary judge asserted that if Gilead had proved that particular compounds within the scope could not be made then the claimed invention was not useful. The expert evidence in this respect, based on expertise and for sound scientific reasons, was all one way and pointed to it most likely not being possible to make particular compounds. On appeal, Idenix contended that there was no impediment to Gilead conducting experiments to prove the point that the particular compounds could not be made. Idenix also argued that the evidence of experts relied upon by the primary judge did not provide probative evidence that such compounds could not be made and that the expert evidence represented a purely theoretical expectation of difficulty rather than a properly empirically based expert opinion as to impossibility.

In its comments on insufficiency, the Full Court affirmed the primary judge’s use of the correct, relevant test for insufficiency as set out in *Kimberly Clark Australia Pty Ltd v Arico Trading International Pty Ltd*, (2001) 207 CLR 1; i.e. “… will the disclosure enable the addressee of the specification to produce something within each claim without new inventions or additions or prolonged study of matters presenting initial difficulty?”

Regarding the insufficiency “synthesis issue”, the text “[t]he nucleosides of the present invention can be synthesized by any means known in the art” was not found to assist Idenix.

In addition, none of Idenix’s criticisms of the treatment of the experts was deemed to have merit. The Full Court observed that “common general knowledge is background knowledge and experience which is available to all in the trade. It must be generally accepted and assimilated by persons skilled in the art and known and accepted without question by the bulk of those who are engaged in the particular art. Information is not common general knowledge merely because it might be found in a journal, even if widely read.”

Regarding the Idenix documents, the Full Court decided the primary judge was “correct to find that the Idenix documents provided a strong indication that the Idenix patent was in relevant respects insufficient.” The Full Court considered that her Honour correctly held that “evidence that the skilled persons resorted to information outside
the common general knowledge in attempting to make an embodiment of the invention is probative to show that the disclosure is insufficient”, that the Idenix team of scientists and consultants was a highly skilled team possessing at least the common general knowledge and that “to the extent that the team possessed more than the common general knowledge … this could only have made it more likely that they would have succeeded without undue effort” (but even then they did not succeed for a significant time).

In respect of the insufficiency “treatment issue”, the Full Court decided that the primary judge had rightly rejected the contention that “the skilled addressee, relying on the Idenix patent and common general knowledge, could make any rational selection of classes of compounds from the trillions available to screen for antiviral activity”.

Regarding inutility, the Full Court deemed that there is no requirement to prove inutility by experiment and that the primary judge rightly accepted the evidence of experts.

Thus the Full Court agreed with the findings of the primary judge that the patent was invalid on the grounds of insufficiency and lack of utility and rejected the challenges to the primary judge’s conclusions that the patent was not also invalid on other grounds. Consequently Idenix’s appeal was dismissed and Gilead’s grounds of contention were rejected.

Implications

This appeal decision reinforces:

a) the dangers of relying on the assertion that the claimed compounds “can be synthesized by any means known in the art”, especially when there is no commonly known way of introducing the specified substituent at the given position at the priority date;

b) risks of not disclosing any biological data or providing any guidance for a skilled addressee to select one compound over another in order to make a compound with the relevant activity; and

c) the fatal problem of including compounds that cannot be made.
$30m for infringement of Bayer’s Australian Yasmin patent, plus indemnity costs – a “small” jurisdiction with big benefits

_Bayer Pharma Aktiengesellschaft v Generic Health Pty Ltd [2017] FCA 250_

_Bayer Pharma Aktiengesellschaft v Generic Health Pty Ltd [2017] FCA 428_

Infringement Damages
Calderbank costs award
Pharmaceutical

_Jagot J_

In a landmark Australian Federal Court decision, Bayer was awarded $30m ($25.7m in damages plus interest) to compensate for lost revenue caused by generic product sales infringing its patent covering the oral contraceptive Yasmin (ethinylestradiol/drospirenone). This sets a new benchmark in Australia for future damages claims against generic manufacturers. The Court’s willingness to adequately compensate the patent holder enhances Australia’s already very attractive “value proposition” for patentees. The Court also penalised Generic Health for its failure to accept Bayer’s reasonable settlement offer during the litigation, ordering it to pay Bayer’s costs on an indemnity basis from the day that offer expired.

Authors:
Duncan Longstaff
Senior Associate, Lawyer

Jacinta Flattery-O’Brien PhD
Principal, Patent Attorney

Katrina Crooks
Principal, Lawyer

Background

Bayer initially sued Generic Health for infringement of its Australian Patent No. 780330, by the manufacture and sale of the competing product, Isabelle. Interestingly, in 2012 during the initial infringement proceedings, Bayer amended the claims of the patent to more directly read on Isabelle, the amendments being approved by the Court.

Generic Health was found to have infringed the Bayer patent. Its subsequent appeal to the Full Federal Court was dismissed and its request for leave to appeal to the High Court was denied, thereby exhausting all avenues for appeal.

Issues and decision

_Damages enquiry_

Bayer sought damages, as opposed to an account of profits, and argued that every sale of Isabelle (and of Bayer’s own generic Petibelle) was a lost sale of Yasmin. Generic Health submitted that:

- Bayer should not be entitled to damages before the date the patent was amended (14 December 2012), because the original specification was not framed in good faith and with reasonable skill and knowledge;

- damages should not be calculated on the basis that each sale of Isabelle and Petibelle was a lost sale of Yasmin;

- a discount should be applied to Bayer’s costings to reflect the risk that Bayer would have incurred more costs in producing additional Yasmin tablets; and

- interest should be calculated on post-tax losses.

However, the Court:

- having considered extensive evidence from experienced patent attorneys, found that the claims were framed in good faith and with reasonable skill and knowledge (i.e. not because Bayer considered that the original claims might be invalid) and that, as such, losses incurred before the amendment of the claims were compensable,
accepted evidence that “but for Isabelle, Bayer would never have put Petibelle on the market” and, moreover, found that Bayer’s loss was best assessed on the basis that every sale of Isabelle – and every sale of Petibelle over the period from its introduction until 30 June 2016, i.e. just over two years after Isabelle was removed from the market – was a lost sale of Yasmin (it was found that the number of women who would have bought Isabelle but not Yasmin was immaterial);

found that “in respect of the costings used to assess Bayer AG’s loss, the only discount should be in the amount of 2% to account for the risks associated with uncertainty about Bayer’s costings”, and

while noting that there is no guidance in the relevant legislation regarding whether interest should be applied to pre-tax or post-tax amounts, found that interest should be assessed on Bayer’s pre-tax losses.

**Indemnity costs awarded to Bayer**

The damages award exceeded the amount of $19,891,858 which Bayer offered to accept in settlement of the proceedings, in an offer to compromise served under Rule 25.14(3) of the Federal Court Rules 2011 (Cth) on 6 May 2015.

Jagot J ordered that Bayer is entitled to recover its costs of the damages aspect of the proceedings on the higher “indemnity” scale (rather than the usual “party-party” scale). This indemnity costs order was made because of Generic Health’s failure to accept Bayer’s offer to compromise, which represented more favourable terms (ie, less money) than the judgment Bayer ultimately obtained. This means that it will be entitled to recover all actual costs reasonably incurred after the expiry of its offer to compromise. The party-party scale usually results in a costs award of around 50-75% of actual costs. The indemnity costs order covers a 19-month period involving intensive work on its substantial evidence and submissions and the trial hearing regarding the quantification of its damages claim. The costs can therefore be expected to be substantial.

The Federal Court Rules 2011 (Cth) provide a process under which a party to a proceeding can make a “without prejudice” offer to settle the proceeding. A party who does not accept such an “offer to compromise” and obtains a judgment on less favourable terms must pay the other party’s costs on an indemnity basis, and is not entitled to its own costs, from the time after the offer to compromise expires. The offer to compromise is served on the other party to the proceeding but is not filed with the Court and cannot be mentioned in any court documents, unless and until a party asks the Court (after determination of the claims and cross-claims) to make costs orders in light of the other party’s failure to accept the offer. An offer of compromise is therefore similar to a Calderbank offer, although much briefer.

Bayer’s offer of compromise was served 2 months before its first affidavit was filed in the damages enquiry phase of the proceeding and almost 19 months before the conclusion of the damages hearing on 20 December 2016. Jagot J identified a series of circumstances – such as Generic Health’s sophistication and resources as a generic pharmaceutical company and consequent knowledge of pricing and other implications of its generic launch – that supported her conclusion that the offer was reasonable and failure to accept it should lead to an indemnity costs award:

“The objective circumstances indicate that Generic Health, if it had wished to do so, could have sufficiently informed itself about its overall exposure to liability for infringement of Bayer’s patent when the offer was made for the purpose of deciding whether or not the offer represented a genuine compromise (which it did). This is so despite the fact that, when the offer was made, Bayer had not quantified its claim for damages or filed its evidence in support.

…[H]ad it wished to do so, Generic Health would have had no real difficulty in assessing its maximum total liability for the infringement and had no reason to suppose that Bayer, if forced to litigate, would claim anything materially less than that maximum amount. The fact that Generic Health sought no explanation from Bayer as to how it had calculated the amount of the offer, when the precision of the amount indicates that it resulted from a calculation, supports my conclusion that Generic Health was not interested in whether the offer represented a genuine compromise.
...Generic Health [which subsequently made a lower settlement offer, after seeing Bayer’s evidence] was prepared to chance its hand to save itself some $6 million by seeing if Bayer could discharge the onus of proof on it under s 115 [of the Patents Act 1990 (Cth)] to establish that the patent specification in its unamended form had been framed in good faith and with reasonable skill and knowledge.

**Implications**

The Bayer decision provides a useful benchmark for innovator companies to rely on in relation to future damages claims, and generally assessing the possible relief which might be obtained in patent infringement proceedings – particularly for a prescription pharmaceutical product listed on Australia’s Pharmaceutical Benefits Scheme (PBS). The finding that the quantum of damages was “best assessed” on the basis that every sale of a generic product is a lost sale of the innovator product, will no doubt be relied upon as a precedent by patentees. Further, the amount of damages awarded and the methodology by which they were calculated may influence the strategies adopted by generics when considering entering into the Australian market and may ultimately act as a deterrent.

Coupled with the relatively low cost of obtaining patent protection in Australia, not to mention our generous provisions relating to the extension of pharmaceutical patent terms, this case further enhances the attractiveness of Australia to patentees in the pharmaceutical area.

Despite our vast landmass, Australia is often considered a relatively small jurisdiction when developing a global patent strategy due to our population size of around 24 million. However, Australians are high consumers of pharmaceuticals, owing largely to the substantial government subsidies available under the PBS. In the financial year ending June 2016, we spent over $10 billion on pharmaceuticals, representing an increase of 19.5% from the previous year. Moreover, many patented drugs generated revenues well in excess of $100 million in the 2016 financial year eg. Denosumab ($126 million, Amgen), Adalimumab ($339 million, AbbVie) and Sofosbuvir/Ledipasvir+Sofosbuvir ($213 million / $358 million, Gilead).

Hence, overlooking Australia in a national phase patent filing programme, especially in relation to patents covering pharmaceuticals, carries with it the risk of foregoing significant revenue in what some might consider a “small jurisdiction”.

This decision is also a salient reminder of the potential significance of offers of compromise (and similar Calderbank letters) in Australian intellectual property litigation. In particular, careful consideration needs to be given to the time at which such offers are made and received, and the extent to which they might need to be analysed by the receiving party to properly assess their reasonableness.
Long-awaited decision on repair v rebuild provides guidance on when modifications to patented article will and will not enable a patentee to maintain control post-sale

**Seiko Epson Corporation v Calidad Pty Ltd [2017] FCA 1403**

**Infringement** Repair v rebuild  
**Implied licence** Mechanical Electrical

**Burley J**

In this first instance Federal Court of Australia proceeding, Burley J considered the tension between the rights of the purchaser of a patented product, and the rights of the patentee to maintain control of the product in order to determine under what circumstances the importation and sale of refilled printer cartridge will infringe patent rights applicable to the original cartridge. Ultimately his Honour confirmed the “implied licence” approach applied in *National Phonograph Co of Australia Ltd v Menck (1911) 12 CLR 15* and cast a new test to determine whether the repair or refurbishment of a patent product will extinguish the implied licence.

**Authors:**

Scott Philp  
Senior Associate, Patent Attorney

**Background**

Seiko Epson Corporation (Seiko) is a global manufacturing company which manufactures and sells printer products, including printer cartridges under the trademark Epson. Epson products are sold within Australia via its exclusive distributor, Epson Australia Pty Ltd (EAP).

The respondents, comprising the Calidad group of companies (Calidad), purchased “refilled” Epson cartridges from Ninestar Image (Malaysia) SDN BHD (Ninestar) and imported the refilled cartridges into Australia for resale as Calidad branded cartridges fully compatible with Epson printers (Calidad cartridges).

The process used by Ninestar to refill the cartridges is relatively complex requiring more than simply replenishing the ink reservoir with ink. Each cartridge includes a memory chip which records and stores data indicative of the amount of ink in the cartridge. This ink data is used to prevent printing if the amount of ink remaining in the cartridge falls below a threshold level. The chip also acts as an inbuilt restriction since simply refilling a depleted cartridge will not restore it to a functional state. Accordingly, Ninestar’s process necessarily made an un-trivial modification to the cartridge to either “reset, reprogram or replace” the memory chip.

**Issues and decision**

The proceedings brought by Seiko and EAP against Calidad contended that the importation and sale of the Calidad cartridges infringed the claims of its Australian patents (Australian Patents Nos. 2009233643 and 2013219239).

Both patents relate to a printing ink cartridge adapted to be attached to an inkjet printer by means of a plurality of electrical terminals. The patents propose “a structure for preventing the information storage medium [or memory] from shorting and becoming damaged due to a drop of liquid being deposited on the terminals connecting the printing apparatus with the storage medium”.

Authors:

Scott Philp  
Senior Associate, Patent Attorney
Calidad did not dispute that the refilled cartridges fall within the relevant claims of the patents. Rather, Calidad submitted that under principles established in National Phonograph it is the beneficiary of an implied licence to use the cartridges including the right to resell.

The central dispute in these proceedings concerns the intersection of a patentee’s rights to control the use of patented goods after sale with the rights of the purchaser as the owner of those goods to deal with them.

**Implied Licence**

In some jurisdictions, this tension is dealt with by a “doctrine of exhaustion” under which the patent right is said to be exhausted following the first sale (e.g., the recent landmark United States Supreme Court decision in Impression Products, Inc. v Lexmark Intern., Inc. 137 SCt 1523 (2017)). However, under Australian law, the most relevant authority is National Phonograph, in which the Privy Council adopted the implied licence approach. Under this approach, where the sale of goods is made without any restriction by the patentee, (sale sub modo) the purchaser or subsequent owner of a patented product is conferred an unrestricted right of use or an implied licence, which covers at least the rights to import, use and dispose of the product. In his Honour’s view, as supported by more recent Australian judgments (Austshade Pty Ltd v Boss Shade Pty Ltd [2016] FCA 287; (2016) 118 IPR 93), this remains the correct approach under Australian law.

Burley J noted that while the implied licence approach allows the patentee to impose limitations on the implied licence, the onus lies upon the patentee to notify the purchaser of those restrictions at the time of sale otherwise they may not hold. Furthermore, any restriction or limitation notified by the patentee does not reside or run with the goods so that any restriction will not be encumbered on subsequent owners unless they are made aware of the restrictive conditions upon taking title.

Significantly his Honour saw no difficulty, with reference to the authorities, of implying the licence where the patented goods are first sold outside of the patent area (that is, broadly, outside Australia).

Having examined and established the above law and principles, his Honour found that the initial sale of the Epson Cartridges to purchasers overseas granted an implied licence to those purchasers to dispose of the cartridges as they wished, including giving or selling them to another party. Furthermore, his Honour was not satisfied by Seiko’s submission that the cartridges included an “inbuilt restriction” by virtue of the technical limitations imposed by the memory chip. Therefore, the implied licence was without restriction and could be attached to cartridges imported and sold in Australia irrespective of the original sale being made elsewhere or that the cartridges may have been discarded by the original purchaser and collected by Ninestar.

**When do modifications extinguish an implied licence?**

In the present case however, the Epson cartridges had been refilled and the memory reset, reprogrammed or replaced by Ninestar to restore the original function. Ordinarily, such a modification might be regarded as a question of either repair to, or the “making” of, a patented product – whereby the former is permissible and the latter an infringement. However, since the modification to the cartridges had been made outside the Australian jurisdiction, the modification could in no way amount to a “making” infringement of the Australian claims, irrespective of degree.

Thus, the critical question was not based on a repair / making analysis, but rather whether Calidad could rely on the umbrella of the original implied licence attached to the cartridges at sale, or whether the modifications were such that the implied licence could be considered as extinguished.

Having not found any authority directly addressing the issue, Burley J was of the view that the threshold question to be considered is “whether or not the modified product is materially the same embodiment of the invention as claimed as the product that the patentee sold without restriction.”

His Honour further explained that in order “to assess whether or not the implied licence continues after modifications are made one must consider the significance of modification work done on a product and how the modifications in question relate to the features of the patented product that are defined by the claim. Where that work done, or alteration
made, does not concern a claimed feature, then the work is irrelevant to the analysis. That is because the patentee’s rights to limit the use of the patented product arise because the product represents an embodiment of the claimed features” [178]

Furthermore, Burley J applied a three stage test as follows:

1. What is the scope of the invention as claimed?
2. What is the manner in which the patentee’s product is an embodiment of the invention as claimed?
3. To what extent do the modifications made affect the patented product insofar as it represents an embodiment of the claims?

*The Calidad Cartridges*

His Honour applied the three step test to the Calidad cartridges.

In respect of the claimed invention, the parties had agreed that the trial should be focused entirely upon claim 1 of Australian Patent No. 2009233643. That claim and its relevant features, is broadly summarised by Burley J at [201]:

“*It may be seen that the features of the product claimed, broadly, are that it is an ink cartridge that can be attached to a printer by inserting it, with both the ink cartridge and printer having a plurality of terminals. The ink cartridge must have a memory driven by a memory driving voltage (integer [2]), an electronic device driven by a higher voltage (integer [3]), terminals electrically connected to the memory and terminals electrically connected to the electronic device (integer [4]), and contact portions for the terminals which are arranged in a particular way (integers [5]-[11]).*”

His Honour interpreted the “memory” feature as being a hardware component rather than information or data.

The modifications made by Ninestar involved eleven different types of Epson cartridges and nine different refilling processes. As previously noted, a key step to refilling the cartridges and restoring them to a functional state was to “reset, reprogram or replace” the memory so that it would not indicate the cartridge as being depleted. Ninestar accomplished this by either:

- Re-writing the memory without physical replacement of the unit; or
- Replacing the memory chips entirely – a process which involved cutting out the printed circuit board (including the memory chip) from the cartridge; replacing the memory chip on the board with a generic chip; and refitting the board to a cartridge (which in all likelihood was a different cartridge).

In the former case his Honour found that re-writing the memory did not materially alter the product as it represented an embodiment of the claims of the Seiko Patent. However, where the chips had been replaced with a generic chip, his Honour found that the modifications materially affected, and changed, the embodiment, and thereby represented a material change to the embodiment that Seiko sold. In such cases the implied licence was extinguished by the modification.

Burley J found another modification in Ninestar’s refilling process which extinguished the implied licence from the original sale. This was where Ninestar’s refilling process included a step of cutting off a physical interface pattern used to “key” the cartridges to a particular model of printer. His Honour noted that the modification to the interface pattern was borderline in the context of the present analysis. He concluded that since the claim recited “*A printing material container adapted to be attached to a printing apparatus by being inserted in an insertion direction*” the modification fell on the wrong side of the line and would serve to terminate the implied licence.

**Implications**

In addition to providing a contemporary review of the correct legal approach for determining the purchaser’s rights to use a patent good under Australian law, the judgment provides excellent guidance for patentees who may wish to maintain control of patented goods after sale.

Furthermore, the case breaks new ground by establishing a test for determining the scope of modification which would extinguish an implied licence.
Oh, snap! Dincel loses patent infringement action for snap-lock formwork panels

*Dincel Construction System Pty Ltd v AFS Systems Pty Ltd* [2017] FCA 262 (17 March 2017)

*Dincel Construction System Pty Ltd v AFS Systems Pty Ltd (No 2)* [2017] FCA 791 (14 July 2017)

*Dincel Construction System Pty Ltd v AFS Systems Pty Ltd (No 3)* [2017] FCA 919 (11 August 2017)

**Interlocutory injunction Infringement Mechanical**

**Nicholas J**

In this Federal Court of Australia decision, Dincel Construction System Pty Ltd sued AFS Systems Pty Ltd for infringement of a patent to which it was the exclusive licensee. After establishing that the circumstances warranted an interlocutory injunction, the Court focused on the key issues of claim construction arising from use of the non-technical term “ramp surface”.

**Background**

Dincel Construction System Pty Ltd (*Dincel*) is the exclusive licensee to a patent entitled “Hollow interconnecting panels as lost formwork”. The patent is related to hollow building panels which are used as permanent formwork in construction of concrete walls. Multiple panels are assembled in a desired configuration to create a wall structure, into which wet concrete may be poured. The claims of the patent were directed to a snap-locking feature which facilitated easier interconnection of panels.

AFS Systems Pty Ltd (*AFS*) is one of the CSR group of companies and had historically sold a similar hollow formwork panel product called the “Rediwall”. AFS was preparing to launch a new product, having a similar snap-locking connection, at a cheaper price and with free delivery to compete with Dincel.

**Issues and decision**

Dincel claimed that the new AFS product infringed multiple claims of the patent, each dependent on claim 1. Dincel also applied for an interlocutory injunction to prevent AFS from offering their product for sale until the rights of the parties could be determined.

Claim 1 required, inter alia, flanges which snap engage into respective adjacent grooves. The claim begins by defining relative movement between the groove and the flange required to effect snap engagement, but later recites “ramp surfaces that engage the flanges to move the flanges for said snap engagement of the flanges in the grooves”.

It was undisputed that the AFS product contained all the essential elements of claim 1, with the exception of the “ramp surfaces”. Although the AFS product clearly contained a ramp surface, it was located on the flange and thus effected movement of the grooves rather than the reverse arrangement required by claim 1. Dincel argued that a curved upper surface on the groove of the AFS product was also a ramp surface and satisfied the requirements of claim 1.

AFS counter-claimed for revocation of the claims on the basis that, if Dincel’s proposed construction of the term “ramp surface” was correct, then the invention as defined by claim 1 was not novel and lacked fair basis in the body of the specification.

**Authors:**

Michelle Catto
Patent Engineer

Russell Davies
Principal, Patent Attorney
At the interlocutory hearing, it was agreed that, although the term “ramp surface” has a functional meaning, it is not defined as a technical term and as such it fell to the Court to determine the meaning as used in claim 1. Nicholas J considered the arguments from both parties and ruled a prima facie case to have been established, saying:

“I do not accept either party’s characterization of the strength of Dincel’s case. Dincel’s infringement case is certainly not strong, but nor would I describe it as weak. I am satisfied that the construction of claim 1 that it advances is a plausible one.”

His Honour then found the balance of convenience strongly in favour of Dincel. He acknowledged that Dincel, as a “one trick pony” with a single product offering, would likely suffer detriment which would not be adequately compensated by the usual award of damages. In particular, the potential loss of experienced Dincel staff due to decreased revenue was taken into account. In contrast, AFS had not yet launched the allegedly infringing product and would be able to substitute with their existing “Rediwall” product without undue burden. Accordingly, interlocutory injunctive relief was granted.

At the final hearing, Nicholas J turned his attention to the key issue of construction of the disputed term “ramp surface”, first commenting on the danger of imposing an “impermissible gloss” on the language used when applying a purposive construction and also noting that infringement of a claim for a combination requires that the working parts must act on each other in the manner claimed.

The primary judge found that the person skilled in the art would interpret the “ramp surface” of claim 1 as a “sloping surface that is configured so as to assist the movement of the flange as it travels to the point at which snap engagement occurs, and that it does this by reducing the amount of force required to achieve this result”, and found that “the ramp surface must engage the flange to move the flange, which clearly implies that the ramp surface must assist the movement of the flange.”

His Honour acknowledged that the presence of a ramp surface on the flange did not preclude the curved edge of the groove from also acting as a ramp surface. However, the contribution of the curved groove edge to the snap-engagement of the parts was found to be insignificant. The Court concluded:

“It is clear that in the AFS Product, it is the outer surface of the flange that performs this function. To the extent (if any) that the curved surface at the top of the groove also performs this function, its contribution to the movement of the flange into the groove is not shown to be anything more than de minimus.”

Accordingly, it was ruled that the curved edge of the groove was not acting as a “ramp surface” for the purposes of claim 1 and that the AFS product did not infringe.

Nicholas J further indicated that neither action for revocation of the claims on grounds of invalidity or fair basis would have been successful.

Implications

Parties considering bringing an infringement action should consider the option of seeking interlocutory relief, and take note of the willingness of the Court to consider a variety of factors relevant to both parties in assessing such an application. These include business factors that may be difficult to quantify monetarily, but that have a very real impact on the operation of the businesses and the balance of the marketplace.

Interestingly, the contested term “ramp surface” and the language around the movement of the flanges were not present in claim 1 of the patent as originally accepted. Although the reasons behind the subsequent amendment cannot be known, it is worth noting the effect on the outcome of the infringement action. This case highlights the importance when drafting claims of considering carefully alternative ways in which a competitor might achieve the same functional outcome. This is particularly pertinent to claims for a combination, in which the invention is defined not merely by the presence of all the features but also by the way interrelated features work together. The rules of purposive construction do not allow the Court to ignore the clear wording of a claim; as Nicholas J put it, “the features must perform the function attributed to them by the other language of the claim”. It is therefore important not to limit the features of a claim by including an unduly prescriptive definition of their interactions, else risk allowing room for a competitor to avoid infringement.
Doric and APT all wound up over winder

*Doric Products Pty Limited v Asia Pacific Trading (Aust) Pty Ltd* [2017] FCA 849

**Innovation patent** Novelty
**Innovative step** Mechanical

**Burley J**

In this first instance Federal Court of Australia proceeding, Doric Products Pty Limited sued Asia Pacific Trading (Aust) Pty Ltd for infringement of the claims of two innovation patents relating to window winders. Asia Pacific Trading (Aust) Pty Ltd advanced a cross-claim asserting that those claims of the innovation patents are invalid on the grounds of lack of novelty and lack of innovative step. The key issues in the case were the correct construction of identified terms within the claims, whether the alleged infringement falls within the claims of the innovation patents, and whether the claims of the innovation patent are novel and innovative.

**Background**

The applicant, Doric Products Pty Limited (*Doric*) is the exclusive licensee of innovation patents number 2012100818 (*818 patent*) and number 2012100260 (*260 patent*), each having a priority date of 24 March 2009. Each innovation patent is entitled “a window winder”, and claims an invention for a device that is used for opening and closing windows.

The window winder includes a chain that determines the extent the window can be opened. An identified problem is that the chain must necessarily be detached, the length altered, and the chain reattached in order to vary the extent of opening. The innovation with the window winders of the patents was the use of a stop means (*818 patent*) or stop member (*260 patent*) which can be used to alter the maximum travel of the chain without altering the total length of the chain.

Doric contends that Asia Pacific Trading (Aust) Pty Ltd (*APT*), the first respondent in these proceedings, has exploited the invention claimed in claims 1 to 5 of the 818 patent and claims 1 to 4 of the 260 patent (asserted claims) by making, importing, selling and offering to sell its window winder called the “APT product”. APT denied that the APT product infringes the asserted claims and made a cross-claim that those claims are invalid on the grounds of lack of novelty and lack of innovative step.

Azuma Design Pty Ltd (*Azuma*) is the registered owner of the innovation patents and joined these proceedings as the second respondent.

**Issues and decision**

The issues for determination in these proceedings include:

A. The correct construction for identified terms “*body*”, “*window winder*”, and “*winder mechanism*” in the patent claims.

B. Whether the APT product falls within the asserted claims.

C. Whether claims 1 and 2 of the 818 patent are novel over the disclosure contained in US patent number 4,382,349 (*Dunphy*).

D. Whether claims 1, 2, and 3 of the 260 patent are novel over the disclosure contained in US patent number 8,468,747 (*Mingardi*).
E. Whether claims 1 and 2 of the 260 patent involved an innovative step in light of the disclosure contained in US patent number 4,521,993 \textit{(Tacheny)}.

F. Whether the claims of the 260 patent involve an innovative step in light of the disclosure of EU patent number 943,774 \textit{(Lambertini)}.

\textit{Construction}

Expert witnesses, Dr Lozzi for Doric and Mr Hunter for APT, prepared a joint expert report addressing the key points of difference and agreement between them. They gave concurrent evidence during the course of the hearing. Burley J considered their evidence to be helpful, but noted that “in accordance with accepted principles of patent construction, it is for the Court to determine the correct meaning to be ascribed to words and phrases in the patents and the prior art documents”. These principles were not in dispute and the determined meanings were as follows:

- \textit{body} is to be understood as the main or central part of the window winder that has the relationship with the other components identified in the claim

- \textit{a window winder} might be regarded as a device for opening and closing a window that is operated by the user with a winding action, typically by winding a rotary handle

- \textit{a winder mechanism} is a mechanism that is operated by the user using a winding action

\textit{Infringement}

The case pleaded by Doric on infringement is that APT has directly infringed claims 1 to 5 of the 818 patent and claims 1 to 4 of the 260 patent. APT relevantly admits that it has engaged in acts in respect of the APT product which would amount to an exploitation of the patents, if the APT product falls within the scope of any of the pleaded claims, and if those claims are held not to be invalid. The dispute that arises between the parties concerns whether or not the APT product falls within the claims. There is no disagreement about how the APT product operates.

It was determined that the APT product does not possess a stop means “moveable relative to said body, by insertion and by removal” or that it is so moved to change the desired maximum length of the chain. As a result, the APT product was determined not to infringe any of the claims of the 818 patent. The APT product was determined to satisfy the requirement that the winder mechanism is mounted on the body.

As a result, the APT product was considered to infringe each of the claims of the 260 patent.

\textit{Validity}

It was found that essential features of the claims of the 818 patent are not disclosed in Dunphy. Accordingly, the novelty challenge to claims 1 to 5 of the 818 patent based on that publication fails. It was also found that essential features of the claims of the 260 patent are not disclosed in Mingardi. Accordingly, the novelty challenge to claims 1 to 4 of the 260 patent based on that publication fails.

The claims of the 260 patent were found to be innovative in light of Tacheny and Lambertini. For both publications, the differences between the claims of the 260 patent and the publication were agreed, with the question being whether these differences make a substantial contribution to the working of the invention. For both publications, the differences were considered substantial by way of the physical means of operation and the functional effect.

\textit{Summary}

In summary, the claims of the 260 patent are infringed by the APT product and the claims of the 818 patent are not. Claims 1 to 5 of the 818 patent and claims 1 to 4 of the 260 patent are novel and involve an innovative step. The conduct of APT amounts to an infringement of the asserted claims of the 260 patent.

The parties are to come back with orders reflecting this outcome and also the parties’ position on costs. As this hearing only concerned liability, the parties also have to consider next steps, if any.

\textit{Implications}

This case provides a reminder regarding the importance of selecting appropriate claim terms. This is relevant to both the construction of the terms used as well as any limitations on scope that may result from relationships between claim features. For example, in these proceedings, use of the term “winder mechanism” rather than, say, “mechanism” had the result that the mechanism required some rotary action - and therefore that the claims were distinguished from the prior art.
Janssen granted interlocutory injunction for threatened PBS listing of generic pharmaceutical products

**Janssen Sciences Ireland UC v Alphapharm Pty Ltd [2017] FCA 1399**

**Interlocutory injunction**

**Pharmaceutical**

**Yates J**

Janssen was granted interim injunctive relief to avoid Pharmaceutical Benefit Scheme (PBS) listing of generic pharmaceutical products for treating HIV infection. In addition to restraining the generic, Alphapharm, from making, selling, offering to sell, using or otherwise exploiting generic products, Yates J of the Federal Court of Australia ordered the respondent to discontinue assurance of supply of generic products for the purpose of obtaining PBS listing and to withdraw the assurance of supply it has already given, pending the determination of the final hearing. The judgment was delivered on 27 November 2017, just three days before the threatened PBS listing and launch of generic products on 1 December 2017.

**Background**

Janssen Sciences Ireland UC (Janssen) is the owner of Patent No. 2007316562 (the 562 patent) which discloses methods for preparing Hexahydrofuro [2, 3-b] furan-3-ol (the Hydroxy Compound). The Hydroxy Compound is an important precursor in the synthesis of the human immunodeficiency virus (HIV) protease inhibitor called darunavir. In Australia, Janssen-Cilag has been exclusively licensed by Janssen to import, sell, supply and market PREZISTA and PREZCOBIX products, both of which contain darunavir as an active pharmaceutical ingredient (API). These products are used to treat HIV infection and are on the PBS listing for public and private hospital use.

In May 2017, Alphapharm, operating under the name Mylan Australia, obtained regulatory approval (ie. inclusion on the Australia Register of Therapeutic Good (ARTG) for two darunavir products (the Mylan products). The respondent intended to launch the Mylan products in Australia and obtain PBS listing on 1 December 2017. The Mylan products are bioequivalent with PREZISTA. If a generic version (Mylan product) of the innovator product becomes listed on the Schedule, the innovator product will move from the F1 formulary to the F2 formulary and the price at which the innovator may sell their product is immediately and substantially reduced.

The evidence revealed that two attempts were made by Janssen, first in 2016 and then in June 2017 after becoming aware of the ARTG registration for the Mylan products, to obtain information from the respondent about the manufacturing process of these products. Following agreement to confidentiality, the respondent provided a description of the manufacturing process and details of the structure and characteristics of the Mylan products to Janssen in August and September 2017. In the following month, Janssen filed suit for infringement claiming that the Mylan products are manufactured using the process of claims 14 and 15 of their 562 patent. Amongst other relief, an interlocutory injunction was sought by Janssen to avoid PBS listing of the Mylan products.

**Authors:**

Candace (YeeWen) Wu PhD
Patent Scientist

Jacinta Flattery-O’Brien PhD
Principal, Patent Attorney
Issues and decision

The dispute relates to whether Janssen should be granted interim injunctive relief to restrain Alphapharm from infringing the 562 patent and importantly to avoid PBS listing of the Mylan products.

In order to be granted an interlocutory injunction, the Court must make two main inquiries:

- has the applicant established a prima facie case for final relief; and
- does the balance of convenience favour granting the injunction?

To determine if there is a prima facie case, Yates J examined the construction of claims 14 and 15 of the 562 patent and whether the manufacturing preparations of the Mylan products include the process of those claims. The expert opinion from the side of the respondent identified three different interpretations of claim 14 (the independent claim) while the applicant submitted a fourth interpretation and disagreed with the former three interpretations. Yates J articulated at [88] “the debate is not a factual one” but “a debate concerning the proper construction of claims 14 and 15”. Yates J considered that the fourth interpretation submitted by the applicant is arguable and can be advanced on cogent bases, and as such it was held that the applicant has established a prima facie case of threatened infringement of claims 14 and 15.

To rebut, the respondent challenged the validity of the claims in suit, asserting that they lack novelty, fair basis (under the “old” unamended Australian Patents Act that covered the patent) and utility. However, due to the opposing theoretical analyses presented to the Court concerning novelty and the fact that the fourth interpretation is arguable on a cogent basis, Yates J was not persuaded to alter his conclusion that the applicant has a prima facie case of threatened infringement. The position on the challenge of validity was stated in [96] as explained by Jessup J in Interpharma Pty Ltd v Commissioner of Patents [2008] FCA 1498, (2008) 79 IPR 261 at [17]:

“It is the applicant’s title to interlocutory relief which is under consideration, and the bottom-line question, as it were, is whether the applicant has a serious question, or a probability of success, not whether the respondent does in relation to some point of defence raised or foreshadowed.”

On the balance of convenience, the respondent submitted that the task of constructing a hypothetical market for darunavir products would be exceedingly complex and rife with uncertainty. Further, the respondent argued that if it were to be restrained from supplying the Mylan products now, it would not only lose significant sales but the first-mover advantage as they anticipate Janssen-Cilag would move to appropriate that advantage itself by launching its own generic darunavir product to compete with PREZISTA or by the time the final proceeding has been determined, other generic suppliers will be ready to launch their own brands of darunavir. In response, the applicant asserted that Janssen-Cilag has no present intention to launch a generic darunavir product in Australia and that if the respondent is restrained now the only thing they will have lost is the period of time when it could compete only with Janssen-Cilag, which would be relatively short in the scheme of things.

As a prima facie case for final relief was conceded (as discussed above), the question before the Court for the purpose of the interlocutory injunction was “how difficult will it be to calculate the damages that are claimed?” if an interim injunction is or is not granted against the respondent. The Court rejected the respondent’s argument relating to the difficulty of constructing a hypothetical market at [163]:

“However, the simplicity of that proposition is deceptive...its own experience as a supplier of generic pharmaceutical products, as well as its own business plans for the Mylan products, must surely inform it of the likely volume of the market it should attain; the price at which it should sell the Mylan products to best achieve that volume; and the costs it would likely incur in achieving that object, absent the intervention of further generic competition in the market. I accept that this necessarily involves a degree of uncertainty, but business decisions are nevertheless made and implemented in such circumstances on informed estimation. Routinely, damages are calculated on the same basis.”
On the one hand, Yates J accepted there is a real likelihood that the respondent would lose a first mover advantage if interim injunction is granted but on the other hand, he held that if the respondent is not restrained now, the launch and PBS listing of Mylan products will cause irreparable damage (i.e. damages will not be an adequate remedy), see [168]:

“...if the respondent is not restrained now, its conduct will inevitably put in train a series of events which the applicant cannot control, and which would be very damaging to it. Apart from anything else, the important and legitimate market position enjoyed by the PREZISTA and PREZCOBIX products, with the price benefits that that position entails, will be lost in circumstances where, on the present evidence, the applicant has shown that there is a real possibility that it will be entitled to final relief restraining the conduct in question. Thus, the loss and damage in question can be avoided at the outset by granting the interim injunctive relief that is sought. Leaving the applicant with the burden of prosecuting a damages claim that is likely to be complex and difficult—in circumstances where it has demonstrated, on cogent bases, a prima facie case for injunctive relief—is a poor alternative. In other words, damages will not be an adequate remedy.”

In an effort to maintain the status quo brought on by the granting of the interim injunctive relief, Yates J ordered certain undertakings in addition to the usual undertakings as to damages. First, the applicant is required to give 30 days’ written notice to the respondent prior to an application to obtain PBS listing which includes darunavir as an API and which would cause PREZISTA to move from the F1 formulary to the F2 formulary. Secondly, the applicant is required to inform the respondent if it becomes aware of any person other than Janssen-Cilag seeking to exploit pharmaceutical product in Australia that includes darunavir as an API.

Implications

The decision demonstrates that the Australian Court remains disposed to granting interlocutory injunctions to pharmaceutical patentees provided:

a) there is at least some arguable case for infringement (low threshold required to establish a prima facie case);

b) the challenge on validity is weak (there is no triable question on validity); and

c) the perceived extent of loss is greater than that of the respondent if interim injunctive relief is not granted, especially if the competing product is to be listed on the Schedule.

The judgment delivered by Yates J also reveals that the Court does not consider the task of estimating damages from a hypothetical market any more difficult than the routine calculations required for determining damages from an existing market. Further, the Court accepts the likelihood that generic products may lose the first mover advantage if interlocutory injunctive relief is granted but is inclined to grant the relief anyway because the market position enjoyed by the originator product, if lost, should be a damage that is likely to be complex and difficult to claim if not impossible to recover (i.e. an irreparable damage). Notwithstanding, the grant of interlocutory injunctive relief is likely to include certain undertakings in addition to the usual undertakings as to damages.
Pfizer companies obtain interlocutory injunction restraining launch of generic sedatives

*InterPharma Pty Ltd v Hospira, Inc (No 3) [2017] FCA 1536*

**Interlocutory injunction**

**Pharmaceutical**

**Kenny J**

The Federal Court of Australia (Kenny J) has granted Pfizer companies Hospira and Orion an interlocutory injunction precluding InterPharma from marketing generic dexmedetomidine product despite InterPharma raising triable issues under several grounds of patent invalidity.

**Authors:**

Jennifer Enmon PhD

Kieran Williams PhD
Principal, Patent Attorney

**Background**

InterPharma Pty Ltd (*InterPharma*) commenced a proceeding against Hospira, Inc (*Hospira*) and Orion Corporation (*Orion*) on 8 August 2017 seeking an order revoking all claims of Australian Patent No 754484 (*484 Patent*). On 17 August 2017, Orion transferred all of its rights to Hospira who then granted an exclusive license to Pfizer Australia Pty Ltd. On 18 August 2017, Hospira and Pfizer Australia Pty Ltd (*collectively, Pfizer*) brought cross-claims seeking to restrain InterPharma from marketing its generic dexmedetomidine product as well as declaratory and injunctive relief. Pfizer was granted interim injunctive relief on 11 September 2017.

The 484 Patent concerns method of treatment and Swiss-style claims relating to intensive care unit (ICU) sedation by administering dexmedetomidine. The 484 Patent has an effective filing date of 31 March 1999, with the earliest priority claim to a U.S. provisional application filed 12 April 1998. Accordingly, the 484 Patent is set to expire on 31 March 2019.

Before a pharmaceutical product can be marketed in Australia, it must be approved by the Therapeutic Goods Administration (*TGA*) and, consequently, listed in the Australian Register of Therapeutic Goods (*ARTG*). As part of the listing requirement, the indications for which the product can be used are specified.

Interpharma generic dexmedetomidine received approval from the TGA and was entered in the ARTG on 13 July 2017. The Product Information (*PI*) for the generic product indicated that it was for use in ICU sedation, which is the same use as the originally listed product, Pfizer’s Precedex®.

**Issues and decision**

*Prima facie* patent infringement

InterPharma conceded there was a strong *prima facie* case that importation and sale of the generic product would fall within several of the claims of the 484 Patent.
In view of the evidence relating to the ARTG listing and InterPharma’s concession of a strong *prima facie* case of threatened infringement, Kenny J found that there is a probability that Pfizer will succeed on its cross-claim at trial.

**Prima facie** patent validity

InterPharma argued that the specification disclosed, with reference to an earlier granted US Patent ([US Patent 214](#)), that dexmedetomidine was known for the generation of sedation/analgesia. Therefore, the medical use claimed in the 484 Patent was not to a previously unknown medical use but to a previously known medical use applied to a subset of patients. Pfizer countered that the subset of patients, ICU patients, distinguished the claimed use from the previously known use. As the expert evidence from InterPharma and Pfizer conflicted on whether the use of dexmedetomidine in sedation, as described in the specification of the 484 Patent with reference US Patent 214, was the same as sedation of ICU patients, as claimed, Kenny J found that InterPharma raised a triable issue as to this ground of invalidity.

In arguing lack of novelty, InterPharma relied on three separate disclosures: the US Patent that was the basis of the manner of manufacture allegation, a journal article, and consent forms for the clinical trials of Pfizer’s listed product supplied to patients prior to April 1998, for which there was only indirect evidence. Pfizer countered that the disclosures of the US Patent would have discouraged the use of dexmedetomidine as claimed, that the journal article lacked teachings relating to use of the product in ICU patients, and that the clinical trials consent forms should be excluded by operation of the grace period afforded by section 24(1) of the [Patents Act](#). Pfizer tried to argue that section 24(1) applied to publications or uses within 12 months of the date of filing of a priority application but ultimately conceded that “there was at best a triable issue” as to whether the grace period was applicable. Kenny J found that neither US Patent 214 (despite the finding relating to the manner of manufacture ground) nor the journal publication established a strong *prima facie* case of lack of novelty. However, as to the clinical trials consent forms, InterPharma had raised clear triable issues.

InterPharma argued that the 484 Patent lacked inventive step in view of the common general knowledge concerning the use of dexmedetomidine or that common general knowledge in combination with the journal article asserted under lack of novelty or a presentation in Australia by the author of the journal article. Pfizer countered that the common general knowledge did not include knowledge of the sedation activity of dexmedetomidine as applicable to ICU patients. Kenny J was not convinced that the sedative property of dexmedetomidine with regard to ICU patients was part of the common general knowledge. Thus, InterPharma failed to make out a strong *prima facie* case of lack of inventive step.

InterPharma argued that the specification described only a narrow type of sedation whereas the claims cover the complete spectrum of sedation. While Kenny J determined that InterPharma has raised a triable issue with regard to fair basis, a strong *prima facie* case was not accepted.

Kenny J explained that raising triable issues cannot warrant the refusal of the interlocutory injunctive relief especially in view of the strong *prima facie* case of threatened infringement. Rather, it was stated that the grant or refusal requires consideration of the balance of convenience.

**Balance of convenience**

Pfizer argued that in around 2003, it or its predecessor, had been the sole and continuous distributor of dexmedetomidine. Therefore, grant of the interlocutory injunction would preserve the *status quo*. Kenny J agreed that the grant of interlocutory injunctive relief would best protect the practical status quo until the trial.

InterPharma sought discharge of the interim injunction on the basis of material non-disclosure by Pfizer in its interim injunction application. InterPharma argued that Pfizer misrepresented information relating to the details of arrangements and contracts governing the sale of Pfizer’s listed product. InterPharma argued that the circumstances should be taken into account in considering the grant of the interlocutory injunction. Although Kenny J agreed that Pfizer “misrepresented[ed] its position in some of the material filed in support of its application for interim injunction”, the errors “were not sufficiently egregious to warrant the
discharge of the interim injunction, or to justify considering the current application on the basis that the status quo should have been different from what it was in fact”.

InterPharma did not contest that it knew or should have known that the generic dexmedetomidine would infringe the 484 Patent. However, InterPharma argued that it should not have been expected to clear the way because it could not market the product until the ARTG listing was obtained and, even if revocation proceedings had begun when it applied for the listing, the case would not have been finally heard by all possible instances. Further, seeking revocation would have jeopardised its “first mover advantage” with respect to other generic competitors. InterPharma thus argued that this factor should not be considered.

While Kenny J agreed that not all instances of a revocation action would have been completed by the time InterPharma obtained its dexmedetomidine listing in the ARTG, at least a first instance could have been heard and determined. Despite the potential commercial disadvantages argued by InterPharma, completely disregarding the failure to clear the way as a factor is not justified. However, Kenny J found that while the factor is to be considered, it does not weigh heavily in the balance.

Pfizer argued that it would be difficult to calculate damages because the listed product was a substitutable product with competitor products that were significantly cheaper, the market for the listed product was not mature as it was not steady over a material period of time, the use of the listed product varied across the market, Pfizer would likely decrease investment into the listed product, and the effect on price would likely extend beyond the expiry of the 484 Patent. Kenny J agreed that assessing Pfizer’s damages would be “difficult and uncertain” and outweighed any potential difficulty in assessing InterPharma’s damages.

Kenny J decided that the strong prima facie case of infringement in combination with the balance of convenience weighed in favour of the grant of the requested relief. This decision was reached upon taking into account (1) the maintenance of the status quo from 2003 (2) the significant harm that Pfizer will suffer with ‘unascertainable’ damages and (3) that InterPharma failed to “clear the way” notwithstanding knowledge of the potential to infringe, despite the Court’s earlier statement that this factor would not weigh heavily in the balance.

**Form of injunction**

Pfizer proposed the order be with regard to “Generic Dexmedetomidine Product” while InterPharma proposed the order be with regard to “Generic Dexmedetomidine Product for Procedural Sedation”. Pfizer argued that InterPharma’s proposed order was a means to avoid infringement and launch the product with the expectation that customers would obtain and use the generic product regardless of the indications in the PI. The order followed Pfizer’s proposal as this was essentially the form of the interim injunction previously granted and corresponded with Pfizer’s interlocutory injunction application. Accordingly, Pfizer was granted injunctive relief encompassing the generic product per se even though the “threatened” 484 Patent comprised only claims directed to specific therapeutic uses.

**Implications**

In cases where a patent includes a therapeutic claim covering an indication listed in the ARTG, there is a significant likelihood that a generic manufacturer that is about to (at least arguably) infringe the claim will face an interlocutory injunction. In such a scenario, the generic manufacturer will usually have to concede to a strong prima facie case of threatened infringement based on the filing of an application for an ARTG listing as well as the information in the proposed accompanying PI. The inadequacy of damages for the patentee (or ARTG originally listed product holder) may successfully be argued in such cases as demonstrated by Pfizer in the present proceedings. Accordingly, in the absence of a strong prima facie case of invalidity and despite a finding of several triable issues in the accused infringer’s favour, the likely outcome will be a grant of interlocutory injunctive relief precluding the marketing of an approved generic product prior to resolution of a trial on the issues.
Cipla and Meda obtain interlocutory injunction in the face of manner of Apotex’s manufacture attack on combination pharmaceutical product

**Apotex Pty Ltd v Cipla Limited**

[2017] FCA 1627

**Interlocutory injunction**

**Pharmaceutical**

**Beach J**

The Federal Court of Australia (Beach J) has granted Cipla and its exclusive licensee an interlocutory injunction restraining Apotex from infringing its patent by launching a nasal spray combining an antihistamine and a corticosteroid. Although Apotex raised assertions of invalidity with some merit (particularly regarding manner of manufacture), Beach J considered that Cipla had an undoubtedly strong prima facie case on infringement and the balance of convenience also favoured the grant of the interlocutory injunction.

**Authors:**

Duncan Longstaff
Senior Associate, Lawyer

Natasha Faigenbaum
Lawyer

Katrina Crooks
Principal, Lawyer

**Background**

Cipla Limited (Cipla) is the owner of Australian Patent No. 2003244799 (the Patent) relating to pharmaceutical products and formulations for nasal and ocular use for preventing or minimizing allergic reactions, containing a combination of azelastine hydrochloride (an antihistamine) and fluticasone propionate (a steroid). Meda A.B (Meda) is Cipla’s exclusive licensee. Meda’s azelastine-fluticasone combination nasal spray has been available in Australia since July 2014 under the brand name DYMISTA. Since Meda was acquired by Mylan Health Pty Ltd (Mylan) in November 2017, Mylan has purchased DYMISTA products from Meda and Mylan has marketed and supplied them to the Australian market.

Apotex Pty Ltd (Apotex) commenced proceedings seeking revocation of the Patent following correspondence between the parties’ lawyers precipitated by regulatory approval of Apotex’s generic azelastine-fluticasone combination nasal spray in August 2017. Cipla and Meda cross-claimed for infringement of the Patent and applied for an interim injunction, which Beach J granted in November 2017 pending a contested interlocutory injunction application in late December 2017. Apotex effectively conceded infringement for the purposes of the interlocutory injunction application.

**Issues and decision**

Following established principles, Cipla (as patentee) and Meda (as purported exclusive licensee) needed to demonstrate a prima facie case of infringement of at least one valid claim of the Patent and that the balance of convenience favoured the grant of an injunction up to the trial of the proceeding. Apotex submitted that the interim injunction should not be extended as the evidence established a strong prima facie case of invalidity of each of the claims alleged to be infringed, noting there is no presumption of validity of a patent under Australian law.

**Prima Facie Case**

Beach J confirmed that there was little doubt that Cipla had a very strong prima facie case on infringement. On turning to Apotex’s invalidity case, in summary, Beach J agreed that the assertions
of invalidity had some merit but was not satisfied that these assertions rose to a level of a strong prima facie case that was equal to or exceeded Cipla’s prima facie case on infringement. Beach J noted that he was being circumspect on matters of patent validity, given (1) he was the likely trial judge, making it inappropriate for him to be too definitive in the expression of his views at this early stage, (2) the relevant witnesses had not been called and cross-examined and most of the evidence was hearsay, (3) assertion countered by assertion provided little appropriate foundation to be definitive on invalidity; and (4) the relative speed with which the matter had been brought on.

Manner of Manufacture

Beach J considered the strongest invalidity ground raised by Apotex to be manner of manufacture.

Apotex raised two aspects of this ground:

1. On the face of the specification of the Patent, the claims are for nothing more than the use of known materials (antihistamines and steroids) in the manufacture of known articles (nasal spray) for a purpose for which those materials’ known properties make them suitable (relief of rhinitis and other nasal conditions).

2. The claimed invention is a mere collocation of parts, each performing its own separate function, rather than a patentable combination of known features working together to produce a new result.

Apotex argued that the lack of inter-relationship between the antihistamine and steroid was emphasised in the Patent by statements that the two agents did not interfere with one another or cause adverse reactions in patients. Apotex argued that the statement in the Patent that the lack of adverse interactions was “surprising” was not supported by the other information in the specification, and that the statement that the antihistamine and steroid had an “advantageous synergistic therapeutic effect” was an error. Beach J noted that Apotex’s arguments were not without merit, but considered that Apotex had read the specification too narrowly and disagreed that it has been shown that any statements had been made in error. Overall he found that Apotex had a reasonable case on lack of manner of manufacture, but not a strong case.

Inventive Step

Apotex argued that the idea of combining antihistamines and steroids in a nasal spray, when both agents had been widely used in nasal sprays to treat rhinitis and other nasal conditions, was obvious. Apotex contended that invention could only possibly lie in the selection of the particular antihistamine and steroid agents, and the formulation of the combination nasal spray comprising them. Apotex led evidence from an experienced formulation chemist in support of its case that each of these steps was a matter of routine and obvious, both in light of common general knowledge alone and a prior art patent. However, Beach J noted the difficulties in making any meaningful assessment of obviousness on an interlocutory application, when this turned on detailed and technical factual issues of common general knowledge and the likely relevance of prior art documents. He concluded that Apotex had not established a strong prima facie case of lack of inventive step.

Novelty

Beach J was not satisfied that Apotex had a strong prima facie case for lack of novelty, noting the prior art patent relied upon did not expressly disclose fluticasone, let alone its specific combination with azelastine in a nasal spray.

Balance of Convenience

His Honour concluded that the balance of convenience favoured the grant of the interlocutory injunction sought by Cipla for many reasons. These included: (a) the status quo was that Apotex was not in the market, (b) granting an interlocutory injunction would not practically put an end to the litigation (as Apotex could still launch a commercially-viable generic azelastine-fluticasone nasal spray should it succeed at trial, albeit perhaps having lost its “first-mover advantage”), and (c) the Patent was longstanding.

Interestingly, Beach J considered damages would not be an adequate remedy for Cipla’s loss of market share, even though DYMISTA was not listed on the PBS and therefore no associated irreversible reimbursement price drops factored into the issue. He also considered that Meda’s lost sales to its sub-licensee (and parent company) Mylan were relevant losses.
Implications

This case is the third from the last few months of 2017 in which a pharmaceutical patentee has sought and obtained an interlocutory injunction. This followed a long period in which there were no interlocutory injunction decisions in pharmaceutical patent cases, perhaps due to the uncertainty for patentees arising from the damages claims currently pursued by the Australian Government against Sanofi (regarding clopidogrel), Wyeth (regarding venlafaxine) and AstraZeneca (regarding rosuvastatin) for alleged “overpayments” of PBS reimbursements at higher prices maintained due to interlocutory injunctions, in cases where the patents were ultimately held invalid.

The decision illustrates the circumspect approach the Court will take on issues of invalidity during an interlocutory injunction application and the difficulty of establishing the more “superficial” grounds such as manner of manufacture, even with expert evidence.
Amendments to a patent during court proceedings – how much transparency is required?

**Apotex Pty Ltd v ICOS Corporation** [2017] FCA 466

**Post-grant amendments**
**Amendments during litigation**
**Pharmaceutical**

**Besanko J**

The Federal Court has provided guidance regarding the level of disclosure required by a patentee in order for a court to exercise its discretion in allowing amendments to the specification during court proceedings.

**Background**

Eli Lilly and Company (Lilly) is the holding company of ICOS Corporation (ICOS) and holds a number of patents worldwide that relate to a compound known as tadalafil (a PDE5 inhibitor that is useful in the treatment of erectile dysfunction).

As part of a Federal Court proceeding brought by Apotex relating to the validity of Australian Patent No. 773666 (the 666 Patent, relating to compositions containing tadalafil, including in micronised particle sizes, and methods of treatment using such compositions) and Australian Patent No. 769946 (the 946 Patent, relating to compositions containing particular daily dosages of tadalafil for oral administration and methods of treatment using such dosages), ICOS sought orders to amend the specifications of the patents under section 105(1) of the *Patents Act 1990*, which deals with court-directed amendments such as during litigation.

**Issues and decision**

The proposed amendments to the 666 Patent involved the addition of 15 dependent claims directed to specific doses or dosage ranges of tadalafil. The purpose of these amendments was to strengthen ICOS’s defence to Apotex’s inventive step challenge.

The proposed amendments to the 946 Patent involved removing statements in the specification concerning the side effect profile of tadalafil when co-administered with organic nitrates. One of the grounds of invalidity raised by Apotex was inutility on the basis that tadalafil did not eliminate particular side effects, or reduce them to clinically insignificant levels, when co-administered with an organic nitrate. The purpose of the amendments was to strengthen ICOS’s defence to Apotex’s utility challenge by removing any promises that could be found to have not been met (in *Ronneby Road Pty Ltd v ESCO Corporation* [2016] FCA 588, Jessup J found that failure of one of the promised results, even though others were attained, could give rise to revocation for inutility).

Apotex opposed the amendments for both the 666 Patent and the 946 Patent, arguing that ICOS had failed to make full disclosure of all relevant matters relating to the proposed amendments, that it had unreasonably delayed the proposed amendments, and that it had not adequately explained the reasons...
for the proposed amendments (Apotex subsequently withdrew their opposition to the amendments for the 666 Patent).

The Commissioner of Patents found that the amendments to the 666 Patent and the 946 Patent met the requirements of section 102 of the Act, which deals with amendments which are not allowable. As such, the only issue was whether the amendments should be allowed in the exercise of the Court’s discretion.

The relevant principles in relation to an application to amend a patent under section 105(1) have been previously summarised by the Full Federal Court in Laboratoires Servier v Apotex Pty Ltd [2016] FCAFC 27; (2016) 117 IPR 415. In that case, the Court refused to allow the patentee to amend its specification to overcome a failure to describe the best known method of working the invention. The relevant principles established in that case were:

- the onus to establish that amendment should be allowed is on the patentee;
- generally, a permissible amendment (i.e. one which is permitted under section 102 of the Act) will be allowed unless there are circumstances which would lead the court to refuse amendment;
- the patentee must make full disclosure of all relevant matters;
- amendment should be sought promptly and where a patentee delays for an unreasonable period, the patentee has the onus of showing that it delayed on reasonable grounds;
- unreasonable delay is a circumstance likely to lead to refusal of an amendment;
- in assessing delay, the relevant time is from when the patentee knows of the likely invalidity, or has its attention drawn to a defect in the patent, or is advised to strengthen the patent by amendment;
- mere delay is not, of itself, sufficient to refuse to exercise the discretion to amend. The fact of delay is, however, relevant to whether the respondent or the general public have suffered detriment; and
- if a patentee seeks to take unfair advantage of the unamended patent, knowing that it requires amendment, then refusal of the amendment is likely.

ICOS relied on affidavits sworn by a lawyer and patent attorney at the firm acting for ICOS, two in-house patent attorneys at Lilly and the former Medical Director at Lilly, collectively setting out in detail the reasons for the proposed amendments to the 666 Patent and the 946 Patent, and the timing of events leading up to the application to amend. ICOS also provided verified discovery which included emails between Wrays and Lilly, emails between internal Lilly patent counsel and Lilly’s clinical study reports. ICOS did not maintain a claim for privilege in respect of these documents.

The Court found that ICOS’s conduct was reasonable, that it had made full disclosure and that there had been no unreasonable delay in seeking to amend the specifications of the the 666 Patent and the 946 Patent. The Court also found that there was no evidence that Apotex would suffer any prejudice if the amendments were allowed, other than the possible effect on its utility challenge. Apotex had given an undertaking not to market, sell or exploit its generic tadalafil products during the term of Australian Patent No. 689205 (Lily’s tadalafil composition patent), so the patents which ICOS sought to amend had not been instrumental in Apotex refraining from entering the market. In addition, the Court noted that the application to amend had been made before trial, and that no third party had sought to oppose the application to amend.

Apotex identified four matters which it submitted were relevant to the Court’s exercise of its discretion.

First, Apotex submitted that the amendments to the 946 Patent did not involve a narrowing of the claims so as to avoid an argument based on a piece of prior art. Rather, they involved the removal of statements about the co-administration of tadalafil and organic nitrates. Apotex submitted that the obligation to make promises that were met or could be met crystallised on the filing of the patent application or, in the alternative, on the grant of the patent. However, the Court found that unlike best method and sufficiency, the patentee was not required to make statements regarding the utility of the invention, so that no such obligation crystallised on filing.
Secondly, Apotex argued that ICOS’s conduct in relying on statements about the co-administration of tadalafil and organic nitrates in correspondence with the Commissioner of Patents during prosecution of the 946 Patent should be taken into account and was a reason not to allow the amendments. However, the Court was not satisfied that the statements made by ICOS during prosecution were material in overcoming the objections raised by the examiner.

Thirdly, Apotex argued that the amendments sought by ICOS involved the removal of the main promises in the 946 Patent. However, the Court found that while the statements about the co-administration of tadalafil and organic nitrates were an important aspect of the specification, they were not the only advantage identified.

Fourthly, Apotex argued that the 946 Patent is a selection patent and that the advantages of the selected members are critical to the validity of the patent. However, the Court found that even if the 946 Patent is a selection patent and the amendments are allowed, a number of advantages or benefits of the invention remain in the specification.

The Court was not satisfied that the matters identified by Apotex warranted a refusal of the application to amend. Consequently the Court directed that, pursuant to section 105(1), the complete specification of the 666 Patent and the 946 Patent be amended.

Implications
This decision demonstrates the extensive disclosure of prevailing circumstances required of a patentee if it seeks to amend its patent post-grant during litigation, if it is to receive the benefit of the Court exercising its discretion in favour of allowing the amendments. Patentees should not assume that they will necessarily be able to amend their patents post-grant, should it become necessary during litigation, as the Court will scrutinise how long the patentee has known about the issue and what steps it took.

The invalidity trial proceeded during June 2017 and the judgment of Besanko J remains reserved at the time of this publication.
Federal Court of Australia confirms that offers made during patent term to supply after patent expiry constitute infringement, also highlights importance of Swiss-style claims in Australia

**Apotex Pty Ltd v Warner-Lambert Company LLC (No 3) [2017] FCA 94**

**Infringement Mere offer Pharmaceutical**

**Nicholas J**

In this decision, the Federal Court of Australia (Nicholas J) delivered a significant judgment in confirming that an Australian patent will be infringed by offers made during the term of the patent, without the patentee’s consent, to supply infringing products after the patent has expired. The decision also highlights the importance of including Swiss-style claims in Australian pharmaceutical patents.

**Authors:**

Kieran Williams PhD  
Principal, Patent Attorney  

Duncan Longstaff  
Senior Associate, Lawyer

**Infringement by mere offer to supply**

The reasons of Nicholas J observe that the exclusive rights of a patentee under section 13 of the Patents Act 1990 (Cth) include the right to offer the invention for sale, and confirm that the mere making of such an offer constitutes exploitation and therefore infringement of a patent claim covering the invention. This outcome is likely to restrict the marketing activities of potential infringers (such as generic pharmaceutical companies) in seeking to secure customers for their products in the lead-up to patent expiry.

Importantly, Nicholas J found that applying to list a generic (infringing) product on the Pharmaceutical Benefits Scheme (PBS) from a date after patent expiry “would fall short of offering to sell or otherwise dispose of the products”. This is consistent with previous decisions that the act of applying for PBS listing of a generic pharmaceutical product does not itself constitute patent infringement, but that obtaining a PBS listing which starts before the patent expires arguably constitutes patent infringement because the generic party must guarantee supply of the product from the first day of PBS listing under the provisions of the National Health Act 1953 (Cth).

The patentee (Pfizer) succeeded in establishing infringement and validity and obtained a permanent injunction restraining the infringing products (pregabalin) of the generic party (Apotex) until the expiry of the asserted patent. It is notable that Pfizer sought to be released from the “usual undertaking as to damages” it had given as a condition of obtaining an interlocutory injunction in March 2014, but that Nicholas J refused to make such orders and left the usual undertaking in place because of the possibility of a successful appeal by Apotex (in which case the interlocutory injunction would ultimately be found to have been improperly imposed).

**The importance of Swiss-style claims**

Another interesting aspect of the Court’s decision relates to the types of second medical use claims that are infringed by an offer made during the term of a patent to supply an infringing product after the term of the patent has expired.
In Australia, second medical use claims (i.e., new uses of a known pharmaceutical) are acceptable in the method of treatment format (A method of treating disease X comprising administering compound Y) or the Swiss-style format (Use of compound X for the manufacture of a medicament for the treatment of disease Y). While not allowable in many jurisdictions (including Europe, Canada, Japan and China), method of treatment claims have been deemed patentable in Australia by the High Court (Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd [2013] HCA 50). Swiss-style claims are construed in Australia as defining a method or process for the manufacture of a medicament (Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd (No 4) [2015] FCA 634) and have been found to confer eligibility for a patent term extension if the medicament contains a pharmaceutical substance produced by a process that involves the use of recombinant DNA technology in some way (AbbVie Biotechnology Ltd Commissioner of Patents [2016] AATA 682).

Importantly, in the present decision, Nicholas J distinguished between the scope of method of treatment claims and Swiss-style claims. In the context of the excerpt from the decision below, it is important to note that, under the Patents Act 1990 (Cth), a patent confers on the patentee the exclusive rights, during the term of the patent, to “exploit” the invention. As defined in the Act, “exploit” includes:

“(a) where the invention is a product—make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or

(b) where the invention is a method or process—use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.” (emphasis added).

Given that, to find infringement, exploitation of the invention has to take place during the term of the patent, Nicholas J stated the following regarding potential infringement of method of treatment claims and Swiss-style claims by an offer made during the term of a patent to supply an infringing product after the term of the patent has expired:

20 In the present case, the method of treatment claims are not methods that result in the making of any product. It follows that the reference in paragraph (b) of the definition of exploit to “any act mentioned in paragraph (a) in respect of a product resulting from [use of the method]” cannot apply to any of the method of treatment claims. To the extent that there will be any exploitation of the invention claimed in any of the method of treatment claims, it will be by medical practitioners or patients who perform the claimed method.

27 There are two short points to make in relation to the method of treatment claims. First, there will be no relevant exploitation of the claimed method unless it is performed during the term of the Patent. Secondly, [section] 117 [which relates to contributory infringement] cannot apply because it is concerned only with acts of supply. Apotex will be restrained from supplying any of the products during the term of the Patent. Hence, even if it were correct to say that by applying for a PBS listing Apotex will have offered to supply the products, this would not amount to an exploitation of any of the method of treatment claims.

28 In relation to the Swiss-style claims, Pfizer submitted that, by applying for a PBS listing, Apotex will be exploiting the claimed invention by offering to sell or otherwise dispose of products that result from the use of a method of manufacture the subject of those claims. I accept that the products that Apotex intends to supply (after patent expiry) result from the use of such a method and that, therefore, para (b) of the definition of exploit is engaged. The question is whether by applying for a PBS listing Apotex will be offering to sell or otherwise dispose of the products.

It is clear from the above, that an offer made during the term of the patent to supply an infringing product after the term of the patent has expired will infringe a Swiss-style claim, but not necessarily a corresponding method of treatment claim.

Implications

The Court’s decision confirms that method of treatment claims and Swiss-style claims are directed to different infringing acts and highlights the importance of including both claim types in Australian pharmaceutical patents.
Sense of entitlement not enough to save Intervet

*Merial, Inc. v Intervet International BV (No 3) [2017] FCA 21*

*Merial, Inc. v Intervet International BV (No 4) [2017] FCA 223*

**Entitlement Patent Office appeal Veterinary medicine**

*Moshinsky J*

The first of these decisions (No. 3) concerned an appeal by Merial, Inc. from an Australian Patent Office opposition proceeding in which Intervet International BV successfully defended its patent application relating to an anti-parasitic soft chew formulation. The Federal Court appeal was based on two grounds, inventive step and lack of entitlement, the latter of which was raised for the first time before the Court. The key issue was whether Intervet was entitled to grant of a patent from named inventor Mark Pieloch, an independent contractor whom Intervet Inc. had engaged to assist with formulating and producing the soft chews. Having found that Intervet was not entitled to grant of a patent from named inventor Mark Pieloch, an independent contractor whom Intervet Inc. had engaged to assist with formulating and producing the soft chews. Having found that Intervet was not entitled to grant of a patent, the second of these decisions (No. 4) concerned whether Intervet could remedy the entitlement defect by amendment before the Commissioner of Patents.

**Background**

In early 2002, Susan Cady (then an employee of Intervet, Inc.) approached Mark Pieloch, sole owner of Pharma Chemie, Inc. (*Pharma Chemie*), to develop palatable soft chew products containing anti-parasitic ingredients for horses and dogs. Pharma Chemie and Intervet entered into a Manufacturing Supply Agreement (the *Agreement*) in 2002 in relation to this work. Pharma Chemie was in the business of producing palatable animal health products and had been developing soft chew formulations since at least 1992.

Later in 2002, Intervet International BV (*Intervet*) filed two US provisional applications directed to chewable or soft chew dosage forms, which served as priority documents for a PCT application upon which the Australian patent application central to these proceedings was based. Each application named three inventors, Susan Cady, Sebastien Huron (also an employee of Intervet, Inc.) and Mark Pieloch.

Although the corresponding US applications were ultimately abandoned by Intervet, and faced obstacles due to the refusal of Mr Pieloch to sign an Inventor’s Declaration, the Australian counterpart application proceeded to acceptance. At this time, Merial, Inc. (*Merial*) opposed its grant before the Australian Patent Office on the basis that the claimed invention lacked novelty, lacked inventive step, and failed to satisfy the “manner of manufacture” requirements. Merial failed on all grounds in the opposition.

Merial then appealed the Australian Patent Office decision to the Federal Court on the ground of lack of inventive step and pressed a new ground, lack of entitlement.

**Issues and decision**

Under Australian law, 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, be entitled to have the patent assigned to them; or (c) derives title to the invention from the inventor or a person mentioned in (b): *Patents Act 1990* (Cth) section 15(1). During these proceedings, Merial contended that Intervet was not entitled to the grant of a
patent on the basis that it did not derive title to the claimed invention from Mr Pieloch (who Intervet acknowledged was “an actual inventor”). Merial’s (and Mr Pieloch’s) position was that Pharma Chemie owned the soft chew technology in the patent application, and that there was no express or implied term of assignment that transferred the rights in that technology to Intervet.

Intervet’s opposing view was that it gained entitlement to the invention from Mr Pieloch by virtue of the Agreement, which it submitted provided for the assignment of rights from Pharma Chemie to Intervet. However, Intervet were unable to produce a copy of the Agreement, or any other documentation that supported their position that Pharma Chemie expressly assigned rights in the invention as claimed to Intervet. Intervet argued in the alternative that there was an implied term of assignment in the Agreement that provided for Intervet to own the intellectual property rights arising from the work with Pharma Chemie based on the “hired to invent” doctrine under US law.

In respect of the express assignment issue, Moshinsky J found that excerpts of the Agreement supported Merial’s position that there was no express assignment of rights in the soft chew technology to Intervet. His Honour noted that if such an assignment had existed, it likely would have been retained by Intervet Inc. and at least produced in 2003 to refute Mr Pieloch’s contention that he owned the soft chew technology.

In respect of the “hired to invent” issue, Moshinsky J found that there was no implied term of assignment as Pharma Chemie “was not engaged by Intervet Inc. to develop a soft chew dosage form; it was engaged to incorporate Intervet Inc.’s active ingredients into a formulation using Pharma Chemie’s soft chew technology” (Merial, Inc. v Intervet International BV (No. 3) [2017] FCA 21, [89]). Further, in light of the IP-related excerpt of the Agreement presented to the Court, his Honour considered there was no room to imply any additional terms assigning IP.

Accordingly, the Court found Merial’s lack of entitlement ground to be made out.

Intervet then requested orders that they be allowed to amend the patent application before the Commissioner to remedy the entitlement defect (e.g., by adding Mr Pieloch as a co-applicant or by amending the Notice of Entitlement) and thereby secure a granted patent. However, Moshinsky J denied this request, noting that the Court’s reasons (in No. 3) had dealt with the entitlement issue in full and that the opportunity for Intervet to present evidence relating to its ability to make any such amendments had passed. Indeed, having concluded that Intervet was never entitled to file the patent application, it would not have been correct for the Court to enable Intervet to continue to prosecute it. Accordingly, his Honour ordered that the patent application not proceed to grant.

Implications

This case highlights the importance of securing an assignment of rights when engaging an independent contractor to perform work in relation to a potential innovation. The assignment or agreement should preferably be in writing and be retained during the pendency of the intellectual property rights – which could be for decades in some cases.
Pre-grant amendments in patent proceedings

*Electronic Tax-Free Shopping Ltd v Fexco Merchant Services (No 3) [2017] FCA 569*

**Post-acceptance amendments**

Appeal from Patent Office opposition Computer-implemented

Yates J

This case considered the allowability of amendments to a patent specification sought under section 105(1A) of the Patents Act, which allows for amendments to be granted by the Court in an appeal from a decision of the Patents Office. The Court considered whether the requirements of section 102 of the Patents Act were met and the way in which the discretionary exercise of the power of the Court to direct amendments should be approached in relation to patent applications not yet granted. The Court directed that the amendments be made.

**Background**

Electronic Tax-Free Shopping Limited (ETFS) was the applicant for a patent relating to dynamic currency conversion for card payment systems. The grant of the patent had been opposed in the Patents Office by a number of parties and amendments had been sought to the patent specification in the Patents Office. The Patents Office refused such amendments and that decision was appealed. In 2015, judgment was given in that appeal dismissing the appeal and refusing the amendments. Meanwhile, an appeal to the decision in the substantive opposition to the patent application had also been lodged in the Federal Court. Following the 2015 judgment in relation to the amendments, ETFS filed a further amendment request in the opposition appeal proceedings seeking to make a more limited set of amendments.

**Issues and decision**

The respondents did not oppose the amendments at the hearing. ETFS was required to satisfy the Court that the proposed amendments were allowable under section 102 of the *Patents Act 1990* (Cth) (in this case, in its form prior to the “Raising the Bar” amendments), in particular that the amendments would not result in the specification claiming matter not in substance disclosed in the specification as filed or not claimed before amendment. The discretion of the Court in relation to amendment requests was also considered.

Having reviewed the proposed amendments, Yates J was satisfied that all amendments were allowable under section 102 of the Act. As to his discretion, Yates J noted the applicant’s argument that the rationale underlying the Court’s discretion to refuse amendment under section 105(1) in relation to granted patents did not apply to the power of amendment under section 105(1A) since no abuse of monopoly can arise in respect of a patent application (as opposed to a granted patent). Yates J stated:

“I do not feel that it is appropriate that I should embark on an analysis of the likely or possible differences between the exercise of power under s 105(1A) and the exercise of power under s 105(1) of the Act, given that I have no contradictor before me on that question.”

**Author:**

Katrina Crooks
Principal, Lawyer
or, indeed, on the application to amend more generally. Nevertheless, I think that the context in which the power under s 105(1A) comes to be exercised is quite different to the context in which s 105(1) comes to be exercised and that there is much to be said for the proposition that many of the considerations usually taken into account when exercising the Court’s discretion under s 105(1) (see, for example, the summary in Bayer Pharma Aktiengesellschaft v Generic Health Pty Ltd (2012) 99 IPR 59; [2012] FCA 1510 at [160]-[164]) are not relevant to the operation of s 105(1A). It is, perhaps, sufficient for me to note further that, absent any opposition to the present application, I can see no discretionary reason to refuse the proposed amendments.”

Implications

The question of the Court’s discretion when considering amendments to a patent application under section 105(1A) is one which is likely to arise again in future cases. Yates J’s comments in this case suggest that such discretion may not necessarily be exercised in the same way as may be the case where amendments to a granted patent are sought in Court proceedings.
Another small victory for Australian Government in pursuit of damages for PBS “over-payments”

Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis) [2017] FCA 382

Damages Interlocutory injunction Undertaking Pharmaceutical

Nicholas J

The Australian Government has had another small victory in the most recent interlocutory decision in the clopidogrel damages enquiry, which is likely to be the test case for its claims for reimbursement of PBS “over-payments” for the patentee’s listed pharmaceutical products during the period of an interlocutory injunction restraining generic entry (and consequent price drops), where the patent was ultimately revoked.

Background

The decision related to a confined issue of contractual interpretation regarding terms of the settlement agreement between the patentee Sanofi and the alleged infringer Apotex. Apotex was the generic party which had been specifically restrained by the interlocutory injunction and which ultimately revoked the asserted patent on an appeal to the Full Federal Court some two years later.

The Government had been a passive party to that point but became active when the matter returned before a single judge for an assessment of damages payable to parties affected by the interlocutory injunction. However, after the damages enquiry had proceeded for some time, and Apotex had filed substantial evidence from 12 witnesses (including its Australian managing director and several other of its employees) in support of its damages claim, Apotex and Sanofi reached a commercial settlement on confidential terms.

Issues and decision

The settlement deed provided, among other things, that the witnesses who had given sworn evidence for Apotex would not give any voluntary assistance to the Government in its ongoing claim against Sanofi. In short, Nicholas J of the Federal Court held that term of the settlement deed to be unenforceable because it was contrary to the public interest and would interfere with the administration of justice. Accordingly, Apotex’s witnesses (including those who are employed by Apotex companies) are free to assist the Government in pursuing its claims, and presumably at least those who are independent experts will readily do so if compensated for their time. As Nicholas J stated:

“It is a matter for each of the Apotex witnesses to decide whether he or she wishes to participate in any interview with the Commonwealth’s solicitors. Needless to say, I expect all the parties’ legal representatives to comply with Rule 23.1 of the Conduct Rules [prohibiting solicitors from taking any step to prevent or discourage a prospective witness from conferring with an opponent or being interviewed by any other person involved in a proceeding] and I am confident they will do so.”

The decision therefore removed what could
have been a significant practical barrier to the Government in proving its damages claim, although it must still convince the Apotex witnesses to cooperate.

This follows a decision in late 2015 in which the Government successfully overcame an objection raised by Sanofi that it had no valid damages claim because its entire possible compensation had been legislated for in the *Therapeutic Goods Act 1989* (Cth), under which a patentee giving a false certificate that it believed its pharmaceutical patents are reasonably believed to valid could be liable to pay substantial fines. The Court held the Government is not so precluded from making its damages claim.

**Implications**

The lengthy damages trial in the proceeding was held from the end of August to the beginning of October 2017, with Nicolas J’s judgment still reserved at the time of this publication. A decision is therefore likely to be more than a year away, meaning there is unlikely to be any certainty as to the risk of Commonwealth PBS damages associated with a pharmaceutical patentee obtaining an interlocutory injunction for some time yet.
Not the Sweetest Ending for Morellini’s Unjustified Threats Claim in his Sugar Cane Saga Against Mizzi

Mizzi Family Holdings Pty Ltd v Morellini (No 3) [2017] FCA 870

Unjustified threats Damages Mechanical

Dowsett J

The Federal Court has declined to award damages in a successful claim for relief from unjustified threats on the basis that no damages as a result of the threats were proved to be suffered by the threatened party.

Background

Both Mr Mizzi (Mizzi) of Mizzi Family Holdings Pty Ltd (MFH) and Mr Morellini (Morellini) had independently been engaged in the development of technology relating to cane billet planters. Both had been aware of the other’s involvement with the technology, and it was fairly well known in the industry that the two were involved in a dispute about the technology, and who was entitled to use it. Mizzi began working on the technology in about 2005. In June 2007, MFH lodged a patent application and around that time also received financial assistance from the government in relation to the technology, which was reported in a local newspaper. In 2009, Morellini displayed his technology at an industry open day. In 2010, MFH published a notice in an industry publication regarding its products which embodied the technology, claiming that Mizzi was the inventor. In 2011, Mizzi spoke to a customer who had used Morellini’s technology, and made a clear allegation that the technology infringed MFH’s patent right. He demanded the payment of a royalty.

MFH commenced proceedings against Morellini for infringement of its Australian Innovation Patent No. 2010100955 (955 Patent) entitled “A cane billet planter”. Morellini denied infringement and filed a cross-claim seeking revocation of the 955 Patent on various grounds of invalidity, as well as damages for unjustified threats of patent infringement. At the first instance, the Federal Court found that Mizzi’s claim for infringement was not proven, but Morellini’s claim for unjustified threats was successful. However, the Court did not award damages as the trial judge believed that the claim had been abandoned. Both parties appealed, and in Morellini v Mizzi Family Holdings Pty Ltd [2016] FCAFC 1, the Full Court revoked the 955 Patent on the basis of false suggestion or misrepresentation; found that the unjustified threats claim had not been abandoned, and remitted the question of damages for unjustified threats to the trial judge.

Issues and decision

Morellini claimed that MFH’s 2010 notice and related article, and Mizzi’s conversation with Morellini’s customer (collectively Threats), separately amounted to two unjustified threats, which caused him actual damage and reputational
damage. Morellini did not lead any evidence of any specific discussions with prospective customers about the Threats. However, he did give evidence relating to discussions with prospective purchasers before the Threats were made. One such customer was reluctant to purchase Morellini’s product as they were “waiting for this all to be over”, while another contractor was unwilling to build Morellini’s product as he had “heard about what was happening”, both apparently references to the dispute with Mizzi. However, both these incidents took place before the Threats were made. Morellini also claimed that his reputation suffered damage as a result of the Threats, as customers were wary of dealing with him.

The Court rejected Morellini’s claim for damages. First, the judge found that there was no evidence of causation between the Threats and any actual loss or damage suffered by Morellini. Morellini’s evidence regarding the customer and contractor, and their reluctance to deal with him, occurred prior to either of the Threats. While this “reluctance” may have been due to the dispute with Mizzi, Morellini could not prove that it was due to any specific unjustified threat made by Mizzi.

The judge then noted that while damages can be awarded due to injury to commercial reputation, Morellini had not put on any evidence about how his commercial reputation had suffered, or how any commercial exploitation of the technology suffered due to the Threats. Further, the judge noted that Morellini had not attempted to commercially exploit the technology in the period since his invention was found to not infringe the 955 Patent by the Full Court, meaning that it was difficult to make any inference that Morellini or his technology would have experienced greater financial success, but for the unjustified threats. The judge “reluctantly” dismissed the cross-claim for damages, stating while “one may speculate about the possible effects of the threats, I see no proper basis for attributing any part of the disadvantage to either or both of them”.

Implications

This is another important recent case from the Federal Court, which demonstrates some of the difficulties associated with claims for unjustified threats. The case reinforces the need to establish a clear connection between any unjustified threat, and actual loss or damage, for a claim for compensation to be successful. It also illustrates the importance of obtaining clear evidence of loss or damage occasioning from an unjustified threat.

Given Morellini was exposed to a potential adverse costs order as a result of the hearing, the case also demonstrates the fact that unjustified threats cross-claims should not be automatically included in proceedings, as is often the case, where no evidence of actual loss or damage can be obtained.
Australian Patent Office confirms grace period extends to “whole of contents” novelty citations

Rozenberg & Co Pty Ltd. v Velin-Pharma A/S [2017] APO 61

Patent Office Grace period
Whole of contents novelty
Pharmaceutical

The Australian Patent Office has issued an opposition decision notable for the Hearing Officer’s interpretation of the grace period provisions, which were held to extend to “whole of contents” novelty citations (earlier-filed patent applications).

Author:
Ean Blackwell

Jacinta Flattery-O’Brien PhD
Principal, Patent Attorney

Background

Generally, in order to be eligible for patent protection, an invention must be novel and involve an inventive step. Both novelty and inventive step are tested against all information publicly available at the priority date of the application including any disclosures made by applicants or inventors themselves. Publicly available information includes the so-called “whole of content” citations, i.e. Australian patent applications having an earlier priority date but a later publication date than the priority date of the claim under consideration. Such “whole of contents” applications may only be cited in relation to the novelty of an application, and not inventive step.

However, like many other jurisdictions, Australian patent law includes a “grace period”, which effectively removes from consideration disclosures made during a prescribed time period by or deriving from the applicant (or their predecessor) for a patent application (section 24(1) Patents Act 1990 (Cth)). The “grace period” provisions in Australia currently permit a patent application to be validly filed during the 12 months following a relevant disclosure.

At the relevant date of the Rozenburg opposition, Subsection 24(1) stated:

“24 Validity not affected by certain publication or use

(1) For the purpose of deciding whether an invention is novel or involves an inventive step or an innovative step, the person making the decision must disregard:

(a) any information made publicly available, through any publication or use of the invention in the prescribed circumstances, by or with the consent of the nominated person or patentee, or the predecessor in title of the nominated person or patentee; and

(b) any information made publicly available without the consent of the nominated person or patentee, through any publication or use of the invention by another person who derived the information from the nominated person or patentee or from the predecessor in title of the nominated person or patentee;

but only if a patent application for the invention is made within the prescribed period.”
September 2010 and had an earliest priority date of 10 September 2009. During the opposition, Rozenberg & Co. relied on six citations to allege lack of novelty:

Among the six novelty citations, WO 2010/118979 A1 (D13) was raised by Rozenberg & Co as a “whole of contents” citation, as it had a priority date of 7 April 2009 but was ultimately published on 21 October 2010 (i.e., after the filing date of the 197 Application, which was 10 September 2010). D13 was, however, filed in the name of Velin-Pharma A/S (the same applicant as that of the present opposed application).

Velin-Pharma A/S responded that D13 could not be cited as prior art against the opposed application because D13 is subject to the “grace period” provisions of paragraph 24(1)(a) of the Patents Act 1990 (Cth), relating to self-publication by the patent applicant less than 12 months before the filing of the complete application for the patent, and therefore must be disregarded.

Rozenberg & Co. responded at the oral hearing that the date of publication of D13 (21 October 2010) was after the filing date of the opposed application (10 September 2010) and therefore the grace period provisions were not available to disregard D13. Consequently, Rozenberg submitted that D13 could be cited against the opposed application.

Rozenberg & Co.’s submission attempted to argue that the publication of D13, being after the filing date of the opposed application, is not a prescribed circumstance as required by subregulation 2.2(1A), and consequently D13 could not be disregarded as a prior publication against the opposed application.

The Hearing Officer therefore considered whether D13 was part of the prior art on the basis of “whole of contents”.

The grace period also includes information published in a relevant “whole of contents” citation, as decided in Biogen Idec MA Inc. [2014] APO 25 (Biogen).

Thus, a prima facie reading of the information in the above regulations would suggest that for the grace period to apply, the relevant citation must have been published before the filing of the patent application under consideration. Therefore, in many cases, applicants would not enjoy the benefit of the grace period for their own “whole of contents” publications, because they would often be published after the filing date of the application under consideration.

This has long been a matter of uncertainty and debate among practitioners and was tested in the Rozenburg hearing.

**Issues and decision**

Grant of Australian Patent Application No. 2010294197 (197 Application) for a “method for the preparation of micro-RNA and its therapeutic application” in the name of Velin-Pharma A/S was opposed by Rozenberg & Co. The opposition was determined under the law existing before the “Raising the Bar” reforms of 15 April 2013 were implemented. The 197 Application was filed on 10 September 2010 and had an earliest priority date of 10 September 2009. During the opposition, Rozenberg & Co. relied on six citations to allege lack of novelty:

Among the six novelty citations, WO 2010/118979 A1 (D13) was raised by Rozenberg & Co as a “whole of contents” citation, as it had a priority date of 7 April 2009 but was ultimately published on 21 October 2010 (i.e., after the filing date of the 197 Application, which was 10 September 2010). D13 was, however, filed in the name of Velin-Pharma A/S (the same applicant as that of the present opposed application).

Velin-Pharma A/S responded that D13 could not be cited as prior art against the opposed application because D13 is subject to the “grace period” provisions of paragraph 24(1)(a) of the Patents Act 1990 (Cth), relating to self-publication by the patent applicant less than 12 months before the filing of the complete application for the patent, and therefore must be disregarded.

Rozenberg & Co. responded at the oral hearing that the date of publication of D13 (21 October 2010) was after the filing date of the opposed application (10 September 2010) and therefore the grace period provisions were not available to disregard D13. Consequently, Rozenberg submitted that D13 could be cited against the opposed application.

Rozenberg & Co.’s submission attempted to argue that the publication of D13, being after the filing date of the opposed application, is not a prescribed circumstance as required by subregulation 2.2(1A), and consequently D13 could not be disregarded as a prior publication against the opposed application.

The Hearing Officer therefore considered whether D13 was part of the prior art on the basis of “whole of contents”.

The Hearing Officer interpreted subregulation 2.2(1A) as providing a start date for the “prescribed circumstances” of section 24(1)(a) of the Act but not a final date for the period. Thus, the Hearing Officer considered that the “prescribed circumstances” period of section 24(1)(a) effectively extends forward in time without specified limit. The Hearing Officer concluded that the publication of D13, although occurring after the filing date of the opposed application, still met the requirements to be a “prescribed circumstance” in accordance with subregulation 2.2(1A).
The Hearing Officer then interpreted subregulation 2.3(1A) as merely establishing a final deadline (of 12 months after the information was first made publicly available) by which a complete application must be filed, but not giving a start date. Accordingly, the Hearing Officer concluded that the filing date of the 197 Application met the requirements of subregulation 2.3(1A), even though it occurred before D13 was published.

The Hearing Officer further considered that this approach was consistent with that taken in *Biogen*. Consequently, the Hearing Officer concluded that the grace period provisions apply to the publication of D13, and thus D13 was disregarded for the purposes of deciding whether the opposed invention was novel or involved an inventive step.

**Implications**

The *Rozenburg* Decision is likely to benefit patent applicants by providing clarity to the grace period provisions, particularly in respect of whole of contents applications.

It should be noted that the “Raising the Bar” amendments, which came into effect on 15 April 2013, changed the regulations relating to the grace period. Under the current provisions, Regulation 2.2C(2) no longer provides a specific date or time period, specifying that a prescribed circumstance is any self-disclosure that is not covered by a separate regulation. Regulation 2.2C(3), however, still specifies that the prescribed period for making a complete application for the invention is “12 months from the day the information was made publicly available”.


Australian Patent Office clarifies enablement requirements for polypeptide claims

Evolva SA [2017] APO 57

**Patent Office Support Enablement Biotechnology**

Australia has relatively recently implemented support laws (as part of the “Raising the Bar” amendments applicable to applications where examination was requested after 15 April 2013) that require a specification to provide sufficient information to enable the skilled person to perform an invention over the entire scope of the claims without undue burden or the need for further invention. These new support laws have been stringently applied by the Australian Patent Office, in particular in relation to claims defining chemical compounds, such as proteins where, in many cases, the only claims considered to be enabled are ones directed to embodiments exemplified in the specification.

The Patent Office considered the enablement of claims directed to polypeptide sequences covered by at least 90% sequence identity to defined polypeptide sequences.

**Background**

Patent Application No. 2012342114 covers methods and materials for the synthesis of low calorie naturally-occurring sweeteners. Specifically, the sweeteners include glycosylated mogroside compounds produced by methods involving glycosylating enzymes, uridine-5’-diphospho dependent glucosyltransferases (UGTs).

Claim 1 defines a method of producing a mogroside compound, using a UGT polypeptide having at least 90% sequence identity to one of five specific sequences. During prosecution, the Examiner found that it was not reasonable that every single peptide covered by claim 1 would exhibit transverse activity. Moreover, the Examiner also asserted that the skilled person would be required to produce every single peptide covered by the claim and then conduct an assay on each to determine which exhibited the desired activity. This was considered to amount to an undue burden. For these reasons, the claims were rejected for lack of enablement.

**Issues and decision**

In determining whether the claims were enabled, and in particular claims to polypeptides having at least 90% identity to the defined sequences, the Hearing Officer of the Patent Office considered the Explanatory Memorandum to the relevant support legislation as well as European and UK case law. Based on this, the Hearing Officer settled on a two-step enquiry consistent with that taken under UK law (Eli Lilly v Janssen [2013] EWHC 1737).

The first stage involved determining whether the disclosure of the patent, read in the light of the common general knowledge of the skilled person, makes it plausible that the invention will work across the scope of the claim. If so, the second stage required consideration of whether the invention can be performed across the scope of the claim without undue burden.

**Plausibility**

The specific issue considered by the Hearing Officer was whether it was plausible that polypeptides which have as low as 90% identity would exhibit functional activity. According to the relevant European case law, the Hearing Officer found that the requirement of plausibility is a low threshold test where in certain cases a “plausible” or “reasonably credible”
claimed use, or an “educated guess”, can suffice (Human Genome Sciences v Eli Lilly [2012] RPC 6). Notwithstanding the focus on European case law, the Hearing Officer emphasised the fact that near identical claims had been accepted in Europe was of little assistance and that merely referring to the outcome of corresponding overseas prosecution will not discharge the onus on the Applicant to demonstrate enablement of the Australian claims.

In coming to a conclusion regarding the plausibility of the claims, the Hearing Officer referred to a discussion in the specification regarding the manner in which functional UGT homologues may be generated. He also referred to the fact that conservative substitution of amino acids in polypeptides is widely practiced, and that the properties of the resulting variants can be predicted with some certainty, particularly where the active binding regions of the proteins are known, which was true for the relevant UGTs. For these reasons, the Hearing Officer found it plausible that the invention could be worked across the full scope of the claims.

**Undue burden**

In reaching a conclusion on the undue burden part of the enablement test, the Hearing Officer found that the specification provided adequate guidance as to the manner in which UGT variants may be generated and tested, and that this did not present any apparent difficulties that would require the skilled person to undertake any prolonged research or experimentation that would be considered an undue effort. While the work to produce UGT variants could involve a reasonable degree of experimentation or trial and error, and even be time-consuming, the Hearing Officer found that the nature of the work did not appear to constitute a research programme. Accordingly, the specification was found to meet the relevant enablement requirements.

**Implications**

This decision provides much-needed clarity regarding the test for determining enablement of chemical/protein and polypeptide claims and permits Examiners greater latitude for allowing claims directed to subject matter that goes beyond embodiments exemplified in the specification.
Australia’s best method requirement bares its teeth again!

*Kineta, Inc. [2017] APO 45*  
(31 August 2017)

**Patent Office Best method**

In this decision, the Patent Office has followed the Full Court’s decision in *Les Laboratoires Servier v Apotex Pty Ltd* [2016] FCAFC 27 (8 March 2016) and rejected an application for failure to disclose the best method of performing the invention. Given the facts of the case, a single sentence included in the specification would have satisfied the best method requirement. Accordingly, it is crucial that attorneys, when drafting specifications intended for prosecution in Australia, understand Australia’s best method requirements.

**Background**

Patent Application No. 2012315953, filed by Kineta, Inc., disclosed compounds and methods useful for treating viral infection in vertebrates, including RNA viral infections. The Examples described the anti-viral and pharmacological properties of the disclosed compounds. Importantly, however, the Examples did not include any information regarding how any of the compounds could be prepared or obtained.

During prosecution, the Examiner noted that the examples in specification demonstrated that the applicant possessed the compounds of invention and tested them for activity. Accordingly, the Examiner concluded that the applicant must have either synthesised the compounds, or otherwise obtained them, but did not state at least one method of doing so, which is a requirement for disclosing the best method under section 40(2)(aa) of the *Patents Act 1990* (Cth), following the “Raising the Bar” amendments which took effect for applications where examination was requested after 15 April 2013. For this reason, the Examiner rejected the application.

**Issues and decision**

The Deputy Commissioner of Patents considered three issues in determining this case.

1. what is the invention for which a best method must be provided

2. what method is described in the specification; and

3. was the applicant aware of a better method?

In relation to point 1, the Deputy Commissioner determined that the nature of the invention resided in both the identification of new compounds and their use. The Deputy Commissioner also concluded, in relation to point 2 above, that a person skilled in the art would not have appreciated how to prepare any of the compounds from a reading of the specification in the light of the common general knowledge.

In its evidence, the Applicant said that nothing was withheld from the specification because the method of preparing the compounds was contracted to a third party, Life Chemicals Inc. and the applicant was not informed how the compounds were prepared. Ultimately, however, the Deputy Commissioner of

**Author:**

Grant Shoebridge PhD  
Principal, Patent Attorney
Patents found that the applicant knew the compounds could be purchased from the contractor and that this information was not, but should have been, included in the specification. For this reason, it was found that the applicant did not provide the best method of performing the invention.

Notably, in reaching his decision, the Deputy Commissioner of Patents also found that the specification did not comply with section 40(2)(a), in that it did not disclose the invention in a manner which is clear enough and complete enough for it to be performed by a person skilled in the relevant art.

This second finding means that the applicant is likely to face difficulties if they attempt to amend the specification to overcome the lack of best method rejection. In this regard, under a previous incarnation of the Patents Act 1990 (Cth), it was possible to amend a patent specification up until at least the date of grant to include the best method known to the applicant at the date of filing (Pfizer Overseas Pharmaceuticals v Eli Lilly and Co [2005] FCAFC 224). The law, however, that applies to this case means that an amendment of the specification is not allowable if, as a result of the amendment, the specification would claim or disclose matter that extends beyond that disclosed in the complete specification as filed. As the Deputy Commissioner of Patents considers that the specification has not disclosed the invention in a manner which is clear enough and complete enough for it to be performed by a skilled artisan, the addition of the best method in the present application would likely be considered as adding material and therefore not allowable.

Implications

The purpose of Australia’s best method requirement is to ensure that the public is able to enjoy the full benefit of an invention when a patent expires and that a patentee does not deliberately withhold information that gives the best results. In this case, the applicant knew that the compounds could be purchased from Life Chemicals Inc but did not disclose this information.

The majority of applications that are filed in Australia originate in jurisdictions such as Europe and the US, where a best method requirement is not a major consideration. Accordingly, we strongly recommend that foreign patent attorneys discuss the best method requirements with their Australian attorneys with a view, if necessary, to making appropriate amendments to the specification, preferably before filing.
Patent Office rejects application for digital advertising technology; Federal Court to consider

_Rokt Pte Ltd [2017] APO 34_

**Patent Office Manner of manufacture Computer-implemented**

In this case, a method and system for linking a computer user to an advertising message by way of an intermediate engagement offer was held not to be eligible subject matter resulting in refusal of the patent application. The decision has been appealed to the Federal Court and is set to be heard in July 2018.

**Background**

This decision was a final determination in relation to patent application 2013201494 (“the application”), filed by Rocklive Pte Ltd (subsequently Rokt Pte Ltd, “the applicant”) on 13 March 2013.

Following withdrawal of an opposition in relation to the application, the Hearing Officer commenced re-examination. In response to a fifth adverse re-examination report, which maintained that the claims did not define a “manner of manufacture”, that is, the claims were not considered patent eligible subject matter, the applicant requested to be heard.

While the Hearing Officer found that the claims were not directed to patentable subject matter in a decision dated 11 October 2016 (“the original decision”), the applicant was invited to file amendments and present submissions with respect to those amendments.

The present decision relates to the final determination of the matter in light of amendments and submissions dated 11 November 2016, filed in response to the original decision, and further submissions dated 20 June 2017, filed in response to a further re-examination report.

The claims as amended and considered in the present decision relate to a computer implemented method and system for linking a computer user to an advertising message by way of an intermediate engagement offer.

**Issues and decision**

In the original decision, the Hearing Officer determined that the substance of the invention was in: “...the use of analysed data to insert an engagement offer before advertisements, whereby advertisements are only provided to a user if the user accepts the engagement offer, there being no direct advertising benefit to the subsequent advertisers of the selected advertisements other than encouraging positive engagement by the user with the advertising system.”

The applicant’s submissions focused upon the analysis of the law and the appropriateness of the Hearing Officer’s original decision.

In the context of the amendments to claim 1, the applicant submitted that the substance of the invention was in the creation of an ad-hoc,
networked pairing of the user’s computing device (the ‘computer’) with a central server, which interact via a computer program or programs running on each of those two devices. Accordingly, it was the applicant’s view that the amendments clarified that the invention related to two computer programs to interoperate in real time over the internet over an ad hoc network connection. Each of the programs carrying out substantial calculation and processing, including processing that is unique to the user.

In the applicant’s submissions, it is argued that the invention involves ‘an invention in the way in which the computer is utilised’, to use the words in RPL Central [2015] FCAFC 177, and that all the claimed steps involve the creation of custom software to utilise both the user’s computer and the server in a novel way. The applicant concluding that there is a ‘contribution to the claimed invention [that] is technical in nature’.

In relation to the applicant’s submissions on the analysis of the law and the appropriateness of the Hearing Officer’s original decision, the Hearing Officer did not find new arguments that altered the findings of the original decision.

The Hearing Officer considered the applicant’s amendments added the following subject matter to the substance of the invention:

- Multiple engagement offers are ranked (based on certain metrics) and a selection is made of an offer to present based on those rankings
- Collection of data regarding interactions with advertisements is made wherein this data is used for selecting subsequent advertisements

However, the Hearing Officer did not consider the features to add anything more than further specifics to the advertising methodology. The Hearing Officer’s view was that ranking based on non-technical metrics, and collecting further data to use in the future to select subsequent advertisements, are contributions that are simply strategic innovations in the field of advertising for improving customer engagement with ads that amount to a mere scheme.

The Hearing Officer rejected the applicant’s submissions that the invention lies in the way the computer is utilised and was of the view that the claimed features were merely implemented by the “custom software”. With reference to Research Affiliates and RPL Central, the Hearing Officer concluded that the amendments and submissions made by the applicant did not overcome the original decision of Rokt Pte Ltd [2016] APO 66. Accordingly, it was held that the claims were not directed to patentable subject matter and the application was refused.

Implications

This decision adds to a list of computer-implemented inventions rejected by the Patent Office in 2017 for failing to overcome subject-matter objections. However, there will be developments in this area of law as the decision in this case has been appealed to the Federal Court and is set to be heard in July 2018.
Just a “scheme” — Patent Office invalidates claims to GPS-tracking related invention; Federal Court to review

**Todd Martin** [2017] APO 33

**Patent Office Manner of manufacture Computer-implemented**

In this case, a system and method for tracking usage of athletic equipment of an athlete using a computer web-based training log server and a GPS-enabled mobile device was found not to be eligible subject matter. Innovation patent was revoked. The decision in the case was one of a number of Australian Patent Office decisions in 2017 that applied a controversial four step approach from a UK Court decision in Aerotel.

**Authors:**
Tam Huynh  
Senior Associate, Patent Attorney  
Jack Redfern  
Principal, Patent Attorney

**Background**

Todd Martin (the **patentee**) filed innovation patent application 2012/100801 on 31 May 2012.

After being granted and following a request for certification, the innovation patent (the **patent**) was subjected to four adverse examination reports with the outstanding issue being that the claims did not define a “manner of manufacture”; that is, the claims were not considered patent eligible subject matter.

At the invitation of the Patent Office in the fourth examination report, the patentee requested to be heard.

The claims of the patent relate to a system and method for tracking usage of athletic equipment of an athlete using a computer web-based training log server and a GPS-enabled mobile device.

In particular, independent claim 1 relates to a system for tracking usage of athletic equipment of an athlete using a computer web-based training log server, a processor and a GPS-enabled mobile device. Independent claim 5 relates to a method for tracking usage of athletic equipment of an athlete engages in training activities using a computer web-based training log server and a GPS-enabled device.

Claim 5 predominantly focuses on a distance warning system, as compared to claim 1 which defines the recording of further data types such as training time and additionally defines a processor configured to generate a graphical user interface with multiple fields for enabling data entry regarding the use of the athletic equipment.

**Issues and decision**

In the hearing submissions, the patentee primarily relied on two lines of arguments as summarised below:

(i) The patentee asserted that the substance of the claimed invention lay in a combination of integers, only one of which was a computer implementation. With reference to **British Celanese Ltd v Courtaulds Ltd**, (1935) 52 RPC 171, the patentee then argued that the law relating to combinations of interrelated components as per the **British Celanese** case was the most appropriate law for considering whether the claimed invention was a manner of manufacture.
The patentee argued that the combination of interrelated components, including a specifically programmed processor and computer web-based training log server together with a GPS-enabled device, produced a synergistic effect in that the GPS device communicated training data live to the training log server to automatically update the server while the user was training, the result permitting timelier issuance of a warning.

(iii) The patentee also argued that the claimed invention was a technical innovation and thus defined a manner of manufacture. Reference was made to the following statement from Commissioner of Patents v RPL Central Pty Ltd (“RPL”), [2015] FCAFC 177 at [100]:-

“... there is a distinction between a technological innovation which is patentable and a business innovation which is not.”

The patentee argued that the operations within the processor and training log server were technical in nature, and the communication between those integers and the GPS-enabled device were also technical in nature. On this basis, it was argued that the combination of interrelated components, including a specifically programmed processor and computer web-based training log server together with a GPS-enabled device, was thus technical in nature.

The patentee submitted that the combination of claimed integers solved a technical problem of dynamically ascertaining the need to replace or cease use of athletic equipment before such use becomes dangerous or causes injury. Accordingly, it was concluded that the substance of the claimed invention solved this technical problem by issuing a timelier warning to an athlete.

In the decision, the Hearing Officer stated that it was essential to establish the substance of the claimed invention over the form of the claims, as per D’Arcy v Myriad Genetics Inc [2015] HCA 35.

The Hearing Officer determined that the matter rested substantially on the construction of the claims and the supposed contribution to the art. On this basis, the Hearing Officer applied the four step “technical effect” approach outlined in United Kingdom case law thanks to Aerotel Ltd v Telco Holdings Ltd; Macrossan’s Application [2006] EWCA Civ 1371; [2007] RPC 7 at [40]:-

“(1) properly construe the claim
(2) identify the actual contribution;
(3) ask whether it falls solely within the excluded subject matter;
(4) check whether the actual or alleged contribution is actually technical in nature.”

In considering the matter, the Hearing Officer determined that it was appropriate to ignore all elements relating to utilisation of technology, and in doing so asserted that the alleged invention was a scheme for acquiring, monitoring and using training data in real-time to issue a timely warning to the athlete as appropriate, and the contribution to the art was not in any computing aspect of the alleged invention.

The Hearing Officer’s approach is of interest because the High Court did not cite Aerotel in D’Arcy, and the Full Federal Court has referred to Aerotel only in passing while discussing the position in overseas jurisdictions, and in some general Obiter Dicta remarks. However, the Examiner’s approach is consistent with the current Examination Manual.

Ultimately, the Hearing Officer concluded the claims of the patent were not eligible subject matter and revoked the innovation patent.

Implications

This Australian Patent Office decision was one of a number of decisions in 2017 that applied the four step approach from Aerotel. Although a UK decision, the four step Aerotel approach found its way into the Australian Examiner’s Manual as a general principle of examination in August 2017. Accordingly, it is likely that the Aerotel approach will see continued application in the short term.

The decision in this case has been appealed to the Federal Court.
Sydney
Level 21, 60 Margaret Street
Sydney, NSW 2000
P (+61) 2 9777 1111
F (+61) 2 9241 4666

Newcastle
Level 1, Industry Development Centre
University Drive
Callaghan, NSW 2308
P (+61) 2 4921 7366
F (+61) 2 4921 7367

Auckland (New Zealand)
Level 22
BDO Tower
120 Albert Street
Auckland Central 1010
P (+64) 9638 5300

Shelston ip
Intellectual property: mind to market

General
DX 10339
Sydney Stock Exchange
email@ShelstonIP.com
www.ShelstonIP.com