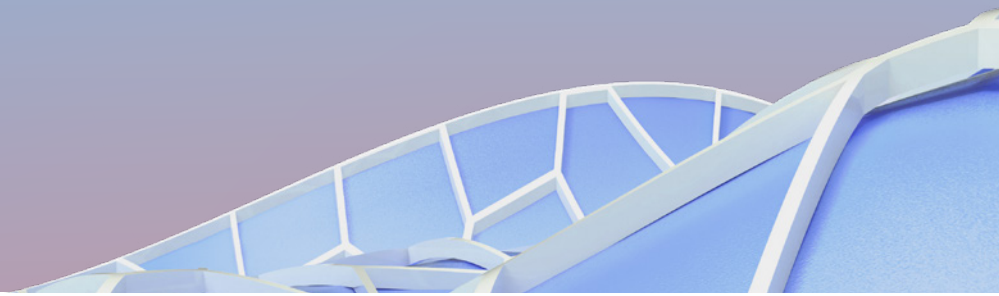
Strategic risk signals

How life sciences leaders stay ahead of disputes in Australia

MinterEllison.

Contents



Foreword

Professor Bruce Robinson AC

Disputes between parties in the life sciences sector are increasing.

The size of the Australian life sciences sector is small compared with our US and European counterparts, in part because of the poor commercialisation record of Australian universities and the lack of long-term capital willing to support early-stage work through to commercialisation. The lack of a clear, reliable and well-trodden path creates fertile ground for disputes, since expectations and the path to them often vary.

Professor Bruce Robinson is a renowned physician, academic, and advisor with over 25 years' experience as a leader in healthcare. In addition to being a highly experienced practising endocrinologist, Professor Robinson AC currently serves on the boards of major listed healthcare entities. He is Chair of Mayne Pharma Group Limited and a Non-Executive Director of Cochlear Limited and Healius. He is also a Non-Executive Director of British speciality pharmaceutical company CS Pharmaceuticals Ltd and an advisor to MinterEllison.

Professor Robinson's former roles include Chair of the Australian Government's taskforce of expert clinicians charged with reviewing the Medicare Benefits Schedule, the Medical Benefits Schedule Review Taskforce, and chair of Australia's peak advisory and funding body for medical research, the National Health and Medical Research Council. He is a former Dean of the University of Sydney's Medical School, the former head of the Cancer Genetics Unit at the Kolling Institute, Royal North Shore Hospital, and the former Head, Division of Medicine, Royal North Shore Hospital.

Professor Robinson was awarded a Doctor of Medicine from the University of Sydney in 1990, having earlier undertaken a fellowship at Harvard Medical School and graduated from the University of Sydney with a Master of Science degree. Professor Robinson is a Fellow of the Australian Institute of Company Directors.

A critical factor in avoiding disputes at this early-stage is a clear understanding of intellectual property ownership between investors, students and universities, and agreement on the intended path to commercialisation. Once funding becomes available, the use of that funding, milestones and the future pipeline of capital all need to be very clear to avoid disagreement. The role of the board, founders and senior management in any start up needs to be clear, and, where companies become publicly listed, the role of all participants in the stewardship of investor capital needs to be even more clearly spelled out.

These early-stage tensions, however, are only part of the picture. As life sciences organisations scale, partner globally and operate in increasingly regulated and data-driven environments, the disputes landscape broadens considerably. In Australia, the role of regulators such as ASIC and the TGA continues to expand, and disputes with these entities can become costly and distracting for all concerned. These regulatory pressures sit alongside other sources of conflict arising across the sector, including intellectual property disputes, product liability claims, class actions and the increasing influence of technology, including AI, across the life sciences landscape. Together, these forces are reshaping how and when disputes emerge, and the speed at which they can escalate.

It is against this backdrop that this report considers dispute activity across the Australian life sciences landscape, with a focus on the trends, pressure points and risk pathways most relevant to those responsible for investment, governance and commercial decision making. Time spent preparing strategy, being familiar with rules and regulations, and being advised by those who have been down these paths previously, will be rewarded.

There have been few truly global biotech success stories from Australia; CSL, Cochlear and ResMed remain the best recognised. Each had financial support from investors and government grants. Unlike in other jurisdictions, such as the UK, the Commonwealth has not taken shareholder stakes in these companies. While this may create certain complications, it would surely help biotech startups to get to commercialisation and as an experienced partner, could help prevent some disputes from arising in the first place.

Ultimately, we need a national supportive strategy for the life sciences sector to smooth the path to commercialisation and provide investors with greater confidence in making critical investments in the sector.

Executive summary

The Australian life sciences sector is entering a period of heightened legal and regulatory complexity.

The accelerating pace of change in scientific innovation, expanding regulatory oversight and the growing use of digital technologies are reshaping how disputes arise and how organisations manage legal risk.

Historically, disputes in the life sciences sector were often concentrated in areas such as patent litigation and product liability claims. While those risks remain significant, organisations are now facing a broader and more interconnected dispute landscape. Regulatory investigations, data governance issues, cybersecurity incidents and the deployment of emerging technologies such as artificial intelligence (AI) are increasingly giving rise to complex disputes involving multiple legal frameworks.

In tandem, regulators in Australia are demonstrating a greater willingness to pursue enforcement action in areas affecting the sector. Developments in relation to privacy and therapeutic goods laws and regulations and an enhanced focus on consumer protection are contributing to a more active regulatory environment, in which compliance failures may result in both regulatory proceedings and civil litigation.

Technological innovation is also reshaping the dispute landscape. AI, digital health platforms and data-driven research are transforming the way life sciences organisations develop products and deliver healthcare solutions. However, these technologies also introduce new legal questions relating to intellectual property, privacy, regulatory classification and liability.

Against this backdrop, several key trends are emerging across the life sciences sector:

- **increasing regulatory enforcement** in areas affecting patient safety, advertising, data governance and emerging technologies;
- **growing litigation risk** associated with the handling of sensitive health information and large-scale data ecosystems;
- **evolving intellectual property challenges** arising from the use of AI in research and development; and
- **greater financial exposure from disputes** where insurance coverage does not align with emerging operational risks.

For life sciences organisations, these developments highlight the importance of proactive governance and dispute preparedness. Many disputes arise from operational or regulatory issues that escalate before legal risks are fully assessed. Organisations that establish clear governance frameworks, integrate legal oversight into technology deployment and regularly review their regulatory and insurance strategies are better positioned to manage these risks.

Looking ahead, disputes in the life sciences sector are likely to become increasingly complex, cross-border in nature and closely intertwined with regulatory oversight. As innovation accelerates, organisations will need to ensure that governance, compliance and risk management frameworks evolve at the same pace as scientific and technological change.

For organisations operating at the intersection of healthcare, technology and regulation, effective dispute readiness will increasingly become a core strategic capability rather than a reactive legal function.

Insights from health and life sciences leaders

Method

In May 2026, MinterEllison surveyed more than 50 Australian health and life sciences leaders, including General Counsels and company owners to capture their perspectives on class actions risks, sensitive health data, privacy compliance, the use of AI and AI governance and regulatory concerns.

The survey was multiple-choice with some free text options. The anonymised results were pooled and analysed. Survey findings were supplemented by our own market intelligence and review of relevant public sources, case law and regulatory developments.

Key insights are summarised on this page and feature throughout the report.

Demographics

95%
of leaders surveyed are aged 35-54 years

91%
of leaders surveyed are General Counsels

7%
are company owners

2%
are CEOs

Key insights

Rising class action exposure is being felt by leaders.

79%
expect class action exposure to increase over the next 3–5 years.

Confidence in responding to a class action is high, but preparedness is uneven.

69%
report high or very high confidence in responding to a major class action.

32%
have material readiness gaps.

Class action drivers: Product liability leads, but the risk mix is broadening.

Anticipated class action drivers include:

Risk type*	%
Product liability	60%
Misleading or deceptive conduct / misrepresentation	53%
Regulatory-driven follow-on class actions	49%
Data privacy / cyber-related class actions	46%
Personal injury	32%
ESG-related class actions	21%
Shareholder / securities class actions	11%
Employment-related class actions	7%

**multi-select response*

Key insights

Privacy and regulatory scrutiny are core concerns.

75%

are at least moderately concerned about increased OAIC scrutiny.

Regulatory and **data/privacy/cyber** are tied as the top perceived legal vulnerabilities.

When asked whether their organisation had established formal governance frameworks or policies across key AI risk areas, respondents reported the strongest coverage for product safety and privacy.

Governance is notably less developed across AI bias and ethics, regulatory risk, workforce capability and human oversight, and third-party and vendor AI risk.

AI risk area*	Yes	Working on it	No
Product safety and quality	**81%**	7%	12%
Data, privacy and confidentiality	**72%**	5%	23%
IP and data ownership	**70%**	19%	11%
Decision-making and liability	**61%**	26%	12%
Operational use and misuse	**54%**	26%	19%
Governance and organisational readiness	49%	**33%**	18%
Bias, ethics and regulatory	44%	**39%**	18%
Workforce capability and human oversight	40%	**37%**	23%
Third party / vendor / supply chain AI	40%	**33%**	26%

**multi-select response*

There is strong support for IP reform and genuine industry debate around how to balance innovation incentives with generic and biosimilar market access.

Statement*	Yes	No	Unsure
Reform is necessary for timely resolution of IP disputes	**81%**	18%	2%
Australia would benefit from an Orange Book patent linkage system	**74%**	18%	9%
PBS reform to restore prices on patent infringement finding	**70%**	11%	19%
Legislated first mover advantage for generic entrants	51%	33%	16%

**multi-select response*

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.