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The 2026 Pharmaceutical Patent Review

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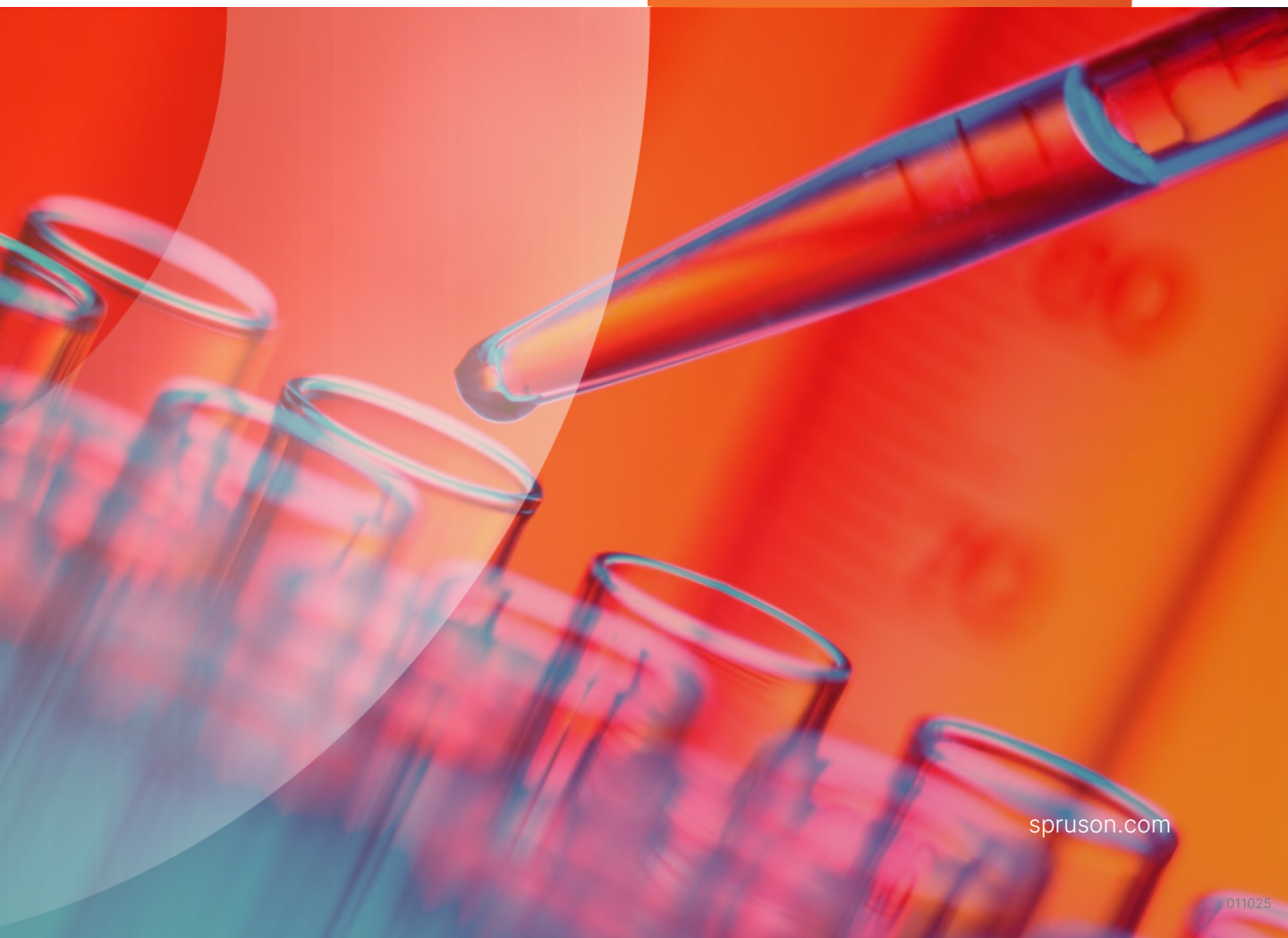

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Welcome

The 2026 Pharmaceutical Patent Review is Spruson & Ferguson's mid-year summary of the key legal, regulatory and policy developments shaping the Australian pharmaceutical patent landscape.

Katrina Crooks
Head of Spruson & Ferguson Lawyers

The past twelve months have marked a notable inflection point for pharmaceutical patent law in Australia, with appellate courts revisiting foundational questions of patent scope and remedies that will set the direction of originator-generic disputes for years to come.

Several major pharmaceutical patent disputes still before the Court (Pfizer v Samsung (etanercept) and Otsuka v Generic Health (aripiprazole – Government damages)) have moved closer to final resolution, while a number of new cases have also been filed.

As the Federal Court's new practice directions designed to streamline patent litigation now taking effect, we expect to see meaningful procedural efficiencies in how these cases are managed. We hope that bringing these developments together serves as a practical resource for navigating this evolving terrain.

The High Court of Australia has granted special leave to appeal the Full Federal Court's decision in *Otsuka Pharmaceutical Co Ltd v Sun Pharma ANZ Pty Ltd* [2025] FCAFC 161, a case that may redefine the eligibility of pharmaceutical formulation patents for patent term extensions. The grant of special leave signals that the boundaries of the extension of term regime remain unsettled, with significant implications for the effective patent life of reformulated products.

The recent resurgence of interlocutory injunctions in pharmaceutical patent litigation represents a meaningful shift in the risk calculus for generic entrants. After a seven-year hiatus, the Federal Court's decisions in *Janssen Pharmaceutica NV v Juno Pharmaceuticals Pty Ltd* [2025] FCA 1538 and *AstraZeneca AB v Pharmacor Pty Ltd* [2026] FCA 88 demonstrate that injunctive relief remains a live weapon for originators.

The *Newron Pharmaceuticals S.p.A. v Arrotex Pharmaceuticals Pty Ltd* [2025] FCA 1321 and [2025] FCA 1437 decisions confirm the relatively low threshold for obtaining preliminary discovery, underscoring its utility as an early strategic tool.

The Federal Court's decision in *Gilead Sciences Pty Ltd v Minister for Health and Ageing* [2026] FCA 232 confirms that statutory price reductions triggered by generic entry on the Pharmaceutical Benefits Scheme can flow through to combination products sharing a common listed component drug, a ruling with substantial potential commercial consequences for originators whose revenue concentration is tied to combination therapies anchored by a single active ingredient approaching loss of exclusivity.

Beyond case law, we examine emerging areas of commercial and strategic importance: orphan drug patenting strategies and regulatory incentives; Australia's new mandatory merger control regime that commenced on 1 January 2026; and the rapidly evolving field of needle-free vaccine delivery systems, from microarray patches and mucosal vaccines to jet injectors and solid-dose devices, and the cross-disciplinary IP strategies required to protect these innovations.

In our policy update, we report on significant regulatory and legislative developments, including IP Australia's consultation on the reform of exclusive licensing provisions, and key pharmaceutical measures in the 2026–2027 Federal Budget. We also provide an update on ongoing pharmaceutical patent litigation in the Court.

We welcome you to reach out to any of our authors for further information or assistance.

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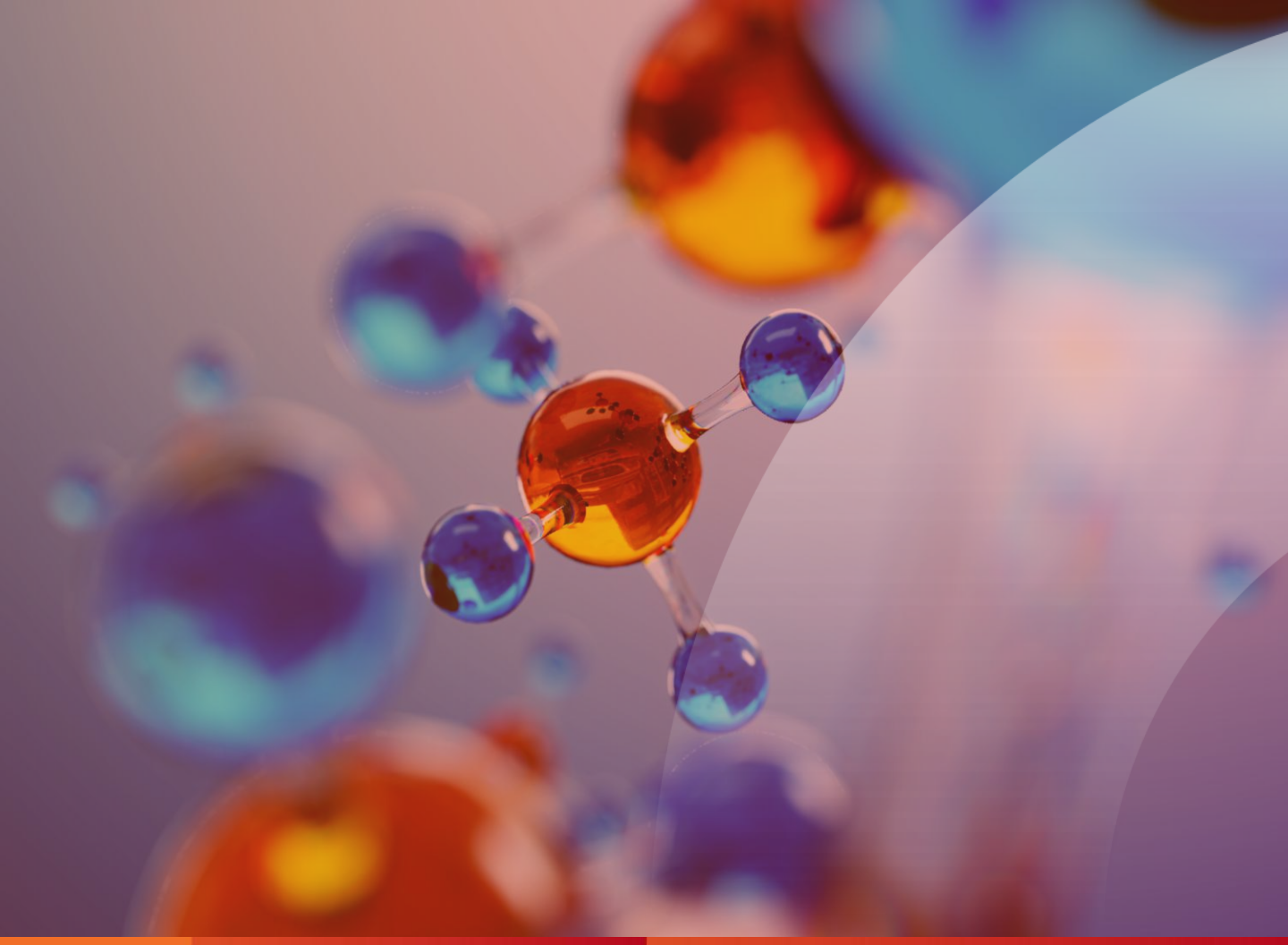

Case law

Australia's High Court to decide the future of patent term extensions for pharmaceutical formulation patents

Authors: Dr Michael Christie | Andrew Rankine | Dr Candace Wu

The High Court of Australia – Australia's highest appellate court – has granted special leave to appeal the Full Federal Court's decision in *Otsuka Pharmaceutical Co Ltd v Sun Pharma ANZ Pty Ltd* [2025] FCAFC 161 (Otsuka v Sun Pharma).

Pharmaceutical innovators will be buoyed by this development, as Otsuka v Sun Pharma significantly curtails patent term extensions (PTEs) for patents to pharmaceutical formulations. At issue before the High Court will be Otsuka's patent to controlled-release injectable formulations of aripiprazole and its eligibility for a PTE based on the regulatory approval of Abilify Maintena. But the High Court's decision is likely to have broader implications for current and future PTEs for patents covering pharmaceutical formulations.

Background

Australia's Patents Act provides an extension of up to five years beyond the standard 20-year term for patents that in substance

- disclose and claim a pharmaceutical substance *per se* or
- a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, provided goods containing, or consisting of the substance are included in the Australian Register of Therapeutic Goods (i.e., have been granted marketing approval in Australia). The Patents Act defines a 'pharmaceutical substance' as:

a substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves:

a. *a chemical interaction, or physico-chemical interaction, with a human physiological system; or*

b. *action on an infectious agent, or on a toxin or other poison, in a human body;*

but does not include a substance that is solely for use in in vitro diagnosis or in vitro testing.

The Australian Patent Office has long taken the view that this definition encompasses pharmaceutical formulations comprising an active and excipients and that patents claiming pharmaceutical formulations are, therefore, eligible for a PTE. This position has been supported by several first instance decisions of the Federal Court.

However, in Otsuka v Sun Pharma, the Full Court held that a "pharmaceutical substance" as defined in the Patents Act is confined to active substances and *excludes formulations*.

The Full Court considered that only an active ingredient is capable of interacting with a human physiological system (or acting on an infectious agent, toxin or poison) in the manner contemplated by the statutory definition of "pharmaceutical substance". Turning to the legislative history of the PTE regime, the Full Court concluded that this also supported the view that Parliament intended the definition of "pharmaceutical substance" to be limited to active pharmaceutical ingredients

In the view of the Full Court, this interpretation is consistent with the legislative purpose of the PTE regime, which serves to compensate patentees for delays encountered when seeking regulatory approval for new and inventive substances. The Full Court suggested that improvements in delivery systems or dosage forms (i.e., new formulations) do not face the same regulatory delays.

Consequently, the PTE granted on Otsuka's controlled-release formulation patent was found to be invalid.

Consequences of Otsuka's High Court Appeal

Although Otsuka v Sun Pharma concerns a specific pharmaceutical formulation, the case has potential consequences for patents to pharmaceutical formulations more broadly.

The Full Court's decision, if upheld by the High Court, will significantly narrow the range of patents that are eligible for a PTE under Australian law, and render many PTEs granted on the basis of pharmaceutical formulations vulnerable to challenge.

While the precise timing will depend on the Court's workload and the availability of the parties' counsel, a decision of the High Court could be expected within the next 12 months.

Until then, there will be a degree of uncertainty surrounding the PTE eligibility of patents to pharmaceutical formulations in Australia. IP Australia has said it will pause processing PTE applications which may relate to formulations.

That pause may now be extended until the matter is resolved by the High Court. We are closely monitoring developments and will provide updates as they arise.

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https://www.spruson.com/australias-high-court-to-decide-the-future-of-patent-term-extensions-for-pharmaceutical-formulation-patents/

Lessons from recent interlocutory injunctions in pharmaceutical patent cases

Authors: Andrew Rankine | Lucy Hartland

Is it becoming easier to obtain interlocutory injunctions in Australian pharmaceutical patent cases? We provide an overview of recent decisions in Australia's Federal Court that shine a light on some key lessons for patent owners.

Overview

In the decade to 2018, pharmaceutical patent owners were successful more often than not when seeking an interlocutory injunction to restrain Australian market entry by generic competitors pending the outcome of patent litigation. A seven-year period then followed in which no interlocutory injunctions were obtained.

However, two recent decisions of Australia's Federal Court suggest that interlocutory injunctions might, once again, be more readily available.

Key takeaways

- The Federal Court has acknowledged that quantifying a generic's losses (if an injunction is granted) may be more difficult than quantifying the originator's losses (if an injunction is refused) – and that this factor generally weighs in favour of refusing an interlocutory injunction.
- The Court also made clear that a decision to grant or refuse injunctive relief depends on the weighing of numerous factors, some of which are likely to be case-specific.
- It remains crucial for the parties to interlocutory injunction proceedings to adduce detailed evidence concerning the strength of their substantive case on both infringement and validity.
- Evidence should also be adduced to explain, in detail, the financial consequences of granting or refusing injunctive relief, addressing the possibility that multiple generics will enter the market and the financial impacts of such competition over the long term.

Background

For pharmaceutical originators, an interlocutory injunction is a key defensive tool. Once a generic has entered the market, it typically offers substantial discounts and quickly gains market share. Where the medicine in question is listed on Australia's Pharmaceutical Benefits Scheme (**PBS**), generic market entry has additional pricing implications.

The first generic to enter the market ordinarily triggers automatic cuts to the medicine's PBS price, as well as price disclosure mechanisms that serve to progressively reduce the price received by all suppliers of the medicine, including the originator.

These features of Australia's pharmaceuticals market mean that, once a generic enters, the market often changes in a permanent way.

For these reasons, if a patentee can demonstrate

1. that there is a *prima facie* case of patent infringement of sufficient strength, and
2. that the balance of convenience favours maintaining the status quo,

then a court will be likely to grant an interlocutory injunction, restraining the generic from entering the Australian market pending the outcome of patent litigation.

Importantly, as a condition for obtaining an interlocutory injunction, the patent owner must give what is known as the "usual undertaking as to damages".

Based on this undertaking, a patentee who obtains an interlocutory injunction but is ultimately unsuccessful in patent litigation may be required to compensate not only restrained generics, but also third parties adversely affected by grant of the injunction, such as Australia's Commonwealth Government (which pays higher prices for PBS-subsidised medicines while an injunction is in force).

Broadly, three phases may be discerned in the attitude of Australia's Federal Court to the grant of interlocutory injunctions in pharmaceutical patent disputes.

Phase 1 | Before July 2018

During the decade from 2008 to 2018, applications for interlocutory injunctions had a high success rate in Australian pharmaceutical patent cases.

Two factors assumed importance during this phase:

- First, courts demonstrated some reluctance to weigh the relative strength of infringement and invalidity arguments at the interlocutory stage, being more inclined to find that there was a "serious question to be tried"
- Secondly, when assessing the balance of convenience, courts gave considerable weight to the fact that generic market entry would trigger (apparently irreversible) reductions in the medicine's PBS price (including for the originator product).

Phase 2 | July 2018 to November 2025

From mid-2018, interlocutory injunctions were less frequently obtained in pharmaceutical patent cases. Two shifts help explain this.

Shifting perspective on the balance of convenience

One of the factors taken into account when assessing the balance of convenience is:

- the relative difficulty of quantifying the originator's losses – if an injunction is refused and the infringement case ultimately succeeds, versus
- quantifying the generic's losses – if an injunction is granted, but the patent is ultimately found to be invalid or not infringed).

In *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2018] FCA 1556, Justice Jagot suggested that it may be more difficult to evaluate a generic's losses (if an injunction is granted) than to evaluate the originator's losses (if an injunction is refused).

In a similar vein, in *Sanofi-Aventis Deutschland GmbH v Alphapharm Pty Ltd* (No 3) [2018] FCA 2060, Justice Burley observed that the originator's starting position (e.g., market share) is a known fact, whereas the position a generic would have achieved but for grant of an interlocutory injunction is largely speculative.

His Honour considered the generic's losses may be harder to quantify and refused an interlocutory injunction. These concerns were echoed in subsequent cases.

Commonwealth claims for compensation

A second change involved claims by the Commonwealth for compensation, under the usual undertaking, where grant of an interlocutory injunction sustained high PBS prices and the patent was later found to be invalid.

The first such claim involved the Commonwealth's pursuit of more than $300 million in damages from Sanofi in proceedings relating to Plavix® (clopidogrel). Although the first hearing took place in 2017, the Commonwealth's claim was not finally resolved until 2024 (by a decision of the High Court, in Sanofi's favour).

During the intervening period, these proceedings had a chilling effect on the number of originators prepared to seek interlocutory injunctions (requiring them to give the usual undertaking).

In the seven years from 2018, the number of applications for interlocutory injunctions halved, compared to the seven years prior.

Phase 3 | December 2025 onwards

In two recent decisions of Australia's Federal Court, originators were successful in obtaining interlocutory injunctions to restrain generic launch pending final judgment.

In *Janssen Pharmaceutica NV v Juno Pharmaceuticals Pty Ltd* [2025] FCA 1538, Justice Burley granted an interlocutory injunction restraining launch of Juno's generic long-acting paliperidone products, and preserving market exclusivity for Janssen's Invega Sustenna®, pending the outcome of patent infringement and validity proceedings.

Justice Burley maintained his view (noted above) that quantifying a generic's losses (if an injunction is granted) may prove more difficult than quantifying the originator's losses (if an injunction is refused), given the entirely hypothetical nature of the former inquiry.

However, his Honour made clear that this is merely one of the factors to be taken into account when weighing the balance of convenience.

Factors favouring the grant of an interlocutory injunction in this case included the strength of Janssen's infringement case (by contrast, Juno's invalidity case was merely "arguable"), and the fact that two additional generics had obtained marketing approval for long-acting paliperidone products.

This indicated that multiple generics could enter the market prior to final judgment, eliminating any "first mover" advantage for Juno – leading to substantial, irreversible discounting. Janssen had also undertaken not to launch an authorised generic while the injunction remained in force.

In *AstraZeneca AB v Pharmacor Pty Ltd* [2026] FCA 88, Justice Downes granted an interlocutory injunction restraining launch of Pharmacor's generic dapagliflozin products, and preserving market exclusivity for AstraZeneca's Forxiga®, pending the outcome of infringement and invalidity proceedings.

As in the *Janssen case*, there was a strong prima facie case of patent infringement, while Pharmacor's invalidity arguments were considered merely arguable.

In common with Burley J, Justice Downes accepted that, if an interlocutory injunction was granted, depriving Pharmacor of any "first mover advantage", and the patent was ultimately found to be invalid, difficulties would arise in seeking to quantify the losses suffered by Pharmacor and third parties, including the Commonwealth.

However, once again, this factor was not decisive. Factors favouring grant of an injunction included evidence that Forxiga® was "critically important" to AstraZeneca, being its largest brand by revenue and "number one revenue growth driver", as well as evidence of "a very real possibility of rapid, multiple generic entry prompted … which would intensify pricing competition".

Responding to a submission that third parties (including the Commonwealth) would benefit from refusal of injunctive relief, Justice Downes noted countervailing considerations:

While lower prices for FORXIGA would benefit the Commonwealth and the public, the patent system grants a temporary monopoly to encourage and reward invention, which benefits all. It is therefore in the public interest that such invention occurs and continues.

On balance, the *Janssen* and *AstraZeneca* decisions do not suggest there has been any substantive change in the attitude of the Federal Court towards the granting of interlocutory injunctions in pharmaceutical patent cases.

In both cases, the difficulty of quantifying generic losses where an injunction is granted, but the patent is ultimately found to be invalid, was acknowledged. However, both cases demonstrate that the fate of interlocutory injunction applications turns upon a careful weighing of numerous factors, at least some of which are likely to be case-specific.

The *Janssen* and *AstraZeneca* decisions demonstrate the importance of establishing the strength of their substantive cases on infringement and validity (for both originators and generics). It also highlights the importance of adducing detailed evidence concerning the financial impacts of generic launch, including the prospect of market entry by other generics and the long-term consequences of the resulting price competition.

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https://www.spruson.com/australia-lessons-from-recent-interlocutory-injunctions-in-pharmaceutical-patent-cases/

Generic entry: Preliminary discovery in pharmaceutical patent disputes

Authors: Katrina Crooks | Jacqueline Macmeikan | Kelly Guo

The decisions of Justice Needham in *Newron Pharmaceuticals S.p.A. v Arrotex Pharmaceuticals Pty Ltd* [2025] FCA 1321 and [2025] FCA 1437 provide a recent and instructive application of the principles governing preliminary discovery under rule 7.23 of the Federal Court Rules 2011 (Cth).

Introduction

Preliminary discovery is a procedural mechanism available in Australia that enables a prospective applicant to obtain documents from a prospective respondent before commencing substantive proceedings. It is governed by rule 7.23 of the Federal Court Rules 2011 (Cth), which permits a party to apply to the Court for an order for the production of documents where that party reasonably believes it may have a right to obtain relief, lacks sufficient information to decide whether to commence proceedings, and reasonably believes that the prospective respondent has or is likely to have documents directly relevant to the question of whether the prospective applicant has a right to relief.

The provision is designed to enable a person who believes they may have a right to seek relief to obtain information necessary to make a responsible decision as to whether to start court proceedings. It is not a mechanism for establishing a prima facie case; rather, it serves a more limited purpose of allowing prospective litigants to make informed decisions about whether proceedings are warranted.

The decisions of Justice Needham in *Newron Pharmaceuticals S.p.A v Arrotex Pharmaceuticals Pty Ltd* [2025] FCA 1321 and [2025] FCA 1437 provide a recent illustration of the operation of rule 7.23, particularly in the context of pharmaceutical patent disputes, and confirm the relatively low threshold for obtaining preliminary discovery in the Federal Court of Australia.

Background

The prospective applicants, Newron Pharmaceuticals S.p.A. (Newron) and Zambon S.p.A (Zambon), are the patentee and exclusive licensee of two patents related to a process of producing high purity safinamide, which contains two particular impurities at a level less than 0.03% by weight, and the resulting product. Safinamide is the active pharmaceutical ingredient in Xadago®, a product used in the treatment of moderate-to-late-stage Parkinson's disease.

Arrotex Pharmaceuticals Pty Ltd (Arrotex) holds four registrations on the Australian Register of Therapeutic Goods (ARTG) for safinamide products, which were approved as generic versions of Xadago®. Arrotex expected to commence supply in the near future, following the listing of its products on the Pharmaceutical Benefits Scheme.

The prospective applicants sought production of documents from Arrotex for the purpose of deciding whether to commence proceedings for actual or threatened infringement of two patents.

Newron and Zambon relied principally on the evidence of Zambon's General Counsel, Ms De Dominicis, who was primarily responsible for making legal decisions on Zambon's behalf regarding its concerns about possible

infringement of the patents. Ms De Dominicis gave evidence that she inferred that the Arrotex products must have been approved on the basis of bioequivalence with Xadago®, and that there was nothing in the material available to her which would lead her to believe that the Arrotex products differed from Xadago® in terms of efficacy and safety. Accordingly, she believed, but did not know, that the Arrotex products might contain high purity safinamide and/or might be made using the patented processes.

Arrotex principally relied on the expert evidence of Professor Michael Roberts, an Emeritus Professor of Clinical Pharmacology and Therapeutics at the University of Queensland.

Professor Roberts stated, among other things, that the determination of bioequivalence did not require determination of whether two drug products have the same or similar levels of impurities, and that there was no reason to believe the percentage of the impurity in the Arrotex products might be below the claimed threshold of 0.03%, because even amounts of the impurity far above that threshold would still result in blood plasma concentrations so low as to be therapeutically meaningless.

Issues

The key legal issues considered by the Court across both decisions were as follows:

1. Whether Newron's and Zambon's belief that they may have a right to relief against Arrotex was reasonable within the meaning of rule 7.23 of the Federal Court Rules 2011 (Cth). This required the Court to determine whether the prospective applicants' belief was one that could reasonably be held, having regard to all of the material before the Court, including the expert evidence adduced by Arrotex.
2. The Court was required to determine the appropriate access regime for the production of documents ordered to be disclosed by Arrotex, and to resolve the question of costs of the preliminary discovery application.

Decision

Reasonable belief by the Prospective Applicants

Justice Needham found that Newron's and Zambon's belief that they may have a right to relief against Arrotex was reasonable. Her Honour held that the belief was not one based on "unreasonable, untenable, irrational or baseless" considerations or views.

In reaching this conclusion, Justice Needham applied the principles established by the Full Court (Allsop CJ, Perram and Nicholas JJ) in *Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd* [2017] 257 FCR 62, which held that:

a. rule 7.23 is a beneficial provision which enables a person who believes they may have a right to seek relief to obtain information to make a responsible decision as to whether to start court proceedings;
b. the party seeking preliminary discovery must prove that it has a belief that it may (not does) have a right to relief, and must demonstrate that the belief is reasonable;
c. the question of whether the belief is reasonable requires one to ask whether a person, in light of all of the material before the person holding the belief (or subsequently the Court), could reasonably believe that they may have a right to obtain relief; and

d. to defeat a claim for preliminary discovery, the party from whom discovery is sought will need to show either that the subjectively held belief does not exist, or, if it does, that there is no reasonable basis for thinking that there may be (not is) such a case, which may be done by demonstrating that no reasonable person, faced with the evidence relied on by the prospective applicant, would think that a right to relief might exist.

Her Honour noted that rule 7.23 must be applied in a way which gives full weight to its purpose, which is to allow a person to make up their mind whether to commence proceedings. Critically, Newron and Zambon did not need to establish a *prima facie* case of patent infringement, and the relevant question was not whether one scientific view was more or less persuasive than another.

In considering the expert evidence of Professor Roberts, her Honour acknowledged that the prospective applicants' evidence did not demonstrate affirmatively that the safety level of impurities in safinamide was lower than 0.03%, nor did it demonstrate affirmatively that the bioequivalence of the Arrotex products meant that they were the same high purity formulation as Xadago®. However, Justice Needham did not consider that she needed to be persuaded to that level. Given the range of scientific views on whether safinamide containing impurities above 0.03% by weight (as expressed in the patents) is unsafe for therapeutic use, and given that the Arrotex products did contain safinamide, her Honour held that there was a reasonable basis for the belief that Newron and Zambon might have a right to relief.

Justice Needham rejected several of Arrotex's arguments. Her Honour did not find persuasive the submission that, because the Therapeutic Goods Administration did not recognise the 0.03% impurity level as a safety threshold, Ms De Dominicis' belief was unreasonable. Nor did her Honour accept that bioequivalence of the parties' products, and reliance on the same testing for each product's Product Information, did not give rise to a belief that the impurity factor may be present. Neither argument ruled out the possibility that the claimed impurity level might be present.

Her Honour also considered Professor Roberts' reasoning to be circular: he stated that, as his calculations showed safinamide with higher impurity levels was not toxic, there was no reason to believe that the Arrotex products were high purity products. To the contrary, Justice Needham considered that it was equally open to believe that they might be high purity products. Her Honour further noted that Professor Roberts' analysis was based on his calculations of toxicity by reason of blood plasma concentrations *in vivo*, and that in the context of the preliminary discovery application, she had not been able to accept that the calculations on the various assumptions were unassailable.

Accordingly, Justice Needham held that, when all of the evidence was considered, including the expert evidence of Professor Roberts, a belief that Newron and Zambon might be entitled to relief appeared to be reasonable.

The access regime and costs

An access regime in pharmaceutical patent matters is common, given the highly confidential nature of manufacturing processes and product formulations that are typically disclosed through preliminary discovery.

In this case, the dispute on access centered on whether two external IP advisers of the prospective applicants located in Italy should be subject to additional restrictions beyond the standard confidentiality undertaking. The prospective respondent sought conditions including that the advisers not be involved in future patent prosecution relating to safinamide in any jurisdiction, and that they only use the documents for Australian proceedings.

Justice Needham rejected the additional conditions, finding that confidentiality undertakings and the Harman undertaking sufficiently protected the prospective respondent's position. Her Honour noted that no specific risk had been identified with the advisers receiving the documents, and that they had previously been granted access to confidential materials without those conditions.

Her Honour ordered that the costs of the preliminary discovery application be costs in the cause of any infringement proceedings if subsequently commenced. However, should no infringement proceedings be commenced within 2 months of the orders giving effect to her decision, there would be no order for the costs of the preliminary discovery application, with the intent that each party bear their own costs. Whilst this approach may reflect the nature of preliminary discovery as a procedural step ancillary to potential substantive proceedings, rather than an adversarial contest producing a winner entitled to costs, it raises a tension with the "entering the fray" line of authority in preliminary discovery applications.

The doctrine of "entering the fray" holds that the more a prospective respondent treats a preliminary discovery application in an adversarial manner (by, for example, adducing competing expert evidence, filing extensive submissions and actively contesting the application), the greater the risk that the prospective respondent will bear the costs of its unsuccessful opposition to that application. The principle has been applied broadly in decisions where prospective respondents have vigorously but unsuccessfully opposed a preliminary discovery application, a recent example of which *is University of New England v Boerner* [2025] FCA 368.

The decisions of Justice Needham appear somewhat inconsistent with this doctrine where Arrotex has likely "entered the fray" by adducing expert evidence, advancing multiple substantive arguments directed to undermining the scientific basis of the prospective applicants' belief and effectively inviting the Court to determine whether the prospective applicants' case had merit.

The prospective applicants are also ordered to pay costs of the prospective respondents for giving discovery and production.

Extensions of time

One practical aspect to be noted is the prospective applicants' repeated requests for extension of the initial deadline for filing substantive infringement proceedings after judgment was given. The repeated extensions illustrate a practical reality of pharmaceutical patent litigation: even after obtaining preliminary discovery, the decision to commence proceedings can remain genuinely difficult and time-consuming, whether because documents reveal a complex picture or because the parties are engaged in without-prejudice discussions.

Key takeaways

The *Newron Pharmaceuticals* decisions have several practical implications for parties considering or responding to preliminary discovery applications in the Federal Court of Australia, particularly in the context of potential infringement of a pharmaceutical patent:

1. The decisions confirm that the threshold for obtaining preliminary discovery under rule 7.23 remains low. The prospective applicant is not required to establish a *prima facie* case of infringement. The applicant need only demonstrate a reasonable belief that it *may* have a right to relief, and that the requested documents would assist in making the decision whether to commence proceedings.
2. The decisions demonstrate the limited utility of expert evidence in opposing preliminary discovery applications. Although Arrotex adduced expert evidence from Professor Roberts directed to undermining the scientific foundation of the prospective applicants' belief,

Justice Needham held that the existence of competing scientific views did not render the applicants' belief unreasonable. In the context of a preliminary discovery application, the Court is not called upon to determine which scientific view is more persuasive; rather, it need only determine whether the prospective applicant's belief is one that could reasonably be held.

3. The practical implications arising from the decisions of Justice Needham for prospective respondents on the question of costs is unclear. Whilst the decisions suggest on one hand a pragmatic approach that avoids penalising either party at the preliminary and procedural stage to enable a prospective applicant to decide whether to litigate, it is inconsistent to earlier decisions and suggests that vigorous opposition to a preliminary discovery application may not carry the costs penalty that the "entering the fray" doctrine would otherwise predict. The position on costs, however, is not settled, and prospective respondents who choose to contest such applications should remain alert to the costs risks articulated in earlier case law.
4. In the pharmaceutical patent context, the decisions confirm that the registration of generic products on the ARTG as bioequivalent to an innovator product is capable of forming a reasonable basis for a belief that the generic products may infringe an associated patent, even where the precise manufacturing process or product composition of the generic is not known to the patent holder.
5. The establishment of an access regime underscores the importance of confidentiality protections in pharmaceutical preliminary discovery. Respondents to such applications should expect that the Court will impose appropriate access restrictions on commercially sensitive documents, and applicants should be prepared to propose and agree to such a regime.

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PBS price reductions: How far do they reach?

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On 12 March 2026, the Federal Court of Australia handed down its decision *in Gilead Sciences Pty Ltd v Minister for Health and Ageing* [2026] FCA 232. The decision is significant as it confirms a broad reading of "combination item" and "listed component drug" under the *National Health Act* 1953 (Cth), with potentially substantial commercial consequences for pricing across product portfolios.

The case concerns the proper construction of key pricing provisions under the *National Health Act 1953* (Cth) (**NH Act**), specifically whether statutory price reductions triggered by the listing of a generic pharmaceutical product on the Pharmaceutical Benefits Scheme (**PBS**) could flow through to other combination products marketed by the same originator company.

Background

Gilead Sciences Pty Ltd (**Gilead**) commenced proceedings under s 39B of the *Judiciary Act 1903* (Cth), seeking declarations and an injunction against the Minister for Health and Ageing (**Minister**).

Gilead had four products listed on the PBS: Descovy, Odefsey, Genvoya and Biktarvy. Descovy was the only product listed for the drug "emtricitabine with tenofovir alafenamide", available in two tablet forms for oral administration. Each of the other three products (Odefsey, Genvoya and Biktarvy) also contained emtricitabine and tenofovir alafenamide in combination with additional active pharmaceutical ingredients, and each was listed on the Combination Drug List (**CDL**) or considered by the Minister as belonging there.

On 8 January 2026, Alphapharm Pty Ltd registered a generic version of Descovy on the Australian Register of Therapeutic Goods. The parties agreed that, upon listing of that generic on the PBS, price reductions under ss 99ACB and 99ACQ of the NH Act would apply to both the generic and to Descovy itself.

The central dispute was whether those same price reductions could also apply to Odefsey, Genvoya and Biktarvy - that is, whether each was a "combination item" containing a "listed component drug" (being "emtricitabine with tenofovir alafenamide") for the purposes of the definitions in ss 84(1) and 99ACA(1) of the NH Act. Gilead contended they were not; the Minister contended they were.

In the alternative, Gilead argued that if the Minister's construction was correct, then reg 65A of the *National Health (Pharmaceutical Benefits) Regulations 2017* - which prescribed the formula for calculating price reductions - was invalid on the basis that it was arbitrary and unworkable.

Decision

Statutory construction: "combination item" and "listed component drug"

Downes J agreed with the Minister's construction. Her Honour held that the word "drug" should be read consistently across the relevant statutory definitions and given its natural and ordinary meaning in context. A "drug" could include a drug that itself contained other "individual constituent drugs", and the Minister's decision to list a drug was not arbitrary but was an exercise of discretion under s 85(2) of the NH Act. Applying the statutory definition, a "combination item" is a pharmaceutical item that has a drug containing at least two other drugs, at least one of which is a listed drug (s 84(1)). The phrase "pharmaceutical item that has a drug" is defined in s 84ABA(1).

The term “other drugs” isn’t defined but, construed correctly, is a reference to a “drug” that was or could become the subject of the general listing power under s 85(2). A "component drug", in relation to a drug in a combination item, need only be "contained in" the drug of a combination item to fall within the definition. A component drug could itself be a listed drug comprised of one or more “individual constituent drugs”.

The upshot of the above definitions is that a “combination item” is a pharmaceutical item that has a listed drug, and that listed drug contains at least two “other drugs” and at least one of those other drugs is itself a listed drug.

Turning to Gilead's products, "emtricitabine and tenofovir alafenamide" were listed together as the drug of the pharmaceutical item associated with Descovy. Each of Odefsey, Genvoya and Biktarvy was a drug containing at least two other drugs, at least one of which was the listed drug "emtricitabine with tenofovir alafenamide". Accordingly, each was a “combination item” and contained the relevant listed component drug, meaning the statutory price reductions would apply to all three products upon the listing of generic Descovy.

Validity of reg 65A

Reg 65A contains a formula for working out the price reduction:

$$\text{Reduction day component AEMPs} \times \frac{\text{Day before combination item AEMP}}{\text{Day before component AEMPs}}$$

with each of the relevant terms defined in the legislation. The AEMP is the approved ex-manufacturer price.

Gilead's alternative argument was that reg 65A did not provide adequate direction for choosing between different possible combinations of a combination item's constituent drugs when applying the price-reduction formula, rendering the formula arbitrary. Gilead provided some tables and explanations of why the formula didn’t work. However, Downes J was not persuaded, finding that Gilead had not adequately demonstrated how or why reg 65A did not work. The Minister demonstrated that the formula, when rearranged (without altering its mathematical outcome, as shown below), operated transparently.

Key takeaways

- The Court endorsed the Minister's reading of the NH Act, confirming that statutory price reductions triggered by the listing of a generic drug can flow through to other combination products that contain the same listed component drug - even where those products also contain additional active ingredients.
- Pharmaceutical companies with multiple PBS-listed products sharing a common drug component should be aware that generic entry in respect of one product may trigger price reductions across their broader portfolio.
- Gilead's challenge to the validity of reg 65A was unsuccessful, with the Court finding the price-reduction formula workable. Parties seeking to challenge delegated legislation on the grounds of ambiguity or arbitrariness will need to articulate with precision how the provision fails.

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Australia's new merger control regime: What it means for patent transactions

Authors: Sylvie Tso | Lucy Hartland | Jesmine Medina

Key takeaways

- **Australia's new mandatory merger control regime**, which commenced on 1 January 2026 under Part IVA of the *Competition and Consumer Act 2010* (Cth), requires parties to notify the ACCC and obtain clearance before completing acquisitions that meet specified monetary thresholds.
- **Patent transactions are notably affected** because they are expressly excluded from the "ordinary course of business" exception that applies to other IP acquisitions such as copyright and trade mark licences, meaning patent deals that meet the thresholds must go through the ACCC's formal notification and assessment process.
- **Significant uncertainty remains** around how the regime will apply in practice to patent transactions, particularly regarding the definition of "acquisition," the treatment of exclusive licences, and multi-jurisdictional portfolio deals. Parties are advised to factor in the ACCC's expected at least 20 business day review timeline when planning transactions.

The new mandatory merger control regime

The new regime, introduced by Part IVA of the *Competition and Consumer Act 2010* (Cth) (**the Act**), replaces the former voluntary notification framework with a mandatory system that requires approval from the Australian Competition and Consumer Commission (**ACCC**) before affected transactions can proceed. Depending on the size of the business and the nature of the acquisition, a business may be required to notify the ACCC and obtain clearance before the acquisition can proceed. Failure to do so can result in the transaction being rendered void and expose the parties to substantial civil penalties. The regime applies broadly to acquisitions of both shares and assets, with assets including intellectual property interests.

While acquisitions of assets made "in the ordinary course of business" are generally excluded, this does not apply where the asset being acquired is a patent, or an interest in a patent. This means that even routine patent acquisitions, including standalone portfolio transactions, may trigger the mandatory notification and suspensory obligations under Part IVA of the Act if the relevant thresholds are met. Companies contemplating any patent transaction should therefore assess at an early stage whether notification is required.

Broadly, the notification thresholds are currently:

In most cases:

- the combined Australian revenue of the parties to the transaction (including related bodies corporate and connected entities of the buyer) is at least $200 million; and
- either the revenue attributable to the assets being acquired is at least $50 million, or the global transaction value is at least $250 million.

For acquirers with an Australian revenue over $500 million, notification is triggered if the revenue attributable to the assets being acquired is at least $10 million. Where it is not reasonably practicable to attribute Australian revenue to a particular asset, the legislation deems the revenue to be 20% of the market value of that asset.

Given the inherent difficulty in isolating revenue streams attributable to individual patents, this 20% market value proxy is likely to be the operative measure for patent portfolio transactions.

Once a notification is made, the ACCC will assess the proposed transaction to see whether it would be likely to substantially lessen competition. Most assessments are expected to be completed in 20 business days, although a minority will take considerably longer. Some particular scenarios that may apply in the pharmaceutical patents space are set out below.

Patent licences granted in settlement of infringement proceedings

Where parties to patent infringement proceedings agree to settle on terms that include the grant of a patent licence, the licensee may be treated as acquiring an "interest in a patent" for the purposes of the new regime.

If the relevant monetary thresholds are met, the settlement may constitute a notifiable acquisition requiring ACCC clearance before it can be given effect. This has significant implications for the structuring and timing of patent litigation settlements. Without clearance from the ACCC, the acquisition (including certain pre-emptive actions) would be considered a breach of the Act, substantial civil penalties may apply, and the transaction may be void. It is not yet clear how long the ACCC's assessment will take in such cases, and parties should factor this uncertainty into their settlement negotiations.

The parties may also need to consider how much non-public financial information will be required to be disclosed as part of the notification process.

Reorganisations and Intra-Group transactions

The new regime provides an exemption for acquisitions that are part of a restructure or reorganisation of related bodies corporate (within the meaning of s 4A of the Competition and Consumer Act 2010 (Cth)) or other persons that are related by means of trust or partnership. The rationale for this exemption is straightforward: where there is no change of ultimate control — for example, a transfer of assets between wholly-owned subsidiaries, the transaction does not raise the competitive concerns that the regime is designed to address. Accordingly, internal corporate reorganisations that involve the transfer of patent holdings between group entities should generally fall within this exemption and not require ACCC notification, even where the monetary thresholds would otherwise be met.

However, a critical distinction arises between the outright transfer of patent holdings and the grant of a patent licence (including an exclusive licence) within a corporate group. The reorganisation exemption is directed at structural reorganisations of existing arrangements, such as the consolidation or redistribution of assets within a group.

The initial grant of a new exclusive patent licence to a subsidiary, particularly where it is done for a specific commercial or litigation purpose, rather than as part of a broader group restructure, may not sit comfortably within the concept of "reorganisation." This is because the licence creates a new legal interest rather than merely moving an existing one within the group.

For example, where a foreign patent owner wishes to enforce a patent in Australia but it is the local subsidiary that has suffered damage, the patentee may seek to give its subsidiary standing by granting an exclusive licence under the Patents Act 1990. Because such a licence constitutes the conferral of an interest in a patent, it would amount to an acquisition of an "asset" within the broad definition in s 51ABN of the Act. If the relevant monetary thresholds are met, ACCC notification may be required — even though the transaction is entirely intra-group and may have no competitive significance.

By contrast, the position is more favourable for other forms of intellectual property. Acquisitions of assets in the ordinary course of business are generally excluded from the merger control regime — and, unlike patents, trade marks, designs, copyright (including software) and plant breeders' rights are not carved out of this exception. This means that routine intra-group licences of trade marks or designs will generally qualify for the ordinary course of business exception and will not require ACCC notification, even if the monetary thresholds are otherwise met. Patents are therefore subject to materially more restrictive treatment than other categories of intellectual property.

Multinational groups should therefore carefully consider how IP-related transactions within corporate groups are structured. While internal transfers of patent holdings as part of a genuine reorganisation should be exempt, the grant of new exclusive patent licences, particularly for specific commercial or enforcement purposes, may require ACCC notification. Parties should review their IP licensing arrangements with Australian subsidiaries to assess whether existing or contemplated transactions may trigger the notification and suspensory obligations under the Act.

Notification waivers

It will be possible to apply for a notification waiver, which may be granted for straightforward acquisitions that do not require further investigation by the ACCC, i.e. acquisitions that do not give rise to competition concerns or risk of harm to competition or consumers.

However, further consideration will need to be given to whether a waiver can apply to the acquisition of a patent or an interest in a patent, whether between third parties or within a corporate group. Given the significant value of pharmaceutical patents and the highly regulated nature of market entry, it is unclear whether a waiver would be readily available in this context.

The practical effect of these changes is that patent transactions many of which would previously have proceeded without any engagement with the ACCC now require early and careful assessment against the new notification thresholds. This includes not only outright patent assignments and portfolio acquisitions, but also the grant of patent licences — whether in the context of litigation settlements, commercial licensing, or intra-group arrangements. Practitioners advising on patent transactions should build ACCC notification timelines into their transaction planning and settlement negotiations from the outset.

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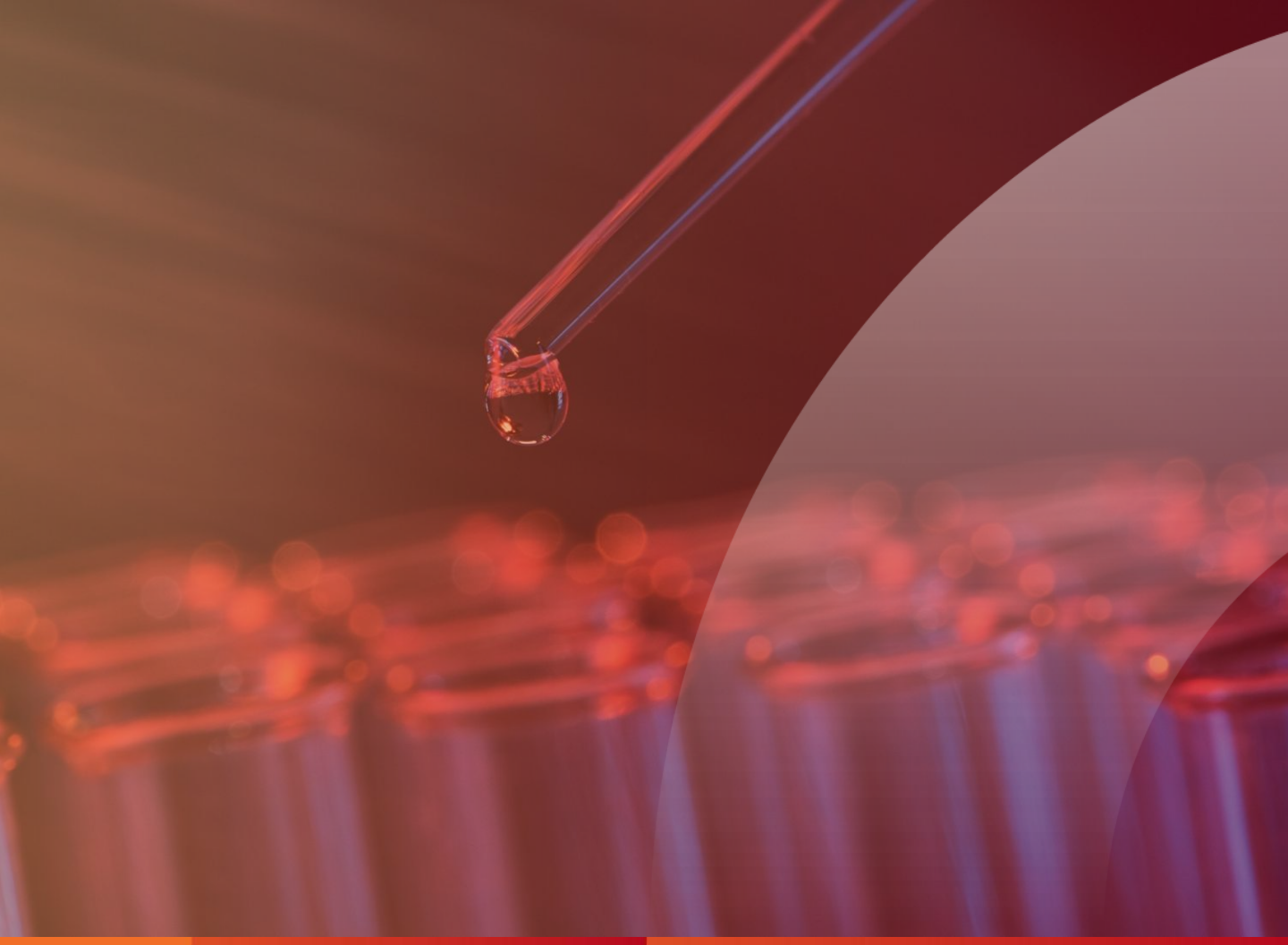

Hot topics

Orphan drugs series | Patenting considerations

Authors: Dr Catherine Winbanks | Lucy Hartland | Dr Abrey Yeo

Collectively, rare diseases impact approximately 8% of the Australian population, or around 2 million people. Orphan drugs are pharmaceutical products developed to treat rare diseases, however with each drug involving small patient populations and high development costs, these therapies require carefully crafted patent and regulatory strategies to be commercially viable.

Patent strategies for orphan drugs: Start early, think long

A robust patent strategy for orphan drugs, as with other drugs, generally involves both primary patents, covering the substance, and often including claims to method of manufacture, formulation and the like, and secondary patents covering other key aspects of the substance, such as newer methods of manufacture, medical uses for lead indications or improved formulations.

Additional patent filings can be critical for orphan drugs, as it can take at least 10 years, and often longer, to bring a drug to market. By the time an orphan drug receives marketing approval, there may be limited patent term remaining to provide exclusive rights. For this reason, sponsors often seek further patents covering aspects such as new medical uses, dosing regimens, formulations, delivery routes, combination therapies, or treatment of specific patient subgroups.

This approach is often referred to as "evergreening", a strategy in which pharmaceutical companies extend the effective life of their patent monopolies by filing multiple follow-on or secondary patents around an original invention. These patents may relate to relatively minor changes, such as new formulations, dosages, or methods of use, and may offer limited inventive advances. Evergreening is common for high-cost, high-selling drugs and is particularly relevant for orphan drugs.

While such follow-on patents can be a legitimate means of protecting the significant investment required to develop new therapies, they should be pursued transparently, grounded in scientific merit, and applied ethically to avoid delaying access to affordable medicines.

Examples of common claim types relevant to orphan drug development include:

1. **Claims to the substance**: Where available, these claims offer the strongest form of protection. If it is possible to patent the relevant class or subclass of compounds, that should also be considered at an early stage, as this would create a broader fence around the core IP.
2. **Claims to medical uses**: There are various forms in which claims to medical uses can take depending on the jurisdiction:

Method of treatment claims: These claims typically take the form of "A method of treating disease Y comprising administering compound X to a subject in need thereof." While this form is available in Australia and the United States, they are not acceptable in many other jurisdictions including Europe, Canada, China, India, and New Zealand. These claims are particularly useful where dosing regimens, treatment schedules, or routes of administration form part of the inventive contribution.

Swiss-style claims: These claims typically take the form of "Use of compound X in the manufacture of a medicament for treating disease Y". These are designed to capture infringement by manufacturers or suppliers who produce or market a medicament for the patented therapeutic use. These claims may also be, and often are, used in Australia, in addition to the above method of treatment claims since they can capture infringement under different circumstances. Other countries that accept these claims include New Zealand, Japan and Canada.

The 'purpose limited' EPC 2000 format: Noted for completeness, this claim type is in the form of "Compound X for use in treating disease Y", and is the preferred form under the current European Patent Convention.

3. **Formulation and delivery claims:** These claims can cover the formulation per se, modifications thereof, such as sustained-release mechanisms, liposomal carriers, or targeted delivery. This claim format can be a valuable source of additional protection. These claims can under certain circumstances sidestep some of the prior art issues affecting use claims.
4. **Biomarker-based claims:** When a drug is particularly effective in patients with a specific biomarker, claims directed to methods of treatment for those biomarker-defined subpopulations can be pursued. This is especially relevant for personalised medicine approaches in rare diseases with genetic causes.
5. **Method of manufacture/process claims:** If the drug involves a novel or improved method of synthesis, these claims can offer added value, albeit with narrower prospects for enforcement. In some cases, scalable or green synthesis methods may offer additional leverage in partnering discussions.
6. **Combination therapy claims:** Many orphan drugs are used in combination with other agents. Where possible, securing claims to synergistic combinations or dosage regimens can extend exclusivity, especially when the individual components are off-patent.

Patent term extension: a crucial window

In Australia, patent term extension (PTE) provides a mechanism whereby a patentee may apply for an extension of up to five years for a standard patent that claims a pharmaceutical substance, in recognition of the long development timelines and regulatory burdens associated with bringing new medicines to market.

This mechanism may be relevant where the orphan drug is a new drug, and has not previously been included on the Australian Register of Therapeutic Goods (ARTG). Clinical development of these drugs may be particularly prolonged by funding constraints, recruitment challenges and limited trial populations.

To qualify, the patent must claim: (i) one or more pharmaceutical substances per se, and/or (ii) pharmaceutical substance(s) produced by recombinant DNA technology. Goods containing, or consisting of, the substance must also be included on ARTG. The PTE is calculated based on the first regulatory approval date of a product containing that substance.

An important consideration arises when a patent covers more than one pharmaceutical substance that ultimately receives regulatory approval.

Under Australian law, any extension of term must be based on the product that first obtains registration on the ARTG, even if that product is owned by a third party.

This can be particularly significant for orphan drugs, where the patentee may be relying on a later-approved product for commercialisation. If an earlier-approved product encompassed by the same patent has already triggered the calculation of the extension period, it may substantially reduce, or entirely eliminate, the available term extension for the orphan drug.

In other words, the patentee has no discretion to nominate a different, later-approved product to maximise the extension period. Furthermore, it is also important to note that if a product is registered less than five years after the patent's filing date, no effective extension will be available, regardless of when the second product receives approval.

In Australia, divisional filings may offer a strategic workaround where a patent covers multiple pharmaceutical substances. By filing a divisional for each individual substance, particularly where separate commercial products are expected to receive ARTG registration at different times, applicants may preserve the ability to obtain separate and potentially longer PTEs provided that each divisional patent meets the eligibility criteria.

This strategy can be especially important in the orphan drug context, where market sizes are small, and delays in approval can have a disproportionate impact on commercial viability.

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https://www.spruson.com/australia-patenting-orphan-drugs-part-1/

Orphan drugs series | Regulatory considerations

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This article outlines the key regulatory considerations for orphan drug development in Australia.

Orphan drug patent strategy recap:

Start early, think long: broaden patent protection with primary and secondary patents covering additional commercially relevant aspects of the technology

Patent protection may be broadened by pursuing claims directed to the substance per se, medical uses, formulations & delivery routes, as well as claims directed to biomarkers, methods of manufacture and combination therapies

In Australia, patent term extensions can provide an additional 5 years protection for orphan drugs.

Orphan drug designation

In Australia, drugs are regulated by the Therapeutic Goods Act 1989 and delegated legislation including the Therapeutic Goods Regulations 1990 (TG Regs) and assessed by the Therapeutic Goods Administration (TGA).

The TG Regs have special provisions to reduce the costs of having orphan drugs included on the Australian Register of Therapeutic Goods (ARTG). If a drug is designated as an "orphan drug," it is eligible for a waiver of the application and evaluation fees otherwise payable to register the drug as a prescription medicine.

The definition of "orphan drug" for the purpose of the TG Regs is not confined to drugs for rare diseases. It covers drugs that are indicated for the treatment, prevention or diagnosis of life – threatening or seriously debilitating conditions in a particular class of patients and, in the case of drugs that do not involve a new dosage form, one or more of the following must apply: [1]

the drug is intended to treat a disease that affects fewer than 5 in 10,000 individuals in Australia;

the drug is intended to prevent or diagnose a condition, where, if it were included in the ARTG, would not be likely to be supplied to more than 5 in 10,000 individuals in Australia during each year that it is included; or

the drug is not likely to be financially viable for the sponsor to market the medicine in Australia unless it receives a fee waiver.

Orphan drug designation may be granted for previously unregistered medicines, already registered medicines with a new orphan indication or new dosage forms under certain circumstances. [2]

Data exclusivity

Another feature of the regulatory regime under Australia's therapeutic goods regime are the data exclusivity provisions. Although not specific to orphan drugs, data exclusivity provides an important incentive for orphan drug development by providing an appropriate mechanism to keep generic competition off the market for a period of time sufficient to justify the expense and risk associated with development of the drug.

While the sponsor of a generic drug that seeks to have a generic drug included on the ARTG may be able to rely upon information supplied by the originator sponsor, s 25A of the

1. Therapeutic Goods Regulations 1990, Reg 16J(3), which also sets additional conditions. See Reg 16J(4) for new dosage forms.
2. *Therapeutic Goods Regulations 1990*, Reg 16J.

Therapeutic Goods Act 1989 may limit that reliance. In particular, where the information concerns an application to register therapeutic goods and it has been less than five years since those goods were registered, that information may be protected from disclosure.

Australia's approach to data exclusivity is narrower than that of the US or Europe. Exclusivity is available only for confidential information submitted to support the registration of a new chemical entity. This means that clinical data used to support other types of applications, such as new indications, dosage forms, routes of administration, or combination products, is not afforded the same protection.

In practice, this leaves applicants who are first to register, say, a new therapeutic use of an existing drug, reliant solely on patent protection to maintain a competitive advantage.

Pharmaceutical Benefits Scheme

Where the TGA has designated a drug as an "orphan drug", then an applicant seeking to have that drug included on the Pharmaceutical Benefits Scheme (**PBS**) may be able to seek a fee exemption, although additional conditions may apply. These are presently detailed in the *National Health (Pharmaceuticals and Vaccines–Cost Recovery) Regulations* 2022.

Other government programs may also assist with the costs related to the regulatory costs associated with drugs, including orphan drugs.

One such example includes Zolgensma (onasemnogene abeparvovec), which marks a significant milestone as the first gene therapy listed on Australia's PBS.

Approved by the TGA in early 2021 and added to the PBS in May 2022, it offers life-changing, one-time treatment for infants under 9 months with spinal muscular atrophy (SMA), a condition previously managed with continual therapies. Given its staggering cost (reported to exceed AUD 2 million), PBS listing eases the financial burden for families and healthcare systems, illustrating how orphan-drug incentives and regulatory mechanisms can facilitate access to cutting-edge treatments.

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https://www.spruson.com/australia-regulatory-considerations-for-orphan-drugs-part-2/

Piercing the limits | Patenting in the age of needle-free vaccines

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For more than a century, the needle and syringe have been the standard tools of immunisation. Now, advances in engineering and formulation are driving a shift toward needle-free vaccine delivery systems, reshaping both global health and patent strategy.

Valued for their simplicity, the needle and syringe method has been limited by cold-chain storage requirements, the need for medical supervision, the safe disposal of sharps waste, and the fear and anxiety they frequently evoke, particularly in children and those with needle-phobia.

Needle-free systems are no longer experimental; they are progressing into late-stage development and commercial adoption. By improving patient access and simplifying vaccine distribution, these technologies help overcome both clinical and logistical barriers, while at the same time opening fertile ground for building strong, commercially valuable patent portfolios.

As patent activity increasingly extends beyond formulations to include devices, coatings and delivery mechanisms, we review some of the delivery systems currently in development and outline key IP protection areas for strategic innovators.

Microneedle and microarray patches

Microarray patches (MAPs) use microscopic projections to deliver vaccine into the outer skin layers, where immune cells are concentrated. The approach is painless, efficient, and often more stable than traditional injections.

Brisbane-based Vaxxas has emerged as a global leader. Its High-Density Microarray Patch (HD-MAP) platform has entered late-stage clinical development with support from the Coalition for Epidemic Preparedness Innovations (CEPI) and the Biomedical Advanced Research and Development Authority (BARDA).

Earlier this year, the company secured a new US patent covering its precision print-head coating process, expanding its portfolio to more than 40 issued patents worldwide spanning patch/applicator design, coating and loading processes, and vaccine formulations, demonstrating how process and materials innovation can be just as strategically important as the device itself.

Internationally, US-based Micron Biomedical is developing a CEPI-supported dissolvable microarray “button” for pandemic preparedness. The skin-applied patch delivers vaccine through microscopic projections that dissolve within minutes, offering a needle-free, thermostable, and self-administered alternative to injections.

Micron is also exploring applications of the technology beyond vaccines, including its use for injectable therapies such as those for obesity and diabetes. Their patent filings focus on dissolvable microarray structures, fabrication methods, and applicators, together with scale-up and clinical translation.

Collectively, these efforts show how patch platforms are evolving into modular, multi-antigen systems with broad commercial and patent potential.

Mucosal delivery systems

Mucosal vaccines, delivered through the nose or mouth, aim to trigger immunity where many infections start. Nasal sprays, inhalable powders, and oral films are all in development as painless, self-administered alternatives to injections.

FluMist®, a live-attenuated intranasal influenza vaccine (LAIV), was developed in the late 1990s by Aviron and later acquired by MedImmune. It became the first FDA-approved intranasal LAIV in 2003 and moved to a quadrivalent formulation in 2012 using cold-adapted, temperature-sensitive attenuated strains. This platform has been protected by patents, now held by MedImmune/AstraZeneca, encompassing strains, intranasal formulations, and methods. More recently, it has been announced that FluMist® will be added to several Australian state immunisation programs from 2026, marking the first large-scale public rollout of a mucosal vaccine in Australia.

Several other products have recently received regulatory authorisation. In India, Bharat Biotech's iNCOVACC®, an adenovirus-vectored intranasal COVID-19 vaccine, received emergency-use authorisation in September 2022. In China, CanSino's Convidecia Air®, an aerosolised booster version of its Ad5-nCoV vaccine, received emergency-use authorisation that same month, supported by patent filings dating back to 2020 covering the inhaled formulation and nebuliser-based delivery.

The journal Science also recently profiled a proof-of-concept "floss vaccine", studied at North Carolina State University, where tape-style dental floss coated with vaccine was

applied at the gumline's junctional epithelium. The approach produced strong mucosal and systemic responses in mice, with early human feasibility studies indicating that oral-gingival targeting may be achievable, pointing to a potential new needle-free route.

From a patent perspective, mucosal delivery is an interdisciplinary space where formulation, aerosol physics, and device engineering meet. Patent filings often couple composition with device parameters such as nozzle geometry, plume characteristics, particle size, and mucoadhesive chemistry, signalling a shift toward protecting the integrated system rather than isolated parts.

Jet injectors

Jet injectors deliver vaccines through a fine, high-pressure liquid stream that penetrates the skin within milliseconds. These systems, powered by either a spring or compressed gas, deliver intradermal or intramuscular doses within milliseconds. The approach reduces sharps waste, eliminates the risk of needle-stick injuries, and simplifies large-scale immunisation campaigns by allowing faster administration with minimal training.

US-based medical technology company PharmaJet offers two needle-free platforms: Tropis® for intradermal delivery and Stratis® for intramuscular/subcutaneous delivery. The Tropis® device is the only WHO-prequalified needle-free injector and was used in Pakistan's 2025 polio campaign, reaching more than 1.5 million children. The same platform has been adopted for both DNA and mRNA vaccines, demonstrating compatibility with next-generation vaccine formats. PharmaJet's patent portfolio covers nozzle design, cartridge systems, and pressure regulation, illustrating how mechanical engineering can secure durable protection.

In India, innovation in needle-free delivery is accelerating. In May 2024, the Serum Institute of India (SII) acquired a 20% stake in IntegriMedical to advance its spring-powered jet injector technology. The device uses a high-pressure piston to deliver medication through a micro-orifice in the skin, reducing pain and needle-related hazards. Following local approval in 2022 and commercial launch in 2024, adoption has grown among clinicians treating children and needle-phobic patients. The system is also currently in trials comparing COVID-19 booster delivery with conventional needles.

Solid-dose injectors

Solid-dose vaccine delivery systems replace liquid injections with dry, thermostable formulations administered through compact, needle-free devices. These systems deliver a small solid pellet or tablet into or onto the skin, where it dissolves and elicits an immune response.

Solid-dose injectors, such as the aVaxziPen® system developed in the UK, take a different path by delivering thermostable vaccine pellets through a reusable pen-type device. Supported by CEPI, the technology eliminates cold storage and sharps waste. Recent patent filings from aVaxziPen cover solid-dose compositions and cassette/applicator mechanisms, reflecting a comprehensive protection strategy around both product and device.

Other emerging methods

Researchers are also exploring other physical approaches to improve vaccine uptake. These approaches include:

- Electroporation (Inovio's CELLECTRA®), which uses short electrical pulses to create temporary pores in cell membranes, improving uptake of DNA or RNA vaccines;
- Skin-stretch applies mechanical tension, which creates transient microchannels, activates immune cells, and enhances vaccine uptake;
- Thermal and optical ablation, which uses heat or light to remove the outer cellular barrier to allow vaccine delivery; and
- Ultrasound delivery, which uses sound waves to propel vaccines through the skin by acoustic cavitation, creating microchannels that allow molecules to reach immune-rich tissues.

Each modality opens a different technical and patent space, covering device architecture, control parameters, and energy modulation, where cross-disciplinary innovation often drives the most valuable IP.

Patents and IP strategy

The shift toward device-based vaccination is also reshaping IP strategy. Traditionally, vaccine portfolios were built around antigen design, adjuvants, and formulation chemistry.

In the emerging landscape, however, competitive advantage increasingly lies in the delivery platform itself and in how biological and mechanical innovations interact to achieve immunogenicity, stability, and scalability.

With innovations increasingly bridging biology, engineering, and manufacturing, effective protection demands a layered and cross-disciplinary patent strategy.

Key areas of protection now include:

- **Device architecture**: encompassing applicators, nozzles, cartridges, and coating systems. Small variations in geometry or pressure regulation can materially affect dose precision and patient outcomes, giving rise to strong, defendable claims.
- **Formulation-device interfaces**: where the performance of the vaccine depends on how it interacts with a polymer matrix, microneedle coating, or dissolvable film. These hybrid innovations often yield valuable process or composition claims that sit alongside device patents.
- **Manufacturing and loading processes**: especially those that improve scalability, thermostability, or uniformity of dosing. Process patents in this space can extend exclusivity even when product claims are narrow.
- **Combination and method claims**: linking a defined vaccine type to a particular delivery mechanism or dosing approach, ensuring protection for the integrated platform rather than its individual parts.

As delivery technologies become more sophisticated, the IP landscape is also becoming more complex. Overlaps between biologic and device patents increasingly demand close collaboration between R&D teams and patent counsel from the earliest stages of development.

The strongest portfolios are those that recognise the delivery technology not as an accessory but as a core component of the vaccine's inventive concept, one that shapes both its clinical performance and its commercial life cycle.

Freedom-to-operate analyses are also evolving. The convergence of medical device and biopharmaceutical patent spaces means that overlapping ownership, licensing structures, and regulatory classifications can create hidden barriers to market entry. A coordinated strategy that aligns patent drafting, regulatory planning, and design-around considerations is now essential to avoid downstream bottlenecks.

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https://www.spruson.com/piercing-the-limits-patenting-in-the-age-of-needle-free-vaccines/

In the courts

Currently in the courts

Authors: Kelly Guo | Jesmine Medina

Pfizer Ireland Pharmaceuticals & Anor v Samsung Bioepis Co. Ltd & Ors

This matter concerns the same patent which led to judicial clarification of the principles of preliminary discovery in patent infringement cases a number of years ago.

Following the preliminary discovery that was given by the respondents, Pfizer issued proceedings alleging infringement of Australian Patent no 2005280034, which covers methods of producing polypeptides, relevant to the production of Etanercept, an autoimmune disorder biologic.

The eight respondents have cross-claimed alleging that the patent is invalid. The matter was heard in the second half of 2025 and judgment has been reserved.

Otsuka Pharmaceutical Co., Ltd & Anor v Generic Health Pty Ltd (NSD837/2015)

This case concerns the Australian government's claim to damages based on undertakings as to damages given by Otsuka as a condition of the grant of an interlocutory injunction against Generic Health to prevent the entry onto the market of generic aripiprazole. The subsequent infringement proceedings resulted in Otsuka's patent being found be invalid. As a result, the injunction was found to be wrongly granted.

The Australian government's interest in the injunction, and in the undertakings, is because of its role in subsidising the cost of certain medicines via the Pharmaceutical Benefits Scheme (**PBS**). When an originator drug is first listed, the amount paid by way of subsidy depends on the price negotiated between the PBS and the originator pharmaceutical company.

Once generic companies obtain listings for generic versions of the originator drug, there are various mechanisms that serve to ratchet down the price paid to the originator for its product.

The Australian government contends that as a direct consequence of the injunctions imposed on Generic Health preventing entry of generic aripiprazole on to the PBS, it paid millions of dollars more under PBS than it otherwise would have paid for aripiprazole and seeks compensation in respect of those overpayments.

The claim has been the subject to several court proceedings and a Referee's Report. The parties are awaiting a decision in relation to the outcome of competing applications to challenge the adoption of the Referee's Report.

Otsuka Pharmaceutical Co., Ltd v Sun Pharma ANZ Pty Ltd

See our article on page 5 for a summary of the proceedings.

On 12 March 2026, the High Court granted special leave to the Otsuka parties to appeal the decision of the Full Court which found the patent term extension granted on Otsuka's patent for long acting injectable aripiprazole invalid on the basis that the formulation covered was not eligible for PTE protection.

At first instance, the trial judge had found the formulation to be eligible subject matter but rejected it on the basis that the underlying patent claims were invalid for lack of clarity. The Full Court overturned both findings, finding the claims clear but holding that at least in this case, the formulation was not a 'pharmaceutical substance per se'. The case raises important issues of principle in relation to PTE protection for formulations and the outcome may have significant ramifications for the timing of generic entry.

As of the time of writing Otsuka parties had filed submissions with all submissions to be filed by the beginning of June.

Janssen Pharmaceutica Nv & Anor v Juno Pharmaceuticals Pty Ltd

Please see page 9 for further information on the decision.

Since the grant of an interlocutory injunction to restrain launch of Juno Pharmaceutical's generic long-acting paliperidone products, further preliminary steps have been taken in the proceedings. As yet no evidentiary timetable or trial date has been set.

AstraZeneca AB & Anor v Pharmacor Pty Limited ABN 58 121 020 835

Please see page 9 for further information on the decision.

Since the grant of an interlocutory injunction to restrain the launch of Pharmacor's generic dapagliflozin products, Pharmacor sought to amend its pleadings. While some amendments were permitted, leave to include the ground of failure to disclose the best method of performing the invention was refused.

The proceedings are set down for hearing for 7 non consecutive days from 31 August 2026.

Telix Pharmaceuticals (Innovations) Pty Ltd v Purdue Research Foundation

Telix Pharmaceuticals (Innovations) commenced proceedings earlier this year against Purdue Research Foundation seeking to revoke its patent covering prostate cancer treatment Pluvicto. Purdue Research Foundation has filed a cross claim for infringement. The proceedings are still at an early stage with no evidentiary timetable or hearing date set.

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Federal Court launches Standard Directions to streamline patent disputes

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A new Practice Note [1] introduced by the Federal Court of Australia promises to facilitate more efficient and economical resolution of patent disputes in Australia.

The complexities of patent litigation, including the centrality of expert witnesses and the many common construction issues and challenges to validity, must be carefully managed to ensure that patent disputes can be resolved quickly and cost effectively.

The new Practice Note provides the Court with a range of tools to achieve this, centred around the keystone expectation of a trial within 12-18 months of commencement.

Background

Many of the measures introduced have been used in recent years by patent judges on a discretionary basis. However, their codification into a default position, with cogent reasons required to depart from the framework, is likely to have significant impact on patent litigation in Australia.

Following a pilot program of the new procedures earlier in 2025, the Practice Note came into effect on 8 August 2025 and now applies to all patent proceedings including those already in progress. Below, we consider the key new procedures and how patent litigants can expect to see patent litigation change in Australia. We also provide a timeline graphic incorporating the new procedures for clarity.

Key takeaways

Parties in Australian patent litigation proceedings should:

- identify and retain suitable experts as early as possible once the prospect of litigation arises
- prepare for earlier costs
- consider carefully whether interlocutory applications are appropriate

Appeals from decisions of the Commissioner of Patents are not within the scope of the Practice Note, although it is possible that judges may have regard to its principles, particularly in respect of evidence, expert conclaves and pre-trial matters.

First case management hearing and the Standard Directions

The first case management hearing is crucial to the new framework, and will continue to take place around 4-6 weeks after commencement of the proceeding. At that hearing the Court will consider the appropriateness for the particular case of Standard Directions, as set out in the Practice Note. We anticipate the Court will not lightly depart from these directions.

In a substantial change, other than in exceptional cases, a trial date will be set at the first case management hearing around 12 to 18 months after that hearing. This provides a 'back-stop' on the proceeding, and parties will be expected to 'cut their cloth' so that all preparatory steps are completed within that timeframe.

1. Intellectual Property Practice Note – Standard Directions For Australian Patent Proceedings (IP-2) (Practice Note IP-2)

At the first case management hearing parties will need to be ready to discuss matters such as any need for experimental evidence, the length of trial, and potential separate questions.

Together with other steps which will be required early in the proceeding (see further below), the new framework will require parties to be well advanced in understanding their respective cases at a very early stage. This could prove a significant strategic advantage for applicants who have had the opportunity to prepare over a longer period of time. In particular, identifying and securing experts at an early stage will be crucial.

Position statements | Product/process descriptions

The Standard Directions require the exchange of position statements on infringement and validity within 5 weeks of the first case management hearing. Where a respondent does not admit infringement, this includes the filing of a product/process description directed to any integers of the relevant claims in dispute.

Product/process descriptions have been in use in patent infringement proceedings for some time, often offered by a respondent in order to avoid the need for discovery on relevant features. They involve a detailed explanation of relevant features of the product/process, to make clear the basis on which infringement is disputed, and must be verified by a person who can be called for cross-examination.

Given the consequences that can flow from the description, the task of preparing it is often an onerous one, requiring a very detailed analysis of the relevant product or process.

Ideally engagement with the expert(s) will also have commenced before the description is completed. While the Practice Note does not rule out discovery being sought on disputed integers, it is likely that a well executed description, supported by business records, will at least significantly reduce the discovery required.

Discovery | Multiple patents, claims & grounds of invalidity

A number of recent IP judgments have raised concerns about overly complex proceedings, including the assertion of multiple patents, large numbers of claims and invalidity attacks run on many grounds. The Practice Note:

- Indicates that parties should confine their claims of infringement and invalidity as far as possible, including seeking to assert only one patent if possible.
- Contemplates a direction to a patentee to propose determination of infringement and validity of a subset of patents, claims or infringement types as separate questions, or that the case is run on the basis of exemplar claims. This aims to reduce complexity, and a similar approach might apply where infringement is alleged in respect of a range of products.

To meet these expectations, the parties will likely need to discuss at the outset how the case can be confined on both sides, and what agreement can be reached with regard to exemplar claims and products, to allow for the outcome on certain claims or products to be extended to others.

Given that each patent claim represents a separate bargain, trading off between claim breadth and potential validity issues, the Court will need to balance the entitlement of the patentee to exercise its patent rights with the interests of efficiency. The proposal to use separate questions is also an interesting one.

The Court has often been reluctant to deal with separate questions, considering that they are more likely to increase cost and time, than create efficiencies. Over time, the factors supporting a separate question approach will likely become clearer.

Expert evidence

Overall, the Standard Directions with respect to evidence do not significantly change current practice. The Directions contemplate that the number of experts and their technical fields will be stipulated in the orders made at the first case management conference, underscoring the need to engage early with experts.

They formalise a process for the experts to seek to agree in written evidence on a technical primer, and on matters of common general knowledge. Page limits for expert evidence may be imposed after consultation with the parties.

The Directions also include a summary of the law relevant to the concept of common general knowledge which may be supplied to the experts.

Costs payable forthwith on interlocutory applications

Currently, costs awarded on interlocutory applications are generally not quantified by the Court and consequently are not enforced until conclusion of the proceedings since it makes sense to quantify all costs together.

By contrast, the Practice Note specifies that the Court may make an order for lump sum costs, payable within 14 days of the costs order. Each party must file and serve a statement of costs claimed for an application shortly before the hearing of that application.

In this regard it refers to a similar approach in the UK, introduced by the Woolf reforms in 1999. The Jackson Review of Civil Litigation Costs published in the UK in 2009 was generally supportive of the concept, noting that it deterred frivolous applications. It is likely to have a similar deterrent effect in the Federal Court, or at least encourage early resolution of such applications, and we will await future assessments of the impact that this measure has.

Security for costs

A respondent to patent proceedings may wish to consider whether the applicant would be able to satisfy an adverse costs order if unsuccessful. Since proceedings will move quickly under the new procedures, a respondent will need to consider this question early, and should foreshadow any such application at the first case management hearing, if the application is not filed beforehand.

Conclusion

The Practice Note reflects a shift toward tighter case management, earlier and more substantive engagement on key issues, and greater discipline in the conduct of proceedings. As a result of this and the generally compressed timeline, early preparation will be critical.

While it is hoped that the measures will reduce overall costs of proceedings, the compressed timetable means that costs will be incurred over a shorter period of time with some of those costs shifted to the early weeks and months of the proceeding – including before the first case management hearing. Litigants will need to plan accordingly.

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https://www.spruson.com/australia-federal-court-launches-standard-directions-for-patent-disputes/

Policy updates

Policy updates

Author: Lucy Hartland

Key developments in Australian health and IP policy

The past year has seen a flurry of activity across Australia's regulatory landscape, with significant developments in health research governance, therapeutic goods enforcement, and intellectual property reform. Below is a snapshot of the most noteworthy policy movements.

A single front door for health research

On 2 October 2025, Health Minister Mark Butler unveiled $13.6 million in funding for the "National One Stop Shop" - a unified national platform for health-related human research. The NOSS represents a decisive shift away from fragmented state and territory-based approvals processes, promising researchers a single national system for ethics approvals and data management. It forms part of a broader suite of reforms designed to make Australia a more attractive destination for clinical trials.

Therapeutic Goods Administration | TGA sharpens its enforcement focus

In January 2026, the Therapeutic Goods Administration (**TGA**) set out its compliance management and enforcement priorities for 2026 and 2027. The list is wide-ranging: direct-to-consumer IVD kits, erectile dysfunction and weight loss medications, foetal dopplers, advertising of listed medicines, melatonin and medicinal cannabis, sunscreens, cosmetic procedures involving therapeutic goods, and software as a medical device (SaMD). Vaping products, unsurprisingly, remain firmly in the TGA's sights. A notable thread running through these priorities is a heightened focus on the online environment - encompassing digital advertising and promotion, e-commerce platforms, and AI-generated content - with regulators intent on tackling disinformation and the promotion of unapproved therapeutic goods.

Clarity on software as a medical device

In February 2026, the TGA followed up with updated guidance on how SaMDs are regulated. The central message is that regulation turns on how the software is used, not merely on the fact that software is involved. Software-based medical devices follow the same ARTG registration pathway as other devices, though three software-specific principles apply. Among other things, these bring cyber security requirements squarely into the regulatory frame - an increasingly important consideration as digital health tools proliferate.

IP Australia eyes reform of exclusive licensing (among other things)

In March 2026, IP Australia released its consultation paper "Streamlining and Simplifying IP Regulation," seeking views on a targeted set of technical and administrative changes to IP legislation. Of particular interest to patent litigators is a proposal to expand the definition of exclusive licensees under the Patents Act 1990. At present, only the patentee and/or the exclusive licensee may commence proceedings to enforce a patent. While it is usually desirable for a foreign patentee to have its Australian licensee joined as a party to enforcement proceedings, a recurring difficulty arises where the licensee's rights fall short of a true exclusive licence.

In the context of a global pharmaceutical business, granting local licensees exclusive licences may be undesirable and inconvenient. The consultation closed in April 2026, and IP Australia will now advise the Australian Government on whether this and other proposed amendments should be taken forward to legislative reform.

Federal Budget 2026-2027

Expenditure Pharmaceutical Benefits Scheme

In the 2026-2027 budget, payments related to the Pharmaceutical Benefits Scheme are expected to increase by $123.5 million in 2026-27 and $757.0 million over five years to 2029-30. This is to reflect updated pharmaceutical pricing assumptions and changes to predicted prescription volumes.

Specific medicines

The Government is providing $5.9 billion for new and amended PBS listings, including treatments for cystic fibrosis, chronic kidney disease, various cancers and more. There is also $449.3 million to list the respiratory syncytial virus (RSV), vaccine Arexvy® on the National Immunisation Program at no cost to patients. The Budget also permanently subsidises COVID-19 oral antiviral medicines through the PBS.

Contingent asset

As in previous budgets, the current budget has identified the expectation of recovery of compensation against pharmaceutical companies in respect of wrongly granted interlocutory injunctions as a "contingent asset – unquantifiable".

This is described as:

The Commonwealth is engaged in legal action against Otsuka to recover compensation for losses associated with the delayed listing of generic brands of aripiprazole on the Pharmaceutical Benefits Scheme. The Commonwealth is claiming that this is due to interim injunctions granted to Otsuka in unsuccessful patent litigation, which had the effect of delaying statutory and price disclosure related price reductions for this drug.

Research and Development Tax Incentive

The Research and Development Tax Incentive, which currently supports research and development carried out by eligible entities is to be recalibrated. While it presently covers both core R&D activities (uncertain, experimental work conducted to generate new knowledge) and supporting R&D activities, a greater offset will be provided for core R&D activities. Supporting R&D activities will no longer be eligible for a tax offset.

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About the Spruson & Ferguson industry team

At Spruson & Ferguson, our strength lies in our deep expertise in all aspects of intellectual property law and practice spanning across the entire IP life cycle. We also recognise that an understanding of the commercial and regulatory environments in which our clients operate, is vital to maximise the impact of IP strategy.

Our Pharmaceutical Industry Group includes Principals, lawyers and attorneys from across our firm working together to meet the needs of our pharmaceutical industry clients. This includes patent and trade mark prosecution experts, and litigators and commercialisation specialists, allowing us to build a team with appropriate skill set for any matter. We all share a strong knowledge of the pharmaceutical industry and ensure that our advice is always commercially appropriate and relevant.

Our team has many decades of experience in intellectual property, and represents one of the largest groups of its kind in Australia.

Our patent attorney Principals are PhD qualified, between them representing a huge breadth of specialist scientific expertise in the life sciences. Our litigation and commercialisation team are also highly experienced - our team members having acted in a number of Australia's largest pharmaceutical litigation matters.

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