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Patent Law – Updates and Insights

Recap of a selection of recent patent law cases and Patent Office decisions, and their impact on patent strategies and best practices in Australia.

PREPARED BY
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DATE
13/03/2025

AGENDA

Zoetis Services LLC v Boehringer Ingelheim Animal Health USA Inc [2024] FCAFC 145

CQMS Pty Ltd v ESCO Group LLC [2024] (APO 17 & 29)

Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents [2024] FCA 987

Cipla Australia Pty Ltd v Novo Nordisk A/S [2024] FCA 1414

Sandoz AG v Bayer Intellectual Property GmbH [2024] FCAFC 135

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Zoetis Services LLC v Boehringer Ingelheim Animal Health USA Inc [2024] FCAFC 145

Date: 15 November 2024

Court: Full Federal Court of Australia

Issue: Appeal concerning the "best method" requirement for patent specification. Zoetis's patent applications related to vaccines against diseases affecting pigs. Boehringer opposed, arguing that Zoetis had failed to disclose the best method known to it of performing the invention. Specifically, the absolute antigen concentrations of experimental vaccines (IVPs) were allegedly known but not disclosed.

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Zoetis Services LLC v Boehringer Ingelheim Animal Health USA Inc FCAFC 145

Background

This case involved an appeal to the Full Federal Court concerning three Australian patent applications filed by Zoetis Services LLC (Zoetis) in April 2013.

The applications were broadly directed to vaccines against diseases affecting pigs.

- AU 2013243535 (AU '535): Mycoplasma hyopneumoniae (hyo) vaccine.
- AU 2013243537 (AU '537): Multivalent hyo and porcine circovirus type 2 (PCV-2) vaccine.
- AU 2013243540 (AU '540): Trivalent hyo, PCV-2 and porcine reproductive and respiratory syndrome virus (PRRSV) vaccine.

Boehringer Ingelheim Animal Health USA Inc (Boehringer) opposed the grant of these applications.

The Australian Patent Office (APO) initially found some claims in AU '535 lacked inventive step but considered AU '537 and AU '540 valid.

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Boehringer appealed the APO's decision to the Federal Court, and Zoetis cross-appealed regarding AU '535.

At first instance, Rofe J found that all claims (except claim 2 of AU '535) were invalid for reasons including lack of support. In a supplementary decision, claim 2 of AU '535 was also invalidated because Zoetis had not disclosed the best method known to it of performing the invention defined in that claim.

The core of the "best method" issue was Boehringer's argument that Zoetis had formulated several experimental vaccines (IVPs) before filing, some performing better than others in terms of efficacy.

Zoetis only disclosed the antigen concentrations of the IVPs relative to a reference vaccine, but the absolute antigen concentration of the reference vaccine was not disclosed in the specifications.

Rofe J concluded that one IVP must have been the most efficacious, and the method of manufacturing it was known to Zoetis but not disclosed, thus breaching the best method requirement under Australian law.

Zoetis appealed Rofe J's findings on best method (and inventive step)

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Zoetis Services LLC v Boehringer Ingelheim Animal Health USA Inc FCAFC 145

Key Takeaways

- The Full Federal Court reaffirmed the importance of disclosing the best method known to the applicant at the time of filing.
- The court highlighted that the nature and extent of the required disclosure depends on the invention and its claimed advantages ("promises"). In this case, the efficacy of the vaccine was a key promise.
- The Full Court agreed that the concentrations of the antigens were material to achieving the claimed advantages.
- The Court rejected Zoetis' argument that disclosing a range of antigen concentrations fulfilled the best method requirement. They clarified that applicants may be required to do more than just identify a range from which the best method could be found.
- Because the disclosed experimental vaccines showed fluctuating levels of efficacy due to different antigen concentrations, the Full Court found that Zoetis had not disclosed the best method. Skilled persons would be left to discover the appropriate concentrations themselves.
- This case serves as a stark reminder that failing to disclose the best method known at the time of filing can be fatal to an entire patent.
- It is now well-established that the best method requirement applies even when the invention is directed to a product (like a vaccine), requiring disclosure of the best method of making that product.
- There are very few mechanisms to remedy a failure to disclose the best method, especially for applications where examination was requested on or after 15 April 2013.
- Patent applicants in Australia must ensure the best method known to them of performing the invention is included in the specification at the time of filing to avoid this ground of invalidity.

CQMS Pty Ltd v ESCO Group LLC – Patent Oppositions [2024] (APO 17 & 29)

Dates: 8 May 2024 and 28 June 2024

Office: Australian Patent Office – Oppositions (Delegates G. Powell and D. Carberry)

Issue: Oppositions to two patent applications by ESCO for mining equipment technology (wear part monitoring systems). CQMS argued that the specifications lacked sufficient detail (support and sufficiency) to enable the full scope of the claimed inventions and that the claims did not deliver on the "promise" of the invention. The second case also involved an unpleaded ground of inutility.

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CQMS Pty Ltd v ESCO Group LLC – Patent Oppositions (APO 17 & 29)

Background:

These related Patent Office decisions involved oppositions by CQMS Pty Ltd (CQMS) to two patent applications by ESCO Group LLC (ESCO) for mining equipment technology, specifically wear part monitoring systems on excavating machinery.

The first application (AU2018201710) concerned a bucket with an inbuilt sensor for detecting wear.

The second application (AU2018201726) related to a system for monitoring wear in real time on excavation equipment.

CQMS opposed both applications primarily on the grounds of lack of sufficiency and support, arguing that ESCO's patent specifications did not provide enough detail to enable the full scope of the claimed inventions. They also argued that the claims did not deliver on the "promise" of the invention.

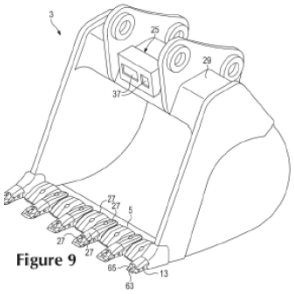

Figure 9

CQMS Pty Ltd v ESCO Group LLC – Patent Oppositions (APO 17 & 29)

Significantly, in the '710 case (APO 17), the Hearing Officer independently raised two additional issues after the hearing, drawing on the Full Federal Court's decision in Jusand Nominees Pty Ltd v Rattlejack Innovations Pty Ltd FCAFC 17820:

- That the claims lacked sufficiency because they included a "relevant range" (specifically, the manner in which the sensor was mounted) that encompassed embodiments not sufficiently enabled by the description.
- That the claims lacked utility because they failed to meet the "promise of the invention" across the entire scope of the claims.

The concept of a "relevant range" stems from UK case law (e.g., Regeneron) and was endorsed in Jusand. It refers to any range within a claim that significantly affects the value or utility of the product, requiring sufficient disclosure to enable all plausible embodiments within that range without undue burden.

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CQMS Pty Ltd v ESCO Group LLC – Patent Oppositions (APO 17 & 29)

CQMS argued that the specification lacked detail on how the sensor was mounted robustly enough for the harsh excavating environment, requiring undue experimentation by a skilled person. ESCO argued the description was sufficient.

Regarding the "promise of the invention", the Hearing Officer considered the promises to include monitoring wear, providing timely warnings, and protecting downstream equipment. The lack of detail on sensor protection from damage or obscuration was deemed a failure to meet these promises across all claimed embodiments.

CQMS Pty Ltd v ESCO Group LLC – Patent Oppositions (APO 17 & 29)

Key Takeaways

- In both oppositions, the Patent Office refused ESCO's patent applications, finding that the specifications lacked sufficient support and clarity to enable a skilled person to perform the invention across the full scope of the claims.
- The delegates found that key details were missing, making it implausible that the invention could be performed without undue experimentation.
- In the '710 case, the delegate explicitly applied the concept of "relevant range" from Jusand and Regeneron, finding that the manner of sensor mounting was a relevant range not sufficiently disclosed.
- The Hearing Officer also upheld the ground of inutility (lack of a useful result across the claim scope) due to concerns that the invention wouldn't work as broadly claimed, highlighting the "promise of the invention" not being met due to a lack of detail on sensor protection.
- These decisions reinforce the stringent disclosure requirements in Australian patent law, especially post-"Raising the Bar" reforms. Patents must not claim broader than what is demonstrated as workable.
- Applicants must ensure patent specifications enable the invention's scope fully, providing adequate guidance for each meaningful variation within a claimed class or range.
- The Patent Office demonstrated a willingness to apply the "relevant range" concept zealously to mechanical inventions following Jusand.
- The case also highlights the risk of running afoul of the "promise of the invention" approach to utility if necessary features to achieve the promise are not claimed, derivable from the specification, or part of common general knowledge.
- Patent applicants should avoid speculative claiming and ensure claims with descriptive or functional language are sufficiently enabled. The Patent Office has the discretion to raise issues like sufficiency, support, and utility independently in opposition proceedings.

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Is a range a "relevant range"?

Does the range include an **embodiment that is not exemplified** in the specification but which could *plausibly* be made?

Does making such an embodiment require **undue burden or further invention** (or "**ingenuity**")?

Once made, would that embodiment **significantly affect the value or utility** of the claimed product in achieving its relevant purpose?

If the answer to any of these questions is "**NO**", the range is arguably **NOT a "relevant range"**

Practical implications

Changes to drafting practice
Particularly in mechanical space

Narrower claims being allowed
Less reliance on principle of general application

Importance of dependent claims
Strong fall-back positions to preserve validity

Application of UK / EP case law
Including post-RTB decisions like *Regeneron*

Changes to Patent Office practice
Application of *Jusand* and *Regeneron*

Increased litigation
New "hot" grounds for challenging patents

Pre-filing considerations
Drafting with "relevant range" issue in mind

Prosecution considerations
Addressing "relevant range" objections

Post-acceptance considerations
"Shoring up" claims for potential challenge

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***Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents* [2024] FCA 987**

Date: 30 August 2024 (Leave to Appeal Decision)

Court: Federal Court of Australia (O'Bryan J)

Issue: This case is part of ongoing litigation concerning the patentability of Aristocrat's electronic gaming machine (EGM) patents, testing the boundaries of patentable subject matter for computer-implemented inventions. Aristocrat sought leave to appeal a decision that found its remaining claims unpatentable. The key issue is whether the claims (related to an EGM with software-driven features) define a patent-eligible "manner of manufacture" under s 18(1A) of the Patents Act.

Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents FCA 987

Summary:

This is the latest chapter in the protracted litigation over Aristocrat's electronic gaming machine (EGM) patents, which test the boundaries of patentable subject matter for computer-implemented inventions. After the High Court in 2022 split evenly (3:3) on the patentability of an Aristocrat gaming system claim (resulting in the Full Federal Court's view – that the claim was not a patentable "manner of manufacture" – being affirmed by default), the case was remitted to the Federal Court to consider the remaining "residual" claims.

Justice Burley, on remittal in March 2024, likewise found those residual claims unpatentable, applying the reasoning of the Full Court. Aristocrat then sought leave to appeal Burley J's decision, aiming to have a fresh appellate review of whether its claims (drawn to an EGM with software-driven features) define a patent-eligible invention under s 18(1A) of the Patents Act.

Decision: Justice O'Bryan granted Aristocrat leave to appeal. This allows an appellate court to re-examine the patentability of Aristocrat's gaming machine innovations.

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Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents FCA 987

Significance

- Patentable Subject Matter (Software): This development is important for the tech industry (especially software and gaming), signaling a possible reconsideration of the legal test for computer-implemented inventions in Australia.
- The controversy centres on the degree of technical contribution or physical effect required for software-based inventions to be patentable.
- A successful appeal could clarify or adjust the current standard, which many view as restrictive.

Strategy

- Until a final outcome, patent applicants in software/AI/gaming should draft claims emphasizing technical improvements and physical integration to meet the manner of manufacture threshold.
- Aristocrat's separate leave application was a strategic move that enabled a potential "leapfrog" to the High Court.
- All stakeholders are closely watching this saga as it will influence best practices for protecting software-implemented innovations in Australia.

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Cipla Australia Pty Ltd v Novo Nordisk A/S [2024] FCA 1414

Date: 12 December 2024

Court: Federal Court of Australia (Perram J)

Issue: Examination of what constitutes a "pharmaceutical substance per se" under the Patents Act in the context of a patent term extension. Cipla challenged the PTE granted to Novo Nordisk for a patent claiming specific formulations of liraglutide (Victoza®), arguing that a formulation (active + excipients) cannot be considered a "pharmaceutical substance per se", or if it can, the excipients must have an independent therapeutic effect.

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Cipla Australia Pty Ltd v Novo Nordisk A/S FCA 1414

Summary:

Another important case on patent term extensions, this time examining what constitutes a "pharmaceutical substance per se" under the Patents Act. Novo Nordisk owned a patent (AU 2004290862) claiming specific formulations of the anti-diabetic drug liraglutide (the active ingredient in Victoza®). The patent's 20-year term was extended to August 2025 via a PTE, since Victoza obtained regulatory approval. Generic manufacturer Cipla challenged the extension by seeking rectification of the Patent Register to remove the extension, contending that the patent did not meet the criteria for PTE. Cipla's arguments raised two key issues: (1) whether a formulation (active + excipients) can be considered a "pharmaceutical substance per se" as required for PTE eligibility, or if only a new active ingredient alone qualifies; and (2) if formulations can qualify, whether the excipient ingredients must themselves contribute a therapeutic effect distinct from the active.

Essentially, Cipla asserted that Novo's patent was ineligible for extension because it covered a formulation (liraglutide with specific solvents/preservatives) rather than just the drug.

Decision: Justice Perram rejected Cipla's challenge and upheld Novo Nordisk's PTE. The Court held that a claimed formulation can indeed be a "pharmaceutical substance per se", even with non-active components, and that excipients do not need independent therapeutic effect.

Cipla Australia Pty Ltd v Novo Nordisk A/S FCA 1414

Significance

- Extension Eligibility Clarified: This ruling clarifies that formulation patents (not just those claiming a new pure active compound) can qualify for PTE in Australia.
- This is crucial for pharmaceutical lifecycle management as drug companies often rely on formulations.
- Impact on Generics and Licensing:
- For generics, the decision narrows one avenue to invalidate PTEs – arguing a formulation isn't a "substance per se" is unlikely to succeed now.
- Generics must account for extended patent life even on formulation patents.
- Innovators can be more confident in licensing formulation technologies knowing that PTEs on them are enforceable.

Strategy

- Best practice for patentees is to ensure that at least one claim is directed to the pharmaceutical substance (active alone or in formulation) that will be marketed, to secure eligibility for extension.
- The case strengthens patent holders' ability to extend coverage and incentivizes careful claim drafting to include key formulations.

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Sandoz AG v Bayer Intellectual Property GmbH [2024] FCAFC 135

Date: 23 October 2024

Court: Full Federal Court of Australia (Yates, Burley & Downes JJ)

Issue: Appeal regarding the validity of two of Bayer's patents for rivaroxaban (Xarelto®) for lack of inventive step (obviousness) under the pre-"Raising the Bar" provisions of the Patents Act. The appeal focused on the proper approach to assessing inventive step for patents filed before 2013, including identifying the inventive concept, common general knowledge, and prior art.

Sandoz AG v Bayer Intellectual Property GmbH FCAFC 135

Summary:

Sandoz appealed a first-instance decision upholding two of Bayer's patents for the anticoagulant drug rivaroxaban (Xarelto®). The key issue was whether the patents were invalid for lack of an inventive step (obviousness) under the pre-"Raising the Bar" provisions of the Patents Act. The appeal focused on the proper approach to assessing inventive step for patents filed before the 2013 law reforms, including how to identify the inventive concept and the "ascertainment" of common general knowledge and prior art.

Key Issues on Appeal (Sandoz's Grounds):

- Ascertainment (Ground One): Justice Rofe incorrectly found that WO 01/47919 (WO 919) could not be reasonably expected to have been ascertained by a person skilled in the art (PSITA) under s 7(3) of the pre-RTB Act.

- CGK + WO 919 Obviousness (Ground Two): Justice Rofe incorrectly found that the inventions claimed in both patents involved an inventive step in light of the common general knowledge (CGK) together with WO 919.

Decision: The Full Federal Court unanimously overturned the trial judge, holding both Bayer patents invalid for lack of inventive step. The Court clarified and "recalibrated" the threshold for obviousness under the older law.

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Sandoz AG v Bayer Intellectual Property GmbH FCAFC 135

Key Takeaways

- Ascertainment: The Full Court clarified that s 7(3) requires proof of a reasonable expectation that the PSITA would ascertain the prior art document on the balance of probabilities, not proof that they would ascertain it. It is sufficient to show a reasonable expectation of finding the document through routine searches (e.g., using relevant keywords in patent databases). It is not necessary to prove the PSITA would prioritise that document over all others.

- CGK + WO 919 Obviousness: The Full Court disagreed with the trial judge's application of the reformulated Cripps question.

- The need to carry out routine pre-clinical and clinical tests in drug development, following the selection of a lead candidate, can be considered routine work consistent with obviousness. The focus should not be on the "risks and unknowns" inherent in these steps.

- The relevant expectation of success is measured against the ordinary level of expectation and risk in the field. It is sufficient to expect that the steps may well work, not that they will or would work with certainty at each stage of drug development.

Impact on Patent Strategies

- For Patentees (Pre-RTB Patents): This decision lowers the bar for proving obviousness and recalibrates the ascertainment test, making it easier to challenge the validity of older patents. Be prepared for increased challenges from generic competitors. Even long-standing patents are vulnerable if routine combinations of prior knowledge would have yielded the invention.

- For Challengers: This ruling is a significant win, providing a clearer and potentially easier path to invalidate pre-RTB patents based on obviousness arguments. Carefully framing the CGK and prior art combination, emphasizing the reasonable expectation of ascertainment and a reasonable expectation of success in routine steps, will be crucial.

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