2016 Overview

Welcome to Shelston IP’s round-up of the best patent cases from Australia delivered during 2016.

It was a busy year for Australian patent jurisprudence. Here we report on 11 decisions delivered by the Full Court of the Federal Court of Australia, 7 significant decisions delivered by single judges of the Federal Court of Australia and 2 significant decisions of the Australian Patent Office. As always, there are many examples of issues arising in claim construction, novelty, inventive step, innovative step, fair basis, priority dates and infringement. Less typical issues which received significant attention included the requirements to qualify as an exclusive licensee with standing to sue, patentees’ obligations to sufficiently describe their inventions including the best method known at filing, applications to re-open validity proceedings based on allegedly deficient discovery and estoppels relating to withdrawal of admissions.

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)

Editor
Snapshots of Best Patent Cases (2016)

Full Federal Court Decisions

**Actavis Pty Ltd v Orion Corporation [2016]**
FCAFC 121

**Pharmaceutical Construction Fair Basis Clarity Infringement Exclusive Licensee**

This case illustrates that the Court will not readily read features into patent claims based on selected disclosures in the specification, as well as the benefits of drafting exclusive patent licences using statutory language and making the parties’ intentions as to the effect of the exclusive licence expressly clear. See page 6

**Artcraft Urban Group Pty Ltd v Streetworx Pty Ltd [2016]**
FCAFC 29

**Mechanical Innovation Patent Construction Fair Basis Utility Infringement**

This case illustrates the importance of claim construction issues to infringement and validity. See page 10

**GlaxoSmithKline Australia Pty Ltd v Reckitt Benckiser Healthcare (UK) Ltd [2016]**
FCAFC 90

**Medical Device Construction Fair Basis Omnibus Claim Infringement**

This case highlights the strong commercial position which patent owners can achieve, the vagaries of claim construction, and the importance of, and difficulties associated with, omnibus claims. See page 13

**Konami Australia Pty Ltd v Aristocrat Technologies Australia Pty Ltd [2016]**
FCAFC 103

**Computer-Implemented Construction Fair Basis Inventive Step Innovative Step**

This case demonstrates that it is not necessary to show that each element of a claim is part of the common general knowledge to establish lack of inventive step. See page 16

**Les Laboratoires Servier v Apotex Pty Ltd [2016]**
FCAFC 27

**Pharmaceutical Best Method Amendment**

This case illustrates that it is crucial for an Applicant to disclose the best method of performing an invention known at the time of filing an application. See page 19

**Lynx Engineering Consultants Pty Ltd v The Pilbara Infrastructure Pty Ltd [2016]**
FCAFC 19

**Mechanical Construction Fair Basis Clarity Infringement File Wrapper**

This case confirms the Australian position on the doctrine of prosecution history estoppel. However, the distinction between advocacy and misrepresentation should be noted based on other recent Federal Court judgments. See page 21

**Morellini v Mizzi Family Holdings Pty Ltd [2016]**
FCAFC 13

**Mechanical Novelty Inventive Step False Suggestion Infringement Unjustified Threats**

This case illustrates that the general absence of a doctrine of prosecution history estoppel in Australian practice in no way should be taken as tolerance by the Courts for representations which stray into misdirection. See page 24
Snapshots of Best Patent Cases (2016)

**Multigate Medical Devices Pty Ltd v Braun Melsungen AG** [2016] FCAFC 21

**Medical Device Construction Fair Basis Novelty Incorporations by Reference Infringement**

This case makes a legal distinction between the requirements of internal and external fair basis, and illustrates the benefit of including an incorporation by reference to support priority claims and the importance of claim construction issues to infringement and validity. See page 27

---

**Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd (No 2)** [2016] FCAFC 111

**Pharmaceutical Construction Novelty Inventive Step Infringement Exclusive Licensee**

This case illustrates how crucial claim construction issues can be, the inability of features which merely “elucidate” or “explain” known beneficial uses to confer novelty or inventive step over prior art and the requirements for an exclusive licence of an Australian patent to cover all rights of “exploitation”, without any reservation or qualification. See page 31

---

**SNF (Australia) Pty Ltd v Ciba Specialty Chemicals Water Treatments Ltd** [2016] FCAFC 88

**Chemical Discovery Application to Re-Open Validity Case**

This case demonstrates the high threshold for re-opening cases following final orders on validity, even in light of apparent deficiencies in discovery; Court unlikely to permit a party to rely on a reformulated case advanced for the first time late in a proceeding. See page 35

---

**Upaid Systems Ltd v Telstra Corporation Limited** [2016] FCAFC 158

**Computer-Implemented Construction Infringement**

In this case, leave to appeal was granted due to new, more focused and developed arguments being presented that were not provided to the primary judge. In light of these arguments, it was not found that the appellant had “no reasonable prospect of success”. See page 39

---

**Significant Single Judge Federal Court Decisions**

**Apotex Pty Ltd v Warner-Lambert Company LLC (No 2)** [2016] FCA 1238

**Pharmaceutical Construction Swiss-Style False Suggestion Utility Sufficiency Entitlement Infringement**

This case illustrates that, when considering sufficiency, consideration must be given to the capabilities of the skilled addressee and what is realistically an “undue burden”. The right for a patentee to exploit a patent is not territorially limited. See page 41

---

**Austshade Pty Ltd v Boss Shade Pty Ltd** [2016] FCA 287

**Mechanical Licensing Re-Seller Rights**

This case illustrates how crucial the terms of a licence agreement are, to ensure that the patentee retains a degree of control over its rights after expiry of the licence agreement. See page 44
Snapshots of Best Patent Cases (2016)

Gilead Sciences Pty Ltd v Idenix Pharmaceuticals LLC [2016] FCA 169

**Pharmaceutical Novelty Fair Basis**

**Sufficiency Utility Manner of Manufacture**

**False Suggestion**

This case demonstrates:

(a) the dangers of simply asserting that the claimed compounds “can be synthesized by any means known in the art” if there is no commonly known way of carrying out the required synthesis 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 consequences of claiming compounds that cannot be made. ☞ See page 47

GlaxoSmithKline Consumer Healthcare Investments (Ireland) (No. 2) Limited v Apotex Pty Ltd [2016] FCA 608

**Pharmaceutical Construction Fair Basis**

**Clarity Sufficiency Best Method Inventive Step Infringement**

While it may be obvious to the skilled addressee that the use of a particular word in a claim is a mistake, the hypothetical construct of the skilled addressee cannot be taken so far as to re-write or amend the claim. ☞ See page 50

H Lundbeck A/S v Alphapharm Pty Ltd [2016] FCA 1232

**Pharmaceutical Extension of Term**

**Withdrawal of Admissions Estoppel**

This case illustrates the continuingly hard-fought nature of this litigation (which commenced in 2005) and is another example of the recent trend towards alleged infringers putting the status of the exclusive licensee in issue. ☞ See page 54

Merck Sharpe & Dohme (Australia) Pty Ltd v Genentech Inc [2016] FCA 324

**Pharmaceutical Appeal from Opposition**

**Inventive Step New Prior Art**

This case illustrates the importance for an opponent of putting a full case on all claims to the Patents Office and indicates that appeal may be the only way of seeking to re-open issues arising from the Patent Office decision. ☞ See page 57

Ronneby Road Pty Ltd v ESCO Corporation [2016] FCA 588

**Mechanical Construction Fair Basis**

**Novelty Utility**

This decision demonstrates the potential consequences of including multiple object statements or references to the advantages of the invention within the patent specification, and the importance of providing a sufficient, complete and detailed description of the invention. ☞ See page 60

Significant Patent Office Decisions

Arrowhead Research Corporation [2016] APO 70

**Biotechnology Genetic Patentable Subject Matter**

For a gene-based invention, which is derived from nature, to be considered patent eligible in Australia, it is necessary to demonstrate that the workings of the invention rely, at least in part, on a non-naturally-occurring feature of the claimed invention. ☞ See page 62

International Stem Cell Corporation [2016] APO 52

**Biotechnology Stem Cells Patentable Subject Matter**

A method that includes a step that produces an embryo that cannot give rise to a human being is patent eligible in Australia. ☞ See page 64
Orion and Novartis successfully defend appeal by Actavis and Medis regarding 3-in-1 compositions for treating Parkinson’s disease and challenges to exclusive licence

Read Full Judgment

Actavis Pty Ltd v Orion Corporation [2016] FCAFC 121 (9 September 2016)

Full Court of the Federal Court of Australia (Allsop CJ, Nicholas and Yates JJ)

Pharmaceutical patent claiming compositions comprising levodopa, carbidopa and entacapone for treating Parkinson’s disease

Definition of invention and claim construction, validity (fair basis, clarity), infringement and consideration of what constitutes an exclusive licence conferring standing to sue for infringement

Patent upheld as valid and infringed (but infringement findings reversed on some claims), both validity and infringement hinging on the definition of the invention; licensee held to be exclusive licensee despite its undertaking to procure patent products exclusively from the patentee (but without being positively required to do so), meaning the licensee had standing to sue for infringement

The Parties

The judgment of the Full Court of the Federal Court of Australia (Allsop CJ, Nicholas and Yates JJ) relates to appeals from three separate first instance judgments. The appellants from all three decisions were Actavis Pty Ltd (Actavis) and Medis Pharma Pty Ltd (Medis) as the alleged infringers and parties seeking revocation, and the respondents were Orion Corporation (Orion) as patentee, Novartis Pharma AG (Novartis PAG) as registered exclusive licensee and Novartis Pharmaceuticals (Australasia) Pty Limited (Novartis AUS) as registered exclusive sub-licensee. Actavis and Medis had obtained regulatory approvals for generic levodopa, carbidopa and entacapone combination products and were thereby alleged by Orion/Novartis to have threatened to infringe Orion’s patent.

The Patent

The patent in suit was Australian Patent No. 765932 (2000058306), claiming an invention entitled “Levodopa / carbidopa / entacapone pharmaceutical preparation” (932 Patent). Levodopa is an isomer of D,L-dopa, an amino acid which can reverse or reduce the reduction of dopamine neurotransmitters in patients suffering from Parkinson’s disease. Carbidopa inhibits an enzyme called DOPA decarboxylase (DDC), while entacapone inhibits an enzyme called catechol O-methyl transferase (COMT) – both of which enzymes degrade levodopa. Therefore, the pharmacological effect of administering levodopa with carbidopa and entacapone is to protect the levodopa from being degraded during its passage through the body so as to increase the amount of the levodopa that is able to cross the blood-brain barrier for conversion into dopamine.

The Previous Decisions

The three first instance decisions appealed from were delivered by Rares J:

- Orion Corporation v Actavis Pty Ltd [2015] FCA 909 – in which it was held that:

Authors:

Duncan Longstaff, Senior Associate (Lawyer)
Katrina Crooks, Principal (Lawyer)
the 932 Patent was valid as each of Actavis/Medis’s validity challenges failed: lack of novelty, lack of inventive step, lack of clarity, lack of fair basis, lack of utility; and

Actavis/Medis’s levodopa/carbidopa/entacapone combination products directly infringed the composition claims of the 932 Patent.

- **Orion Corporation v Actavis Pty Ltd (No 2)** [2015] FCA 1026 – which annexed confidential reasons (requested by Actavis) for the decision that Actavis’s combination products infringed claim 17 of the 932 Patent.

- **Orion Corporation v Actavis Pty Ltd (No 3)** [2015] FCA 1373 – in which it was held that Novartis PAG was an exclusive licensee of the 932 Patent with standing to sue Actavis/Medis for infringement. This was despite Novartis PAG having agreed to procure combination products exclusively from Orion, because that was a separate promise (which did not stop Novartis PAG from making its own products) rather than a condition or qualification on the licensed right to “exploit” the invention of the 932 Patent.

The Arguments

- **Definition of the invention**: Actavis/Medis argued that, contrary to the findings of Rares J and the arguments of Orion/Novartis, the 932 Patent disclosed a composition that combined the three active agents in a manner that achieved particular characteristics to solve three identified problems:
  - o the low bioavailability of carbidopa compared with levodopa and entacapone when the three compounds are administered together (bioavailability problem) – Actavis/Medis argued this was solved by use of the method in which a substantial portion of carbidopa is separated from levodopa and entacapone;
  - o incompatibilities with certain excipients leading to instability (stability problem) – Actavis/Medis argued this was solved by using only compatible excipients; and
  - o achieving a three-in-one composition in the form of a tablet that is easy to swallow (size problem) – Actavis/Medis argued this was solved by the solution to the bioavailability problem.

Orion/Novartis argued that the invention was simply the levodopa/carbidopa/entacapone combination product, with characteristics addressing the three identified problems being preferred but not essential.

- **Fair basis**: Actavis/Medis argued that, contrary to the findings of Rares J and the arguments of Orion/Novartis, claims 17 to 22 of the patent were not fairly based because, in each case, the invention as claimed was not limited to require use of a method that:
  - o separates carbidopa from levodopa and entacapone (so as to produce a composition in which a substantial portion of carbidopa is separated from levodopa and entacapone); and
  - o excludes use of the incompatible excipients identified in the specification.

- **Infringement**: Actavis/Medis argued, contrary to the findings of Rares J and the arguments of Orion/Novartis, that combination products would not infringe claims 17 or 18 of the 932 Patent if they were produced by methods in which pharmacologically effective amounts of each of levodopa, carbidopa and entacapone were added in the steps specified in those claims.

- **Clarity**: Actavis/Medis argued, contrary to the findings of Rares J and the arguments of Orion/Novartis, that various claims of the 932 Patent were unclear because:
observed that the 932 Patent specification proceeded by describing various embodiments of the invention which were subsequently claimed, such that the specification could be seen to contain a number of consistory statements for particular embodiments rather than further limitations of the invention. The Full Court did not accept that the 932 Patent specification should be read as proceeding from the starting point that the invention seeks to overcome the three problems identified by Actavis/Medis.

• **Fair basis:** The Full Court affirmed the findings of Rares J that, in light of the definition of the invention of the 932 Patent (which was not limited to compositions with characteristics addressing the identified bioavailability, stability and size problems), its claims were fairly based.

• **Claim construction:** The Full Court overturned the finding of Rares J on the meaning of “comprising” in claim 17, holding that the word “comprises” must yield to the direction that the intended pharmacologically effective amounts of each active agent must be added at the step in the process that is specified for that addition. This was despite the statement in the 932 Patent specification that the use of “comprising...is not intended to exclude other additives, components, integers or steps”.

• **Infringement:** The Full Court overturned the findings of Rares J and held that the products of Actavis and Medis would not infringe claim 17 or 18 of the 932 Patent if they were not produced by methods in which pharmacologically effective amounts of each active agent were added in the steps specified in those claims.

• **Standing to sue for infringement:** Actavis/Medis argued that Novartis PAG was not properly an exclusive licensee because the right of Australian patentees to “exploit” the claimed invention is indivisible, yet Novartis PAG had undertaken to procure levodopa/carbidopa/entacapone combination products exclusively from Orion. Orion/Novartis argued that the exclusive procurement promise was separate to, rather than a condition or qualification of, the exclusive licence to the 932 Patent and further that Novartis PAG was not positively required to procure any products from Orion as it could manufacture the combination products itself.

The Decision

Actavis/Medis’s appeal was dismissed on all grounds, such that the 932 Patent was upheld as valid and infringed and Novartis PAG was upheld as having standing to sue for infringement because it was an exclusive licensee.

• **Definition of the invention.** The Full Court affirmed Rares J’s findings that the invention of the 932 Patent related to a new, oral solid fixed dose composition comprising pharmacologically effective amounts of entacapone, levodopa and carbidopa with at least one pharmaceutically effective excipient, including methods of preparing such a composition and a method of using such a composition in the treatment of Parkinson’s disease. The Full Court did not accept Actavis/Medis’s submission that the “preferable” stability and bioavailability characteristics and ease of swallowing were essential features of the invention described. The Full Court

o “comprise” and “comprises” were ambiguous terms if, contrary to their contention regarding infringement, they meant the claims encompassed additives, components, integers or steps other than those specifically described; and

o “comparable” was ambiguous because it meant something broader than “equivalent” in the context of bioequivalence and therapeutic efficacy.

Standing to sue for infringement

Actavis/Medis argued that Novartis PAG was not properly an exclusive licensee because the right of Australian patentees to “exploit” the claimed invention is indivisible, yet Novartis PAG had undertaken to procure levodopa/carbidopa/entacapone combination products exclusively from Orion. Orion/Novartis argued that the exclusive procurement promise was separate to, rather than a condition or qualification of, the exclusive licence to the 932 Patent and further that Novartis PAG was not positively required to procure any products from Orion as it could manufacture the combination products itself.

The Decision

Actavis/Medis’s appeal was dismissed on all grounds, such that the 932 Patent was upheld as valid and infringed and Novartis PAG was upheld as having standing to sue for infringement because it was an exclusive licensee.

• **Definition of the invention.** The Full Court affirmed Rares J’s findings that the invention of the 932 Patent related to a new, oral solid fixed dose composition comprising pharmacologically effective amounts of entacapone, levodopa and carbidopa with at least one pharmaceutically effective excipient, including methods of preparing such a composition and a method of using such a composition in the treatment of Parkinson’s disease. The Full Court did not accept Actavis/Medis’s submission that the “preferable” stability and bioavailability characteristics and ease of swallowing were essential features of the invention described. The Full Court

o “comprise” and “comprises” were ambiguous terms if, contrary to their contention regarding infringement, they meant the claims encompassed additives, components, integers or steps other than those specifically described; and

o “comparable” was ambiguous because it meant something broader than “equivalent” in the context of bioequivalence and therapeutic efficacy.

• **Fair basis:** The Full Court affirmed the findings of Rares J that, in light of the definition of the invention of the 932 Patent (which was not limited to compositions with characteristics addressing the identified bioavailability, stability and size problems), its claims were fairly based.

• **Claim construction:** The Full Court overturned the finding of Rares J on the meaning of “comprising” in claim 17, holding that the word “comprises” must yield to the direction that the intended pharmacologically effective amounts of each active agent must be added at the step in the process that is specified for that addition. This was despite the statement in the 932 Patent specification that the use of “comprising...is not intended to exclude other additives, components, integers or steps”.

• **Infringement:** The Full Court overturned the findings of Rares J and held that the products of Actavis and Medis would not infringe claim 17 or 18 of the 932 Patent if they were not produced by methods in which pharmacologically effective amounts of each active agent were added in the steps specified in those claims.

• **Standing to sue for infringement:** Actavis/Medis argued that Novartis PAG was not properly an exclusive licensee because the right of Australian patentees to “exploit” the claimed invention is indivisible, yet Novartis PAG had undertaken to procure levodopa/carbidopa/entacapone combination products exclusively from Orion. Orion/Novartis argued that the exclusive procurement promise was separate to, rather than a condition or qualification of, the exclusive licence to the 932 Patent and further that Novartis PAG was not positively required to procure any products from Orion as it could manufacture the combination products itself.

The Decision

Actavis/Medis’s appeal was dismissed on all grounds, such that the 932 Patent was upheld as valid and infringed and Novartis PAG was upheld as having standing to sue for infringement because it was an exclusive licensee.

• **Definition of the invention.** The Full Court affirmed Rares J’s findings that the invention of the 932 Patent related to a new, oral solid fixed dose composition comprising pharmacologically effective amounts of entacapone, levodopa and carbidopa with at least one pharmaceutically effective excipient, including methods of preparing such a composition and a method of using such a composition in the treatment of Parkinson’s disease. The Full Court did not accept Actavis/Medis’s submission that the “preferable” stability and bioavailability characteristics and ease of swallowing were essential features of the invention described. The Full Court

o “comprise” and “comprises” were ambiguous terms if, contrary to their contention regarding infringement, they meant the claims encompassed additives, components, integers or steps other than those specifically described; and

o “comparable” was ambiguous because it meant something broader than “equivalent” in the context of bioequivalence and therapeutic efficacy.
did not restrict its rights to manufacture the combination products itself and did not positively require Novartis PAG to procure the patented products from Orion or a party authorised by it. Even though the exclusive licence agreement included a recital with an apparent qualification that the exclusive licence was “in relation to the Products”, the Full Court did not consider it appropriate to read down the operative licence clause which did not expressly have that qualification.

The Significance

This Full Court decision illustrates that the Court will not readily read features into patent claims based on selected disclosures in the specification. Actavis/Medis were unable to convince the Full Court that characteristics addressing the bioavailability, stability and size problems were essential features of the claimed composition, while Orion/Novartis were unable to convince the Court that the word “comprising” was broad enough that combination compositions produced by processes differing from those claimed would nevertheless infringe.

Perhaps most importantly, this Full Court decision demonstrates that an exclusive licence can be effective, and provide the exclusive licensee with standing, even where the exclusive licensee agrees to procure patented products from the patentee or its agent – provided there is no condition, qualification or restriction on the exclusive licensee’s own rights to make or otherwise “exploit” the invention. The exclusive licence between Orion and Novartis PAG deliberately adopted the exact language of the Patents Act 1990 (Cth) in defining the scope of rights licensed (particularly the statutory definition of “exploit”). It also made clear in a recital that the purpose of the exclusive licence was to enable Novartis PAG to record its exclusive licence on the Register of Patents and thereby provide it with standing to sue for infringement. These approaches assisted Novartis PAG, as it was clear to the Court that the parties intended that Novartis PAG was to be an exclusive licensee as defined by the Patents Act 1990 (Cth) and to have all of the benefits associated with that status. This guidance is particularly valuable to patentees and exclusive licensees following the earlier decision in Bristol-Myers Squibb Company v Apotex Pty Ltd [2015] FCAFC 2 (23 January 2015), in which a licence was held not to be exclusive because the patentee had reserved to itself the right to manufacture the patented products.

The Full Court also commented (without having to decide) that the exclusive licensee (Novartis PAG) took the proper course in not arguing that its Australian subsidiary (Novartis AUS), which it granted an exclusive sub-licence, was an exclusive licensee. The statutory definition of “exclusive licensee” is worded ambiguously and it is arguable that an exclusive sub-licensee could be considered the relevant exclusive licensee of an Australian patent. Nevertheless, at present any exclusive sub-licensee risks having its standing to sue for infringement successfully challenged by the respondent.

**Read Judgment:** Actavis Pty Ltd v Orion Corporation [2016] FCAFC 121 (9 September 2016)
The Parties

The Full Court’s judgment relates to an appeal proceeding (VID 60 of 2015) from a proceeding (VID 853 of 2014) commenced as an infringement suit with a cross-claim of revocation in respect of two innovation patents. In the appeal proceedings, only one innovation patent was in issue, the appellants being Artcraft Urban Group Pty Ltd and its director and general manager John Murray Saint (collectively, Artcraft) as the alleged infringers and the respondent being Streetworx Pty Ltd (Streetworx) as patentee.

The Patent

The patent in suit was certified Australian Innovation Patent No. 2009101103 (103 Patent) claiming an invention entitled “Lighting Assembly” relating to an improved lighting assembly suitable for a range of outdoor uses, particularly in street lighting, and flood lighting for public areas, sporting venues and thoroughfares. This type of lighting assembly was generally known as a “luminaire” and comprised a light source (lamp), a reflector for directing the light, an aperture covered by a lens, an outer casing for lamp alignment and protection, an electrical ballast and connection to a power source.

The specification of the 103 Patent stated at page 10:

“Preferably the components located within the termination chamber as well as the components of the reflector assembly are visible through the visor. A preferred embodiment of the present invention allows a linesman to carry out a visual inspection of the components without having to remove any covers.”

The Previous Decision

The first instance decision appealed from was delivered by Beach J:

- Streetworx Pty Ltd v Artcraft Urban Group Pty Ltd [2014] FCA 1366 – in which it was held that:
  - an Artcraft luminaire product directly infringed claims 1 to 4 of the 103 Patent and claims 1 to 4 of certified Innovation Patent No. 2009101104 (104 Patent);
• **Claim construction:** Artcraft argued that in the 103 Patent the phrase “at least part of the termination chamber being visible through the visor” meant that a linesman was able to carry out a visual inspection of the components of the termination chamber without having to remove any covers. Artcraft relied upon the Page 10 text referring to the Page 10 Text discussing the purpose for the visibility of the visor in relation to a preferred embodiment. Streetworx argued that:

  o there was no error in how the trial judge construed the Phrase, in particular relying on expert evidence as to how a skilled addressee would read the specification of the 103 Patent and applying a purposive construction;

  o in particular that the term “visible through the visor” meant a practical level of visibility so that one can see through the visor the presence of components located within the termination chamber, but not necessarily the components in detail. That is, one can discern that there are components, but one might not necessarily see or need to see what they are. This meant that parts of each of the termination chamber and reflector must be visibly discernible, without necessarily being able to see components in detail; and

  o the need to see what the components are is encapsulated in the preferred embodiment of being able to conduct a visual inspection of the components.

• **Infringement:** Artcraft argued that if it succeeded on its ground of appeal on construction, then the Modified Product would not infringe the 103 Patent. Streetworx argued that if the trial judge’s construction of the Phrase was upheld then the Modified Product infringed the 103 Patent.

• **Fair basis:** Artcraft argued that if the Phrase was properly construed by the trial judge (and hence captured the Modified Product), then the claims were not fairly based as the specification of the 103 Patent only described the termination chamber being visible through the visor to enable a linesman to visually inspect the termination chamber components without removing any covers. Artcraft further argued that there was no disclosure in the specification of the 103 Patent for the broader construction of a practical level of visibility to see the components without observing their details. Streetworx argued that the trial judge was correct in holding that the claims were fairly based on the 103 Patent on the preferred construction of the Phrase, as the need to see the components in detail was only in relation to a preferred embodiment.

• **Utility:** Artcraft argued that if the Phrase was properly construed by the trial judge (and hence captured the Modified Product), then the claims go “beyond” the “promise” of the 103 Patent because the “invention as claimed does not attain the result promised for it by the patentee” – enabling a linesman to visually inspect the components of the termination chamber without having to remove any covers. Streetworx argued that the trial judge was correct in holding that the claims had utility patent on the preferred construction of the Phrase, as the need to see the components in detail was only in relation to a preferred embodiment.

**The Arguments**

The appeal was dismissed by a majority of 2 to 1, so that the 103 Patent was upheld as valid and hence was infringed by the Modified Product. Greenwood J delivered the primary judgment while Jessup J delivered a dissenting judgment. Rares J agreed with Greenwood J but commented on the construction issue using Jessup J’s analysis.
- **Claim construction:** Greenwood and Rares JJ affirmed Beach J’s finding on claim construction that the Phrase meant that the components of the termination chamber only need to be seen but not necessarily their details. Jessup J disagreed noting that the reference to a linesman being able to visually inspect the components was a stated benefit in relation to this particular embodiment, whereas other benefits or advantages of the invention were stated in a separate paragraph in respect of all the described embodiments of the invention.

- **Infringement:** As a consequence of the finding on claim construction, Greenwood and Rares JJ affirmed Beach J’s finding that the Modified Product infringed the relevant claims of the 103 Patent. Jessup J dissented, holding that the Modified Product did not infringe the relevant claims of the 103 Patent based on his conclusions on the claim construction issues.

- **Fair basis:** Greenwood and Rares JJ held that there was a “real and reasonable disclosure” in the specification to support the construction of the term “visible through the visor” in claim 1. Greenwood J relied on the fact that this term was taken from the Page 10 Text, where the benefit of enabling a linesman to carry out a visual inspection of the components of the termination chamber without having to remove any covers related to a preferred embodiment and so was not required in the claims. Therefore, claim 1 was fairly based. Jessup J stated that this ground of appeal would fall away due to his finding on claim construction and infringement. While disagreeing with Greenwood J’s construction of the Page 10 Text, Jessup J deemed that there was sufficient disclosure in the specification of the Phrase for fair basis purposes.

- **Utility:** Greenwood and Rares JJ held that reading the specification of the 103 Patent, several objects and aspects are described in relation to preferred embodiments of the invention. On that reading, including the stated “preferences” of the invention, the result promised by the invention is to solve some of the problems in the prior art with stated “objects”, “aspects” and “preferences” by providing certain features, including a reflector assembly (containing particular components) and a termination chamber (also containing particular components) and a visor of single or unitary construction which encloses both the reflector assembly and the termination chamber in such a way that the components within each chamber are visible through the visor.

Greenwood and Rares JJ held that this promised result did not include a promise that a linesman can look, see and visually inspect the components of each chamber enclosed by the unitary visor without having to remove the enclosing cover – this promised result is only in relation to a preferred embodiment and not the invention in general. Jessup J also stated that this ground of appeal would fall away due to his finding on claim construction and infringement. However, he stated that if the Phrase was construed in the manner stated by Greenwood J, then there would not be any lack of utility.

### The Significance

This Full Court decision shows the difficulties in construing claims for seemingly straightforward and innocuous terms. In this case, the term “visibility” had a variety of meanings, so that the majority felt it could not overturn the trial judge’s construction, resulting in a finding of infringement and validity in terms of fair basis and utility.

The case also illustrates that carefully defining preferred features in a claimed invention provides flexibility in securing enforceable claims while conferring validity – the relevant feature of visibility of the visor was sufficiently broad to capture attempts by Artcraft to modify its products to avoid infringement, yet was expressed as a preferable feature to avoid fair basis and utility attacks. Similarly, the objects and aspects of the invention were limited to embodiments, preventing successful utility and fair basis arguments being used to invalidate the innovation patent.

- **Read Judgment:** Artcraft Urban Group Pty Ltd v Streetworx Pty Ltd [2016] FCAFC 29 (10 March 2016)
The Parties

The dispute was between GlaxoSmithKline (GSK) as the alleged infringer and appellant, and Reckitt Benckiser (RB) as respondent and patentee.

The Patent

The patent in suit was Australian Patent No. 2003283537 for an invention entitled “Improvements in and relating to liquid dispensing” (537 Patent). The invention related to a flat-nosed syringe and bottle neck liner promoted and sold by RB in relation to its Nurofen for Children Product.

The Previous Decision

The first instance Federal Court decision was delivered by Rares J: Reckitt Benckiser Healthcare (UK) Ltd v GlaxoSmithKline Australia Pty Ltd (No 5) (2015) 112 IPR 273; [2015] FCA 486 (20 May 2015) – in which it was held that:

- the 537 Patent was valid for each of the relevant claims 1, 2 to 6 and 9. Each of GSK’s validity challenges on the following grounds failed: not a manner of manufacture, lack of inventive step, false suggestion or misrepresentation, lack of fair basis;
- GSK’s original Children’s Panadol 1-5 years product (First Product) infringed apparatus claims 1, 2 to 6 and 9 of the 537 Patent;
- GSK’s modified Children’s Panadol 1-5 years product (Second Product) infringed omnibus claim 9 of the 537 Patent (but not claim 1).

To illustrate RB’s invention and GSK’s products complained of, Figure 4 of the 537 Patent and photographs of the First Product and the Second Product are provided below.

---

**Authors:**

Greg Whitehead,
Senior Associate (Patent Attorney)

Katrina Crooks,
Principal (Lawyer)
The Arguments

- **Claim construction**: GSK argued that a flat-nosed syringe is one whose barrel terminates at its distal end in a flat face that has a diameter corresponding to the diameter of the syringe barrel and is perpendicular to the barrel axis, and in which the dispensing aperture is formed. RB argued that, in the context of the claims, a flat-nosed syringe is one where the diameter of the flat face corresponds to the diameter of the syringe barrel at the distal end of the barrel (i.e., the portion of the barrel which is received in the “bottle neck liner”).

- **Claim construction**: GSK argued that the primary judge ought to have construed claim 9 by reference to the drawings (Figures 1 to 6) and the corresponding description. RB argued that the primary judge correctly held that claim 9 extends to “the substantial idea disclosed by the specification and shown in the drawings” but is not limited to “the exact expression or illustration of that idea in the patent”.

- **Fair basis**: GSK argued the primary judge failed to give meaning to the word “engaged” in claim 1, with the term requiring a firm interference fit with the effect that the liner and the bottle neck are prevented from separating when in use. RB argued that GSK’s emphasis on the term “engaged” was merely an attempt to shift focus away from the word “sealingly”, which is one of the defined terms in the 537 Patent.

The Decision

The appeal was dismissed by the Full Court (Allsop CJ, Yates and Robertson JJ) in relation to the First Product, other than in respect of the finding of infringement of omnibus claim 9. The appeal was allowed in relation to the Second Product, and the First Product in respect of the finding of infringement of omnibus claim 9.

- **Claim construction**: The Full Court affirmed Rares J’s findings that the skilled addressee would understand that the shape of the barrel that claim 1 specified was one in which the barrel had a generally uniform diameter along its length, apart from the necessary flaring at the proximal end to enable the plunger to be inserted.

- **Claim construction**: The Full Court found that given the consistory statement for the first aspect of the invention finds expression in claim 1, and that the specification makes clear that the example given is of the first aspect of the invention, it must follow that the invention defined in omnibus claim 9 could not be wider in scope than the invention defined in claim 1. The Rares J’s finding that the Second Product did not infringe claims 1 to 6 because the alternative syringe was not the flat-nosed syringe of claim 1, should have led Rares J to conclude, also, that the Second Product did not infringe claim 9.

- **Claim construction**: The Full Court affirmed Rares J’s construction of the term “sealingly engaged”, rejecting GSK’s argument that the manner in which the liner engaged the bottle neck was essential to the invention.

- **Fair basis**: The Full Court found that it did not need to deal with the issue about whether omnibus claim 9, on the construction adopted by Rares J, was fairly based on the matter described in the specification. This matter was resolved by the Full Court’s construction of claim 9. The Full Court, however, commented that it was difficult to see how an omnibus claim, properly construed, could fail for want of fair basis in the required sense.
The Significance

This decision highlights the significant commercial benefits which can be provided to patent owners for mass-produced product inventions. The Full Court’s findings, in particular, illustrate the importance of patent claim construction, particularly in reading the words of a claim with reference to the patent specification as a whole and not to the alleged infringing article. With respect, the Full Court’s decision could be questioned on whether too much was read into claim 1, with perhaps one eye to the preferred embodiment and an overemphasis on the word “the” in the phrase “the diameter of the barrel...” when determining that the syringe of claim 1 must be uniform along its length. It is worth pondering whether the same decision would have been reached had the claim read “a diameter of the finding”.

The decision also illustrates the difficulties which can arise when attempting to prove infringement of omnibus claims. Perhaps most importantly, this Full Court decision provides confirmation that an omnibus claim must be construed, in the same way as any other claim, with particular regard to the nature of the description and examples of the invention in question.

The Parties

This dispute was between Konami Australia Pty Ltd (Konami) as alleged infringer and party seeking revocation, and Aristocrat Technologies Australia Pty Ltd (Aristocrat) as patentee.

The Patents

The two patents in suit were Aristocrat’s Australian Patents Nos. 754689 (689 Patent) and 771847 (847 Patent), both of which related to gaming machines.

The Previous Decisions

The decision appealed from was delivered by Nicholas J: Aristocrat Technologies Australia Pty Limited v Konami Australia Pty Limited [2015] FCA 735 – in which it was held that:

- the 689 Patent was valid and infringed by Konami’s Dreaming Orca’s Free Spin Dragons machine, and
- the 847 Patent was invalid for lack of an inventive step and, consequently, no decision was made as to whether Konami’s Jumpin’ Jalapenos Prize Plus machine infringed on the 847 Patent.

The Arguments

- **Claim construction**
  - Konami argued that, on its proper construction, the 689 Patent did not apply to a machine when the jackpot was triggered by a combination trigger which requires several events or combinations to occur (for example, five aces on the player’s screen). Konami submitted that the term “trigger condition”, used in claim 1, had a particular meaning and would be understood by the notional skilled addressee with the common general knowledge to mean something determined by an event related to turnover. That is, it would not include a combination trigger. Konami relied on several passages from the specification to try and reinforce its submission. In particular, Konami argued

**Authors:**

Garth Berriman,
Trainee Patent Attorney

Matthew Ward,
Principal (Patent Attorney)
that combination triggers were discussed in the background section, but the term trigger condition was not used to describe them.

- The proposition that the relationship between the probability that the trigger condition would occur and the desired average turnover between successive occurrences of the trigger condition had to be “direct” or linear was based on evidence given by Konami’s expert. Although the term “direct” was not used in claim 1, it was used in passages in the description. Konami then interpreted the word “direct” as being “mathematically exact”. Although Konami made use of linear formulas, its argued that due to rounding errors associated with electronic computation they were not “mathematically exact” and therefore did not infringe.

- **Inventive step (689 Patent)** Konami argued that the step of setting the probability of a trigger event as a function of the desired average turnover between jackpots and the amount wagered on each game was anticipated in two sets of documents originating in 1992. The first was a letter from the Queensland regulator to Aristocrat offering a solution to a probability problem that involved using a second random number generator to replace a progressive counter in one of Aristocrat’s machines. The second document set was a series of faxes between Aristocrat offices indicating that use of a machine in which the probability of a jackpot event occurring was made a function of the desired average turnover between jackpots and the amount being wagered, which was known to the Dutch gaming regulators in 1992.

- **Inventive step (847 Patent)** Aristocrat required Konami to prove that each of the integers in the 847 Patent were part of the common general knowledge and made detailed submissions about which integers were part of the common general knowledge and which were not.

The Decision

- **Claim construction:**
  - The Full Court found that the term “trigger condition” as used in claim 1 was broad enough to encompass “combination triggers” and that nothing in the specification would exclude it.
  - The Full Court ruled that the term “direct” was simply intended to mean positively correlated, and not a mathematically exact relationship. It was further found that Konami’s argument that the rounding errors rendered the relationship not mathematically exact was without merit as the relationship could still be direct in the sense the Court interpreted that word.

- **Inventive step (689 Patent)** The Full Court found that the Queensland document did not disclose the feature, as it made no mention about using the second random number generator in such a way as to ensure that the probability of a jackpot event is made a function of the desired average turnover between jackpots and the amount wagered. With regard to the second document set, it was found that the evidence only showed that a man from Holland had thought of creating a machine where the probability of a jackpot event was determined in the same fashion as in the 689 Patent. The evidence did not show that the Dutch regulators were aware of the solution. However, since the “Raising the Bar” amendments to Australia’s Patents Act 1990 (Cth) (which took effect on 15 April 2013) did not apply, the common general knowledge was limited to Australia and this document was of no use to Konami anyway.
• **Inventive step (847 Patent)**: The Full Court rejected Aristocrat’s suggestion that Konami had to prove that each of the integers in the claim were part of the common general knowledge. The first instance trial judge had found that the particular combination of integers was in fact novel, but failed to demonstrate any. Since Aristocrat did not point to any flaws in the reasoning of the judgment in the first instance, but instead focused on the novelty of the integers, the Full Court found that it had failed to advance its argument. Thus, Aristocrat had failed to demonstrate any inventive step and the 847 Patent was found to be invalid.

**The Significance**

The Full Court’s reasons regarding its obviousness findings illustrate that it is not always necessary to prove that every integer forms part of the common general knowledge to establish lack of inventive step. Rather, the Full Court focused on the difficulties overcome or problem solved by the particular combination of integers.

镀锌 Read Judgment: Konami Australia Pty Ltd v Aristocrat Technologies Australia Pty Ltd [2016] FCAFC 103 (12 August 2016)
The Parties
The Full Court’s judgment relates to an appeal by Les Laboratoires Servier and Les Laboratoires Servier (Aust) Pty Ltd (together, Servier) after a Federal Court decision found their patent to be invalid for not disclosing the best method of performing the invention, known to them at the time of filing. The respondents were Apotex Pty Ltd (Apotex) and Symbion Pty Ltd (Symbion).

The Patent
The patent in issue was Australian Patent No. 2003200700, claiming an invention entitled “New salt of Perindopril and pharmaceutical compositions containing it” (700 Patent). Perindopril is a drug used to treat arterial hypertension and heart failure. The 700 Patent claimed an arginine salt of Perindopril which addressed instability exhibited by known Perindopril compositions. The method of preparing Perindopril disclosed in the four-page specification was limited to a single sentence that generically referred to “a classical method of salification of organic chemistry”. At the time of filing, however, Servier had prepared Perindopril arginine by two specific methods, the “1986 method” and the “1991 method”, the latter of which was used to prepare the Perindopril arginine that formed the basis of the stability study of the 700 Patent.

The Previous Decision
The first instance decision appealed from was delivered by Rares J: Apotex Pty Ltd v Les Laboratoires Servier (No 4) [2015] FCA 104 – in which it was held that: (i) the reference to preparation according to a classical method of salification was “pregnant with ambiguity”; (ii) there was insufficient detail to provide a skilled addressee with directions necessary to perform the invention without undertaking potentially extensive trial and error experimentation; (iii) by omitting a sufficient description of a successful method that it had employed, Servier had failed to describe in the complete specification the best method known to it of performing the invention; and (iv) accordingly, the complete specification did not satisfy one of the essential requirements of s 40(2)(a) of the Patents Act 1990 (Cth).

Author:
Grant Shoebridge,
Principal (Patent Attorney)
Following the initial Federal Court decision in relation to best method, Servier sought to amend the patent to introduce the 1986 and 1991 methods of making Perindopril arginine. The allowance of such an amendment is at the discretion of the Court and the primary judge exercised this discretion against Servier and refused to allow the amendment.

The Arguments

• **Sufficiency**: Servier argued that there is no requirement to specify any method of performing an invention where the test for sufficiency of description is satisfied. Such a need only exists where the specification of a method is required to enable the skilled addressee to produce something within the claim without new inventions or additions or prolonged study of matters presenting initial difficulty.

• **Best method**: Servier also argued that the best method requirement was satisfied simply by the identification of the claimed compound and that a best method of producing Perindopril arginine was not essential. Following the initial Federal Court decision in relation to best method, Servier sought to amend the patent to introduce the 1986 and 1991 methods of making Perindopril arginine.

The Decision

The Full Court (Bennett, Besanko and Beach JJ) dismissed Servier’s appeal and found that Servier had failed to describe the best method known to it of performing the invention.

• **Sufficiency**: The Full Court found that the sufficiency and best method obligations are separate requirements, reasoning that if additional information regarding the best method is not included in a specification it could place the patentee in an advantageous commercial position, relative to competitors, for example when the patent expires.

• **Best method**: The Full Court disagreed that the best method requirement was satisfied simply by the identification of the claimed compound. It cited the nature of the invention, namely the increased storage ability of Perindopril arginine, which the experts on both sides agreed could vary depending on the nature of the salt formed – that being method-dependent. Thus, the Full Court found that there is an obligation on the patentee to provide the best method for producing a form of Perindopril arginine that would best fulfill the promise of the invention. The Full Court also reasoned that disclosure of the 1986 or 1991 methods would have saved the skilled addressee from possible “dead ends and false starts” risked in attempting to make the salt by “a classical method of salification” as disclosed in the 700 Patent.

• **Amendment application**: The Full Court also refused an application by Servier to amend the 700 Patent to include the 1986 and 1991 methods of preparing Perindopril arginine. The salient issue considered by the Full Court was the content of correspondence between Servier and its Australian patent attorney during prosecution of the application. Specifically, Servier’s patent attorney made a recommendation to Servier to include a method for the manufacture of Perindopril arginine, even if the method was well known in the art, so as to satisfy the written description requirement. In response, Servier expressed concerns because the method was confidential, and it did not heed their patent attorney’s advice. The Full Court held that Servier erred in forming the view that the proposed amendment was unnecessary and that Servier’s decision to ignore the advice of its Australian patent attorney was not reasonable.

The Significance

This Full Court decision illustrates that it is crucial to disclose in a patent application the best method of performing an invention known to the Applicant at the time of filing. The Full Court decision will also, no doubt, motivate patent litigators to seek discovery in relation to methods known by a patentee but not included in a patent specification.

[Read Judgment: Les Laboratoires Servier v Apotex Pty Ltd [2016] FCAFC 27 (8 March 2016)]
The Parties

Two appeals were brought by Lynx Engineering Consultants Pty Ltd (Lynx) as the patentee of Australian Patent No. 749848, an invention involving bulk transport containers (848 Patent). Respondents included The Pilbara Infrastructure Pty Ltd (TPI), Fortescue Metals Group Ltd (Fortescue), in the first appeal and Bradken Resources Pty Ltd and Bradken Limited (together, Bradken) in the second.

The 848 Patent

The 848 Patent claimed an invention entitled “Side reinforced bulk material transport container”.

The Previous Decision

The 848 Patent itself had a lengthy history. The oppositions to grant were followed by two conjoined appeals: Bradken Resources Pty Ltd v Lynx Engineering Consultants Pty Ltd (2012) 97 IPR 424; [2012] FCA 944. In the primary proceedings, Lynx was unsuccessful in obtaining relief against the respondents for infringement of various claims of the 848 Patent by “Ore Wagons”: Bradken Resources Pty Ltd v Lynx Engineering Consultants Pty Ltd [2015] FCA 1100.

• The essential issue before the primary judge (Nicholas J) was whether, as Lynx alleged, the Ore Wagons “include at least one internal ridge which is integrally formed within said side wall”. In particular the construction of the phrase centred on the meaning of “integrally formed within said side wall” and whether the term “formed” should be given its broader ordinary meaning or a narrower, technical meaning.

• Nicholas J sided with TPI and Bradken in construing the term “formed” and the phrase “integrally formed” as used in claim 1 as requiring that the internal ridge must be formed into the side wall from a piece of material that has been bent, pressed or moulded into shape. Nicholas J dismissed TPI’s attempt to include as evidence a letter from Lynx’s patent attorney to the Commissioner of Patents which favoured the narrow construction (Letter).

Read Full Judgment

Lynx Engineering Consultants Pty Ltd v The Pilbara Infrastructure Pty Ltd [2016] FCAFC 19 (3 March 2016)

Full Court of the Federal Court of Australia (Besanko, Jagot and Edelman JJ)

Patent involving bulk transport containers, and in particular containers used in road and rail transportation

Interpretation of the claims for infringement purposes particularly in view of statements made by the applicant to the Patent Office regarding the meaning of the claims

Ruling confirmed the decision of the primary judge with regard to construction of the claims while rejecting consideration of the 848 Patent Office file as evidence

Authors:

Scott Philp,
Senior Associate (Patent Attorney)

Russell Davies,
Principal (Patent Attorney)
“One plate only is required, and the ridge or ridges are achieved through bending and not through welding or any other connections or fasteners.”

Nicholas J indicated that he had reached his conclusion on the meaning of the claim without regard to the Letter. Therefore, despite suggesting that the application of the doctrine of file wrapper estoppel in Australia to be unsettled, his consideration of its admissibility was unnecessary.

The Arguments

- **Claim construction**: Lynx argued that the primary judge had erred in construing the claims narrowly. It submitted that the technical meaning of “formed” was inapposite in the context of claim 1 of the 848 Patent because a container might not be made of metal or might be a composite of pieces. In the former case it would be nonsensical to speak of “a single piece of metal (e.g., plastics or fibreglass) that has been bent, pressed, or moulded into shape”. Lynx also submitted arguments against the reasoning of the primary judge that “integrally” became redundant in the phrase if the ordinary, rather than technical, meaning were associated with “formed”. Lynx also argued that the primary judge had erred by failing to construe the words “in-built longitudinal structural stiffener” as used in the description in the 848 Patent as having their natural and ordinary meaning, which implies an internal ridge that has been incorporated into the side wall by being joined to the side wall sheet. Lynx submitted that “in-built” meant the same thing as “built in” which involved something that had “become a permanent part of the side wall”.

- **Admissibility of the 848 Patent Office file**: TPI and Bradken submitted, by way of a notice of contention, that the primary judge ought to have admitted the Letter from Lynx’s patent attorney into evidence and then ought to have found that the appellant’s construction of claim 1 was not supportable to the extent it was contrary to that set out in the Letter. It was submitted that the Letter was admissible on two statutory bases:
  - The first was under section 9(1) of the Evidence Act 1995 (Cth) as evidence from a person with “specialised knowledge based on the person’s training, study or experience” involving “an opinion of that person that is wholly or substantially based on that knowledge”. It was further submitted that the Letter was a statement against interest which would not require the opinion giver to be called (Australian Woollen Mills Ltd v F S Walton & Co Ltd (1937) 58 CLR 641, 657; [1937] HCA 51).
  - The second was that the Letter was a business record sent by the agent of Lynx with Lynx’s authority and approval. Bradken asserted that it was admissible under the business record exception to the hearsay rule in section 69 of the Evidence Act 1995 (Cth).

The Decision

Both appeals were dismissed.

- **Claim construction**: The Full Court affirmed Nicolas J’s findings that the correct construction of the term “formed” in the phrase “integrally formed within said side wall” in claim 1 is the narrower technical meaning rather than the ordinary meaning. The Full Court addressed the submission by Lynx that the container might be made of a material other than metal by noting that there was no evidence to suggest that at the date of the 848 Patent application containers had been made of anything other than metal. In any event, there was an analogous use of “forming”, in its technical sense, in relation to plastics. The Full Court disagreed with Lynx’s arguments against the redundancy of the term “integrally”, first because Lynx’s argument required adopting an incorrect meaning of the term; and secondly because of the use of the term “within” textually in the phrase “integrally formed within said side wall”. The Full Court pointed to expert evidence of the view that a ridge which had been added to the inside of a side wall had not been “formed within the side wall”. The Full Court also rejected the argument that “in-built” meant the same thing as “built in”, stating that it is not a legitimate approach.
to interpretation to define one phrase (“in-built”) by reference to different words (“built in”) and then to give it the meaning of those different words.

- **Admissibility of the 848 Patent Office file.** While the Full Court noted that in light of their conclusions it was not strictly necessary to address the notice of contention, nevertheless, they took the time to explain why they would dismiss it. In respect of the first of the bases on which the notice of contention was made, the Full Court noted that the Letter was a submission by the patent attorney on instructions from the patentee and could not be regarded as a statement of opinion under the *Evidence Act 1995* (Cth). Furthermore, the reliance upon Woollen Mills Ltd was misplaced because, in that case, the subjective opinion of the trader was relevant both directly (to his intention) and indirectly (to whether his conduct was likely to deceive, as intended). In addition, there was no evidence to suggest that the patent attorneys were persons who had specialised knowledge in matters such as metal formwork. The Full Court also noted that even assuming the Letter is a business record, and an exception to the hearsay rule under section 69 of the *Evidence Act 1995* (Cth), it does not make it admissible opinion evidence. The Full Court quoted the explanation of French CJ, Heydon and Bell JJ in *Lithgow City Council v Jackson* (2011) 244 CLR 352, 362-363 [19]; [2011] HCA 36, where it was said that section 69(2) “does not provide that the evidence is admissible. It is only admissible if no other exclusionary rule applies”, and that section 76 excludes “[e]vidence of an opinion” not “evidence by a witness of an opinion”.

The Significance

This Full Court decision is significant because it appears to reaffirm the long understood position that, generally, the doctrine of prosecution history estoppel does not apply in Australia, at least to the extent that it does in many other jurisdictions. However, it is noted that in this case inclusion of the submissions made in prosecution were generally moot in terms of the outcome of the judgment. Furthermore, in no way were the submissions made in prosecution to the Patent Office seen to be misleading or fraudulent.

**Read Judgment:** *Lynx Engineering Consultants Pty Ltd v The Pilbara Infrastructure Pty Ltd* [2016] FCAFC 19 (3 March 2016)
Patentee ‘caned’ for use of the phrase ‘It is found…’ in its patent specification

The Parties
Mizzi Family Holdings Pty Ltd (MFH) sued Mr Morellini (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, and damages for unjustified threats of patent infringement.

The Patent
The 955 Patent was directed toward apparatus for a method of planting sugar cane crops whereby short cuttings of sugar cane stalk, known as “billets”, are laid horizontally on a prepared “bed” and covered with soil. The specification described the need to properly position the billets to optimum levels of warmth and moisture so that they sprout and grow into cane plants. The invention also aimed at increasing the number of billets planted across the mound row in order to maximise planting and harvesting efficiency.

The Previous Decision
The primary judge extensively examined the construction of the claims, in view of an argument that the inconsistency as to the features of the mound indicated a lack of clarity and support. While the judge was able to resolve those issues, in the course of the analysis it was revealed by the 955 Patentee that the range of 20° to 60° recited in claim 1 was associated with the natural angle of repose of the soil rather than any warming effect by the sun. Armed with this evidence, and with reference to the specification, the primary judge concluded that any “warming effect” was instead due to the existence of the mound above ground level.

Authors:
Scott Philp,
Senior Associate (Patent Attorney)
Russell Davies,
Principal (Patent Attorney)
Morellini contended that the invention was anticipated by the prior public use of a sugarcane billet planter called the Roncato device. In the invention, the mound is formed after planting of the billets; however, due to an inconsistency in Mr Roncato’s description of his device, the primary judge concluded it was uncertain whether the Roncato device operated in the same manner. Thus, based on the evidence at hand, the invention was regarded as being novel. Furthermore, since the difference between the prior art was regarded to reside in the sequence of steps involved in planting the billets and forming the mound which substantially contributed to the working of the invention, the claims were seen to include an innovative step. However, while the 955 Patent was found to be novel and possessing an innovative step, the primary judge dismissed the claim of infringement and concluded that Morellini’s claims of unjustifiable threats must succeed.

The Arguments

- **Claim construction and Novelty**
  On appeal, Morellini argued for a broader construction of the claims and that any uncertainty in the evidence of prior use was without relevance because, for the purposes of the claims, “it simply doesn’t matter” whether the mounds were formed before or after the billets were planted.

- **False suggestion or misrepresentation**
  Morellini also argued for revocation based on the ground of false suggestion or misrepresentation tied to the notion of an advantageous warming effect due to the angle of the sides of the mound. This relationship is promoted a number of times in the specification, for instance in a passage referred to as the “Statement” in which it was stated that “it is found” that the mound could be much better kept warm using a certain incline on the sides of the mound:

  “In one form, the invention resides in ... profiling the mound such that the soil about the billets is better warmed by the sun’s rays ... It is found that the mound can be much better kept warm by the sun if each side of the mound is an [incline] of between 20°-60° and typically about 40°”

Morellini argued that the Statement comprised representations that not only can the mound be much better kept warm by the sun given the specified angle of incline of the sides, but also, that experiments had been undertaken to establish this as fact. In response, MFH relied on the primary judge’s dismissal of the argument and submitted there to be some advantage in planting cane in a mound and that the “finding” to which the Statement refers is “readily capable” of being Mr Mizzi’s own experience and conclusions. Significantly, however, MFH did not provide any evidence supporting the Statement, admitting they would need to do testing to provide the Court with such evidence.

- **Material Contribution to Grant of the Patent**
  Despite having determined that the representations made were indeed false, the ground of false suggestion or misrepresentation cannot be invoked unless there is a connection between those representations and the grant of the 955 Patent. In *Ranbaxy Australia Pty Ltd v Warner-Lambert Co LLC* (2008) 77 IPR 44, it was found that a patent could be regarded as being obtained by a false suggestion or misrepresentation if the representation materially contributed to the Commissioner’s decision to grant the Patent – even if other circumstances or causes also played a part. The limitation in the 955 Patent that the formed mound be a “shaped mound in which each side of the mound is an incline of between 20° and 60°” was first introduced into the claims of the parent application as an amendment during the course of opposition proceedings. In support of the amendment, it was submitted to the Commissioner, that “the specification teaches that in order for the billets to be kept warm within the mound, the mound should have angled sides” and the Statement was referenced in support.

The Decision

- **Claim construction and novelty**
  The Full Court (Bennett, Greenwood and Yates JJ) rejected Morellini’s submissions and found no error in the reasoning or conclusion of the primary judge on the issues of novelty and innovative step.
• **False suggestion or misrepresentation**
  MFH’s response was rejected by the Full Court, which determined that the Statement clearly conveys a relationship between the stated profile of the mound and the resultant “better warm[ing]” and advances it as a fact which has been “found”. Furthermore, their Honours concluded that the representations were false at the time they were made.

• **Material Contribution to Grant of the Patent**
  The Full Court was not swayed by the degree of separation between the parent case and the 955 Patent, inferring that by association “MFH was intending to present the invention described and claimed in its divisional application as one that was both novel over (the prior art) and involved an inventive step”. Thus, the Full Court agreed that the Statement was intended to contribute, and did contribute, to the Commissioner’s decision to grant the subsequent innovation patent. Notably the Full Court was satisfied of the contribution without input from the Commissioner.

Accordingly, the appeal was allowed and the 955 Patent revoked on the ground of false suggestion or misrepresentation under section 138(3). The claim for damages for unjustifiable threats remitted to the primary judge.

**The Significance**

While Australian courts have generally rejected (e.g., see Bradken Resources Pty Ltd v Lynx Engineering Consultants Pty Ltd [2015] FCA 1100) the notion that what the applicant says during prosecution can be held against the Patentee during later litigation, the general absence of a doctrine of prosecution history estoppel in Australian practice in no way should be taken as tolerance by the courts for representations which stray into misdirection. This is exemplified in this case, which highlights the extent to which courts may go to revoke a patent under section 138(3) of the Patents Act 1990 (Cth), if it is believed the patent was granted due to false suggestion or misrepresentation.

The decision sounds a note of caution to those drafting and reviewing patent specifications. When presented with expected advantages provided by a particular invention, patent drafters should ensure they properly interview inventors and are fully apprised of the basis on which those advantages are put forward. While phrases such as “It is found...” might initially appear innocuous, there is little doubt they are designed to impart a level of legitimacy to a perceived advantage of an invention or feature. If made without due consideration or factual support, their inclusion may be ultimately self-defeating rather than advantageous, particularly if relied upon to establish patentability.

☞ **Read Judgment:** Morellini v Mizzi Family Holdings Pty Ltd [2016] FCAFC 13 (16 February 2016)
The Parties

The Full Court’s judgment relates to two appeal proceedings (VID 681 of 2014 and VID 693 of 2014) from a proceeding (VID 463 of 2013) commenced as an infringement suit with a cross-claim of invalidity in respect of two patents. In both appeal proceedings, the appellant was Multigate Medical Devices Pty Ltd (Multigate) as the alleged infringer and the respondents were B Braun Melsungen AG as patentee and B Braun Australia Pty Ltd as registered exclusive licensee (collectively, Braun).

The Patents

The patents in suit were Australian Patent Nos. 2012258327 (327 Patent) and 201260577 (577 Patent), both claiming inventions entitled “IV Catheter”. The 327 Patent and the 577 Patent relate to a safety needle protecting device used as part of an intravenous (IV) catheter to prevent needlestick injuries. Safety IV catheter devices comprise a needle protecting means which slides to the needle point as the needle is removed from the catheter and permanently blocks the needle point such that the needle point cannot thereafter be inserted into objects or persons.

The 327 and 577 Patents were divisional applications in a chain of divisional applications stemming from Australian Patent Application No. 199895323, which was the national phase application of an international application published as WO 99/08742 entitled “Spring clip as needle tip protection for a safety IV catheter” (Original Ancestor). The Original Ancestor claimed priority to two Priority Applications, one of which was said to disclose the subject matter of the claimed inventions in the 327 Patent and 577 Patent – US Patent Application No. 09/097,170 (Priority Application), filed on 12 August 1998. The 327 Patent had a filing date of 21 November 2012 and the 577 Patent had a filing date of 30 November 2012.

The 327 Patent and the 577 Patent incorporated by reference their immediate parent Patent applications, respectively, but not the Original Ancestor. None of the Patent applications in the chain or the initial national phase application incorporated the Original Ancestor by reference.
The Previous Decision

The first instance decision appealed from was delivered by Pagone J:

- B Braun Melsungen AG v Multigate Medical Devices Pty Ltd [2014] FCA 1110 (17 October 2014) – in which it was held that:
  - the 327 Patent and the 577 Patent were valid as each of Multigate’s validity challenges failed: lack of novelty, lack of sufficiency and lack of “internal” fair basis;
  - the 327 Patent and the 577 Patent were both entitled to the earliest priority date of the Priority Application under “external” fair basis, Pagone J relying on expert evidence of how a skilled person would read the specifications to determine that the references to the Original Ancestor were sufficient to provide an incorporation by reference, even though there was not an expressly stated incorporation by reference;
  - Multigate could not rely on the statutory defence of prior user rights under s119 due to the finding on external fair basis;
  - Multigate’s catheter devices directly infringed the claim of the 327 Patent and claims 1 to 6 of the 577 Patent; and
  - Braun, by establishing infringement of the 327 Patent and the 577 Patent, had defeated Multigate’s claim of unjustified threats.

The Arguments

- **Claim construction**: Regarding the 327 Patent:
  - Multigate argued that “distal end” meant the furthest end point of the needle hub, whereas Braun argued it meant the furthest end region of the needle hub and did not require an end point;
  - Multigate argued that “spaced apart” meant that there is an intended gap between the needle guard and the distal end of the needle hub in the sense of being more than a working tolerance gap, whereas Braun argued it meant that no gap was required and the needle guard and distal end could touch provided that they were not constructed to be connected;
  - Multigate argued that “ready position” meant ready for insertion into the patient, whereas Braun argued it meant any position where the needle tip protrudes from the distal end of the catheter hub;
  - Multigate argued that “resilient portion” did not include the arms that were used to move the needle guard, whereas Braun argued it included the arms that were used to move the needle guard;
  - Multigate argued that “positioned in the interior” meant a majority or all of the needle guard had to be in the interior of the catheter hub, whereas Braun argued it meant a portion of the needle guard had to be in the interior of the catheter hub, which could be less than a majority of the needle guard.

- **Claim construction**: Regarding the 577 Patent:
  - Multigate argued that “preventing further movement” meant that the needle guard had an additional function of stopping movement of the needle tip aside from blocking access to the needle tip, whereas Braun argued it was appropriately given a purposive construction by Pagone J and meant preventing movement of the needle in the distal direction;
  - Multigate argued that “resilient spring clip needle guard” meant a needle guard that is made of a metallic material with spring and resilient characteristics, whereas Braun argued it meant a clip having a resilient feature in the sense of moving back into a position after its static state – there was no limitation as to what material it was made of;
  - Multigate argued that the trial judge did not construe “bump” separately to the term “groove” but referred to the terms as being interchangeable, whereas Braun argued there was no error in how the trial judge construed the term “bump”.

The Arguments
• **Infringement**: Multigate argued that based on its construction of the above terms, its catheter devices did not infringe the 327 Patent or the 577 Patent. Braun argued that the above terms were construed correctly by Pagone J and hence Multigate’s catheter devices infringed both the 327 Patent and the 577 Patent.

• **External fair basis**
  o Multigate argued that the Original Ancestor was not incorporated by reference in the specifications of any of the 327 Patent, the 577 Patent and their predecessor patent applications, and further that the trial judge should not have relied upon expert evidence to support the finding of an incorporation by reference of the Original Ancestor. Multigate also argued that the claims of the 327 Patent and the 577 Patent defined inventions that “distanced” themselves from the invention described in the Original Ancestor and their predecessor patent applications, and so were not “fairly based”.
  o Braun argued that the trial judge was correct to consider that the Original Ancestor had been incorporated by reference in each subsequent divisional application, including the 327 Patent and the 577 Patent, even though there was not an express incorporation by reference. Braun further argued that the trial judge could rely on expert evidence on how a skilled person would read the specifications to determine that references to the Original Ancestor were sufficient to provide incorporation by reference and thus provide external fair basis.

• **Novelty**: Multigate argued that WO 1997/31666 (Kuracina) anticipated the invention of the 327 Patent. Braun argued that there was no such anticipation. Braun did concede that US Patent US 6616630 (Woehr 3) and the Original Ancestor would anticipate the 327 Patent and the 577 Patent if external fair basis requirements were not satisfied.

• **Internal fair basis**: Multigate argued that there was no disclosure (other than the consistory statement) of the term “groove” or the catheter hub feature in the 327 Patent and the 577 Patent as the Original Ancestor had not been incorporated by reference. Braun argued that the trial judge was correct that the Original Ancestor had been incorporated by reference and there was sufficient disclosure of the term and feature in the 327 Patent and the 577 Patent.

### The Decision

The Full Court (Bennett, Yates and Beach JJ) granted one appeal in part and dismissed the other, so that the 327 Patent and the 577 Patent were upheld as valid but the 327 Patent was held not to be infringed.

• **Claim construction**: The Full Court affirmed Pagone J’s findings on each claim construction issue except for the term “spaced apart”. The Full Court instead agreed with Multigate’s construction of this term. This had a flow-on effect on the decision on infringement.

• **Infringement**: The Full Court affirmed Pagone J’s finding that Multigate’s catheter devices infringed the relevant claims of the 577 Patent based on the claim construction issues. However, the Full Court overturned Pagone J’s finding on infringement of the 327 Patent and held that Multigate’s catheter devices did not infringe the 327 Patent due to its construction of “spaced apart”. That is, none of Multigate’s catheter devices had an intended gap between the needle guard and the distal end of the needle hub, and so did not infringe the claim of the 327 Patent.

• **External fair basis**: The Full Court held that the Original Ancestor had not been incorporated by reference into the 327 Patent, the 577 Patent or any of their predecessor Patent applications. The Full Court also held that expert evidence should not be relied upon to determine whether there had been an incorporation by reference of the Original Ancestor. Instead, the analysis should be limited to the text of the patent specification.
The Full Court held that external fair basis only required the claims to be “fairly based on matter disclosed” in the earlier patent specification, which means that for priority date purposes a claim can be fairly based if some part of the overall disclosure discloses relevant matter. Hence, there is a focus on whether in the earlier specification there had been a real and reasonably clear disclosure of the invention that is currently claimed.

The Full Court held that the second reference in the 327 Patent and the 577 Patent to specific figures in the Original Ancestor was sufficient to incorporate the description of those figures by reference. This incorporated part of the Original Ancestor was sufficient to provide a real and reasonably clear disclosure of the claimed inventions in the 327 Patent and the 577 Patent. Therefore, the Full Court affirmed Pagone J’s finding that there was external fair basis in the 327 Patent and the 577 Patent to support the priority claim.

- **Novelty**: Due to the Full Court finding that the 327 Patent and the 577 Patent were entitled to their priority claim, only the Kuracina Patent was considered for novelty of the 327 Patent. The Full Court affirmed Pagone J’s finding that the 327 Patent was novel over the Kuracina Patent because the prior art document did not disclose the feature of a needle guard “positioned in the interior” of the catheter hub as it had the equivalent of the needle guard (the needle trap) always located outside of the catheter hub.

- **Internal fair basis**: The Full Court held that there was sufficient disclosure in Figure 1 to provide fair basis for the term “groove” and the catheter hub feature, even though the Original Ancestor had not been incorporated by reference in the specifications of the 327 Patent and the 577 Patent.

The Significance

This Full Court decision has made a distinction between how internal and external fair basis is applied, whereas it was previously understood that the tests were essentially the same. According to the Full Court, under the Patents Act 1990 (Cth) and Patents Regulations 1991 (Cth) external fair basis only requires the claims to be “fairly based on matter disclosed” in the earlier patent specification. This was in contrast to the requirement for “internal” fair basis that the claims are fairly based on matter “described” in the specification. This distinction means that there is greater flexibility in applying the test of external fair basis compared to internal fair basis – effectively a lower threshold.

This case also indicates that the disclosure in all predecessor patent applications in a chain of divisional applications and priority applications should be included in any divisional application to ensure that there is no doubt as to the entitlement to claim priority. This can be easily done with an explicit incorporation by reference. Otherwise, there is a risk that a divisional application could be found to lack validity due to its priority date being limited to its filing date.

This Full Court decision also illustrates how crucial a single issue of claim construction can be to the determination of infringement and invalidity. The construction of the term “spaced apart” led to a finding of non-infringement of the 327 Patent while the construction of the term “positioned in the interior” led to a finding of novelty of the 577 Patent.

➢ **Read Judgment**: Multigate Medical Devices Pty Ltd v B Braun Melsungen AG [2016] FCAFC 21 (3 March 2016)
Full Federal Court upholds Otsuka’s (other) aripiprazole patent as valid and infringed, again teaching BMS a harsh lesson in exclusive licensing

Read Full Judgment

Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd (No 2) [2016] FCAFC 111 (24 August 2016)

The Parties

The judgment of the Full Court of the Federal Court of Australia relates to an appeal by Otsuka Pharmaceutical Co Ltd (Otsuka) as patentee and Bristol-Myers Squibb Company (BMS) as registered exclusive licensee of a pharmaceutical patent. The respondent was Generic Health Pty Ltd (Generic Health), the alleged infringer and party seeking revocation of that pharmaceutical patent. Generic Health had obtained regulatory approvals for generic aripiprazole products and was thereby alleged by Otsuka/BMS to have threatened to infringe Otsuka’s patent.

The Patent

The patent in suit was Australian Patent No. 2005201772, claiming an invention entitled “Substituted carbostyril derivatives as 5HT1A receptor subtype agonists” (772 Patent). The claimed substituted carbostyril derivatives included the active pharmaceutical ingredient aripiprazole, an atypical antipsychotic agent that is useful for the treatment of disorders of cognitive impairment caused by the treatment-resistant, inveterate and chronic types of schizophrenia.

The Previous Decision

The first instance decisions appealed from were delivered by Yates J: Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd (No 4) [2015] 113 IPR 191; [2015] FCA 634 (29 June 2015) – in which it was held that:

- the 772 Patent was invalid for lack of novelty and lack of inventive step (Generic Health’s other invalidity challenges failed: not a manner of manufacture, inutility, insufficiency and failure to describe best method, lack of clarity, lack of fair basis);
- the supply of Generic Health’s aripiprazole products supply directly infringed the Swiss-type claim 1 of the 772 Patent and indirectly infringed the method claim 7 of the 772 Patent – had those claims been valid (which Yates J found them not to be); and
- BMS was not an exclusive licensee of the 772 Patent with standing to sue Generic Health for infringement because the licence agreement between BMS and Otsuka reserved to Otsuka the rights to manufacture aripiprazole products.

Authors:

Duncan Longstaff,
Senior Associate (Lawyer)

Katrina Crooks,
Principal (Lawyer)
This litigation between Otsuka/BMS and Generic Health concerning the 772 Patent was distinct from the contemporaneous but separate proceedings brought by Otsuka/BMS against Apotex Pty Ltd (Apotex) concerning Australian Patent No. 2002334413, claiming an invention entitled “Low hygroscopic aripiprazole drug substance and processes for the preparation thereof” (413 Patent). As Otsuka had licensed the 772 Patent to BMS under the same licence agreement as the 413 Patent, Yates J found that BMS was not an exclusive licensee of the 772 Patent for the same reasons as he had previously found BMS was not an exclusive licensee of the 413 Patent: see Bristol-Myers Squibb Company v Apotex Pty Ltd [2015] FCAFC 2”.

The Arguments

- **Claim construction**
  - **Association feature**: Otsuka/BMS argued that claims 1 and 7 of the 772 Patent should be read so as to recognise two classes of cognitive impairment caused by the forms of schizophrenia identified, namely those associated with the 5-HT1A receptor subtype and those not associated with the 5-HT1A receptor subtype. BMS/Otsuka contended that Yates J erred by finding in favour of Generic Health’s arguments and:
    - proceeding on the premise that all of the disorders named in the claims are disorders of the central nervous system, associated with the 5HT1A receptor subtype, when the 722 Patent and evidence taught otherwise; and
    - giving no effective meaning to the association feature and, thus, notionally putting it to one side rather than treating it as an essential feature.
  - **Failure to respond feature**: Otsuka/BMS argued that Yates J erred by finding in favour of Generic Health’s arguments and:
    - construing the failure to respond feature as applying to third line (i.e., following two other unsuccessful treatment regimens) or later line treatment, not second line (i.e., following one other unsuccessful treatment regimen) or later line treatment; and
    - treating the failure to respond feature as “arbitrary” and therefore having no effective meaning and, thus, notionally deleting it or putting it to one side rather than treating it as an essential feature.

- **Novelty**: Otsuka/BMS argued that, in light of their contended meaning and significance of the association feature and the failure to respond feature, claims 1 and 7 of the 722 Patent were novel over each of “EP 141”, “US 528”, “Serper” and “Saha”, because none of those prior art documents described either the association feature or the failure to respond feature. Otsuka/BMS argued that Yates J had erred at first instance in finding in favour of Generic Health’s construction arguments, the effect of which was that neither the association feature nor the failure to respond feature was an essential integer which the prior art needed to disclose to destroy novelty.

- **Inventive step**: Otsuka/BMS again argued that, in light of their contended meaning and significance of the association feature and the failure to respond feature, claims 1 and 7 of the 722 Patent involved an inventive step over the common general knowledge, alone or together with either of “Saha” or “Keefe” plus “Serper” together.

Otsuka/BMS argued that the invention was non-obvious, because there was no evidence before the primary judge that any person skilled in the art would try aripiprazole, or even if they might have, that they would have done so with any expectation that it might well be useful. Generic Health argued that Yates J was correct in finding at first instance that the discovery that aripiprazole’s action at the 5HT1A receptor is the reason (or one of the reasons) for its utility cannot provide an inventive step when “Saha” and other prior art had already disclosed that aripiprazole was useful in treating cognitive impairment in patients suffering from chronic schizophrenia.
• **Standing to sue for infringement**: BMS did not contend that its position as licensee of the 722 Patent was any different to its position as licensee of the 413 Patent. Both the 413 Patent and the 722 Patent were licensed by Otsuka to BMS under the same licence agreement. The Full Court had previously upheld Yates J’s primary findings concerning that same agreement – that BMS was not an exclusive licensee of the 413 Patent because the right of Australian patentees to “exploit” the claimed invention is indivisible, yet Otsuka had reserved to itself the right to manufacture aripiprazole. Otsuka/BMS had previously argued in the context of the 413 Patent that the statutory definition of “exploit” included “make” as one of many separate rights covered by a single term.

The Decision

The Full Court’s decision was unanimous, although Beach J delivered separate reasons reflecting a different approach to that adopted by the joint judgment of Besanko and Nicholas JJ concerning the meaning and significance of the phrase “disorders of the central nervous system associated with [the] 5-HT1A receptor subtype” in claims 1 and 7 of the 722 Patent. Otsuka/BMS’s appeals were dismissed on all grounds.

• **Claim construction**: The Full Court rejected Otsuka/BMS’s arguments on the meaning and significance of each of the association feature and the failure to respond feature.

  o **Association feature**: The joint judgment of Besanko and Nicholas JJ upheld the primary findings of Yates J, stating that “the wording of the claims suggests… that (to take one example) treatment-resistant schizophrenia resulting in (i.e., as a symptom) cognitive impairment is a disorder of the central nervous system associated with the 5-HT1A receptor subtype and not that the reference to association with the 5-HT1A receptor subtype is intended as a limitation”.
  
  Beach J agreed with the conclusions of the joint judgment, but provided different reasoning as to why the association feature was not essential to claims 1 or 7 of the 722 Patent:

  “…assuming that [the association feature] constituted a separate integer, claims 1 and 7 would be infected with what patent lawyers would diagnose as **parametritis**. This affliction involves an attempt to re-patent the prior art by limiting claims by reference to a series of parameters not mentioned in the prior art…”

  (emphasis added)

  o **Failure to respond feature**: The joint judgment of Besanko and Nicholas JJ upheld the primary finding of Yates J that the failure to respond feature was arbitrary, rather than technically significant, and that the prior art should not be read down so as to exclude any particular line of treatment, including third or later line treatment, where the patient fails to respond to two or more of the identified antipsychotic drugs. The judgment of Beach J concurred with this finding without commenting further.

• **Novelty**: As the Full Court had upheld Yates J’s primary findings on the construction of the association feature and failure to respond feature, neither of which were held to be essential features of claims 1 or 7 of the 722 Patent, it upheld his Honour’s findings that those claims were anticipated by each of the prior art documents “EP 141”, “US 528”, “Serper” and “Saha”.

• **Inventive step**: As the Full Court had upheld Yates J’s primary findings on the construction of the association feature and failure to respond feature, neither of which were held to be essential features of claims 1 or 7 of the 722 Patent, it also upheld Yates J’s findings that the invention claimed by the 722 Patent was obvious. The Full Court stated that neither of the matters identified by Otsuka/BMS overcame Yates J’s findings that:

  o there would be no reason to read down the prior art to exclude any particular line of treatment, including third or later line treatment, where the patient fails to respond to two or more of the identified antipsychotic drugs;
Consistent with the Full Court’s 2015 decision in the separate proceeding regarding the 413 Patent, this Full Court decision again confirms that, to qualify as an exclusive licensee with standing to sue for infringement, a licensee must be conferred a licence to all forms of “exploitation” of the claimed invention throughout Australia, to the exclusion of the patentee and all other persons: making, hiring, selling or otherwise disposing of a patented product or product of a patented process or method, or using a patented process or method. Loss of standing of a patentee or an exclusive licensee can have significant consequences, as the potential harm to the licensee (which may be commercially exploiting the invention in Australia) may no longer be a major factor in assessing:

- the “balance of convenience”, in the context of an application for an interlocutory injunction to restrain an alleged infringer early in a proceeding; and/or
- the damages ultimately payable if infringement is established, as well as whether or not a permanent injunction is appropriate.


The Significance

This Full Court decision illustrates how crucial a single issue of claim construction can be to the determination of multiple invalidity challenges. It also illustrates the Court critically analysing claims to delineate features which truly constitute features of an “invention” from mere “elucidations” or “explanations” of the scientific mechanisms underlying beneficial uses and effects which were already known. Features which fall into the latter “elucidation”/“explanation” category cannot confer novelty or inventive on a claim, even if they are not expressly disclosed in the prior art – such claims will, in the words of Beach J, be infected by “parametritis”.

o the person skilled in the art would not have understood “Saha” to be disclosing that aripiprazole has a limited utility that is dependent on the medication that had previously been administered to the patient or on the number of times the patient’s previous medication had been switched, as no witness suggested otherwise; and

o the person skilled in the art would have understood from “Saha” that aripiprazole could be used in a method such as that claimed in claim 7 or for the production of a medicament such as that claimed in claim 1 of the 722 Patent.
Full Federal Court denies SNF’s application to re-open patent invalidity proceedings for allegedly deficient discovery by Ciba in long-running litigation

**Read Full Judgment**

SNF (Australia) Pty Ltd v Ciba Specialty Chemicals Water Treatments Ltd [2016] FCAFC 88 (20 June 2016)

Full Court of the Federal Court of Australia (Jessup, Jagot and Nicholas JJ)

Innovation patents relating to flocculants used in treatment of mine tailings upheld as valid and infringed; application to re-open validity based on allegedly deficient discovery prior to first instance trial

Rare application by alleged infringer and party seeking revocation (SNF) to re-open issue of patent validity in light of alleged deficient discovery by the patentee (Ciba); SNF changed its case as to the relevance of the disputed documents in its closing submissions at the hearing

Documents held non-discoverable, even on SNF’s reformulated case; SNF not permitted to rely on its reformulated case as it would have been unfair to Ciba

**The Parties**

The judgment of the Full Court of the Federal Court of Australia (Jessup, Jagot and Nicholas JJ) relates to an application for leave to appeal by SNF (Australia) Pty Ltd (SNF) from a decision refusing SNF’s interlocutory application to re-open the issue of patent validity based on allegedly deficient discovery by the patentee, Ciba Specialty Chemicals Water Treatments Ltd (Ciba). In the original first instance proceeding, Ciba’s five asserted innovation patents relating to processes of treating mine tailings using water-soluble polymers as flocculants were each upheld as valid and infringed. SNF and Ciba (now owned by BASF) were and remain competitors in manufacturing flocculants and supplying them to operators of Australian mines.

**The Patents**

This appeal was part of a long-running dispute between SNF and Ciba concerning Ciba’s Australian Innovation Patents Nos. 2006100744, 2006100944, 2007100377, 2007100834 and 2008100396 (Ciba’s Patents). All of Ciba’s Patents expired on 7 January 2012.

**The Previous Decision**

The decision appealed from was delivered by Davies J: SNF (Australia) Pty Ltd v Ciba Specialty Chemicals Water Treatments Ltd [2016] FCA 787 – in which it was held that:

- certain internal emails and other documents (disputed documents), which had not been discovered by Ciba in its list of documents pursuant to previous discovery orders, were not discoverable;
- as the disputed documents were not discoverable, Ciba was not culpable at any level as there had been no miscarriage of the original hearing caused by its alleged failure to discover those disputed documents;
- apart from the disputed documents not being discoverable, SNF did not exercise reasonable diligence in formulating its invalidity case and acting upon documents which were discovered by Ciba, and

**Authors:**

Duncan Longstaff, 
Senior Associate (Lawyer)

Katrina Crooks, 
Principal (Lawyer)
- even if the disputed documents had been discoverable (which they were held not to be), the public interest in the finality of litigation weighed heavily against SNF’s application to re-open the issue of validity which were “at best tangential”.

The Arguments

- **Discoverability of disputed documents**
  - SNF’s case was that Ciba was obliged to discover the disputed documents because they were directly relevant to its case of lack of innovative step. As noted below, the Full Court upheld the primary finding of Davies J that SNF formulated its case on the relevance of the disputed documents to its innovative step case (impermissibly) differently prior to and during its closing submissions at the hearing before Davies J.
    - SNF’s original argument was that the disputed documents were relevant by disclosing the common general knowledge and/or Ciba’s “development pathway”. The disputed documents included emails authored by Ciba employees during the development of the methods claimed by Ciba’s Patents, including the effect of different aspects, steps and inputs. SNF argued that the obligation of discovery when a lack of innovative step is alleged necessarily extends to documents which are relevant to an understanding of common general knowledge, and that documents which reveal the patentee’s development pathway bear on the extent to which the invention represents an advance over the art.
    - SNF’s reformulated argument was that variations in the inventions of Ciba’s Patents did not involve any material contribution to the working of the inventions, compared to the prior art. The key variations which Kenny J had identified in dismissing SNF’s original invalidity grounds of lack of novelty and lack of innovative step were: (i) the addition of the polymer in the form of an aqueous solution, rather than the prior form of powder or neat emulsion; and (ii) the associated rigidification of the slurry achieved by using this method, rather than the prior processes of settling and sedimentation. SNF contended that the disputed documents evidenced the immateriality of these variations to the working of the methods claimed by Ciba’s Patents.
  - Ciba argued that SNF’s original case was misconceived because assessing innovative step involves only comparing the claimed invention with relevant prior art information and evaluating the materiality of any differences identified from the perspective of the skilled addressee possessed of the common general knowledge. Ciba contended that neither the common general knowledge nor any development pathway are to be compared to the invention in assessing innovative step, and therefore neither is relevant to that ground of invalidity. Ciba contended that SNF should not be entitled to rely upon its reformulated case as a matter of procedural fairness (see below).

- **Culpability of Ciba**: SNF pointed to the lack of an adequate explanation by Ciba of the process by which it determined which documents were discoverable or not, including the process by which documents were selected for consideration by Ciba’s solicitor. Ciba provided what explanation it could through direct evidence of its solicitor and emphasised that discovery had occurred in early 2010, some five years prior to the hearing before Davies J in early 2015.

- **Reasonable diligence of SNF**: Ciba argued that SNF had failed to exercise reasonable diligence in formulating grounds of invalidity and pursuing lines of enquiry, particularly once it had received documents which Ciba did discover.

- **Possibility of different outcome**: SNF argued that if Ciba had discovered the disputed documents, it would have been provided with information which would have enabled it to plead, discover, subpoena (third parties) and prove at trial, invalidating prior uses and
secret uses of the inventions of Ciba’s Patents. Ciba conceded SNF’s argument that, if SNF had amended its case in light of the disputed documents, there was a real possibility that the outcome of the proceeding before Kenny J would have been different.

- **Reformulation of case**: Ciba argued that SNF had reformulated its case in making its closing submissions during the hearing of the re-opening application before Davies J, contending that:
  
  - SNF’s position prior to closing submissions before Davies J had been that Ciba was obliged to discover the disputed documents because they were directly relevant to the common general knowledge and/or Ciba’s development pathway;
  
  - SNF’s position in its closing submissions before Davies J became that Ciba was obliged to discover the disputed documents because they disclosed matters relevant to the variations between the invention and five prior art documents in SNF’s particulars of invalidity before Kenny J;
  
  - in adopting its new position that the disputed documents were relevant to the variations between the invention and prior art, SNF abandoned (rather than maintained as an alternative) its original position that the disputed documents were relevant to the common general knowledge and/or Ciba’s development pathway; and
  
  - SNF should not be permitted to reformulate its case at that late stage given Ciba had filed its evidence, opened its case, cross-examined witnesses and called evidence based on the form of interlocutory application and supporting evidence and opening submissions SNF had led.

SNF denied that its case had changed as it had always pleaded lack of innovative step and the decision of Kenny J on that ground hinged upon her Honour’s consideration of the variations between the invention claimed and the disclosure of each prior art document.

---

**The Decision**

- **Discoverability of disputed documents**: The Full Court upheld the primary finding of Davies J that, even on SNF’s reformulated case, the disputed documents were not relevant or discoverable because they did “not compare the invention to [the prior art documents] at all, let alone compare them for the purpose of identifying any material contribution to the working of the invention by the variations”. The Full Court also confirmed that the disputed documents were not relevant to innovative step on SNF’s original case, accepting Ciba’s arguments regarding the manner in which innovative step is properly assessed.

- **Culpability of Ciba**: The Full Court affirmed the primary finding of Davies J that any culpability of Ciba did not arise given the conclusion that SNF failed to show that any of the disputed documents were discoverable. The Full Court further observed that “unsurprisingly given that discovery was completed in 2010, Ciba’s solicitor could not recall what specific criteria were applied to the exercise at the time” and “on the state of the evidence, Ciba’s culpability could never be anything other than the bald fact that it did not discover the documents”.

- **Reasonable diligence of SNF**: The Full Court upheld the primary finding of Davies J that SNF’s efforts to identify potential grounds of invalidity of the patent were not reasonably diligent, pointing to several circumstances established by the evidence which pointed to the viability of further investigations into possible new claims of prior use and secret use.

- **Possibility of different outcome**: The Full Court did not need to decide whether there was real possibility of a different outcome of the original first instance hearing before Kenny J if the disputed documents had been discovered, because Ciba had conceded this point and the disputed documents were again held not to be discoverable.

- **Reformulation of case**: The Full Court upheld the primary finding of Davies J that SNF had abandoned its original case as to why the disputed documents were discoverable as
This Full Court decision also illustrates the high threshold for a party seeking to re-open a hearing, as it must be clear that the documents which were not discovered clearly should have been in light of the discovery orders made and the case as it was then-pleaded, and further that there was a real possibility the overall outcome of the case would have been different if discovery had been made.

It is also a salient reminder that the Court is unlikely to allow a party to reformulate its case late in a proceeding, particularly during the closing submissions at a contested hearing.

**Read Judgment:** SNF (Australia) Pty Ltd v Ciba Specialty Chemicals Water Treatments Ltd [2016] FCAFC 88 (20 June 2016)

---

**The Significance**

This Full Court decision is a rare example of a party unsuccessful at trial seeking to re-open an issue on which final orders have been made, in light of alleged failure by the counter-party to discover documents of which the unsuccessful party became aware in related disputes in other forums. While the global nature of patent litigation might make scenarios such as these more likely than in other types of commercial disputes, strict rules regarding the confined access, disclosure and use of documents obtained through court and tribunal processes typically prevent documents obtained confidentially or through discovery in a foreign proceeding from being relied upon in Australia.
The Parties
The Full Court’s judgment relates to previous decisions which essentially resulted in dismissal of a claim of infringement of a patent. The appellant was Upaid Systems Ltd (Upaid) as the patentee, and the respondent was Telstra Corporation Limited (Telstra) as the alleged infringer.

The Patent
The patent in suit was Australian Patent No. 2008203853, claiming an invention entitled “Convergent communications platform and method for mobile and electronic commerce in a heterogeneous network environment” (853 Patent). The invention related to handling of mobile services for pre-paid and post-paid service plans.

The Previous Decision
The two first instance decisions appealed from were delivered by Yates J:

- *Upaid Systems Ltd v Telstra Corporation Limited* [2013] FCA 1441 – in which it was held that:
  
  o for each of the 853 Patent and the 646 Patent, infringement particulars filed by Upaid on 8 November 2013 be struck out; and
  
  o Upaid are ordered to file further amended particulars of infringement.

- *Upaid Systems Ltd v Telstra Corporation Limited (No 3)* [2016] FCA 227 (11 March 2016) – in which it was held that:
  
  o for the 853 Patent, amended infringement particulars filed by Upaid on 5 November 2014 be struck out; and
  
  o Upaid indicate to the Court whether it wishes to avail itself of the opportunity to seek further leave to amend its particulars of infringement of claim 1 of the 646 Patent.

Authors:
Nicholas Lakatos,
Senior Associate (Patent Attorney)

Jack Redfern,
Principal (Patent Attorney)
The Arguments

- In relation to pre-paid service plans, Upaid argued that “charging of the account is the recording by Telstra of the MOG fee as a debit in the customer’s account” and “settling of this charge is the use of the pre-paid credit by the reduction in the balance of the customer’s pre-paid credit by the MOG charge”.

- Whilst Upaid also accepted that these two steps were not physically separate steps, there were two steps “with the ‘settling’ step proceeding almost immediately after the ‘charging’ step or the debiting of the pre-paid account”.

- In relation to post-paid service plans, Upaid argued that “the customer’s Telstra account has been charged … by the entry of the debit record” and the debt is “settled by Telstra increasing the balance of the post-paid account in that amount”.

The Decision

Leave to appeal was granted to Upaid, and the dismissal order of the primary judge was set aside. Upaid was ordered to file and serve new particulars, but it will be left to the primary judge to determine the scope of the opportunity to be afforded to Upaid.

In relation to the pre-paid service plan, Yates J’s construction of “charging” and “settling” were adopted and it was also held that these steps were required by claim 1 of the BS3 Patent to be distinct and separate. However, it was also noted that the adoption of Yates J’s construction was contingent upon the meaning of the terms “distinct” and “separate”. In view of Upaid’s arguments, it was found that, although there are “no physically separate steps, we do not see why it cannot be argued with reasonable prospects of success (based on the proper construction of the integers of claim 1) that there are notionally two separate steps”. The first of these steps is the entry of the debit record (charging) and the second being the reduction in the balance of the customer’s pre-paid credit (settling). Even though it was found that the

Upaid case in relation to the pre-paid service plan cannot be said to have “no reasonable prospects of success”, it was accepted that “in fairness to the primary judge … the arguments put before us on this aspect appear to have been more developed and focused than those put to his Honour”.

In relation to the post-paid service plan, and in view of Upaid’s arguments, significant reservations were highlighted with regard to Upaid’s contentions (noting that, in relation to the arguments “one may be forgiven for finding this to be a little counter-intuitive at first”). However, given the findings in relation to the pre-paid service plan that will have to go to trial, Upaid would also be able to argue their case again in relation to post-paid service plans if desired.

The Significance

This case appears to endorse patentees to take infringement action, as the courts seemingly will provide a number of opportunities for a patentee to establish their case. Despite the primary judge ruling some arguments of Upaid to be “nonsensical” and “untenable”, leave to appeal was granted based upon the patentee being given a platform to develop further arguments.

The Parties

Warner-Lambert Company LLC and other members of the Pfizer group (together, Pfizer) commenced separate proceedings in 2014 against each of Apotex Pty Ltd (Apotex) and Generic Partners Pty Ltd (Generic Partners) for anticipated infringement of the claims of Australian Patent No. 714980 (980 Patent). Apotex had previously commenced a proceeding against Pfizer seeking orders revoking the claims of the 980 Patent on the following grounds: the 980 Patent was obtained by false suggestion; lack of sufficiency; lack of utility; and lack of entitlement.

The Patent

The 980 Patent relates to methods of treatment for pain (claims 1-15), and corresponding Swiss-style claims 16-30, wherein the pregabalin compound (the active ingredient in Pfizer’s Lyrica®) is the S-enantiomer of 3-aminomethyl-5-methyl-hexanoic acid (the “(S)-enantiomer”).

The Arguments

• **Claim construction**: Apotex argued that there was an issue to be determined as to the scope of the claims relating to “a method of treating pain”. Apotex argued that the scope of the claims did not extend beyond humans. Apotex argued that claim 3 encompassed just the (S)-enantiomer and the racemate of 3-aminomethyl-5-methyl-hexanoic acid, while Pfizer contended that the reference to “3-aminomethyl-5-methyl-hexanoic” encompassed the (S)-enantiomer, the (R)-enantiomer and any mixture of the two, including the racemate. Apotex argued that there was an issue as to whether “1 mg” used in the specification related to “1 mg” or “1 mg per kilo”.

• **False suggestion**: Apotex contended that, while the most preferred compound of the invention is the (S)-enantiomer, and the claims are to be construed as encompassing the (S)-enantiomer and the racemate of 3-aminomethyl-5-methyl-hexanoic acid, the specification conveyed a false suggestion that the racemate had been tested for the treatment of pain. Pfizer countered that any such suggestion (which it did not concede) would not have influenced the grant of the 980 Patent.

Federal Court finds patent relating to Pfizer’s LYRICA® (Pregabalin) is valid and infringed by Apotex, irrespective of where the medicaments would be made.

**Read Full Judgment**

**Apotex Pty Ltd v Warner-Lambert Company LLC (No 2) [2016] FCA 1238 (12 October 2016) Federal Court of Australia (Nicholas J)**

Pharmaceutical patent consisting of method of treatment and Swiss-style claims relating to the use of certain compounds for the treatment of pain

False suggestion, utility and sufficiency, entitlement, and rights of the 980 Patentee to exploit an invention

All claims found to be valid and potentially infringed.

Authors:

Belinda Hartmann, Associate (Patent Attorney)

Jacinta Flattery-O’Brien, Principal (Patent Attorney)
• **Lack of utility**: Apotex contended that, in view of the data presented, pregabalin is not effective in the treatment of pain that does not involve neuropathic pain or central sensitisation, and therefore, will not work for all of the “pain” conditions identified. Apotex alleged that the clinical relevance of central sensitisation was limited to particular types of pain, while it was Pfizer’s contention that all pain conditions have some element of central sensitisation. Apotex contended that the claims encompassing the (R)-enantiomer were invalid because the compound is not useful for the treatment of any type of pain, citing the examples and published papers and product information for Lyrica®, which demonstrated that the (R)-enantiomer was significantly less effective for the treatment of pain than the (S)-enantiomer.

• **Lack of sufficiency**: Apotex alleged that the invention clearly related to methods for the treatment of pain in humans, but that the specification did not provide sufficient dosage information that would allow the skilled addressee to safely and effectively treat a human patient for pain. Apotex argued that, in view of pregabalin being a new chemical entity at the priority date, the skilled addressee would be required to undertake further research and study to determine an appropriate dosage regime, which imposed an “undue burden”. Apotex cited the costly and laborious nature of the many steps associated with drug development and approval, and alleged that inventive matters may arise during any one of the steps. Apotex also argued that Pfizer had additional relevant safety data at the priority date that was not, but should have been, included in the specification. Pfizer countered this allegation by submitting the relevant question was whether the skilled addressee “could” choose to perform the invention, and not whether, for example, a clinician ”would” choose to use the invention in the absence of approved dosage ranges.

• **Lack of entitlement**: Apotex alleged that the inventor, Mr Singh, did not invent the use of the racemate to treat pain because he did not reduce it to practice.

• **Infringement**: Apotex had conceded that, if the method of treatment claims were valid, then it threatened to infringe them. However, Apotex contended that they would not be infringing any of the Swiss-style claims because the medicaments would be made outside of the “patent area” (i.e., Australia) by a third party, and subsequently imported and sold. Apotex contended that, in the context of the definition of “exploit” provided in Schedule 1 of the *Patents Act 1990* (Cth), the act of making the medicament is the exploitation of the invention, and this should be limited to the “patent area”.

The Decision

• **Claim construction**: The Court (Nicholas J) found that there was no issue to answer and the “claim will be infringed if a person administers a therapeutically effective amount of the relevant compound to a patient in need of treatment for pain for the purpose of providing such treatment even though the treatment may not be effective in that patient” [129]. Nicholas J found that the claims were not limited to humans. Claim 3 was construed by Nicholas J as relating to the (S)-enantiomer and the racemate of 3-aminomethyl-5-methyl-hexanoic acid. Nicholas J found the “1 mg” related to a weight-based dosage calculation.

• **False suggestion**: Nicholas J considered that the test for false suggestion was two-fold, in that the suggestion must have been made (though not necessarily expressly), and that the false suggestion must have deceived or misled the Commissioner in a manner that caused or contributed to the grant of the 980 Patent. Nicholas J found that the claims were not limited to humans. Claim 3 was construed by Nicholas J as relating to the (S)-enantiomer and the racemate of 3-aminomethyl-5-methyl-hexanoic acid. Nicholas J found the “1 mg” related to a weight-based dosage calculation.

• **Utility**: The relevant principles were the same for both issues, in particular, that a claimed invention is only required to give the public a useful choice, and the promised advantages of any invention need not be achievable in all cases or with the same degree of success.
Nicholas J considered the expert evidence indicated that, to differing degrees, central sensitisation is involved in all pain states, and the use of pregabalin would provide any patient with pain with some relief, albeit minor in many cases. Nicholas J was not persuaded that the (R)-enantiomer would not be useful for the treatment of pain when administered at high doses consistent with the upper ranges of the doses recited in the specification. Apotex did not provide any evidence to the contrary. That the (R)-enantiomer was not commercially relevant did not confer a lack of utility. The claims were found to satisfy the requirements of section 18(1)(c) of the *Patents Act 1990* (Cth).

**Sufficiency** Nicholas J clarified that an invention cannot be insufficient just because the skilled addressee may be required to perform complex work that requires significant input of time and resources to perform an invention, provided the work is within the capability of the skilled addressee. Moreover, His Honour made a clear distinction between the work required to “check or test an invention or obtain regulatory approval for its use, and work necessary to perform the invention” [271]. Regardless, his Honour was not persuaded that the work required to obtain regulatory approval of a new drug would necessarily require inventive input. Nicholas J determined that the specification provided enough information to enable the working of the invention, thereby satisfying section 40(2)(a) of the *Patents Act 1990* (Cth).

**Lack of entitlement** His Honour stated that Mr Singh’s status as inventor was not dependent on whether he had personally used or tested any of the claimed compounds. In view of there being no evidence presented that Mr Singh had not conceived the invention, there was no finding of lack of entitlement in accordance with section 138(3)(a) of the *Patents Act 1990* (Cth).

**Infringement** Nicholas J rejected Apotex’s submission in defence of infringement of the Swiss-style claims, with the decision turning on what it means to “exploit” an invention. As “exploit” encompasses the act of importation into, and sale of a product in, the patent area, wherein the product is made using a process patented in the patent area, infringement is not avoided simply by making the product outside of the patent area.

**The Significance**

This decision demonstrates that the work required to perform an invention in view of the information provided in the specification may be considerable, but provided it is within the capability of the skilled addressee and is relatively routine, this does not represent an “undue burden” and the specification will be sufficient. The decision also confirmed that importation and sale of a product made outside of Australia using a patented process is not a defence to infringement.

> **Read Judgment:** Apotex Pty Ltd v Warner-Lambert Company LLC (No 2) [2016] FCA 1238 (21 October 2016)
Federal Court finds patent owner unable to enforce its rights against re-sellers

Read Full Judgment

Austshade Pty Ltd v Boss Shade Pty Ltd [2016] FCA 287 (23 March 2016)

Federal Court of Australia (Dowsett J)

Patents relating to tilt-adjustable shade apparatus

Rights of licensee to sell licensed products to re-sellers, and rights of re-sellers to continue to sell products after expiry of original licence. Whether modifications to articles are permanent or reversible

Court found that the patentee’s rights were exhausted, and that there was no obligation on the re-seller to not sell the patented products, and that no infringement had occurred. Further, that alterations to the articles were considered to be irreversible, meaning that the articles did not infringe certain patent rights.

The Parties

The second applicant, Ekkehard Koehn (Koehn) was the sole director of the first applicant, Austshade Pty Ltd (Austshade). The third respondent, Holger Bauer (Bauer) was the sole director of the first and second respondents, Boss Shade Pty Ltd (Boss Shade) and (Bauer Investments) respectively. The fifth respondent, Stefan Bauer (Bauer) was the sole director of the fourth respondent Bernhel Pty Ltd (Bernhel).

The Patents

The first patent in suit was Australian Standard Patent No. 2003204148, claiming an invention entitled “Tilt-adjustable shade apparatus” (148 Patent). The 148 Patent purported to address the problem of adjusting the configuration of the shade apparatus to maximise the extent of shade available as the earth moves relative to the sun.

The second patent in suit was Australian Innovation Patent No. 2012100717, which concerned a shade apparatus, not limited to an apparatus which is tilt-adjustable (717 Patent). The 717 Patent primarily concerned the use of a hollow “standpost”, containing a winding mechanism for adjusting the umbrella by use of a handle located at the lower end of the standpost. Koehn also owned Australian Design Registration No. 200717590 relating to “an extrusion” (Design Registration).

The Background

In 2009, Austshade and Koehn commenced proceedings against Boss Shade and Bauer for infringement of the 148 Patent and the 717 Patent. These proceedings were settled in accordance with the terms of a Deed of Settlement executed on 30 November 2010 (Deed).

In the Deed, Austshade and Koehn granted Boss Shade a non-exclusive licence to exploit the 148 Patent and the 717 Patent (Licence). The Licence was terminated on 24 January 2011 following which, in accordance with the Deed, Boss Shade was permitted to sell the relevant umbrellas for a further 6 months, until 24 July 2011. The Deed did not place restrictions on Boss Shade as to whom it was entitled to sell the relevant umbrellas.

Authors:

Stuart Hughes, Associate (Lawyer)

Katrina Crooks, Principal (Lawyer)
Accordingly, Boss Shade on-sold all relevant umbrellas which it had in stock to Bernhel and Bauer, at some point around 24 July 2011. Prior to the sale, the umbrellas were modified to remove the “tilt action”, in an effort to avoid infringing the 2013 Patent.

The Arguments

- **Patent infringement**: All parties accepted that the original umbrellas created by Boss Shade would infringe the 148 Patent, the 717 Patent and the Design Registration, but for the Deed. The applicants argued that the sale of the umbrellas by Bernhel and Bauer infringed the 148 Patent and the 717 Patent, as Bernhel and Bauer were not parties to the Deed, and the sales took place after the expiry of the Deed, and that Boss Shade and Bauer acted in concert with Bernhel. In relation to the 148 Patent, Bernhel and Bauer argued that the modification to the umbrellas prevented the distal portion of the lateral arm from rotating around the spigot, that the modification avoided the 148 Patent, and that the modification was permanent or “nearly impossible” to remove. Koehn and Austshade, in turn, argued that it was possible to remove the modification from the umbrellas.

- **Exhaustion of patent rights**: The respondents argued that the sale of the umbrellas by Boss Shade to Bernhel was permitted by the Deed, and that Bernhel took possession of the umbrellas without any restriction, or notice of any restriction, upon its right to resell the umbrellas, according to the decision in *National Phonograph Company of Australia Ltd v Menck* (1911) 12 CLR 15. The respondents argued that as a result of the exhaustion of patent rights, any re-sale of the umbrellas by Bernhel would not infringe the 148 Patent or the 717 Patent. The applicants argued that Bernhel and Bauer were aware of the Deed, and Boss Shade’s obligations in relation to it. The applicants also argued that the decision in *National Phonograph* should be limited in its application, and should not apply in the case of large scale reselling. The applicants also submitted that the sale from Boss Shade to Bernhel was a “sham” and was not an arm’s length transaction.

- **Design infringement**: The applicants made the same arguments in relation to the infringement of the Registered Design as with the 148 Patent and 717 Patent. The respondents relied on the exhaustion of design rights, as it did in relation to the exhaustion of patent rights.

- **Copyright infringement**: whether certain images used were original works.

The Decision

The applicants’ case was dismissed in its entirety by the Court (Dowsett J).

- **Patent infringement**: Dowsett J found any attempt to reverse the modification would involve significant difficulty and a risk of damage to the umbrella, and as a result, for all practical purposes, the modification was irreversible. Dowsett J then found that claim 1 of the 148 Patent contemplated a device in which the distal portion of the lateral arm could rotate about its longitudinal axis, effectively allowing it to “tilt”. As the modified umbrellas were not, on any view of the evidence, tilt-adjustable, the first claim and the dependent claims of the 148 Patent were not infringed by the modified umbrella.

- **Exhaustion of patent rights**: Dowsett J found that all alleged infringements by the respondents occurred after Bernhel had obtained title to them. A fundamental aspect of the Deed was that Boss Shade was entitled to sell the patented umbrellas, including for 6 months after the licence was cancelled. No terms of the Deed limited Boss Shade’s right to sell the umbrellas by stipulating that any purchaser was to be an end-user, or that sale for the purpose of re-sale was forbidden. Further, nothing in the Deed limited the ownership rights which might be acquired by a purchaser. Accordingly, Boss Shade’s sale of the umbrellas to Bernhel was permitted by the Deed, and Bernhel took possession of the umbrellas free of any obligation imposed upon Boss Shade, and Bernhel was entitled to use and dispose of those goods as it saw fit. Accordingly, re-sale of umbrellas did not infringe the 2013 Patent (even without the modification) or the 717 Patent.
• **Design infringement**: For the same reasons, Dowsett J found that the applicants’ design rights had been exhausted, and that resale of the umbrellas by Bernhel did not infringe the applicants’ design rights.

• **Copyright infringement**: Dowsett J found that images did not infringe any copyright owned by the applicant, and noted that the applicants should have assisted Dowsett J to a greater degree by putting on evidence regarding the similarities between the images.

**The Significance**

This decision illustrates how important it is for patent owners to carefully consider any licensing arrangements they may have with third parties, particularly when settling intellectual property disputes. In particular, patent owners should consider restricting the ability for licensees to sell products to re-sellers, which could result in the licensed goods continuing to be sold in the marketplace well after the expiry of any licence agreement. Further, obligations should be placed on licensees to inform any third parties about any restrictions on the goods which are in the licence agreement. Such terms will always need to be carefully balanced against restrictions on exclusive dealing and misuse of market power under the *Competition and Consumer Act 2010* (Cth).

The decision also provides a good outline of how and when modifications to an article allowing it to avoid infringing a patent will be considered to be irreversible and final.

☞ **Read Judgment:** Austshade Pty Ltd v Boss Shade Pty Ltd [2016] FCA 287 (23 March 2016)
Gilead triumphant regarding its Hepatitis C virus (HCV) drug, sofosbuvir, as Federal Court invalidates Idenix’s patent for insufficiency and inutility

The Parties

Gilead Sciences Pty Ltd (Gilead) wanted to sell a new drug, sofosbuvir, for the treatment of Hepatitis C virus (HCV) in Australia. However, Idenix Pharmaceuticals LLC, Università degli studi di Cagliari, Centre national de la recherche scientifique and Université De Montpellier (collectively, Idenix) contended that sofosbuvir infringed their Australian patent. Gilead conceded that sofosbuvir infringed some of the claims but contended that the patent was invalid. The Federal Court’s judgment (Jagot J) relates to the validity of Idenix’s Australian patent.

The Patent

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

The Arguments

• **Internal fair basis.** Gilead contended that there was no real and reasonably clear disclosure in the specification of (a) a compound within claim 7 having F at the 2’ down position of the sugar ring (i.e., R^{13} = F) with a methyl at the 2’ up position (i.e., R^{12} = CH_{3}), (b) a nucleobase including natural bases and (c) a prodrug element only at the 5’ position, but that such compounds were within claim 7 and the dependent claims.

• **Sufficiency (the synthesis issue).** 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 attempts to make a 2’ methyl (up), 2’ fluoro (down) nucleoside (i.e., R^{12} = CH_{3} and R^{13} = F in claim 7) over the relevant time period. 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.

Authors:

Serena White,
Patent Attorney (Australia, New Zealand, United Kingdom, European qualified)

Charles Tansey,
Principal (Patent Attorney)
and the 084 Patent. Idenix also 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 addressee would do. However, Jagot J did not look favourably on the failure of Idenix to call on any of the scientists involved with the Idenix work to give evidence with no suggestion that they were unavailable. Jagot J weighed up the Idenix documents with the other available evidence including written evidence and cross-examination of numerous experts. Her Honour expressed concerns about the way in which some experts approached the 084 Patent and suggested that those concerns were confirmed by their evidence.

• **Sufficiency (the treatment issue):** Jagot J accepted Idenix’s submissions that since claims 7 and 8 were claims directed to compounds there was no requirement that those compounds were effective for treatment. However, this did not assist Idenix because claims 7 and 8 had already been determined to lack sufficiency on the synthesis issue. Regarding claims 10, 12 and 13 (directed to pharmaceutical compositions comprising an effective amount of the compound or pharmaceutically acceptable salt thereof to treat an infection or an infected host) and dependent claims, Jagot J noted that the 084 Patent did not disclose any biological data and it did not provide any guidance by which a skilled addressee would select one compound over another in order to make a compound with the relevant antiviral activity.

• **Inutility (inclusion of compounds that cannot be made):** Jagot J held that if Gilead had proved that particular compounds within the scope could not be made – specifically those where Y in the formula in claim 7 is bromine or iodine – 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 in which Y is bromine or iodine.

• **Inutility (inclusion of compounds which are not useful in treating flaviridae infections):** Idenix argued that the “promise” of the invention could rise no higher than that the compounds of the invention are useful in the treatment of at least one of the flaviridae infections in at least one of a human or an animal and that “usefulness” may take a number of forms, including the compound either alone or in combination with another compound (which may or may not be a compound of the invention) having at least some level of antiviral activity against at least one of the flaviridae virus in either a human or an animal.

• **Manner of manufacture:** Gilead argued that claim 7 and dependent claims represented an arbitrary selection of different components from a broad range of possibilities or an attempt to define a multitude of theoretical compounds, compositions or uses of such compounds, irrespective of whether or not those compounds could have been made by the skilled person at the priority date or would have been understood by the skilled person as useful at the priority date. Idenix submitted that Gilead’s case on this issue was difficult, if not impossible, to separate from its contentions of lack of sufficiency and inutility.

• **False suggestion:** Gilead did not identify any authority to support its submission that a patent may be construed other than as the skilled addressee would construe it or identify a principled basis for such an approach. Gilead conceded that, if construed as the skilled addressee would construe it, none of the alleged misrepresentations was made by the 084 Patent.
The Decision

The 084 Patent was found to be invalid for insufficiency and inutility.

- **Novelty**: Jagot J considered the priority entitlement of claim 7 of the 084 Patent in detail in the context of two earlier applications from which the 084 Patent claimed priority. Her Honour found that claim 7 (and the dependent claims) were entitled to a priority date which was earlier than the priority date of the 860 Patent so the 860 Patent could not deprive the 084 Patent of novelty.

- **Internal fair basis**: Jagot J did not find a lack of internal fair basis.

- **Sufficiency (the synthesis issue)**: Jagot J found the 084 Patent to be insufficient. Jagot J concluded that in 2002 there was no commonly known method of introducing fluorine into a nucleoside at the 2’ down position (R13 = F in claim 7) at all. Her Honour agreed with Gilead’s position that key parts of the affidavits and oral evidence of the experts were explicitly based on information that was plainly not common general knowledge at the relevant date. Critically, Jagot J concluded that Gilead had established that, armed with common general knowledge, the skilled addressee could not make something within claim 7 without new inventions or additions or prolonged study of matters presenting initial difficulty. Therefore claims 7 and 8 were found to be insufficient.

- **Sufficiency (the treatment issue)**: Jagot J rejected the contention that the skilled person, relying on the 084 Patent and common general knowledge, could make any rational selection of classes of compound from the trillions available to screen for anti-viral activity. Her Honour was of the opinion that such a screening process (which would of course also require synthesis of the compounds to be screened) would amount to a research project which exceeds the level of work permitted for a patent to comply with s40(2)(a). Thus claims 10, 12 and 13 were also found to be insufficient.

- **Inutility**: Jagot J concluded that inutility was established because the 084 Patent included compounds which could not be made.

However, inclusion of compounds which were ineffective but could be made did not attract a similar finding of inutility.

- **Manner of manufacture**: Jagot J considered it highly relevant that sofosbuvir, which Gilead admitted infringed claim 7, was said by Gilead to be a highly efficacious compound. In the opinion of Jagot J, this indicated that Gilead’s case, however it was put, was founded on the insufficiency and inutility of the 084 Patent rather than the claimed compounds not being a manner of manufacture. Jagot J did not find the 084 Patent to lack a manner of manufacture.

- **False suggestion**: Jagot J did not accept that the 084 Patent was obtained by false suggestion or misrepresentation.

The Significance

The issue of insufficiency dominates this decision. As noted above, establishment of insufficiency of claim 7 followed from the conclusion that, armed with common general knowledge, the skilled addressee could not make something within claim 7 without new inventions or additions or prolonged study of matters presenting initial difficulty.

In the context of insufficiency, this case demonstrates:

- 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; and

- 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.

Regarding the finding of inutility, the inclusion of compounds that cannot be made proved to be fatal. Jagot J commented that the relevant standard of proof in this circumstance was the balance of probabilities and that absolute scientific proof was not required.

- **Read Judgment**: Gilead Sciences Pty Ltd v Idenix Pharmaceuticals LLC [2016] FCA 169 (2 March 2016)
Federal Court upholds GSK’s sustained release paracetamol patent as valid but finds that Apotex and Generic Partners do not infringe

(gl) Read Full Judgment

GlaxoSmithKline Consumer Healthcare Investments (Ireland) (No. 2) Limited v Apotex Pty Ltd [2016] FCA 608 (31 May 2016)

Federal Court of Australia (Beach J)

Pharmaceutical patent claiming a sustained release paracetamol bilayer tablet with a specified in vitro dissolution profile

Claim construction, infringement and validity (fair basis, sufficiency, lack of clarity, failure to define the invention, failure to describe best method, lack of inventive step)

Claims found to be valid but not infringed. Case has been appealed to the Full Federal Court

The Parties

GlaxoSmithKline Consumer Healthcare Investments (Ireland) (No. 2) Limited (GSK) commenced a proceeding against Apotex Pty Ltd (Apotex) on 3 October 2014 (VID 571 of 2014) and a separate proceeding against Generic Partners on 29 October 2014 (VID 638 of 2014) for anticipated infringement of the claims of Australian Patent No. 2001260212 (212 Patent). Apotex and Generic Partners Pty Ltd (Generic Partners) (together, the respondents) brought cross-claims against GSK filed on 30 October 2014 and 25 November 2014, respectively, seeking orders revoking claims 1 to 6, 8 to 11, 13 and 14 of the 212 Patent.

The Patent

The 212 Patent related to a sustained release paracetamol formulation having an advantageous pharmacokinetic profile.

The Arguments

- **Claim construction**: The respondents argued that a USP type III apparatus has a reciprocating cylinder, not a reciprocating basket (a USP type I apparatus has a basket). Accordingly, claim 1 required measurement of the dissolution profile using a USP type III apparatus that is modified to use a reciprocating basket instead of a reciprocating cylinder. The respondents argued that GSK used an unmodified USP type III apparatus and, therefore, failed to prove infringement.

  GSK argued that the phrase in claim 1 “the USP type III apparatus, reciprocating basket” should be construed as meaning a USP type III apparatus with a reciprocating cylinder (i.e., an unmodified USP type III apparatus).

- **Infringement**: The respondents argued that GSK had not tested the alleged infringing products using the claimed apparatus (i.e., a modified USP type III apparatus) and, therefore, had failed to prove infringement.

- **Fair basis**: The respondents argued that the 212 Patent claims were broader than the disclosures in the examples, on the basis that the skilled addressee would understand that there is no scientific rationale to support the in vitro ranges as claimed. The respondents

Authors:

Kieran Williams,
Senior Associate (Patent Attorney)

Jacinta Flattery-O’Brien,
Principal (Patent Attorney)
argued that there is no “real and reasonably clear” disclosure of an invention having the claimed ranges and, accordingly, the claims are not fairly based on the description.

• **Sufficiency.** The respondents argued that there was insufficient description in the 212 Patent of (1) any matrix-forming polymer other than hydroxypropyl methylcellulose (HPMC) in the sustained-release layer; (2) any formulation with an in vitro dissolution profile other than the formulations in the examples (in which the dissolution rates given were precise figures, not expressed to be within a range); and (3) the apparatus used to determine the in vitro dissolution profile.

• **Lack of clarity.** The respondents contended the following:

  (a) For a USP type III apparatus, one of the variables that is left for the practitioner to specify is the mesh size for the ends of the reciprocating cylinder. In contrast, for a USP type I apparatus the USP specifies a default mesh size of 40 unless a different mesh size is specified.

  (b) Mesh for a USP type III apparatus is available in a number of standard sizes, including 20, 40, 78 and 100.

  (c) Mesh size is an important criterion in one sense for a USP type III apparatus because the size can affect the hydrodynamics of the fluid that moves past the tablet as the cylinder reciprocates up and down. Further, the size can affect whether drug particles clog up the mesh, affecting the hydrodynamics, or alternatively pass through the mesh and out of the reciprocating cylinder to interact with solution with different hydrodynamics.

  (d) It was not clear in the 212 Patent claims what mesh size is to be employed.

• **Failure to define the invention.** The respondents argued that the claims failed to define the invention by reason of the use of the words “USP type III apparatus, reciprocating basket . . .”. The respondents argued that the addressee would not understand what dissolution test was specified and, critically, what apparatus was used. In addition, the test did not specify the materials and size of the mesh to be used, which the respondents argued was critical in determining a particular dissolution profile.

• **Failure to describe the best method.** The respondents argued that the 212 Patent failed to disclose the grade and specific viscosity of HPMC or the method of granulation that was used to produce the sustained release bilayer tablet formulations exemplified in the specification. The respondents argued that the specification of the 212 Patent provided only general descriptions that a “high viscosity HPMC” and “conventional” method of granulation were used, but GSK had in fact used a particular grade and specific viscosity of HPMC and a particular granulation end point. The respondents argued that the method that had actually been used to make the formulations was better than the disclosed method because it would eliminate experimentation involved in trying a variety of possible high viscosity HPMC grades and granulation end points in order to make formulations which were guaranteed to work.

• **Lack of inventive step.** The respondents argued that the claims were obvious in light of the US Patent No. 4820522 (522 Patent) alone or in combination with Australian Patent No. 751194 (194 Patent). The 522 Patent described a bilayer biphasic tablet of paracetamol with an immediate-release and a sustained-release layer and the 194 Patent disclosed a sustained release paracetamol formulation made up of a blend of beads or particles of immediate release and sustained release paracetamol, which was delivered in a capsule or blister.

The Decision

It was found that the patent was valid but not infringed.

• **Claim construction.** Beach J found that the use of the word “basket” rather than “cylinder” in the claim (and specification) was a mistake and would be understood as being such by the person skilled in the art. However, Beach J found that it was not permissible to re-write the claim under the guise of construction as:
o no integer of the claim was ambiguous or uncertain;
o there was no inconsistency between the body of the specification and a claim integer;
o the invention still worked if “basket meant “basket”;
o there was no case of an erroneous stipulation of an underlying scientific theory upon which the invention proceeded;
o a patent cannot be construed with all the latitude and commercial massaging that is permissible for a commercial contract; and
o rules of benevolent construction which would strive to construe the 212 Patent in a way not claimed could not be applied.

Construction that re-writes the claim is in effect construing what ought to have been rather than what is, and it is not permissible to adopt a method of construction that gives a patentee what it might have wished or intended to claim rather than what it did claim.

• **Infringement:** As Beach J construed claim 1 to relate to a USP type III apparatus that is modified to use a reciprocating basket instead of a reciprocating cylinder, it followed that GSK had failed to prove infringement concerning the alleged infringing products as it had used an unmodified USP type III apparatus (i.e., GSK did not test the alleged infringing products using the apparatus required by the claims). Beach J reported that if “basket” was construed as “cylinder” (contrary to his Honour’s conclusion on construction), then the alleged infringing products would have infringed the claims of the 212 Patent.

• **Fair basis:** Beach J found that the evidence demonstrated that a skilled formulator reading the 212 Patent fairly with a view to making it work, would (in light of the common general knowledge) understand that the patentee had reasonably extrapolated the claimed content, ratio and dissolution ranges from the formulations disclosed in the specification. In Beach J’s view, the respondents did not discharge their onus of establishing that there were formulations falling within the claims that did not meet the promise of the invention. Additionally, Beach J found that fair basis had been established on the basis of the matching with the text of the consistory clauses. As such, Beach J found the claims of the 212 Patent to be fairly based.

• **Sufficiency:** Beach J found that only one embodiment within each claim need be enabled for sufficiency purposes. An invention is sufficiently disclosed if a skilled person could make a single embodiment of the invention which falls within the scope of the claims. Beach J also found that the 212 Patent provided sufficient information to enable a skilled formulator to produce a formulation with a profile which satisfied regulatory acceptance targets for replicating the profile of the formulations of the examples without new inventions or additions or prolonged study of matters presenting additional difficulty. Beach J also found that a skilled addressee would have been able to produce a modified USP type III apparatus for testing the dissolution profile as a matter of routine without new inventions or additions or prolonged study of matters presenting initial difficulty. As such, Beach J found that the respondents’ insufficiency attack failed.

• **Lack of clarity:** Beach J found that the 212 Patent was addressed to the skilled addressee, not an uninformed “member of the public”. Beach J found that the skilled dissolution tester could select an appropriate mesh size for the USP type III apparatus without new invention or addition or prolonged study of matters presenting initial difficulty. Beach J found that the claims of the 212 Patent provided a workable standard suitable to their intended use and were clear to the skilled dissolution tester to whom they were addressed. As such, Beach J found the claims of the 212 Patent to be clear.

• **Failure to define the invention:** Beach J found that “basket” should be taken as being a reference to the USP type I apparatus basket used as a substitute for the cylinder in the USP type III apparatus and, therefore, there had been no failure to define the invention. Even if “basket” was to be taken as a reference to
“cylinder”, Beach J also found that the dissolution test method had been adequately specified.

- **Failure to describe the best method**
  Beach J found that GSK proceeded to optimise the manufacture of the formulation for its specific equipment and batch sizes. GSK was not required to set out in the specification of the 212 Patent manufacturing optimisation details developed with respect to its own particular equipment and manufacturing capabilities. In Beach J’s view, such idiosyncratic detail is not relevant to the skilled person’s task of performing the invention claimed and is unlikely to assist a skilled person to perform the invention using his own particular excipients, manufacturing methods and equipment. Furthermore, Beach J was unable to conclude on the evidence that formulations made with grades of HPMC optimised for GSK’s own equipment are any “better” than other formulations which a skilled person would make when reproducing the disclosed method. Accordingly, Beach J found that the best method known to GSK was disclosed in the 212 Patent.

- **Lack of inventive step**: Beach J found that the 522 Patent did not provide any *in vitro* dissolution data for any formulations and disclosed a bilayer tablet which contained 650 mg of paracetamol split equally between two layers (325 mg in an immediate release layer and 325 mg in a sustained release layer). While the 194 Patent provided a dissolution profile, there was nothing in the 194 Patent claims which suggested an unequal split of paracetamol (as required by the claims of the 212 Patent). Beach J found that there was absolutely nothing in the 522 or 194 Patents which suggested that an equal amount of paracetamol in each of the two layers had failed to achieve an acceptable result. Further, Beach J found that there was no basis for saying that any proposed formulations based on the teachings of the 522 or 194 Patents would have a dissolution profile within the limits specified in the claims of the 212 Patent when tested under the conditions specified in the claims. Beach J found that the respondents’ case on lack of inventive step was not made out.

### The Significance

The patentee achieved a somewhat hollow victory in that the Patent was found to be valid but not infringed. Essentially, the case turned on the construction of claim 1. Beach J indicated “I have found that the hypothetical skilled addressee is likely to have perceived that a mistake was made in claim 1 in identifying the relevant dissolution apparatus; ‘basket’ should have read ‘cylinder’ “(at 12). He credits Ms Goddard SC, however, with “astutely perceiving the risk that I might take a more free-wheeling construction approach more apposite to commercial contracts” and noted that she cautioned him against such “liberality”. Beach J indicated “[...] her point was that the specification was a public instrument and that I was not free to, in effect, amend the specification under the pretext or pretence of some construction exercise”. Importantly, therefore, notwithstanding his finding that the “mistake” in claim 1 is likely to have been perceived by the skilled addressee, His Honour stated “... the boundary constraint is that I am obliged to construe the claim as it is, rather than what it should have been” and he proceeded to find that GSK must fail on infringement of claim 1 as a result. The Court’s decision illustrates, therefore, how crucial a single word in a claim can be in infringement proceedings. If the claims (and possibly the specification) had recited “reciprocating cylinder” instead of “reciprocating basket”, the patent would likely have been found valid and infringed. The decision has been appealed to the Full Federal Court.

*Read Judgment:* GlaxoSmithKline Consumer Healthcare Investments (Ireland) (No. 2) Limited v Apotex Pty Ltd [2016] FCA 608 (31 May 2016)
The Parties

The judgment of the Federal Court of Australia (Jagot J) relates to separate questions ordered to determine whether the respondent generic pharmaceutical companies should be allowed to amend their defences to withdraw admissions that the Australian subsidiary of the patentee was an exclusive licensee of the asserted patent, with standing to sue for infringement. The applicants were H Lundbeck A/S (Lundbeck) as patentee and Lundbeck Australia Pty Ltd (Lundbeck Australia) as registered exclusive licensee. The respondents were Alphapharm Pty Ltd (Alphapharm), Aspen Pharma Pty Ltd (Aspen), Apotex Pty Ltd (Apotex) and Sandoz Pty Ltd (Sandoz), as alleged infringers and parties who had sought to revoke both the patent and its 5-year pharmaceutical term extension.

The Patent

The determination of these separate questions was part of a long-running dispute between the Lundbeck parties and the generic parties concerning Lundbeck’s Australian Patent No. 623144 for an invention entitled “(+)-enantiomer of citalopram and process for the preparation thereof” (144 Patent). The compound (+)-citalopram is the (+)-enantiomer of citalopram. Citalopram is a racemic mixture containing equal amounts of (+) and (-) enantiomers of citalopram. Enantiomers are variations of a chemical compound with identical components arranged in different three-dimensional orientations. Lundbeck’s citalopram antidepressant drug Cipramil was registered on the Australian Register of Therapeutic Goods (ARTG) from 9 December 1997. Lundbeck applied for the 144 Patent for (+)-citalopram (also known as escitalopram) on 13 June 1989 and it was granted in 1992. Lundbeck sought and was granted an extension of the term of the 144 Patent from 13 June 2009 until 13 June 2014 under the provisions of the Patents Act 1990 (Cth) (Patents Act) and the Therapeutic Goods Act 1989 (Cth) (Therapeutic Goods Act), relying on the ARTG listing of its escitalopram antidepressant drug Lexapro on 16 September 2003. As explained below, the extended term of the 144 Patent was subsequently adjusted to expire on 9 December 2012, based on the ARTG registration of Cipramil (racemic citalopram), rather than Lexapro (enantiomeric escitalopram).
The Previous Decisions

The decision of Jagot J on the separate questions was delivered early in a proceeding in which the Lundbeck parties sought damages for infringements of the 144 Patent between the expiry of its unextended term on 13 June 2009 and the expiry of its (adjusted) extended term on 12 December 2012. From 15 June 2009, Alphapharm, Aspen, Apotex and Sandoz each launched a generic escitalopram product in Australia. This latest litigation followed over a decade of disputes regarding the 144 Patent, in which various decisions regarding infringement, validity and patent term extension issues were delivered by the Federal Court, Full Federal Court, High Court, Patent Office and Administrative Appeals Tribunal.

The Arguments

- **Issue estoppel.** The Lundbeck parties argued that Lindgren J had found Lundbeck Australia to be an exclusive licensee of the 144 Patent and made orders entitling it to damages for infringement as well as providing it with the benefit of permanent injunctions restraining generic escitalopram products at least until the end of the unextended term on 14 June 2009. The Lundbeck parties pointed to the stays of the orders requiring rectification of the Register of Patents pending their appeals as also involving a determination of Lundbeck Australia’s status of exclusive licensee. The Lundbeck parties also argued that Lundbeck Australia’s status as exclusive licensee had been determined in a previous decision staying orders for rectification of the Register of Patents pending appeal.

- **Abuse of process.** The Lundbeck parties argued that they reasonably assumed from the 2008 decisions of Lindgren J, and the issues raised in subsequent appeals and other proceedings, that Alphapharm and the other generic parties accepted that Lundbeck Australia was the exclusive licensee of the 144 Patent from 22 September 2005. Lundbeck said that, given the history of the litigation in Australia, the Lundbeck parties “did not anticipate that this issue would be raised” and had they done so it is likely that they would have “taken a different approach with regard to maintaining its records, and would have documented and kept track of all important events more systematically”. The Lundbeck parties alleged that the generic respondents should have put Lundbeck Australia’s status as exclusive licensee in issue in their first defences. The Lundbeck parties also complained that these latest applications to withdraw admissions were vexatious or spurious.

The Decision

- **Issue estoppel.** Jagot J found that no issue estoppel arose with respect to the exclusive licensee status of Lundbeck Australia:
  - The issue of the status of Lundbeck Australia after the filing of the cross-claim for infringement was not essential to Lindgren J’s 2008 decisions or any subsequent appeals. It was the parties’ common position in that first instance proceeding that Lundbeck Australia was at that time exclusive licensee of the 144 Patent, but damages were ordered as “to be assessed”, which for Lundbeck Australia would depend on its status as exclusive licensee from time to time. Jagot J also noted that the exclusive licence agreement between Lundbeck and Lundbeck Australia was not executed until after Alphapharm’s past infringements had occurred.
  - Lindgren J only found that Lundbeck Australia was exclusive licensee at the time of his judgments and orders in 2008 (and thus competent to bring infringement proceedings), not at all times or throughout the term (extended or otherwise) of the 144 Patent.
  - The undertakings by the Lundbeck parties to Alphapharm and Arrow were the price they had to pay to obtain the various stays of the orders to rectify the Register of Patents to remove the original term extension, while the Lundbeck parties pursued appeals. The giving of undertakings does not involve any judicial determination at all and thus the principle of issue estoppel was not engaged.
The failure of the generic parties to challenge Lundbeck Australia’s exclusive licensee status in their original defences was based on mere oversight.

The withdrawal of the generic parties’ admissions involved no oppression of the Lundbeck parties and did not bring the administration of justice into disrepute, particularly as the proceedings had been stayed for a lengthy period after the defences were filed while the last High Court appeal proceeded.

The lengthy history of disputes regarding the 144 Patent “...means only that well-resourced and sophisticated participants in the pharmaceuticals market, a description which includes the Lundbeck parties, have chosen to act on all such rights as they might have to support their commercial interests”.

The Significance

This latest decision in the long-running Australian escitalopram patent litigation is indicative of not only the parties’ collective determination to take every possible step to protect their positions, but the broader trend in Australian patent litigation towards challenging the status of exclusive licensees. The strict requirements for a valid exclusive licence to an Australian patent have recently been highlighted by the Full Federal Court’s decisions in Bristol-Myers Squibb Company v Apotex Pty Ltd [2015] FCAFC 2 (23 January 2015) and Actavis Pty Ltd v Orion Corporation [2016] FCAFC 121 (9 September 2016).

By establishing that an Australian company exploiting the patented invention is not a valid exclusive licensee, infringing parties can potentially reduce their exposure to pay damages or to account for profits and may even be able to resist a permanent injunction. As these issues have become increasingly prominent in the past few years, it is perhaps unsurprising that the generic parties sought to put Lundbeck Australia’s exclusive licensee status in issue after the various disputes about the validity and extended term of the Lundbeck’s 144 Patent had been finally resolved and they all faced substantial infringement claims relating to their launch of generic escitalopram products during that period.

Abuse of process: Jagot J also answered the second separate question “No” with respect to all generic respondents, finding that:

“One issue, for the purposes of section 120(1) of the Act, is whether Lundbeck Australia was the exclusive licensee of the [144 Patent] when the proceedings were commenced (26 June 2014). Another issue is whether Lundbeck Australia was the exclusive licensee of the [144 Patent] when the alleged infringements occurred (between 15 June 2009 and 9 December 2012). Contrary to the submissions for Lundbeck Australia, those issues have never been litigated before and thus no question of re-litigation can arise.”

There was no opportunity to litigate the issue whether Lundbeck Australia was the exclusive licensee of the Lexapro patent as at 26 June 2014 or between 14 June 2009 and 9 December 2012 in any earlier proceeding.

Any view the Lundbeck parties reached about Alphapharm’s position on Lundbeck Australia’s status as exclusive licensee after 13 June 2009 could not be based on the conduct of the original first instance proceedings and subsequent appeals from Lindgren J’s 2008 decisions.

It was immaterial that Alphapharm did not challenge on appeal Lindgren J’s 2008 finding that Lundbeck Australia was an exclusive licensee of the 144 Patent, as it is orders (as to declarations of infringement and the payment of damages) and not findings that are appealed.

Nothing said or done in the opposition to the extensions of time and term before the Commissioner or on appeal therefrom could give rise to the alleged issue estoppel. Lundbeck Australia was not a party to those oppositions/appeals, its exclusive licensee status was not in issue, there was no judicial determination to that effect and the statements in the statutory declarations reflected nothing more than the witnesses’ understanding.

The admissions in the defences could not found an estoppel as the proceedings remain undetermined.

The Parties

The Federal Court’s judgment relates to an appeal from one of two patent office decisions.

Merck, Sharpe & Dohme (Australia) Pty Ltd (Merck) commenced the proceedings by filing a notice of appeal against the decision of a Delegate of the Commissioner of Patents given on 12 May 2015 (Second Decision), relating to patent application 2003287257 (257 Application) in the name of the Genentech Inc (Genentech), the respondent in the appeal. The appeal also touched on issues relating to another decision of the delegate of the Commissioner of Patents given in February 2014 also relating to the 257 Application (First Decision). The Commissioner of Patents also appeared, and argued that the appeal was incompetent.

The Patent

The 257 Application claimed an invention entitled “Inhibition of IL-17 production”. The claimed invention was based on the recognition that IL-23 induces IL-17 production in activated T cells and that IL-23 antagonists are capable of inhibiting this process.

The specification stated that IL-23 antagonists, that had the ability to inhibit the induction of IL-17 production by IL-23, would be candidates for drugs to treat inflammatory conditions characterised by the presence of elevated levels of IL-17.

The Previous Decisions

It is important to understand the history of the proceedings, in order to understand the Federal Court’s decision.

Merck opposed the grant of the 257 Application on 10 March 2010. At the hearing of the opposition, importantly, the parties agreed that the opposition could be heard in relation to the independent claims only, with the dependent claims falling the same way. Accordingly, the parties’ submissions were confined to the independent claims.

In the First Decision, the Delegate found that the references to “inflammatory diseases with a distinguishing characteristic of an elevated level of IL-17” in the claims included diseases which were yet to be identified. The Delegate found that three of the four prior art documents relied on by Merck anticipated the use of an IL-23 antagonist in respect...
of certain inflammatory diseases or disorders only, and that as a result, each of claims 1, 4, 5, 14 and 15 lacked novelty. In turn, and according to the parties’ agreement relating to the dependent claims, the Delegate found that the remaining dependent claims 2-3, 11-12, 16-33 also lacked novelty. Importantly, this included dependent claim 28, which listed only a subset of inflammatory diseases. However, the Delegate stated that it was possible for Genentech to overcome the deficiencies outlined in the claims, by amending the 257 Application by reducing the scope of the independent claims to include only those diseases outlined in claim 28. Accordingly, Genentech lodged amendments to the 257 Application, which limited the independent claims to the treatment of certain inflammatory diseases within claim 28 only. Merck did not appeal the decision, or challenge the allowance of the amendments, which were allowed on 13 November 2014.

Merck then requested a hearing upon receiving notification that the opposition was set down for final determination. Merck argued that Genentech could not overcome the novelty deficiencies identified in the First Decision, by importing features from the invalid dependent claim 28, into independent claims. Further, it argued that the amended claims were not novel and lacked inventive step in light of a new prior art document, and that if Genentech was able to effectively retract its concession in the first hearing regarding the novelty and validity of the dependent claims and in particular, claim 28, then Merck should be allowed to raise a new citation.

In the Second Decision, the Delegate found that the amendments to the specification overcame the deficiencies identified in the First Decision. Further, she refused to allow Merck to rely on the new prior art document, finding that if there were valid grounds of opposition relating to the subset of diseases listed in amended claims 1, 2 and 14, those grounds could have been pursued in the first hearing, in relation to the original dependent claim 28. Merck sought to appeal the Second Decision to the Federal Court. The Commissioner of Patent appeared and argued that the appeal was incompetent.

The Arguments

• **Competency of the appeal**: Merck firstly argued that the Commissioner has no power to file an objection as to competency of the appeal. It also argued that section 60(4) of the *Patents Act 1990* (Cth) gave it an appeal as of right from the Second Decision and that the appeal did not seek to reargue the correctness of the First Decision, but rather properly challenged issues that arose only out of the amended claims and the Second Decision. The Commissioner argued that the relief that Merck sought could not be given in the appeal because the First Decision had been a final determination of the subject matter (novelty and inventive step) on which the appeal was based.

• **Novelty**: Merck argued that the application lacked novelty, in light of the four original prior art documents, and the new prior art document. Merck contended that the Delegate erred in finding that the claims 1, 4 and 5 lacked novelty only in relation to the treatment of certain diseases. Merck argued that the effect of the concession should be that the invention lacked novelty in relation to all diseases listed in the specification, including those listed in claim 28, and that Genentech had accepted this.

• **Inventive step**: Merck argued that the 257 Application lacked inventive step in light of the common general knowledge taken alone or when considered together with the disclosure of any of the prior art documents. Merck only pressed this issue if the Judge was to find that there was a material difference between the scope of the original claims and the amended claims.

The Decision

The appeal was dismissed as being incompetent, and Merck was not entitled to rely on the new prior art document in relation to novelty.

• **Competency of the appeal**: The Court (Rares J) found that a patent opposition can be decided in stages, and that in the First Decision, the Delegate found that Claims 1, 4, 5, 15 and 28 lacked novelty in relation to four particular inflammatory diseases only. Genentech’s concession was simply that if an independent
claim was found to have been anticipated by a prior art document, a dependent claim which repeated the anticipated subject matter would also fail. Rares J found that Merck erroneously assumed that in the First Decision, the Delegate found that all of the claims, including claim 28, lacked novelty and could not be amended to overcome those deficiencies. Rather, Rares J held that the Delegate’s First Decision, in finding that amendments could overcome the deficiencies, was actually unfavourable to Merck, and Merck had to appeal that decision instead. Merck’s appeal asserting lack of novelty or inventive step was effectively an attack on the First Decision, in which the Delegate allowed Genentech to amend its claims. As this matter was now finalised, the appeal was incompetent.

• **Novelty.** As the appeal was found to be incompetent, Rares J did not consider the novelty arguments.

• **Inventive step.** As the appeal was found to be incompetent, Rares J did not consider the inventive step arguments.

The Significance

This Court’s decision may be of concern to potential patent application opponents. In particular, it would seem that, to obtain certainty, an opponent may be required to ensure that arguments at the initial hearing cover the entire scope of all dependent and independent claims. Further, an opponent may be required to appeal any decision in which the Delegate finds that amendments would overcome various issues, even if the opponent was generally successful in the decision. Further, an opponent may need to consider what potential amendments could be suggested or allowed, and attempt to deal with same at the hearing.

A further issue highlighted by the Court’s decision is that an appeal from a decision must be filed within 21 days. Despite this, usually 60 days are normally allowed for any amendments to be made. Accordingly, an opponent may need to file an appeal from a decision in which it has been wholly successful, if it considers that any possible matter in the specification could save the application by supporting an amendment that cures invalidity findings.

**Read Judgment:** Merck Sharpe & Dohme (Australia) Pty Ltd v Genentech Inc [2016] FCA 324 (1 April 2016)
The Parties

This case relates to an appeal to the decision of Ronneby Road Pty Ltd v ESCO Corporation [2015] APO 3 (5 February 2015), in which a Delegate of the Commissioner of Patents rejected the opposition of the applicant, Ronneby Road Pty Ltd (RR), to the grant of the standard patent application in the name of the respondent, ESCO Corporation (ESCO).

The Patent

The patent in issue was Australian Patent No. 2011201135 (135 Patent), claiming an invention entitled “Wear Assembly” for securing wear members to excavating equipment.

The Previous Decision

In the previous decision, the Delegate found that the 135 Patent was novel, inventive, clear, fairly based, sufficient and a manner of manufacture.

The Arguments

- **Novelty.** RR’s arguments relied on the public display, oral description, and sale and supply of the Torq Lok product by Quality Steel at a date prior to the earliest priority date of 30 March 2006. In response, ESCO argued that the Torq Lok product did not fall within the scope of the claims (based on a construction of the claims), and that the Torq Lok was not publically available information at the priority date. In particular, ESCO submitted that the claims defined two unique, predetermined positions (the “hold position” and the “release position”), while the Torq Lok’s so-called “hold position” and “release position” are dependent on the condition of the cavity in the base and the subjective judgment of the operator (as to how far to unscrew the Torq Lok relative to the base).

- **Fair basis.** RR submitted that, in the description, the non-threaded first form of the lock was confined to a lock with a very specific kind of action that did not provide basis to the identified claims. ESCO argued that RR made no fair basis objection to independent claim 1, from which claim 4 is dependent, ergo claim 4 must also be fairly based as claim 4 is a subset of claim 1. ESCO further argued that the feature did not change the nature of the invention disclosed in claim 1, particularly in view of paragraph [17] of the specification.
• **Utility.** RR argued that the advantages described in the specification in paragraphs [05] and [06] (in particular, "The present invention pertains to an improved wear assembly for securing wear members to excavating equipment for enhanced stability, strength, durability, penetration, safety, and ease of replacement") were not all delivered by the invention in every claim. In response, ESCO submitted that, in identifying what had been promised by the inventors, it is necessary to consider the specification as a whole rather than one paragraph, and, alternatively, that the advantages set out in paragraph [06] were to be understood distributively across the respective claims, rather than each of the advantages being provided by every claim.

The Decision

• **Novelty.** The Court (Jessup J) found insufficient disclosure in the description of the "hold position" and "release position" to support ESCO’s arguments. As such, the claims were interpreted solely by reference to their own words, as understood by a person skilled in a relevant field of engineering and the industrial setting in which the invention would be used. To this end, the hold position was defined as "where the lock can secure the wear member to the base" and the release position was defined as "where the wear member can be released from the base", and Jessup J found these definitions unconcerned with the precise location of the two positions. Accordingly, it was found that the Torq Lok fell within the scope of the claims. With regard to the public availability, Jessup J found that the Torq Lok was publicly available in accordance with the conditions discussed in *Insta Image Pty Ltd v KD Kanopy Australasia Pty Ltd* (2008) 78 IPR 20, 44 [124]. In view of the above, it was held that claims 1, 6, 7, 9-16 and 18-23 were anticipated by the Torq Lok; however, claim 2 was deemed novel as the Torq Lok did not employ a "pivotal movement" about a "pivot axis".

• **Utility.** On consideration of expert statements and *Pracdes Pty Ltd v Stanilite Electronics Pty Ltd* (1995) 35 IPR 259, Jessup J found that none of the claims would meet every advantage discussed in the specification. Accordingly, RR’s utility objection was upheld in relation to all claims.

The Significance

This decision demonstrates the potential consequences of including multiple object statements or references to the advantages of the invention within the patent specification, as these statements can form the basis for invalidating the patent application by reason of lack of utility. Notably, this applies to statements which assert particular attributes or improvements of the invention over the prior art. According to this decision, utility will only be found where each and every stated object/advantage is met by the invention as defined in each and every claim. It is therefore common practice in Australia to delete any object statement or advantage, or to restrict these statements to relate only to one or more preferred embodiments of the invention.

The decision also emphasises the importance of providing a sufficient, complete and detailed description of the invention in the patent specification, such as to provide a clear understanding of how each and every feature of the claimed invention works and interacts with each other. Failure to do this may result in the claims being interpreted by a plain understanding of the exact wording of the claims by the person skilled in the art of the relevant field, which may differ from the inventor’s intentions.

**Read Judgment:** *Ronneby Road Pty Ltd v ESCO Corporation* [2016] FCA 588 (27 May 2016)
The Parties

Arrowhead Research Corporation (Arrowhead) requested to be heard following four adverse examination reports regarding a lack of patentable subject matter claimed in Australian Patent Application 2013207601 (601 Application).

The Patent

The 601 Application included claims defining double-stranded iRNA compositions capable of treating inflammation by attenuating the expression of spleen tyrosine kinase.

The Issues

As the sequence of nucleotides in the defined iRNA compositions was the same as that which occurs in the genome, the Examiner initially rejected the iRNA composition claims on the basis that they encompassed genetic information that occurs in nature. In particular, the Examiner took the view that the defined sequence of nucleotides was solely responsible for how the invention worked and therefore the “substance of the claims” was directed to genetic information which occurred in nature and had not been “made”.

The Arguments

In its hearing submissions, Arrowhead adduced evidence in the form of an expert declaration that supported its position that the manner in which the iRNA compositions worked is not solely dependent on the sequence of nucleotides in the iRNA. Critical to the invention was the structure of the double-stranded RNA, which does not exist in nature.

The Decision

In view of the evidence submitted, the Delegate of the Commissioner of Patents considered that the substance of the defined iRNA compositions related to a pharmaceutical composition that had been “made” rather than naturally-occurring genetic information. For this reason, the claims directed to the iRNA compositions were considered patent-eligible.
The Significance

This decision clarifies and confirms the limited impact of the High Court of Australia’s decision in *D’Arcy v Myriad Genetics Inc & Anor* [2015] HCA 35, and leaves the door open for patents/applications covering other artificially-created genes, such as cDNA, that are currently considered ineligible for patentability in Australia. In particular, this decision sets an important legal precedent that for a gene-based invention, derived from nature, to be considered patent eligible it must include a non-naturally occurring feature that contributes to the working of the invention. Shelston IP represented Arrowhead Research Corporation in this matter.

🔗 **Read Judgment:** *Arrowhead Research Corporation* [2016] APO 70 (13 October 2016)
The Parties

International Stem Cell Corporation ([ISCC]) requested to be heard following a number of adverse examination reports in relation to a lack of patentable subject matter claimed in Australian Patent Applications 2012216371 (371 Application) and 2013205483 (483 Application).

The Patent Applications

The 371 Application was directed to the production of synthetic cornea from stem cells. The 483 Application was directed to parthenogenic activation of human oocytes for production of human stem cells. The stem cells used to produce cornea in the 371 Application were obtained by the method defined in the 483 Application. Parthenogenesis is defined in the 483 Application as a process by which activation of an oocyte occurs in the absence of sperm penetration, which can result in an early stage embryo known as a blastocyst.

The Issues

In the first instance, the Examiner concluded that the cultivation of an activated unfertilised oocyte as claimed represented the cultivation of a human embryo and therefore the method encompassed a biological process for the generation of a human being, which is specifically excluded from patent eligibility under section 18(2) of the Patents Act 1990 (Cth). Moreover, the Examiner considered that although the claimed methods were not explicitly directed to a method of generating a human being, they included a step where a human being (a blastocyst) is produced. For these reasons the Examiner found that the claims did not define patent eligible subject matter. In view of the adverse examination reports, the applicant, ISCC, requested to be heard.

Two key issues were considered by the Delegate of the Patent Office:

1. Do the provisions of section 18(2) extend to methods that include a step producing a potential human being?
2. Can a blastocyst produced by parthenogenesis be considered a human being?
The Arguments and Decision

In relation to point 1, ISCC submitted that there is no legal basis to reject a claim merely because it includes a step that is not patent eligible. The Delegate, however, considered that this view was inconsistent with the intended purpose of section 18(2) and thus found that a method that includes a step which creates a human being, regardless of any other steps defined, is excluded from patentability.

Regarding point 2, the Delegate emphasised that a fertilised human ovum and all its subsequent manifestations are excluded from patentability. The Delegate ultimately found, however, that a blastocyst produced by parthenogenic oocyte activation does not have the potential to lead to the birth of a human and thus cannot claim the status of a human being. For this reason, the Delegate found that the claimed methods defined patent eligible subject matter.

The Significance

This Patent Office decision makes clear that if a method includes a step that results in the production of a cell-based entity that can give rise to a human being, the method is not patent eligible in Australia. If, on the other hand, a method includes a step that produces an embryo that cannot give rise to a human being, that method is patent eligible.
