Part I – Disputes reshaping the life sciences sector

A number of dispute trends are already reshaping the Australian life sciences sector.

The following chapters examine the most significant developments affecting pharmaceutical, biotechnology and medical device organisations.

1.1 Class actions in life sciences

The billion-dollar question: preparing Australian life sciences organisations for class actions.

Lead author:
David Taylor, Partner

"Australian life sciences organisations should not treat US developments as merely cautionary tales from abroad – but rather as immediate and material risks to their own operations."

David Taylor

Chapter summary

Class actions are becoming an increasingly important feature of the disputes landscape for life sciences organisations operating in Australia. Developments in US product liability litigation often act as an early indicator of the types of claims that may later be pursued in Australian courts.

For pharmaceutical, biotechnology and medical device organisations, this creates a material strategic risk. Even where claims are defensible, the cost, complexity and reputational impact of large-scale litigation can be significant. The issue is not simply whether an organisation can defend a claim, but whether it is prepared for the commercial and operational consequences of large-scale litigation.

Drawing on recent US and Australian proceedings, this chapter examines emerging litigation patterns and highlights the key issues life sciences organisations should be considering now to strengthen preparedness and manage class action exposure.

Introduction

The life sciences and pharmaceutical industry has long been a focal point for product liability litigation and class actions, particularly in the United States, where billion-dollar settlements are now increasingly common. The success achieved by US plaintiffs has prompted Australian class action promoters to assess whether analogous claims can be viably pursued in this jurisdiction. This trend has driven a marked increase in life sciences product liability class actions filed in Australian courts – involving the same or substantially similar products that were the subject of US proceedings – a phenomenon commonly referred to as 'copycat' litigation.

Australia is an attractive jurisdiction for class action promoters. The Australian class action landscape has matured considerably since its inception in 1992 – driven principally by the increasing sophistication of plaintiff law firms, the proliferation of third-party litigation funding, and the demonstrated willingness of Australian courts to adjudicate, and provide vindication for plaintiffs in, among others, complex product liability class actions. The threshold requirements to bring a class action in Australia are low, and, unlike in the US, there is no 'class certification' procedure. This means that once a class action is filed in Australia, it is extremely difficult for a defendant to stop it at an early stage compared to the US.

As a result of these factors, Australia is now commonly stated to be the second most active class action jurisdiction globally, behind only the US.[1]

As Australian class action promoters increasingly consider the viability of filing domestic claims in respect of pharmaceutical products distributed across multiple jurisdictions, a thorough understanding of the current US life sciences litigation landscape is essential for Australian organisations seeking to protect their commercial interests and reputation. Australian life sciences organisations should not treat US developments as merely cautionary tales from abroad – but rather as immediate and material risks to their own operations.

79% of the healthcare leaders surveyed expect their class action exposure to increase over the next 3-5 years.

When asked to describe their organisation's current approach to class action risk:

- **46%** have a formal class action risk framework.
- **16%** have regular board-level reporting on class action exposure.
- **24%** have dedicated internal capability/playbooks or some proactive identification.
- **14%** are primarily reactive.

72% of surveyed leaders have formal or cross-functional governance in place.

12% use proactive horizon scanning with legal input.

16% have informal/inconsistent escalation thresholds or monitor primarily to meet minimum regulatory requirements.

Current US life sciences litigation landscape and trends

The US's multi-district litigation (**MDL**) procedure consolidates civil cases raising common factual questions into a single court for coordinated pre-trial proceedings. This mechanism enables the rapid aggregation of thousands of claims into a single large-scale consolidated proceeding, generating extensive discovery obligations, protracted and costly expert disputes, and complex settlement dynamics – often driven by the sheer volume of individual claims, cumulative defence costs and the inherent risks of litigation and trial.

Multi-district litigation is a US federal procedure consolidating similar claims before one judge for pre-trial purposes.

CASE STUDY

Zantac multi-district litigation – the cost of mass pharmaceutical litigation

The Zantac MDL illustrates the substantial financial and temporal burden that large-scale pharmaceutical litigation can impose on defendants, irrespective of the ultimate outcome.

In litigation commenced against the manufacturers of Zantac, plaintiffs alleged that ranitidine – the active ingredient in the widely prescribed heartburn medication – could degrade into N-Nitrosodimethylamine (NDMA), a probable human carcinogen.

The proceedings were consolidated into multi-district litigation in the US involving numerous manufacturers and distributors.

After approximately four years of litigation, the MDL[2] was dismissed on the basis that the plaintiffs failed to establish general causation. By that stage, however, the defendants had incurred substantial legal costs – estimated in the millions of dollars – and sustained significant reputational harm, a consequence that the Court itself acknowledged. The case illustrates that even a favourable outcome on the merits may nonetheless result in material financial exposure and lasting reputational consequences for defendant organisations, their directors and senior executives.[3]

LESSON

Even successful defendants can incur substantial litigation costs and reputational harm.

While that is practically speaking the best outcome that a defendant in a US class action can achieve, in contrast unsuccessful defendants are exposed to not only the direct costs of litigation, but contagion risks that can spread even to overseas jurisdictions.

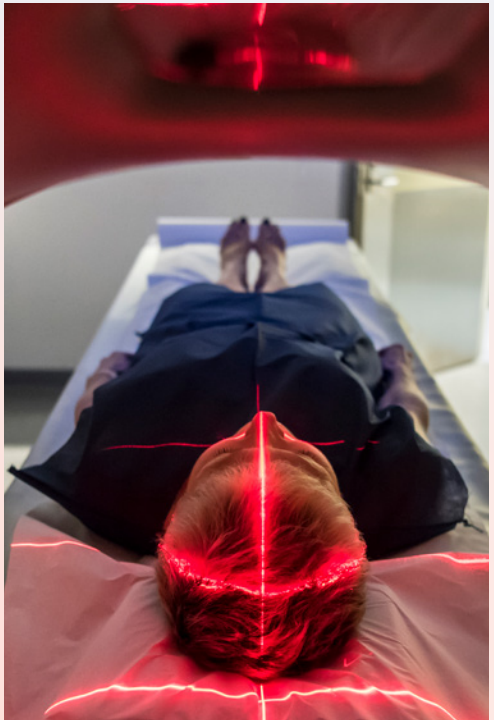
The following examples illustrate instances in which defendants to US product liability proceedings were unsuccessful, with the resulting litigation momentum extending to claims commenced in Australia:

- **In the 'Roundup' litigation against Bayer** (following its acquisition of Monsanto), early plaintiff verdicts in 2018–2019 – including in *Johnson*,[4] *Hardeman*[5] and *Pilliod*[6] – generated powerful litigation momentum. Throughout the litigation, Bayer consistently denied that its products caused cancer[7] relying, among other things, on findings by the US Environmental Protection Agency (**EPA**) and regulatory agencies across Europe and Asia that no scientific link had been established between glyphosate and non-Hodgkin lymphoma.[8]

  Notwithstanding this body of regulatory and scientific evidence, Bayer ultimately agreed to pay a US$10 billion settlement to resolve approximately 100,000 similar claims.[9] Following this settlement, a class action was commenced in the Federal Court of Australia that made similar allegations in respect of Roundup.

- **In the talc products litigation against Johnson & Johnson** – the earliest proceedings having commenced in 2009 – approximately 65,000 plaintiffs alleged that Johnson & Johnson's talc-based products possessed carcinogenic properties causing ovarian cancer, with subsequent claims also alleging asbestos contamination causing ovarian cancer or mesothelioma.[10] This was the largest MDL in the US. Significant plaintiff verdicts, including awards of US$18 million and US$22 million as recently as December 2025,[11] generated sustained pressure on Johnson & Johnson. These outcomes were reached notwithstanding Johnson & Johnson's reliance on evidence and reports from the US Food and Drug Administration (**FDA**) concluding that no asbestos had been detected in any talc samples.[12] Following this momentum, a class action was filed in the Supreme Court of Victoria advancing similar allegations against Johnson & Johnson.

> *"Mass-tort class actions follow a repeatable pattern – once plaintiffs achieve early success, claims proliferate quickly and the litigation spreads across jurisdictions."*
>
> David Taylor



Australia's established reputation as a favourable forum for representative proceedings makes it a natural destination for the transposition of these claims. Critically, the success of claims grounded in negligence or the consumer protection provisions of the Australian Consumer Law (**ACL**) turns on establishing substantially similar elements required to prove similar US causes of action. The doctrinal parallels are particularly evident when comparing a US failure-to-warn claim with an Australian claim for misleading or deceptive conduct under s 18 of the ACL.

In the US, a failure-to-warn claim requires the plaintiff to establish that the product warnings were inadequate, that the inadequacy was a proximate cause of injury, and that the plaintiff suffered actual compensable harm – with questions of loss and damage informed by expert evidence as to the risks known at the relevant time and whether adequate disclosure would have altered consumer behaviour.[13]

In Australia, the same facts can be readily re-characterised as a claim under section 18 of the ACL – for instance, by pleading that express representations concerning known risks in marketing and packaging materials (or, equally, the omission of material information from them) conveyed a misleading or deceptive representation as to the safety profile of the product to the ordinary and reasonable consumer. The causation inquiry on loss is similarly congruent: the plaintiff must demonstrate that the consumer would not have purchased or used the product, or would have done so on materially different terms, had the true risk profile been disclosed. The Johnson & Johnson talcum powder litigation mentioned earlier – presently on foot in the Supreme Court of Victoria – provides an instructive illustration of how a US case theory can be transposed into an Australian ACL claim with minimal reformulation.[14]

Most life sciences organisations adopt a consistent global approach to product design decisions, risk and safety communications, adverse event monitoring and internal responses to emerging risks. Given the global alignment – and the relative ease with which US case theories can be copied, transferred and adapted into an Australian cause of action – any pharmaceutical product that is sold globally (including in Australia) may be exposed to copycat litigation.

We explore in further detail two case studies involving successful proceedings commenced against manufacturers of surgical pelvic mesh and hip/joint implant replacements in the US, and which have already been replicated in Australia.

The majority of healthcare leaders surveyed believe they are prepared, but a first major action could expose significant gaps.

- **69%** report high or very high confidence their organisation could effectively prevent, respond to and manage a major class action today.
- **28%** are moderately confident but have untested processes.
- **4%** report low confidence due to no consistent approach.

When describing their organisation's approach to class action risk:

- **46%** have a formal class action risk framework.
- **24%** are proactive but informal.
- **14%** are primarily reactive.

CASE STUDY

Pelvic mesh litigation – crystallised class action risk in Australia resulting in a A$300 million settlement.

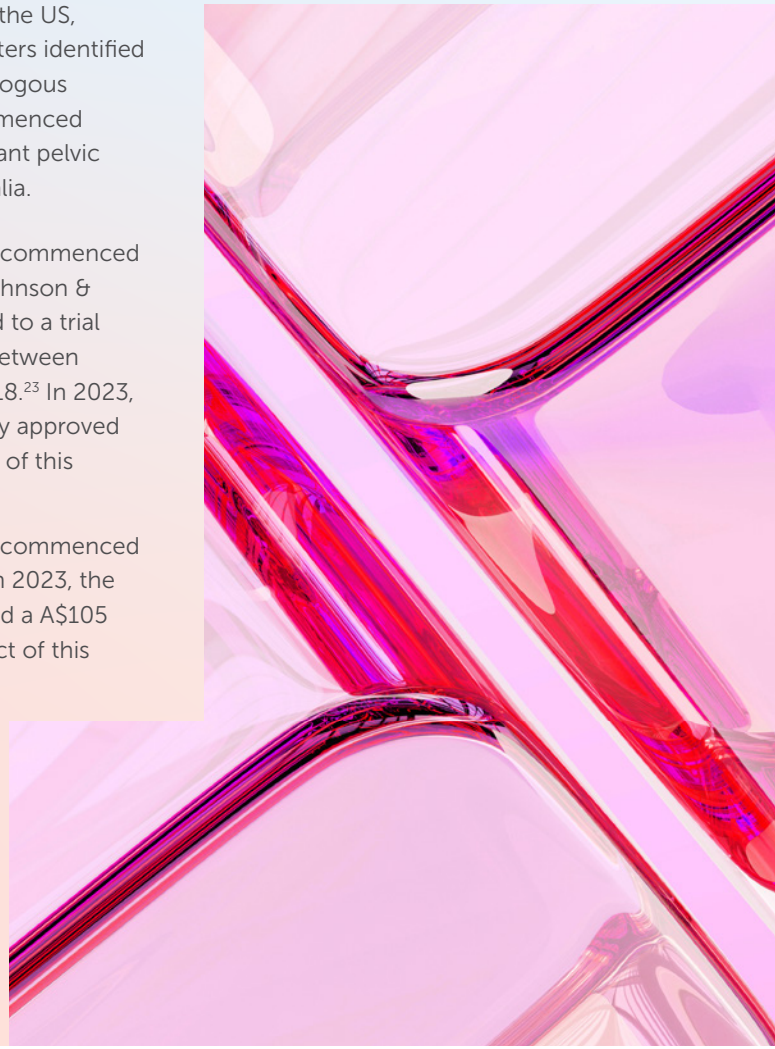
Transvaginal and pelvic mesh litigation represents one of the most instructive examples of how product liability risk in the life sciences sector can crystallise into large-scale, high-value class action exposure across multiple jurisdictions.

The first pelvic mesh case was filed in approximately 2009 in the US,[15] and in 2012,[16] MDLs consolidated similar claims against American Medical Systems,[17] Ethicon,[18] and Boston Scientific[19] (among others) yielding the following significant outcomes for plaintiffs:

- **American Medical Systems:** aggregate settlement payments exceeding US$2.6 billion to plaintiffs in the US.[20]
- **Ethicon:** a US$120 million jury award (the largest single Ethicon mesh verdict), a US$117 million settlement with 41 states and the District of Columbia, and a US$302 million judgment in favour of the State of California in a parallel proceeding to the MDLs.[21]
- **Boston Scientific:** aggregate settlement payments exceeding US$400 million to plaintiffs in the US.[22]

Following these outcomes in the US, Australian class action promoters identified an opportunity to pursue analogous claims domestically and commenced proceedings against the relevant pelvic mesh manufacturers in Australia.

- In 2012, a class action was commenced against Ethicon Sarl and Johnson & Johnson, which proceeded to a trial spanning several months between July 2017 and February 2018.[23] In 2023, the Federal Court ultimately approved a A$300 million settlement of this class action.[24]
- In 2021, a class action was commenced against Boston Scientific. In 2023, the Federal Court also approved a A$105 million settlement in respect of this class action.

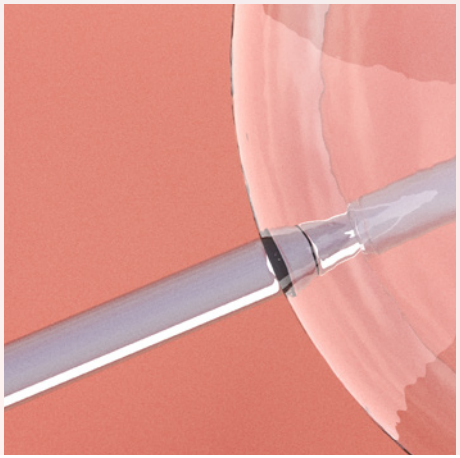


LESSON

Successful US product liability litigation can quickly translate into Australian class action exposure.

"Given the global approach to product design, communications and marketing, the risks that exist in US litigation can be readily adapted into an Australian cause of action."

David Taylor



These Australian class actions demonstrate that mass-tort proceedings originating in the US are both viable and replicable in Australia – owing principally to the substantial overlap between the relevant legal frameworks, the transferability of causation theories, and the availability of third-party litigation funding – with significant settlement sums awarded to group members (and, in the case of Boston Scientific, within a comparatively short timeframe). Importantly, the lessons from the Australian pelvic mesh class actions extend well beyond the manufacturers of implantable devices. Australian class action promoters actively monitor the US litigation landscape and may elect to commence a class action in respect of any pharmaceutical product sold in Australia where material similarities exist – for example, in manufacturing processes, manner of use, packaging or marketing – compared to the matters that are the subject of the US proceedings.

Specifically, in the Australian pelvic mesh class action, the Court held that pre and post-market evaluation of the Ethicon mesh devices were insufficient to discharge Ethicon's duty of care, and that, had Ethicon disclosed the pleaded risks, the applicant would not have consented to implantation of the device.

The pelvic mesh case study shows how quickly class action risk can emerge, increase in scale and ultimately result in significant settlement sums for Australian life sciences organisations. It reinforces the need for all organisations, their directors and senior executives to assume that product design decisions, safety communications, adverse event monitoring and internal responses to emerging risks may be the subject of an Australian class action.

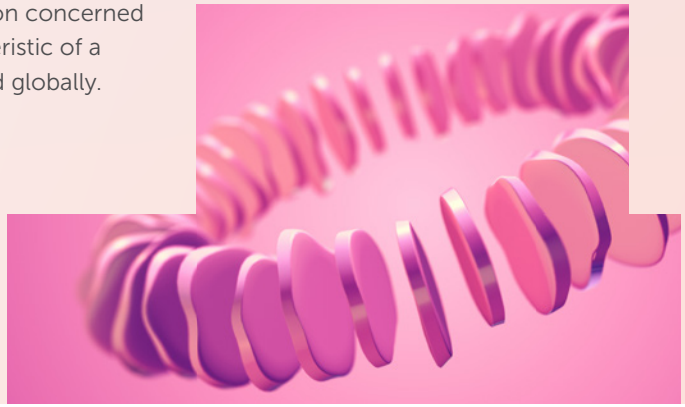
CASE STUDY

DePuy Hip Implant litigation – Australian class action proceedings filed off the back of successful litigation in the US, resulting in a A$250 million settlement.

The DePuy hip implant MDLs provide a clear illustration of how large-scale US medical-device litigation can migrate to Australia with relatively little friction. In re *DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation*,[25] the plaintiffs alleged that a design flaw in a hip implant caused a condition called *metallosis*, which destroyed bone, muscle and other tissue. The causation theory was readily transferable across jurisdictions, as the allegation concerned an inherent design characteristic of a product that was distributed globally.

The initial US trial resulted in a US$502 million verdict for the plaintiffs (which was ultimately reduced to US$245 million following multiple appeals).[26] The plaintiffs' causation arguments centred on design defects, supported by epidemiology expert evidence and internal design documents. The plaintiffs effectively contended that the design in question presented an avoidable risk, given the availability of safer alternative designs.[27]

The verdict subsequently enabled settlements totalling over US$4 billion across approximately 20,000 related claims, together with a global recall of DePuy's ASR hip implant products in 2010.[28]



Following these developments, an Australian Federal Court class action concerning hip implants was commenced in 2011 against DePuy International Ltd, which manufactured the DePuy ASR hip implants, and Johnson & Johnson, which distributed and sold the implants in Australia.[29] The class action settled in 2016 for A$250 million. Though the claims were never tested at trial, the plaintiffs advanced very similar causation arguments to those raised in the US MDLs, indicating that the US claims were capable of translation into Australian causes of action without significant re-formulation – specifically, claims in negligence and under the consumer protection provisions of the *Trade Practices Act 1974 (Cth)* and the ACL (in particular, the provisions relating to defective goods and misleading or deceptive conduct).

The DePuy hip implant litigation not only illustrates the speed at which a defective product claim in the US can be brought over into Australia (similar to the pelvic mesh case study), but it also highlights the fact that international participants are not immune to Australian class action risk. In Australia, the DePuy hip implant claim was brought against the UK-based manufacturer, as well as the Australian supplier of that product (J&J), with little to no re-formulation of the initial claim. This is because the operation of the ACL is far-reaching and applies to foreign entities – regardless of their place of incorporation – as long as that entity supplies goods or services to a consumer based in Australia. Specifically, Australia's High Court held that foreign entities carrying on business in Australia are subject to the ACL even if their contracts with consumers are governed by foreign law, and even if services are to be delivered wholly outside of Australia.[30]

LESSON

US litigation outcomes often serve as early warning indicators for Australian class action risk.

"In our experience, Australian class action promoters regard these developments as favourable indicators and will accordingly accelerate their due diligence and book-building efforts in respect of commencing analogous proceedings in Australian courts."

David Taylor

For Australian life sciences organisations, the experience of pelvic mesh and DePuy demonstrates that US MDLs should be considered upstream risk indicators. Once an adverse judicial finding on defect or the relevant science is made in the US, it's likely to materially reduce the risk and uncertainty for a plaintiff law firm or litigation funder associated with bringing an analogous class action in Australia.

That is particularly the case with the growth of international litigation funders who seek to duplicate a successful case strategy that they have funded in one jurisdiction (such as the US) in another (such as Australia), utilising the learnings and evidence that they have already invested in for further successful returns.

Key lessons for Australian life sciences organisations

Australian life sciences organisations now face materially heightened class action exposure. The demonstrated pattern of successful US litigation catalysing analogous claims in Australia represents a tangible and escalating risk. The above examples show that notwithstanding legitimate and well-developed arguments contesting the relevant scientific and causation issues, the sustained commercial and reputational pressures generated by the scale, cost and duration of large class action proceedings often outweigh the theoretical strength of a defendant's position on the science or the law. This pressure often leads to a defendant choosing to pay a significant settlement sum to compromise the litigation, even if a defendant's case is arguable and far from hopeless.

As outlined above, recent class action trends in US product liability litigation frequently operate as a leading indicator of emerging risk for Australian organisations – particularly where the product in question (or its generic equivalent) is already supplied domestically. There is no lack of products that have faced litigation in the US but are or have also been distributed in Australia. For example, proceedings concerning:

- allegations of a failure to disclose fungal contamination in lubricant eye drops;[31]
- semaglutide injection, alleging a failure to warn of the risks of gastroparesis and other serious adverse events allegedly associated with the product, including gastrointestinal injuries, ischaemic bowel, necrotising pancreatitis, gallbladder disease, deep vein thrombosis, micronutrient deficiencies, Wernicke's encephalopathy and aspiration of gastric contents;[32]

- in respect of antifungal spray products, alleging that the relevant manufacturers failed to disclose the presence of dangerous levels of benzene (a known human carcinogen) in the products;[33]
- teprotumumab injection, indicated for the treatment of thyroid eye disease, alleging inadequate pre-market testing and a failure to warn prescribers and patients of the known risk of adverse effects, including permanent hearing loss and tinnitus;[34] and
- infant formulas, alleging a failure to warn that cow's milk-based formulations could cause, or materially increase the risk of, necrotising enterocolitis – a severe and potentially fatal gastrointestinal condition – in premature babies.[35]

Against this backdrop, prudent directors and senior executives should systematically assess their class action exposure across all products, evaluate the likelihood that proceedings may be commenced in the near term, and take proactive steps to prepare well in advance.

The US experience with pelvic mesh and hip implant litigation yields several instructive lessons for Australian life sciences organisations:

- class action risk may crystallise years after product launch, underscoring the necessity of robust and ongoing post-market surveillance (pharmacovigilance) – in particular, the timeliness and rigour of signal detection (being the systematic identification of potential new safety risks associated with authorised drugs or medical devices) and the adequacy of escalation protocols;
- once a potential safety signal is identified, timely and consistent communication of risk is critical – encompassing both the speed with which organisations respond to emerging data and the degree to which risk communications are harmonised across jurisdictions and markets; and
- despite legitimate arguments about the relevant science and causation issues, the costs to defendant organisations (being financial and reputational) in defending a class action are significant – regardless of the outcome.

The strategic imperative is accordingly not retrospective compliance, but forward-looking preparedness.
This requires more than formulating a defence strategy once proceedings are threatened or on foot. Rather, organisations should proactively embed robust governance, data management, scientific and communications frameworks into their day-to-day operations, implement rigorous documentation and risk-management procedures, and consider the adequacy of, and potentially update their insurance requirements, to anticipate and prepare for potential class action exposure well before any claim is foreshadowed or commenced.

Organisations should also actively monitor emerging safety signals and treat them not merely as regulatory compliance obligations, but as matters warranting rapid, cross-functional escalation across the business.

In particular, medical affairs, regulatory, legal and commercial teams should each participate in the risk management process and develop structured, contemporaneous decision memoranda that record, among other things, the rationale underpinning risk assessments, the basis for labelling updates or the decision to maintain existing warnings, and the justification for any planned post-market studies or ongoing surveillance.

Product information and consumer-facing materials should be updated promptly whenever the risk profile materially changes. As international organisations become increasingly complex and are necessarily divided – and staffed – into different regions (e.g. Asia, EMEA, US), organisations must remember to implement and deploy these strategies at a global level and as part of a cohesive framework.
It is critical to ensure that risk events and knowledge of such events are shared globally within the organisation's legal and commercial teams as soon as they emerge, to proactively manage their class action risk.

> *"The strategic imperative is accordingly not retrospective compliance, but forward-looking preparedness."*
>
> **David Taylor**

Practical guidance: Class action preparedness checklist

The following checklist synthesises the lessons learnt from the US experience into some proposed actionable steps and is intended to assist Australian life sciences organisations in managing – and, where possible, mitigating – their heightened exposure to class action risk.

Risk domain	Key actions	Implementation priority
Pharmacovigilance	■ Implement post-market surveillance across all jurisdictions ■ Promptly evaluate overseas safety signals ■ Comprehensively review and document safety processes ■ Review scientific publications for safety concerns	High
Product information	■ Conduct regular Consumer Medicine Information and Product Information (CMI/PI) reviews ■ Monitor overseas regulatory actions ■ Engage proactively with the TGA on labelling updates ■ Document labelling-decision rationale	High
Document retention	■ Establish retention policies for clinical-trial data and safety reports ■ Ensure legal compliance when litigation is anticipated ■ Train employees on document retention requirements ■ Distinguish privileged from non-privileged communications	High
Litigation monitoring	■ Designate personnel to track US and international developments in respect of similar or related products ■ Assess whether Australian products are impugned in overseas litigation and actively monitor developments ■ Monitor trials, rulings on scientific evidence and causation arguments, and settlements in international jurisdictions ■ Engage Australian legal advisers when overseas litigation trends emerge	Medium
Insurance coverage	■ Review insurance policies for coverage scope, exclusions and notification requirements ■ Assess adequacy of insurance limits given settlement and adverse findings trends ■ Ensure timely insurer notification ■ Evaluate additional insurance coverage needs	Medium
Marketing practices	■ Ensure promotional and public facing materials represent safety accurately ■ Develop a communications protocol to ensure consistency in messaging ■ Implement robust review processes ■ Train sales representatives to deliver balanced presentations ■ Review physician engagement programs	Medium
Healthcare professional engagement	■ Maintain communication channels for safety information ■ Provide evidence-based prescribing information ■ Respond promptly to safety enquiries ■ Document interactions with relevant healthcare professionals	Low
Crisis management	■ Establish protocols for litigation threats and adverse publicity ■ Identify key stakeholders for crisis response ■ Prepare media communication strategies ■ Conduct scenario planning exercises	Low

1.2

Patent litigation and preliminary injunctions in Australia

Interlocutory injunctions in Australian patent disputes: why they are becoming harder to obtain

Lead author: Simone Mitchell, Partner and Life Sciences Lead

"In Australia's current patent landscape, the strategic advantage often lies not in assuming an injunction will be available, but in being prepared for the possibility that it will not."

Simone Mitchell

Chapter summary

Interlocutory injunctions have long been an important mechanism for protecting market exclusivity while patent disputes are resolved for life sciences organisations in Australia. Recent Federal Court decisions, however, suggest a more cautious approach, particularly in pharmaceutical patent matters.

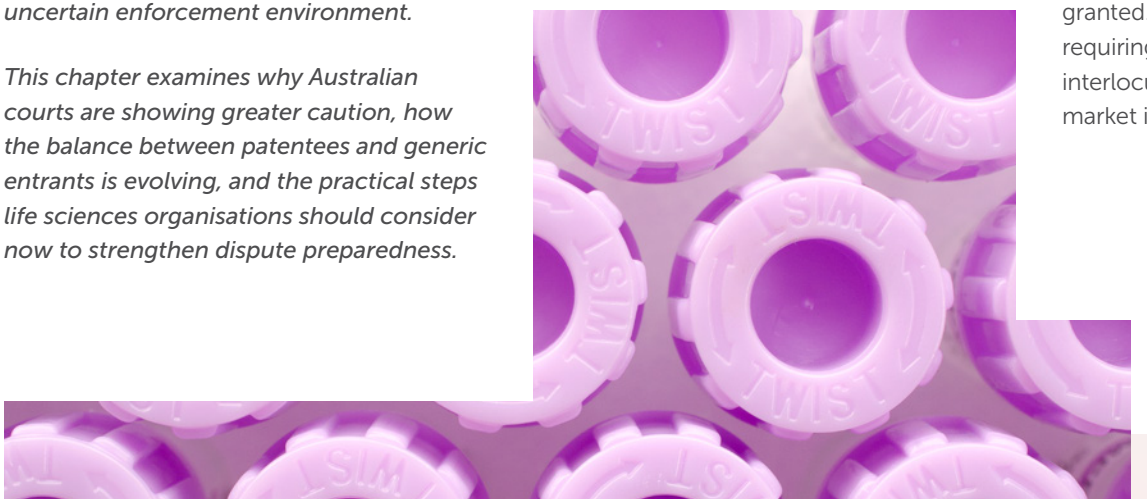
This shift has significant commercial implications. The outcome of an interlocutory injunction application can influence launch timing, pricing, market share, Pharmaceutical Benefits Scheme (PBS) dynamics and the value of a patent portfolio. For innovators and challengers alike, the issue is no longer simply whether an injunction can be obtained, but whether the business is prepared for a more uncertain enforcement environment.

This chapter examines why Australian courts are showing greater caution, how the balance between patentees and generic entrants is evolving, and the practical steps life sciences organisations should consider now to strengthen dispute preparedness.

Introduction

Robust patents are pivotal to the life sciences industry, underpinning investment in research and development, supporting commercialisation and fostering innovation. In an environment where product lifecycles are long, regulatory hurdles are significant, and the cost of bringing new treatments to market is high, decisions about when to enforce – or challenge – patent rights can be critical to commercial success.

Interlocutory injunctions, sometimes referred to as preliminary injunctions, are court orders that temporarily restrain the conduct of alleged infringers pending the outcome of litigation.



Emerging trend: Interlocutory injunctions are becoming harder to obtain

Recent Federal Court decisions suggest a growing judicial caution in granting interlocutory injunctions in life sciences patent disputes, particularly those involving PBS-listed medicines. While each case turns on its particular facts, the combined effect of recent judgments has been to make preliminary relief more difficult to secure than in earlier periods.

Two developments in particular have contributed to this shift. First, courts are applying greater scrutiny to the potential consequences of the 'usual undertaking as to damages', particularly where generic market entrants or the Commonwealth may suffer losses if an injunction is wrongly granted. Secondly, courts are increasingly requiring robust and detailed evidence at the interlocutory stage, especially in relation to market impact and patent validity.

Legal framework

An interlocutory injunction is an extraordinary remedy granted at the discretion of the Court. Its purpose is to preserve the status quo and prevent harm that cannot be adequately compensated by damages before the substantive issues in a dispute are determined at trial. While interlocutory injunctions are not unique to patent litigation, disputes in the life sciences sector – particularly pharmaceutical patent disputes – have been a frequent battleground for such applications.

In patent litigation, the Federal Court of Australia applies a well-established two-limb test when considering whether to grant interlocutory relief.

Prima facie case (serious question to be tried)

The applicant – typically the patentee or its exclusive licensee – must establish that there is a serious question to be tried regarding infringement of the patent. The threshold is relatively low: the applicant does not need to prove its case, but must show that the claim is not frivolous or vexatious and that there is a sufficient likelihood of success to justify preserving the status quo.

A respondent may seek to qualify this element by demonstrating that there is also a serious question to be tried as to the validity of the patent. In practical terms, this means arguing that the injunction should **not** be granted because the patent may ultimately be held invalid, and the competitor would therefore have been wrongly restrained.

Balance of convenience

The Court must weigh the potential harm to each party depending on whether the injunction is granted or refused. Relevant considerations may include the likelihood of a final injunction being granted, potential market disruption, loss of market share, reputational harm, and the public interest – including access to affordable medicines.

The respective strengths of the infringement and validity cases will also influence this assessment.

The Court retains broad discretion and may also consider additional factors, including the conduct of the parties, any delay in bringing the application, and whether the respondent has offered undertakings to limit potentially infringing conduct pending resolution of the dispute.

The undertaking as to damages

A party seeking an interlocutory injunction will generally be required to give the Court the 'usual undertaking as to damages' (as suggested in the Federal Court's Usual Undertaking as to Damages Practice Note (**GPN-UNDR**)).[36] In practical terms, this means the applicant may later be ordered to compensate the respondent or affected third parties if the injunction is ultimately found to have been wrongly granted.

Claims under such undertakings are complex and may only be assessed after the substantive issues in the litigation – including any appeals – have been determined. These assessments often involve extensive expert evidence and analysis of counterfactual scenarios to determine what losses would have occurred had the injunction not been granted.

Key developments influencing the Federal Court's approach

The significance of the undertaking as to damages

From the mid-2000s, it was reasonably common for the Federal Court to grant interlocutory injunctions in pharmaceutical patent disputes. One important reason for this was the weight given by courts to the mandatory price reductions introduced to the PBS in 2005. The listing of the first generic or biosimilar brand on the PBS typically triggers a statutory price reduction that is widely regarded as effectively irreversible.

Historically, this potential price reduction was treated as a form of irreparable harm to the patentee. Courts were therefore prepared, in appropriate circumstances, to grant interlocutory injunctions to prevent a generic entrant from triggering those reductions before the underlying patent dispute had been determined.

However, the Federal Court's decision in Sigma Pharmaceuticals *(Australia) Pty Ltd v Wyeth [2018] FCA 1556 (**Sigma**)*[37] marked a significant turning point in the Court's consideration of interlocutory injunctions in pharmaceutical patent litigation.

In *Sigma*, Wyeth had previously obtained interlocutory injunctions restraining generic competitors from entering the market. After Wyeth's patents were ultimately found to be invalid, several generic manufacturers – together with the Commonwealth of Australia – sought compensation pursuant to the undertaking as to damages Wyeth had provided to the Court when the injunctions were granted. Wyeth was ultimately ordered to pay compensation.

The proceedings that followed were extensive. The judgment alone exceeded 400 pages and followed a 27-day hearing exploring complex counterfactual questions regarding how the pharmaceutical market would have evolved had the interlocutory injunctions not been granted.

Justice Jagot observed[38]**:**
Hindsight makes one thing certain. Knowing what has occurred, it could never have been concluded … that it would be easier for the generics to prove their loss if the interlocutory injunctions were wrongly granted than for Wyeth to prove its loss if the interlocutory injunctions were withheld and the method patent was valid.

The decision highlighted the substantial complexity and potential financial exposure associated with the undertaking as to damages.

> *"The increasing significance of the undertaking as to damages has materially reshaped how courts approach interlocutory injunctions in pharmaceutical patent disputes."*
>
> Simone Mitchell

Following *Sigma*, and in light of the Commonwealth's attempts to recover multimillion-dollar PBS losses as a 'person affected' by the operation of interlocutory injunctions in several pharmaceutical patent cases, the Federal Court's approach to such applications has become noticeably more cautious.

In various subsequent matters, the Court has refused interlocutory relief. While each decision ultimately turns on its own facts, courts have increasingly pointed to the speculative nature and difficulty of quantifying losses suffered by restrained generic entrants – and potentially by the Commonwealth – where injunctions are later found to have been wrongly granted.

Other market dynamics may also influence the balance of convenience. For example, where an innovator organisation is transitioning the market towards a second-generation product, courts may consider whether the market available to a generic entrant would in any event be diminished by the time it is able to launch.

The evolving judicial approach can be seen in the pattern of recent Federal Court decisions summarised on the following page.

PBS price reductions shape the balance of convenience in patent disputes

A distinctive feature of the Australian pharmaceutical market is the PBS, through which the Federal Government subsidises prescription medicines listed on the Schedule of Pharmaceutical Benefits.

Under the PBS framework, the entry of a first generic brand can trigger statutory price reductions and price disclosure mechanisms.

These reductions are widely understood to be practically irreversible.

Prior to the Sigma decision, this factor frequently weighed in favour of granting interlocutory injunctions.

As noted in *Regeneron Pharmaceuticals, Inc v Sandoz Pty Ltd [2025] FCA 1067*, although the Minister technically retains discretion to reverse a PBS price reduction, there is no evidence that such a reversal has occurred once a generic product has launched with supply.

However, following Sigma, the risk of PBS price reductions alone has generally been insufficient to justify the grant of interlocutory relief. Courts have recognised that, despite the complexity of assessing losses associated with PBS price changes, those losses may not necessarily be more difficult to quantify than losses arising from a wrongly granted injunction.

The operation of the PBS therefore continues to play a central role in shaping the commercial dynamics of pharmaceutical patent disputes in Australia.

Decision date	Citation	Outcome
16 February 2026	*AstraZeneca AB v Pharmacor Pty Ltd* [2026] FCA 88	Granted
5 December 2025	*Janssen Pharmaceutica NV v Juno Pharmaceuticals Pty Ltd* [2025] FCA 1538	Granted
3 September 2025	*Regeneron Pharmaceuticals, Inc. v Sandoz Pty Ltd* [2025] FCA 1067	Refused
17 December 2024	*Abbey Laboratories Pty Ltd v Virbac (Australia) Pty Ltd* [2024] FCA 1488*	Refused
16 December 2021	*Biogen International GmbH v Pharmacor Pty Ltd* [2021] FCA 1591	Refused
11 April 2019	*Mylan Health Pty Ltd v Cipla Australia Pty Ltd* [2019] FCA 506	Refused
22 February 2019 19 December 2018	*Sanofi-Aventis Deutschland GmbH v Alphapharm Pty Ltd [2019] FCAFC 28* *Sanofi-Aventis Deutschland GmbH v Alphapharm Pty Ltd* (No 3) [2018] FCA 2060	Appeal dismissed Refused
19 October 2018 *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2018] FCA 1556		
12 June 2018	F. Hoffman-La Roche AG v Sandoz Pty Ltd [2018] FCA 874	Granted in part
22 December 2017	*Apotex Pty Ltd v Cipla Ltd* [2017] FCA 1627	Granted
18 December 2017	*InterPharma Pty Ltd v Hospira, Inc (No 3)* [2017] FCA 1536	Granted
27 November 2017	*Janssen Sciences Ireland UC v Alphapharm Pty Ltd* [2017] FCA 1399	Granted
19 May 2014 18 March 2014	*Warner-Lambert Company LLC v Apotex Pty Ltd* [2014] FCAFC 59 *Warner-Lambert Company LLC v Apotex Pty Ltd* [2014] FCA 241	Appeal allowed – PI granted Granted in part
26 November 2013	*Eli Lilly and Company v Generic Health Pty Ltd* [2013] FCA 1254	Granted
28 May 2013	*Reckitt Benckiser Healthcare (UK) Ltd v GlaxoSmithKline Australia Pty Ltd* [2013] FCA 583	Granted
6 March 2013 16 March 2012	*Generic Health Pty Ltd v Otsuka Pharmaceutical Co., Ltd* [2013] FCAFC 17 *Otsuka Pharmaceutical Co Ltd v Generic Health Pty Ltd* [2012] FCA 239	Appeal dismissed – PI upheld Granted
28 September 2012	*Novartis AG v Hospira Pty Limited* [2012] FCA 1055	Granted
31 August 2012	*Merck Sharp & Dohme Corp v Apotex Pty Ltd* [2012] FCA 928	Granted
9 March 2012	*Watson Pharma Pty Ltd v AstraZeneca AB* [2012] FCA 200	Granted
14 December 2011	*Apotex Pty Ltd v AstraZeneca AB* [2011] FCA 1520	Granted
1 February 2011	*Interpharma Pty Ltd v Aventis Pharma SA* [2011] FCA 32	Refused

*Veterinary product

Increasing evidentiary demands

The quality and scope of evidence presented in interlocutory injunction applications has also become increasingly significant.

Because interlocutory hearings take place on an urgent basis, the Court's assessment of the relevant issues typically relies heavily on written evidence from both expert and lay witnesses. Cross-examination is rarely permitted except in exceptional circumstances. As a result, the Court must assess competing positions without the benefit of a full trial process.

This can present particular challenges in patent cases involving complex scientific or technical questions. For example, allegations concerning inventive step or technical validity often depend on competing expert opinions that are difficult to evaluate without the benefit of full cross-examination or concurrent expert evidence at trial.

As observed in *AstraZeneca AB v Pharmacor Pty Ltd [2026] FCA 88*, certain validity challenges – particularly those based on inventive step – may be ill-suited to resolution at the interlocutory stage because the Court cannot adequately interrogate competing expert evidence within the limited procedural framework of an injunction hearing.

Preparing the necessary evidence can therefore impose substantial demands on both parties. Lay witnesses within the business may be required to give evidence regarding the likely commercial impact of a competitor's market entry, while expert witnesses may need to address complex technical or economic issues within compressed timeframes.

At the same time, both the parties and the Court must ensure that interlocutory proceedings do not evolve into a 'mini-trial'. Maintaining that balance requires careful planning and a disciplined evidentiary strategy.

Strategic alternative: Expedited trials

In light of the challenges associated with obtaining interlocutory injunctions, parties in some patent disputes are increasingly considering expedited trials as a practical alternative.

Under the Federal Court's *Central Practice Note: National Court Framework and Case Management (CPN-1)*[39] and *Intellectual Property Practice Note 1 (IP-1)*,[40] the Court has the ability to significantly accelerate proceedings where appropriate. In certain circumstances, disputes may be resolved within a fraction of the usual timeframe, sometimes in a matter of weeks rather than months or years.

An illustration of this approach can be seen in *AGL Energy Limited v Greenpeace Australia Pacific Limited [2021] FCA 625*. Although the case involved copyright and trade mark claims rather than patent infringement, the Court declined to determine an interlocutory injunction application and instead proceeded directly to a final hearing of the dispute.

The matter was resolved in less than one month from the commencement of proceedings – a timeframe comparable to that typically required to hear an interlocutory injunction application.

While such timelines may not be achievable in all patent disputes, the Federal Court has demonstrated a willingness to accommodate the commercial imperatives of the parties where possible. For example, where a generic manufacturer intends to launch following the expiry of a compound patent but seeks to challenge a secondary-use patent, the Court may attempt to list the matter for final hearing in time to allow a determination before the anticipated launch date. The Court has also shown flexibility in accommodating deadlines associated with PBS listing processes, which can add significant commercial pressure to the timing of proceedings.

In this context, expedited trials may offer a practical substitute for interlocutory relief. Rather than focusing on the balance of convenience analysis required for a preliminary injunction, the dispute proceeds directly to a determination on the merits.

Expedition can also deliver procedural and cost efficiencies. By compressing timelines and narrowing the issues in dispute, parties may avoid the duplication of costs that can arise where interlocutory proceedings are followed by a full trial. Importantly, expedited proceedings also avoid the need for a patentee to give the usual undertaking as to damages at an early stage of the dispute, and remove the requirement for an alleged infringer to demonstrate its financial capacity to meet any future damages award.

Another advantage is that either party may seek expedition. Both patentees and alleged infringers may therefore utilise the mechanism where rapid resolution of the dispute aligns with their commercial objectives.

However, expedited proceedings bring their own challenges. Most significantly, parties must be prepared to present substantial evidence at the outset of the proceedings. Evidence that might ordinarily be developed over many months must instead be assembled in advance, often before litigation has formally commenced.

Not all disputes are suitable for expedition. Matters involving extensive discovery, multiple parties, or highly complex factual questions may be difficult to resolve within a compressed timeframe. In such circumstances, a truncated process may risk undermining the quality of the court's determination.

Accordingly, while expedited trials offer an increasingly attractive alternative in certain circumstances, parties must carefully weigh the benefits of speed and efficiency against the practical demands of preparing a case for rapid resolution.

> *"Where interlocutory injunctions are increasingly difficult to obtain, expedited trials may offer a more predictable pathway to resolving patent disputes."*
>
> Simone Mitchell

Interlocutory injunctions can no longer be assumed in Australian patent disputes

The evolving approach to interlocutory injunctions in Australian patent litigation has significant implications for the life sciences sector.

Historically, innovators could reasonably expect that interlocutory relief would be available in appropriate circumstances to prevent generic entry while a patent dispute was resolved. Recent decisions suggest that assumption can no longer be taken for granted. Courts are increasingly attentive to the potential consequences of wrongly granted injunctions – particularly where generic entrants or the Commonwealth may suffer losses associated with delayed market entry or PBS pricing dynamics.

For innovators, this creates greater uncertainty around the ability to preserve market exclusivity during the life of a patent dispute. The commercial consequences can be significant. Early generic entry may affect revenue forecasts, investment decisions and the broader economics underpinning research and development.

At the same time, the shift reflects competing public policy considerations. Access to affordable medicines, the efficient operation of the PBS and the avoidance of unnecessary market disruption are also important elements of a well-functioning life sciences sector. The increasing difficulty in obtaining interlocutory relief has therefore opened the door to alternative approaches, including expedited trials, which may allow disputes to be determined more quickly on their merits.

Against this backdrop, life sciences organisations should consider whether their patent enforcement strategies remain fit for purpose.

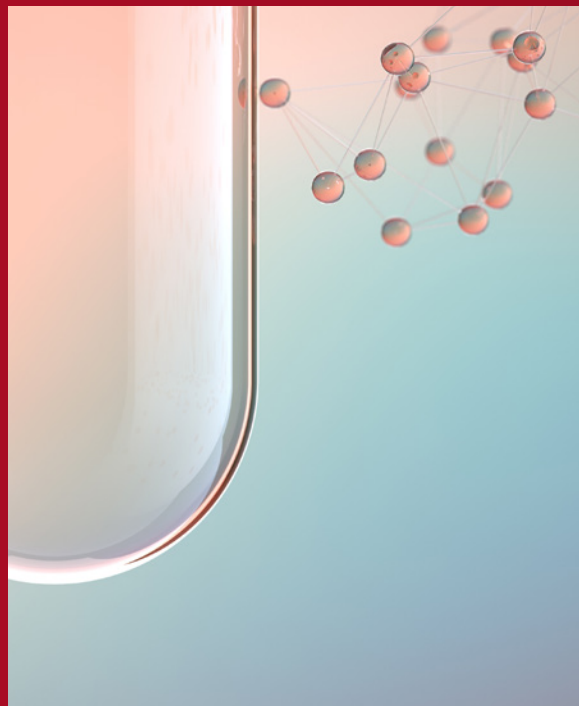
Strategic preparation is therefore likely to become increasingly important. Patent disputes in the life sciences sector frequently involve complex technical questions, extensive expert evidence and detailed economic analysis regarding market impacts. Preparing the evidentiary foundations for an interlocutory injunction application – or for resisting one – may require substantial work well before litigation is formally anticipated.

Organisations may therefore benefit from adopting a more proactive approach to dispute preparedness. This can include identifying potential expert witnesses early, ensuring that key internal data relating to market dynamics is readily accessible, and considering how different litigation pathways – including interlocutory relief, expedited trials or final hearings – may affect commercial strategy.

More broadly, the current landscape also raises questions as to whether the Australian system remains appropriately calibrated when compared with other jurisdictions. For example, the US *Hatch–Waxman legal framework*[41] creates a coordinated system linking regulatory approval and patent litigation, including an automatic stay of generic approval in certain circumstances. While that model is not without criticism, it illustrates how different jurisdictions seek to balance the interests of innovators, generic entrants and public health systems.

In Australia, questions around potential reform – including earlier notification mechanisms for generic entry or other transparency measures – have periodically been raised. Any such reforms would require careful consideration and consultation with industry stakeholders.

However, improving predictability in the timing and resolution of pharmaceutical patent disputes could provide benefits for both innovators and generic manufacturers.



Possible future reforms

In 2020, the Therapeutic Goods Administration (**TGA**)[42] proposed transparency measures[43] that would have required applicants for the first generic version of a medicine to notify the relevant patent holder when their application was accepted for evaluation. The proposal was intended to provide earlier visibility of potential generic entry and allow parties to engage sooner on patent issues.

Under the current framework, patentees typically only become aware of a potential generic threat once the product is entered on the Australian Register of Therapeutic Goods (**ARTG**) – at which point the product may be capable of launching immediately. This compressed timeline can contribute to the urgency surrounding interlocutory injunction applications and expedited proceedings

Although the proposed notification mechanism was not ultimately implemented, the policy discussion illustrates the broader challenge of balancing the interests of innovators, generic entrants and the public health system. Carefully designed transparency mechanisms could provide greater predictability in the timing of pharmaceutical patent disputes while continuing to support competition and access to medicines.

In the meantime, organisations operating in Australia's life sciences sector must navigate a landscape in which interlocutory injunctions remain available but are no longer routinely granted. Strategic planning, robust evidence and a clear understanding of the procedural options available will be essential in managing patent disputes effectively in an environment where such relief cannot be assumed.

Survey results show there is strong appetite from health and life sciences leaders for IP reform, with 81% agreeing reform is needed for timely dispute resolution.

74% support Australia adopting an Orange Book patent linkage equivalent and 70% support PBS reform to restore prices on patent infringement findings.

51% support legislated first mover advantage for generic entrants, indicating genuine industry debate around how to balance innovation incentives with generic / biosimilar market access.

Practical guidance: Interlocutory injunction preparedness checklist

Given the increasingly complex and fast-moving nature of interlocutory injunction proceedings, preparation often needs to begin well before litigation is anticipated. The compressed timeframes for these applications mean that parties must be able to assemble technical, commercial and economic evidence quickly – often within days or weeks.

The following checklist highlights practical considerations for organisations that may seek or resist an interlocutory injunction in Australian patent disputes.

Checklist for preparedness – patentees

1. Identifying the relevant parties

- ☐ Consider whether the ARTG sponsor and/or the PBS Responsible Person (if different from the patentee) should be joined to the proceedings. These entities may be the parties most directly affected by market entry.
- ☐ Review whether an exclusive licence arrangement exists between the patentee and the sponsor and whether that arrangement provides appropriate rights to enforce the patent.
- ☐ Confirm whether existing licence or supply agreements include provisions addressing enforcement of patent rights.

2. Monitoring and early strategic preparation

- ☐ Maintain monitoring of the ARTG and relevant industry sources to identify potential generic entries.
- ☐ Prepare template correspondence addressing potential patent infringement that can be adapted quickly if required.
- ☐ Consider carefully the terms of any pre-litigation undertakings, including arrangements requiring advance notice of launch by a generic entrant.
- ☐ Review the relevant patent portfolio for products approaching potential generic competition and assess likely validity challenges.

3. Preparing technical evidence

- ☐ Identify potential technical experts early. In complex pharmaceutical disputes, multiple experts (for example, formulation chemists and medical specialists) may be required.
- ☐ Ensure that any engagement with potential expert witnesses is conducted through external legal advisers, as communications with experts must be carefully managed.

4. Preparing market and economic evidence

- ☐ Identify internal stakeholders who can provide market evidence, including likely impacts of generic entry on pricing, market share and supply.
- ☐ Ensure relevant commercial data can be accessed and compiled quickly if required for evidence.

5. Understanding the undertaking as to damages

- ☐ Ensure relevant decision-makers within the organisation understand the implications of providing the usual undertaking as to damages, including the potential financial exposure if the injunction is later found to have been wrongly granted.

Checklist for preparedness – defending an interlocutory injunction application

1. Freedom-to-operate analysis

- ☐ Before launching a product in Australia, obtain advice regarding the relevant patent landscape, including potential validity issues and any applicable patent term extensions.

2. Strategic response planning

- ☐ Prepare responses to potential allegations of threatened infringement, including a validity analysis of relevant patents.
- ☐ Consider whether any pre-launch undertakings may be appropriate, such as advance notice of launch.
- ☐ Where relevant patents have been invalidated in other jurisdictions, consider how those decisions may inform the Australian strategy.

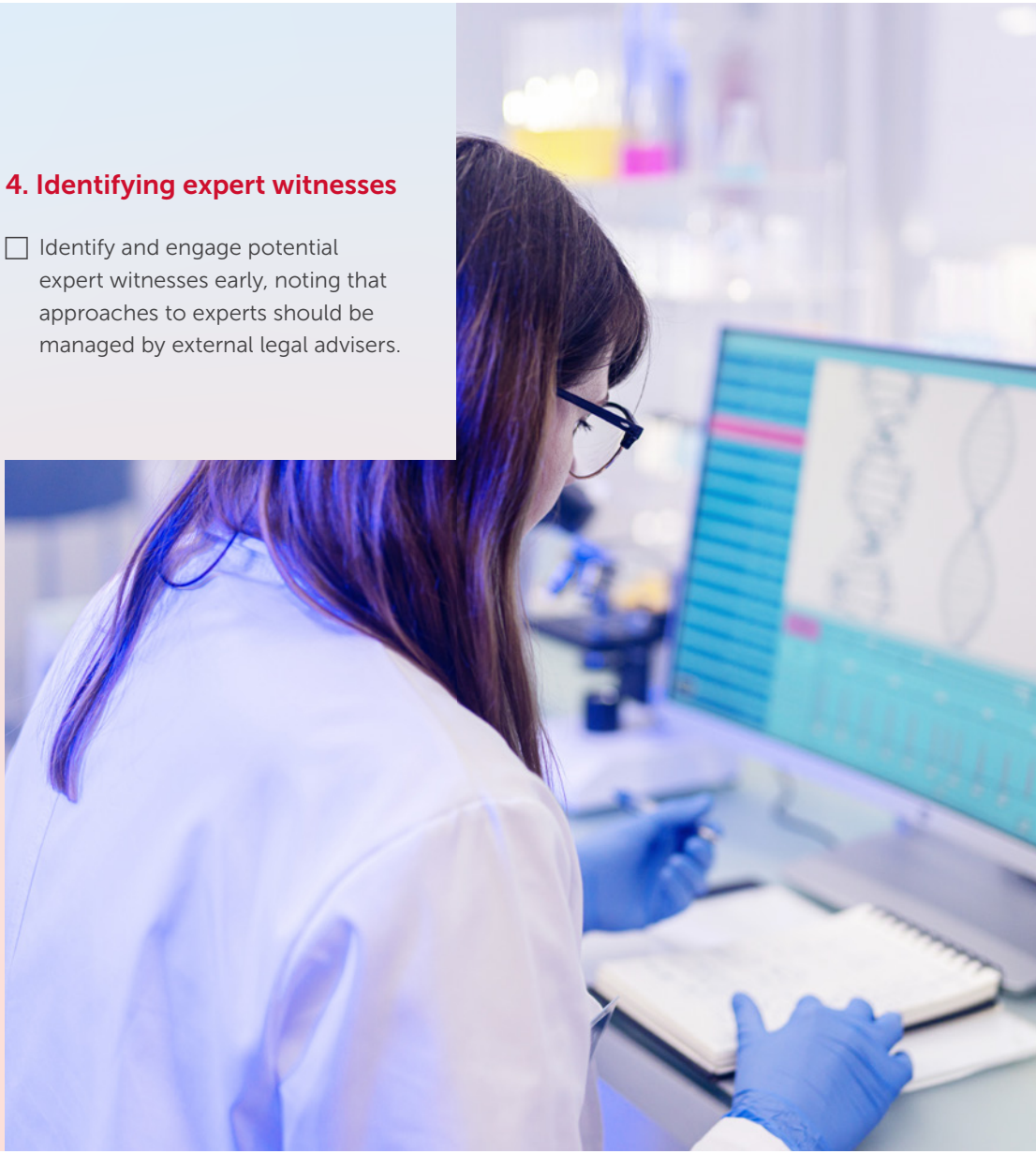
3. Evidence preparation

- ☐ Identify potential validity arguments that may be raised at the interlocutory stage, including prior art or patent term extension issues.
- ☐ For secondary medical use patents, consider whether a skinny-label strategy may reduce infringement risk.
- ☐ Preserve evidence demonstrating readiness to launch, including supply arrangements, manufacturing agreements and product packaging preparation.

Skinny-label strategy involves limiting a product's label to uses not covered by the relevant patent, reducing infringement risk.

4. Identifying expert witnesses

- ☐ Identify and engage potential expert witnesses early, noting that approaches to experts should be managed by external legal advisers.



1.3 An increasingly assertive regulator: TGA enforcement trends

The evolving enforcement approach of the TGA

Lead author:
Jonathan Kelp, Partner

"The TGA is increasingly prepared to pursue significant civil penalties and criminal sanctions where it considers non-compliance to undermine the public protection objectives of the Therapeutic Goods Act."

Jonathan Kelp

Chapter summary

*The regulatory environment for life sciences organisations in Australia is evolving. In recent years, the Therapeutic Goods Administration (**TGA**) has taken a more assertive approach to enforcing compliance with the Therapeutic Goods Act 1989 (Cth) (the **TG Act**), including through civil penalty proceedings, criminal prosecutions and large financial penalties.*

This shift has important implications for sponsors, manufacturers and distributors operating in the Australian market. Regulatory enforcement action can now carry significant financial, operational and reputational consequences.

This chapter examines how the TGA's enforcement posture has evolved, highlights recent regulatory actions and court proceedings, and outlines practical steps life sciences organisations can take to strengthen compliance in an increasingly active regulatory environment.

Introduction

Life sciences organisations operate in a heavily regulated environment. In recent years, the TGA has adopted a more assertive enforcement posture, demonstrating an increasing willingness to take meaningful compliance action, commence court proceedings, and seek substantial civil and criminal penalties.

Historically, the TGA relied primarily on guidance, education and warning letters to address non-compliance, with court proceedings typically viewed as the final enforcement mechanism. However, developments over the past six years indicate a clear shift in regulatory approach, supported by significant Commonwealth funding directed towards strengthening the TGA's compliance and enforcement capability.

Court-based enforcement under the Therapeutic Goods Act

Therapeutic goods for use in humans – including medicines and medical devices – must be registered, listed or included in the Australian Register of Therapeutic Goods (**ARTG**) before they can be lawfully imported into, exported from, manufactured or supplied in Australia, unless an exemption or exclusion applies.

The ARTG is the public record of therapeutic goods that can be legally supplied in Australia and is maintained by the TGA. For sponsors – persons or entities that engage in the import, export, manufacture or supply of therapeutic goods – failure to comply with regulatory obligations can result in significant consequences.

CASE STUDY

Medtronic – record civil penalty for supplying unregistered therapeutic goods

The Medtronic decision illustrates the increasingly significant financial consequences of regulatory non-compliance under the TG Act, even where there is no evidence of deliberate misconduct or patient harm.

In 2024, Medtronic Australasia was ordered to pay a civil penalty of A$22 million for supplying its Infuse Bone Graft Kit while it was not included on the ARTG. This represents the largest penalty imposed in Australia for contraventions of the TG Act.

The conduct in issue arose from a regulatory approval that did not align with commercial practice. The kit had been entered on the ARTG as part of a composite device – the kit together with a metallic spinal fusion cage. When the cage component was withdrawn from supply in August 2018 due to lack of demand, Medtronic continued supplying the kit alone to meet clinical need.

Between 1 September 2015 and 31 January 2020, the kit was supplied 16,267 times across more than 100 hospitals. However, the kit alone was not registered on the ARTG, and its supply in that form contravened the TG Act.

The proceeding was conducted on the basis of agreed facts and admissions. There was no suggestion the contraventions were deliberate, no evidence of patient harm, and Medtronic had no prior non-compliance history.

However, the Court relied on several key factors in imposing the historic penalty:

- each of the 16,267 supplies was treated as a separate contravention rather than a single course of conduct, placing the theoretical maximum penalty in the order of A$162 billion;
- Medtronic received over A$77 million in gross revenue from the unregistered supplies;
- the public protection purpose of the TG Act was materially undermined by the contraventions, even in the absence of proven individual harm; and
- both general and specific deterrence warranted a significant penalty notwithstanding Medtronic's cooperative conduct and absence of prior breach.

LESSON

Regulatory misalignment between product registration and commercial supply can create large-scale liability exposure.

The Court's reasoning on the 'course of conduct' issue – treating each individual supply as a discrete contravention – has significant implications for organisations supplying therapeutic goods at scale.

> *"The Court's reasoning that each individual supply may constitute a separate contravention has significant implications for organisations supplying therapeutic goods at scale."*
>
> Jonathan Kelp

CASE STUDY

Philips – regulatory enforcement following a global medical device recall

The Philips proceeding highlights the TGA's increasing willingness to pursue enforcement action against large-scale medical device suppliers where alleged non-compliance arises in complex post-market and product recall contexts.

In June 2025, the regulator commenced Federal Court proceedings against Philips Electronics Australia Limited. The proceeding concerns the alleged unlawful supply of medical devices containing a polyester-based polyurethane foam used for noise suppression – devices that were the subject of a global recall in 2021.

The TGA alleges that more than 44,000 devices were unlawfully supplied between June 2019 and October 2022 across multiple device types, including devices used by patients with sleep apnoea and those requiring ventilatory support. The regulator further alleges that a replacement silicone foam component introduced for one device model carried its own risk of ventilation failure.

The proceeding will be closely watched by the medical device industry. It involves:

- a major multinational manufacturer;
- a large-scale global recall; and
- complex post-market regulatory obligations.

LESSON

Post-market safety issues and product recalls can quickly escalate into regulatory enforcement proceedings.

The case illustrates how complex safety issues arising during post-market supply can evolve into significant potential regulatory exposure.

The outcome could significantly influence how organisations approach recall management, post-market surveillance obligations and the timing of communications with the TGA.

Insight: The TGA is increasingly willing to pursue significant court-based enforcement

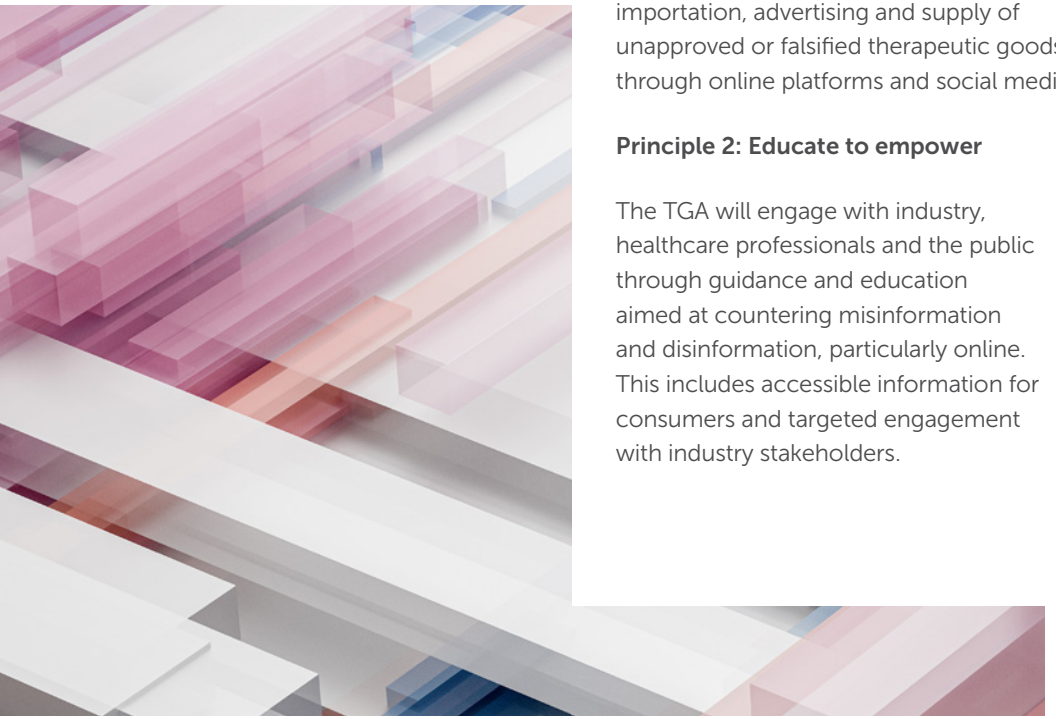
Taken together, the significant penalty imposed on Medtronic and the conduct at the centre of the Philips proceeding reinforce the increasingly assertive enforcement posture being adopted by the TGA.

As the table on the following page illustrates, where alleged contraventions of the TG Act are pursued in court the consequences can be substantial. While the TGA continues to issue infringement notices, particularly for less serious non-compliance, court-based enforcement action – and the scale of penalties imposed – is becoming more prominent.

Organisation	Year	Penalty	Conduct
Peptide Clinics	2019	A$10 million	Advertising unapproved peptide products; ~20,000 contraventions
Oxymed Australia / Director	2021	$2 million (company) A$1 million (director)	Supply and advertising of unregistered hyperbaric oxygen therapy devices
Evolution Supplements / Director	2021	A$11 million (company) A$1 million (director)	Advertising harmful sports nutrition products; 13,000+ contraventions
Enviro Tech Holdings	2022	A$80,000	Importation of face masks in contravention of a COVID-19 exemption
Vapor Kings / Director	2023	A$4.9 million (company) A$100,000 (director)	Unlawful advertising of nicotine vaping products
Medtronic Australasia	2024	A$22 million	Supply of unregistered medical device; 16,267 contraventions
Criminal proceedings			
AusLabs / Smart Labs / iSARMs Director Christopher Ramsay	2023	A$2,225,000 (organisations, aggregate) 2 years' imprisonment and A$300,000 (director)	Manufacture, supply and advertising of unapproved performance enhancing medicines
Elite SARMS Director Ryan McTeigue	2024	2 years' imprisonment (suspended) (director)	Manufacture, supply and advertising of unapproved performance enhancing medicines

The current focus of the regulator

The TGA regularly publishes guidance outlining its approach to compliance and enforcement. Most recently, in January 2026, the regulator released its compliance principles for 2026–2027. These principles continue the TGA's focus on consumer safety, particularly in relation to the online advertising and supply of therapeutic goods through digital platforms, including social media and online marketplaces.



The TGA has identified *five core principles* that guide its compliance and enforcement activities across its regulatory remit, including medical devices, prescription and non-prescription medicines, and other therapeutic goods. These are outlined below.

Principle 1: Safeguarding therapeutic goods

The TGA will continue to prioritise protection of the public from unsafe products. This includes proactive scrutiny of advertising, particularly digital advertising, and enforcement action against the importation, advertising and supply of unapproved or falsified therapeutic goods through online platforms and social media.

Principle 2: Educate to empower

The TGA will engage with industry, healthcare professionals and the public through guidance and education aimed at countering misinformation and disinformation, particularly online. This includes accessible information for consumers and targeted engagement with industry stakeholders.

Principle 3: Protect those most at risk

The regulator will deploy 'diverse and adaptive' strategies to protect vulnerable consumers who may be particularly exposed to harm from therapeutic goods. Risk assessments will consider factors such as the nature of the product, the way it is promoted, the vulnerability of the target audience and the compliance history of the relevant organisation or sector.

Principle 4: Leverage digital capability

The TGA intends to strengthen its digital monitoring capabilities to address emerging technological risks. This includes improved surveillance of online activity and specific attention to risks arising from AI-generated misinformation or misleading endorsements.

Principle 5: Strengthen enforcement

Consistent with recent enforcement activity, the TGA intends to increase public confidence in its regulatory role by taking swift and proportionate action where non-compliance is identified. This includes targeted enforcement against online marketplaces, social media advertising and other digital channels.

These five core compliance principles are supported by *12 priority focus areas*, which are reviewed quarterly and updated as required. As of 1 January 2026, the priority areas include direct-to-consumer in vitro diagnostic (IVD) kits, erectile dysfunction medications, foetal dopplers, listed medicine advertising, medicinal cannabis, melatonin, software as a medical device (SaMD), substandard and falsified therapeutic goods, sunscreen, weight loss medications, therapeutic goods used in cosmetic procedures, and vaping goods.

Notably, the 2023–2025 priority areas relating to unlawful advertising of psilocybin and 3,4-Methylenedioxymethamphetamine (**MDMA**), and medicines and devices promoted as traditional or alternative treatments, no longer feature.

Recent enforcement activity illustrates the TGA's focus on several of these priority areas, including:

(a) **weight loss medications**, with infringement notices issued to businesses for advertising prescription-only weight loss medicines on their websites;

(b) **software as a medical device**, with ongoing monitoring to determine whether the current regulatory framework remains fit for purpose and capable of addressing risks associated with the increasing use of AI-enabled technologies;

(c) **substandard therapeutic goods**, particularly those supplied through online channels, including counterfeit or black-market prescription-only products such as cosmetic injectables and weight loss medicines; and

(d) **sunscreen**, with several product recalls in the second half of 2025 following preliminary testing indicating that SPF levels in certain products may have been lower than stated on labelling.

Practical guidance: Strengthening compliance in an assertive regulatory environment

The evolution in the enforcement landscape gives rise to several important practical considerations for life sciences organisations operating in the Australian market.

Organisations should conduct a risk assessment through the lens of the TGA's priority areas, with particular focus on therapeutic goods and promotional activity involving in vitro diagnostics (IVDs), software as a medical device (SaMD), online advertising, the use of influencers and engagement with healthcare professionals (HCPs).

Advertising and promotional content should be *regularly reviewed across all channels*, including social media, influencers and online marketplaces, having regard to the TGA's proactive scrutiny of digital advertising and its increasing focus on deceptive endorsements and online misinformation.

Organisations should also *treat warning correspondence from the TGA with urgency*. Continued conduct following receipt of a warning – whether formal or informal – has been treated by courts as a significant aggravating factor. A warning from the TGA should not be viewed as an invitation for prolonged negotiation; rather, it is often a signal that enforcement action may follow if the conduct does not cease.

More broadly, governance and escalation procedures should be reviewed to ensure that potential compliance issues can be assessed and remediated quickly. This is particularly important given the TGA's risk-based and graduated enforcement approach, which considers factors such as the risk of harm posed by the conduct, the vulnerability of affected populations, and the size, reach and compliance history of the relevant organisation.

Organisations should also ensure that *internal training and compliance guidance remain current*, reflecting the TGA's continued emphasis on voluntary compliance supported by education and accessible regulatory guidance.

Regulatory approval should be treated as *an ongoing obligation rather than a one-time event*. The Medtronic decision highlights the risks that can arise where regulatory classification and commercial supply practices diverge over time.

Similarly, *post-market surveillance and recall management should be treated as enforcement issues*, not merely operational processes. The Philips proceeding suggests the TGA will closely scrutinise the handling of safety issues, including the timing and adequacy of recalls and the regulatory status of replacement products. Organisations should ensure that safety signals are escalated promptly and that any decision to continue supply pending or following a recall is carefully assessed from a regulatory perspective.

Finally, organisations should ensure that *compliance investment reflects the current enforcement environment*. Significant and ongoing government investment in the TGA's enforcement capability indicates that the regulator's more assertive posture is unlikely to be temporary. Organisations that calibrate their compliance frameworks to an earlier, more permissive regulatory environment may face material risk.

In an environment where the TGA is increasingly prepared to deploy significant enforcement powers, proactive compliance and early escalation of potential issues are likely to be critical in managing regulatory risk.

Policy perspective

Professor The Hon Greg Hunt
Minister for Health 2017-2022

From a policy perspective, why are disputes and regulatory enforcement becoming a more visible feature of the life sciences sector?

The life sciences sector now sits at the centre of some of the most vital trends shaping our future, with rapid advances in genomics, personalised medicine, AI-enabled healthcare/research and surgical robots being used to improve care. This comes at a time when Australia's health system will be facing pressure from ageing populations and increased expectations from Australians as to what healthcare should deliver in safety, efficiency and affordability.

As such, regulatory scrutiny and dispute activity has sought to keep pace with these developments. This should not be read as a sign of hostility to innovation but rather as a signal of maturity to the point that governments, regulators and investors understand the significance of safeguarding the work being done in this vital sector.

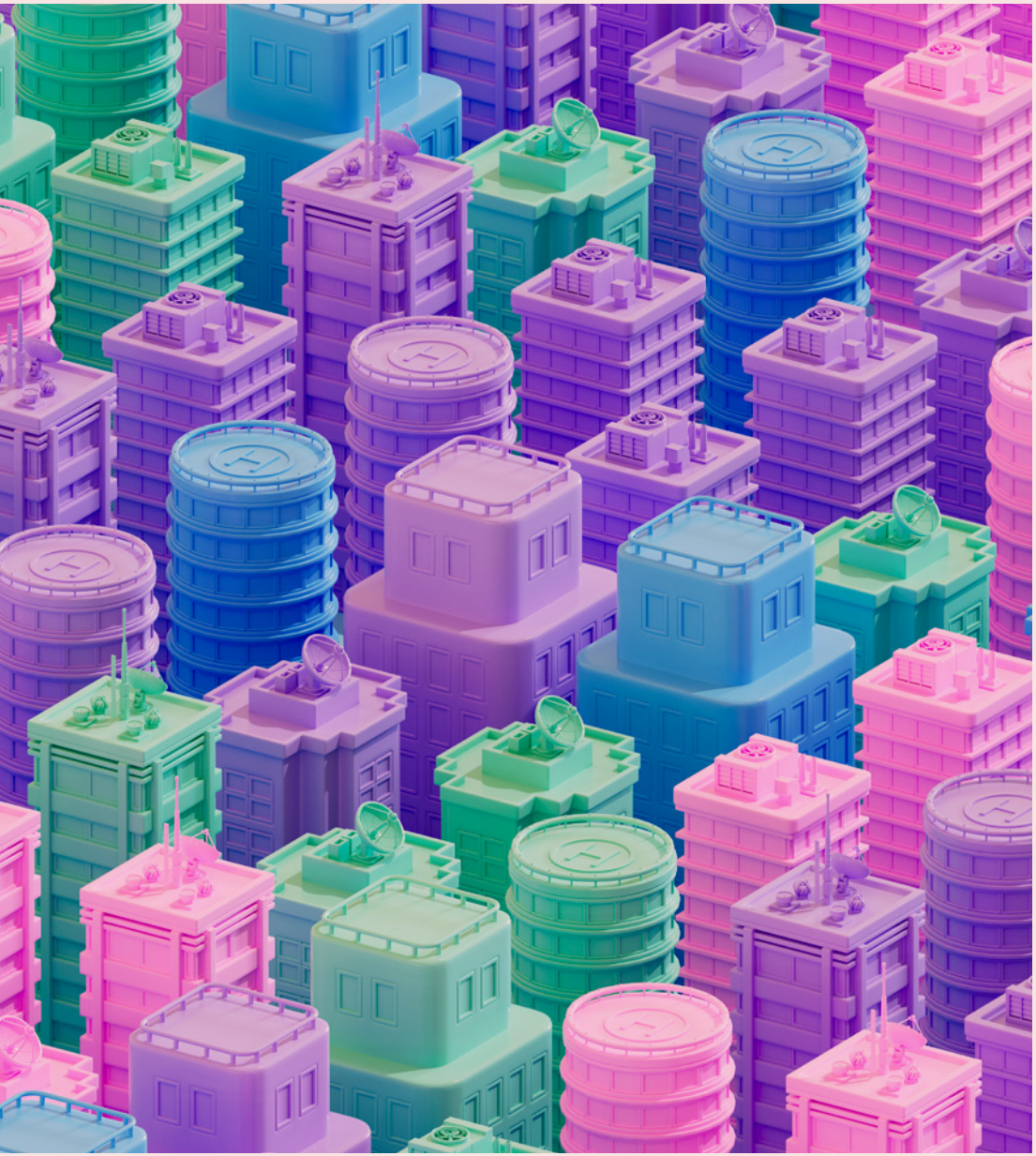
Life sciences products are not ordinary consumer goods. They affect human health, act at points of vulnerability, and rely on clinical evidence, quality, professional conduct and trust. For example, innovations such as AI and algorithm-assisted (or supported) decision making are raising new questions around accuracy, explainability and patient safety. Greater use of health and genomic data is increasing scrutiny around consent and cybersecurity. Faster commercialisation of emerging technologies means regulators must act quickly. And expanded use of telehealth and remote monitoring models is creating new regulatory questions around clinical responsibility and standards of care.

Ultimately, my experience in health policy has reinforced that as the life sciences sector grows in capability and economic significance, the regulatory system must simultaneously protect patients, sustain confidence and enable responsible innovation. From a policy perspective, governments are required to play a much more active role in setting the conditions under which this innovation can be trusted and sustained.

How should life sciences leaders interpret Australia's increasingly active regulatory posture when making investment, innovation or market-entry decisions?

From a policy standpoint, clear regulations should not be interpreted as anti-innovation. If well constructed, a clear regulatory environment can be a hallmark of a durable innovation environment. In practice, whilst unregulated environments allow for short term expansions in technology, reliable investment and market entry decisions will rely on a combination of scientific capability and institutional credibility. Companies are far more likely to succeed when they can operate in an internationally respected framework. This is, for example, why Australia has a disproportionate part of the world's Phase 1 trials.

For leaders making these decisions, the central question is not whether the regulation will matter but how well they understand and engage in it. Recent policy thinking has continued to emphasise research, clinical trial work, genomics, mRNA capabilities and responsible use of digital data. The opportunities in each of these environments come with the expectation that companies will treat regulation as a strategic function and not a downstream compliance exercise.



To create competitive advantage this means engaging with regulatory frameworks, embedding quality systems from the outset with a view to predicting future regulatory standards and recognising that safety and data governance will shape public acceptance. In life sciences, trust can take years to build and only one isolated event to lose, and the consequences are rarely confined to single products or businesses.

What role does trust, particularly around safety, data and technology, play in shaping both regulation and disputes in the life sciences sector?

Trust in this sector is important in three key areas. The first is that of safety. Patients and clinicians must believe that claims about the technologies being used are supported. The second is that of data. Where inadequate, regulatory intervention is likely to follow.

Next, organisations need to show that the increasing amount of data collected for precision medicine, AI and remote monitoring is protected in ways the community considers to be in good faith. If the community loses confidence, regulatory scrutiny and legal risk follows.

The third is the adoption of technology itself – the public will be far more comfortable in supporting innovation when they see a system that can govern it competently and fairly. These pressures will only intensify as digital healthcare and other personalised life sciences technologies become embedded as a staple of daily patient care.

Appropriate and careful scrutiny by lawmakers is not a sign that Australia is becoming closed to innovation. Rather, it is an acknowledgement that innovation in health will continue to carry greater consequence and responsibility.

The most successful organisations will be those that assess this regulation as not an anathema to growth, but as a necessary facet in a sector built on human outcomes. Indeed, precisely because of our hybrid public and private system, Australia has the opportunity to increase our share of discretionary global trials and innovation in health, thereby benefitting both the economy and above all else, patients.

Q&A with Chela Niall

Head of Legal – Walter and Eliza Hall Institute of Medical Research

What is your current role and how long have you been at WEHI?

I am currently the Head of Legal at WEHI (Walter and Eliza Hall Institute of Medical Research). I started at WEHI in 2018, leading a team that was focused on technology transfer and commercialisation, and last year took on responsibility for a consolidated legal function that supports the entire organisation.

How has the role of the in-house legal function evolved in life sciences companies over the past few years?

As in most sectors, legal teams in the life sciences area are expected to evolve and take up new technologies to 'do more with less'. As a not-for-profit in the life sciences/medical research space, this is not a new pressure but it is definitely driving an increased focus on efficiency and particularly what might be achievable with AI and automation. The funding environment is also becoming more fragmented and complex, which creates additional, and very interesting, work for legal teams.

Over my time at WEHI, I have felt a shift in the organisation's approach to legal. When I started, it was viewed as being quite reactive and largely focused on processing high-volume contracts. However, as operations and external engagement have become more sophisticated, the legal team has taken on a more strategic and proactive role.

What is the single most important legal trend that every life sciences company needs to be paying attention to right now and why?

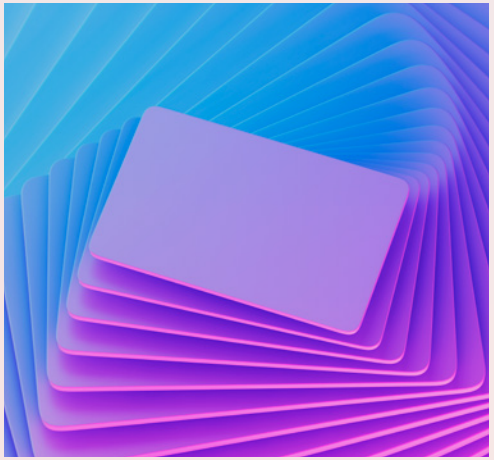
The intersection of AI, data governance and privacy laws. The arrival of AI is changing the way we collect and use data. In the life sciences sector, this includes patient data as well as data that consists of or could lead to valuable IP. Regulators are starting to implement rules and regulations to govern these new interactions which organisations must implement alongside embedding AI in business processes, and be ready to adapt as these laws inevitably evolve.

AI is transforming drug discovery and development – how is your legal team upskilling to advise on the legal risks and opportunities this presents?

We are upskilling in the technology itself to gain a deeper understanding of AI and how WEHI might use it. This enables us to spot emerging issues and advise appropriately. For example, WEHI receives or accesses large numbers of datasets for its research. The providers of those datasets increasingly include AI-related restrictions in data transfer/access agreements – it is important that we advise the business on the need to capture these new categories of restrictions in WEHI's data management processes. These are not new skills, as such: we are learning to apply our existing skills to new subject matter. In parallel, and this goes without saying, we keep up our knowledge of new regulation as it is introduced.

Looking ahead five years, what does the life sciences legal landscape look like?

Provision of legal services will inevitably be AI-enabled, and advising on AI-enabled research will be a greater proportion of our work mix. More routine legal work will be undertaken largely through AI and legal departments will be skewed towards senior lawyers who will undertake the more complex or strategic work that cannot be done by AI. The increasing use of AI will result in a smaller number of junior lawyers being trained and it will therefore become more difficult to recruit lawyers who have the right level of prior experience. This problem won't be unique to those working in life sciences: I think it is a challenge for the entire profession.



Key contacts

Simone Mitchell
Life Sciences Sector Lead
M +61 407 234 079
Simone.Mitchell@minterellison.com

James Hutton
Health Industry Lead
M +61 416 197 158
James.Hutton@minterellison.com

David Taylor
Partner
M +61 423 182 320
E David.Taylor@minterellison.com

Jonathan Kelp
Partner
M +61 408 669 914
E Jonathan.Kelp@minterellison.com

Sonja Read
Partner
M +61 411 276 772
E Sonja.Read@minterellison.com

Zeina Milicevic
Partner
M +61 401 181 568
E Zeina.Milicevic@MinterEllison.com

Chelsea Gordon
AI Lead – Legal
M +61 413 804 145
E Chelsea.Gordon@minterellison.com

Kemsley Brennan
Partner
M +61 402 974 557
E Kemsley.Brennan@minterellison.com

About MinterEllison

MinterEllison is Australia's leading independent law firm enhanced by specialist consulting.

Our dedicated, full-service, multidisciplinary life sciences team advise across the life sciences product and business lifecycle – from concept to commercialisation, and beyond.

This report was prepared with contributions from Jaimie Wolbers, Rebecca Pereira, Jacky Wong, Jasper Choi, Laura Skazlic, Maria Rychkova, Fiona Chui, Mikah Pajaczkowska-Russell, Meghan Philp, Adam Karras and Sophie Whalley.