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Product Liability & Safety 2022

Australia: Law & Practice
and
Australia: Trends & Developments

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AUSTRALIA

Law and Practice

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1. PRODUCT SAFETY

1.1 Product Safety Legal Framework

The principal law governing product safety in Australia is the Australian Consumer Law, which codifies a single set of consumer protection laws for the whole of Australia, including but not limited to laws relating to product safety and product liability.

The Australian Consumer Law is Schedule 2 to the federal Competition and Consumer Act 2010 (Cth). However, its operation across Australia also depends on state and territory laws, which provide that it has effect as a law of each Australian state and territory.

In addition to the Australian Consumer Law, there are a number of specific types of products that have their own safety regimes. For example, gas and electrical safety continues to be regulated at a state and territory level, so that each Australian jurisdiction has its own gas and electrical safety legislation, which applies to gas and electrical appliances. Other areas, such as therapeutic goods (ie, medicines and medical devices), food, agricultural and veterinary products, genetically modified organisms and industrial chemicals (including cosmetics), have their own federal safety regimes (pursuant to the Therapeutic Goods Act 1989 (Cth), the Australia New Zealand Food Standards Code, the Agricultural and Veterinary Chemicals Act 1994 (Cth) and the Agricultural and Veterinary Chemicals Code Act 1994 (Cth), the Gene Technology Act 2000 (Cth) and the Industrial Chemicals Act 2019 (Cth), respectively).

In each case, these regimes do not prevent the products in question from being subject to the Australian Consumer Law, subject to certain limited carve-outs.

In addition to these statutory obligations, product manufacturers and suppliers are subject to obligations under the common law. In particular, persons who are injured by a product may have a right to sue the supplier of the product in negligence (as well as under statutory causes of action created by the Australian Consumer Law), and an analysis of a supplier's duty to users of their product in negligence will often be important in assessing the appropriate response to a potential product safety risk.

1.2 Regulatory Authorities for Product Safety Federal

The principal Australian product safety regulator is the Australian Competition and Consumer Commission (ACCC), which is responsible for administering the Competition and Consumer Act 2010 (Cth), including the Australian Consumer Law.

The ACCC has regulatory, investigatory and prosecutorial powers granted to it under the Act. In relation to product safety, those powers include the power to require the production of documents or the provision of information, including the power to examine witnesses and to enter premises, conduct searches and seize consumer goods, equipment and documents. Typically, the powers of entry, search and seizure must be exercised pursuant to a warrant, unless there are circumstances which require their exercise without delay in order to protect life or public safety.

The ACCC also has powers to take a range of actions to protect consumer safety, including commencing compulsory recall actions, issuing substantiation notices and product safety notices, and prohibiting the making of certain representations in relation to a consumer product. Finally, the ACCC can issue penalty notices for breach of the Australian Consumer Law, or

commence proceedings seeking declaratory and injunctive relief as well as civil penalties. It may also refer certain breaches of the Australian Consumer Law to the Commonwealth Director of Public Prosecution for consideration of criminal prosecution, with associated criminal penalties.

State

In addition to the federal regulator, each state and territory has a Department of Fair Trading, or similar, although the role of these entities in relation to product safety diminished following the commencement of the Australian Consumer Law in 2011. Each state also has offices responsible for safety issues relating to gas, electricity and home building products. Product liability issues in these subject areas will often require engagement with both federal and state (or territory) authorities.

Sector-Specific

The other important sector-specific regulators are:

- the Therapeutic Goods Administration (TGA) in respect of medicines, medical devices and a range of other therapeutic goods;
- Foods Standards Australia New Zealand (FSANZ) in respect of food;
- the Australian Pesticides and Veterinary Medicines Authority (APVMA) in respect of agricultural and veterinary chemicals;
- the Office of the Gene Technology Regulator (OGTR) in respect of genetically modified organisms;
- the Australian Industrial Chemicals Introduction Scheme (AICIS) in respect of industrial chemicals; and
- state and territory fair trading and electrical safety regulators (as above).

The TGA, APVMA, OGTR and AICIS each operate registration or licensing regimes that require

certain products to be assessed and registered before they may be supplied or used in Australia. These regulators also have various investigatory, regulatory and enforcement powers, the precise scope of which varies from regulator to regulator, but which are generally similar in scope to the ACCC's powers in relation to consumer goods, tailored to the particular products in question. Subject to certain carve-outs, the regimes are not exclusive, so that a product that falls, for example, within the TGA's remit may also be, in some circumstances, a consumer product that is regulated by the ACCC, and subject to the Australian Consumer Law.

1.3 Obligations to Commence Corrective Action

The powers of the ACCC and other Australian regulators, as summarised in **1.2 Regulatory Authorities for Product Safety**, include powers to compel local sponsors, suppliers and/or manufacturers to take certain actions in relation to goods. For example, the ACCC may require corrective action or information to be supplied regarding goods, order a compulsory recall (in rare circumstances), issue an interim or permanent ban on the supply of specified products, or create an information or safety standard in relation to particular products.

However, outside situations where the ACCC or TGA has created a specific obligation in relation to particular goods, the institution of voluntary recall action is generally a matter for manufacturers or suppliers to determine for themselves.

The concept of product recall is well recognised under Australian law as covering a range of corrective actions in relation to products in the marketplace. The analysis of whether a recall is necessary in respect of a particular product safety issue is typically conducted by reference to the standards established by the tort of negligence. That is, what are the reasonable steps required

of the supplier as a result of a foreseeable risk of injury to users of the product?

If a supplier initiates a recall action, there are no specific legal requirements as to how such recalls must be conducted. However, the various regulators (in particular the ACCC, the TGA, FSANZ and the electrical safety regulators) publish guidelines in relation to the conduct of recalls. As a result of those guidelines, there are:

- common notification requirements to regulators regarding recall actions;
- commonly expected formats for recall notices; and
- common ongoing reporting obligations regarding the progress of recalls.

1.4 Obligations to Notify Regulatory Authorities

There are two notification obligations in relation to consumer goods in Australia: one risk-based and one incident-based.

Risk-Based

A supplier who voluntarily takes action to recall consumer goods because of a safety risk (including non-compliance with bans and certain safety standards) must, within two days of taking such action, give the relevant federal minister (which is in effect the ACCC) written notice that such action has been taken (Section 128 of the Australian Consumer Law). Such notice is typically given using the online form available on the ACCC's recalls [website](#). The online form requires the provision of relatively detailed information about the nature of the product, the extent of its distribution in Australia and the reason for the recall.

Careful and detailed completion of the notification is recommended because the information provided could otherwise be formally compelled by the ACCC.

Recently, the ACCC has taken an active and detailed interest in the initiation and continuing conduct of recall actions, to ensure that the best possible return rates are achieved and that continuing recall actions are taken by suppliers and manufacturers.

Incident-Based

There is a broad ranging requirement to report to the ACCC incidents related to products. A supplier of consumer goods who becomes aware of the death or serious injury or illness of any person that was:

- caused;
- may have been caused; or
- in the opinion of any other person was or may have been caused,

by the use or foreseeable misuse of those consumer goods must notify the ACCC of that fact within two days of becoming aware of it (Section 131 of the Australian Consumer Law).

The Australian Consumer Law defines “serious injury or illness” as meaning any acute physical injury or illness that requires medical or surgical treatment by, or under the supervision of, a medical practitioner or a nurse (whether or not in a hospital, clinic or similar place), but does not include:

- an ailment, disorder, defect or morbid condition (whether of sudden onset or gradual development); or
- the recurrence, or aggravation, of such an ailment, disorder, defect or morbid condition.

There are certain limited exceptions to this obligation where:

- it is clear that the death or serious injury or illness was not caused by the use or foreseeable misuse of the consumer goods;

- it is very unlikely that the death or serious injury or illness was caused by the use or foreseeable misuse of the consumer goods; or
- the goods in question are subject to one of a number of alternative incident-based notification regimes in accordance with an industry code of practice or Commonwealth, state or territory law that is specified in the regulations to the Competition and Consumer Act 2010 (Cth) (these include notification regimes relating to therapeutic goods, agricultural and veterinary chemicals and motor vehicles).

Notification pursuant to Section 131 is also typically undertaken by way of an online form available on the ACCC's recalls website.

1.5 Penalties for Breach of Product Safety Obligations

Under the Australian Consumer Law, the maximum pecuniary penalties that may be imposed for breach of product safety obligations generally are, in the case of a corporation:

- a fine of up to AUD10 million;
- a fine of three times the value of the benefit obtained by the corporation that is, directly or indirectly, reasonably attributable to the act or omission; or
- if the court cannot determine the value of the benefit, a fine of 10% of the annual turnover of the corporation in the 12-month period ending at the end of the month in which corporation committed, or begun committing, the offence.

The maximum penalty that may be imposed on an individual is a fine of AUD500,000.

In either case, the pecuniary penalties identified above can be sought in either a criminal prosecution or a civil penalty proceeding.

The fines outlined above are the maximum fines payable in respect of breaches of substantive provisions of the Australian Consumer Law. There are some breaches that may attract lesser penalties – for example, penalties for breach of the recall notification obligations outlined under **1.4 Obligations to Notify Regulatory Authorities** include (at present) AUD16,650 for a corporation and AUD3,330 for an individual but can also include, for example, orders disqualifying individuals from managing corporations for a period (on application by the regulator).

Infringement Notices

In addition to the criminal and civil penalty regimes outlined above, the ACCC also has the power, pursuant to Section 134A of the Competition and Consumer Act, to issue infringement notices in respect of certain breaches of the Australian Consumer Law. The ACCC may issue an infringement notice if it has reasonable grounds to believe that a person has contravened one of the provisions of the Australian Consumer Law specified in Section 134A.

An infringement notice issued pursuant to Section 134A will specify a pecuniary penalty that must be paid for the purported breach of the Australian Consumer Law. The maximum penalties that may be imposed by an infringement notice vary according to the particular provision said to have been breached. Payment of an infringement notice precludes any further penalty (civil or criminal) being sought from that person in respect of the breach.

Examples

Civil penalties

There are numerous examples of the ACCC seeking and obtaining civil penalties in respect of breaches of the Australian Consumer Law.

For example, in relation to product safety, in February 2016, a large Australian retailer was

ordered by the Federal Court of Australia to pay a penalty of AUD3.057 million in respect of false or misleading representations about the safety of five consumer products as well as breaches of the obligation to report serious injuries.

There are more recent examples of civil penalties being imposed in relation to breaches of the Australian Consumer Law that did not relate to product safety. For example:

- in December 2016, a supplier of anti-inflammatory medication was ordered to pay AUD6 million in respect of misleading conduct related to the sale of products purportedly for the relief of specific types of pain, but in fact not different from one another (the penalty imposed by the Federal Court at first instance was AUD1.7 million, increased to AUD6 million on appeal);
- in April 2018, a major car manufacturer was ordered to pay AUD10 million in respect of unconscionable conduct in dealing with consumer complaints about a transmission issue in its vehicles;
- in June 2018, a global computer company was ordered to pay AUD9 million in respect of misleading representations made in relation to faults in its products;
- in June 2019, an Australian art company was ordered to pay AUD2.3 million for making false and misleading representations that art was hand painted by Australian Aboriginal persons and made in Australia, when this was not true;
- in December 2019, a global car company was ordered to pay AUD125 million in respect of misleading representations made to regulators about the composition, standard or grade of certain vehicles (this penalty was significantly higher than the penalty jointly proposed by the ACCC and the company, and it was upheld on appeal).

- in May 2021, a telecommunication provider was ordered to pay AUD50 million in respect of unconscionable conduct in its dealing with more than 100 Indigenous consumers across Australia;
- in June 2021, an energy retailer was ordered to pay AUD1.2 million in penalties and to pay consumer redress in respect of false or misleading representations that it made in selling electricity plans to consumers; and
- in April 2022, a company operating an online hotel booking site was ordered to pay AUD44.7 million in respect of misleading representations in its advertisements about hotel room rates.

Criminal penalties

Examples of criminal penalties and referral to the Commonwealth Director of Public Prosecutions are much rarer, and relate to breach of the cartel provisions in the Competition and Consumer Act 2010 (Cth). For example, in 2017 Australia's first criminal cartel case concluded with a fine of AUD25 million in a global vehicle shipping company cartel case.

On the other hand, the use of infringement notices is quite common, with over 30 notices being issued since the start of 2020, almost exclusively related to breaches of Section 29 of the Australian Consumer Law (which prohibits false or misleading representations about goods or services).

The ACCC publishes a register of such notices, which identifies the person or company subject of the notice and the provisions of the Australian Consumer Law (or other applicable industry standard) that have been breached. However, the register does not disclose the particular products or conduct to which the notice relates.

2. PRODUCT LIABILITY

2.1 Product Liability Causes of Action and Sources of Law

Liability for a faulty or defective product that causes injury, loss or damage may be brought on a number of grounds. The causes of action most commonly pleaded are the common law tort of negligence or a breach of the Australian Consumer Law. The Australian Consumer Law creates a number of bases for liability, including:

- engaging in false, misleading or deceptive conduct (although these claims may not be relied on in personal injury cases);
- breach by a supplier of consumer goods of statutory guarantees – for example, guarantees of acceptable quality;
- derivative liability for manufacturers in respect of goods that breach the statutory guarantee of acceptable quality; and
- being the manufacture of goods with a safety defect.

Negligence

At common law, a manufacturer or supplier of products also owes a duty of care to both the purchaser and the user to take reasonable steps to protect them from any foreseeable injury when using a product as it was intended.

The content of the duty owed by a particular manufacturer or supplier will depend upon the role they play in the supply chain and the steps which are reasonably and practicably available to them to address the risk.

Since the early 2000s, common law negligence in Australia has been substantially impacted by statutory reforms designed to create a uniform national approach and curtail excessive negligence claims. These led to the introduction of various civil liability regimes, which are in place in Australian states and territories.

False, Misleading or Deceptive Conduct

The Australian Consumer Law prohibits persons from engaging in false, misleading or deceptive conduct in trade or commerce. It does not matter whether the person intended to mislead. Breach of this prohibition gives rise to a right to sue for loss or damage (although not for personal injury) in respect of losses suffered because of that conduct.

This prohibition is relied on in all manner of claims, including product liability claims for economic loss. For example, if goods are represented – expressly or impliedly – to have certain qualities that they do not have, a purchaser or end user of the product may sue for damages on the basis that the representations are misleading.

Statutory Guarantees

Part 3-2 Division 1 of the Australian Consumer Law provides that a supplier of goods to a consumer supplies those goods subject to a number of statutory guarantees. These guarantees cannot be limited or excluded by contract. They require that the goods:

- correspond with their description;
- are of acceptable quality;
- are fit for any stated purpose;
- conform to any sample provided; and
- comply with any express warranties given in relation to them.

Remedies for breach of the above consumer guarantees are provided in Part 5-4 of the Australian Consumer Law. For actions against suppliers, consumers have a number of remedies available, including in some cases the right to return the goods and demand a refund, as well as the right to recover any reasonably foreseeable losses suffered by reason of the failure of the goods to comply with the guarantee.

Part 5-4 also provides an extended right to sue the manufacturer of goods for damages if they breach guarantees of acceptable quality, supply of goods by description, as to repairs and spare parts or express warranties.

Strict Liability Regime

Part 3-5 of the Australian Consumer Law imposes liability on manufacturers of goods with safety defects. It is closely modelled on the European Product Liability Directive.

Goods have a safety defect if their safety is “not such as persons generally are entitled to expect”. Regard is to be had to relevant surrounding circumstances in making this safety inquiry. If such goods cause personal injury or damage to land, buildings or fixtures, persons who suffer loss as a result of such injury or damage may sue the manufacturer for damages.

Expanded Concepts of Consumer and Manufacturer Under the Australian Consumer Law

There are specific definitions of “consumer” and “consumer goods” as well as “manufacturer” in the Australian Consumer Law.

“Consumer goods” or “goods acquired as a consumer” are goods that:

- cost AUD40,000 or less, are a vehicle or trailer acquired for use principally in the transport of goods on public roads or are otherwise goods that are of a kind ordinarily acquired for personal, domestic or household use or consumption;
- were not acquired for the purposes of using them up or transforming them in a process or production or manufacture or repair or treatment of other goods or fixtures; and
- were not acquired for the purpose of resupply.

The term manufacturer has a deeming function, and “manufacturer” means not only the actual manufacturer of goods, but also:

- a person who cause or permits their name or brand to be applied to the goods;
- a person who permits themselves to be held out as the manufacturer of the goods; and
- if the actual manufacturer of the goods does not have a place of business in Australia, a person who imports the goods into Australia.

Contract

Another cause of action for a person who has been injured or suffered loss or damage is under the law of contract. However, the number of these claims has diminished due to the growth of statutory remedies and remedies available under the tort of negligence.

2.2 Standing to Bring Product Liability Claims

Under the Australian regime, the original purchaser is not the only person who may make a claim for injuries caused by a product. Apart from the remedies available for breach of the consumer guarantees, which may only be sought by the consumer who received the goods from the supplier, the other causes of action outlined in **2.1 Product Liability Causes of Action and Sources of Law** may be relied upon by any person who suffers loss and damage that is compensable under the relevant cause of action.

2.3 Time Limits for Product Liability Claims

The limitation period for bringing a product liability claim will depend on a number of factors, including the cause of action, the type of claim (for example, in relation to an alleged safety defect), whether the claim is brought under common law or statute, the relevant Australian jurisdiction, and the date of the alleged act or omission.

However, in relation to claims for personal injury, the applicable limitation period for an action to be commenced is:

- in most jurisdictions, either within three years of the date the cause of action is discoverable by the plaintiff (the date of discoverability), or 12 years from the date of the act or omission alleged to have caused the death or injury (the long-stop period); or
- three years from the date the cause of action accrued.

There may also be a mechanism for an extension to be granted by the courts in relation to the applicable limitation period for personal injury claims. In determining whether to grant an extension, a court is generally required to consider a number of factors, including having regard to the justice of the case. Again, in most jurisdictions an extension of up to three years can be granted. There are also circumstances in which limitation periods are suspended, such as where a claimant is suffering from a legal incapacity (for example, the claimant is a minor or suffers from a mental or physical disability), or when a class action is commenced in which case the limitation period will not begin to run again until a group member opts out or the proceedings are determined.

The limitation period for claims that do not relate to personal injury is, in most cases, six years from when the cause of action accrued.

2.4 Jurisdictional Requirements for Product Liability Claims

Australia has both a federal court system and a hierarchy of courts in each of the states and territories. The High Court of Australia deals with constitutional disputes and appeals (with leave) from either the Full Federal Court or a state or territory Court of Appeal. Both federal and state courts may exercise jurisdiction in respect of the

causes of action under the Australian Consumer Law outlined in **2.1 Product Liability Causes of Action and Sources of Law**. Insofar as a claim relates to defendants and conduct within Australia, proceedings may be commenced in any court of competent jurisdiction, regardless of where the conduct occurred. However, there is cross-vesting legislation which provides that the proceedings may be moved from one jurisdiction to another if they are in an inappropriate forum.

The Australian Consumer Law has long-arm jurisdiction, and also regulates the conduct of foreign corporations which are “carrying on business” in Australia. In order for an Australian court to validly exercise jurisdiction over a foreign corporation, that corporation must be validly served with initiating process. Some courts require leave to be obtained to serve overseas corporations, and for the court to be satisfied that the claim has a sufficient nexus to Australia to justify it being brought in Australia. In other courts there is no requirement to seek leave to serve an overseas corporation when certain claims (such as those under the Australian Consumer Law) are being made. The court rules in each jurisdiction set out a list of circumstances in which service outside of Australia may be permitted. One such circumstance is that the claim is seeking recovery of damage suffered wholly or partly in Australia, and that is often sufficient in product liability claims to justify service on a foreign defendant.

Australia is party to the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters, 1965 so, if authorised, service may be effected through Hague Convention means on other treaty parties.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

There are mandatory steps that must be taken at a federal level and in some states and territories in Australia before formal proceedings can be commenced in relation to product liability claims. Federal legislation obliges parties to take “genuine steps” to resolve a dispute before commencing proceedings in the Federal Court. Under the federal legislation, genuine steps include the requirement to file a statement specifying the steps that have been taken to resolve the issues in dispute, or the reasons why such steps were not taken.

Many states and territories also have various different pre-action procedures in place, which must be undertaken before formal proceedings can be commenced. For example, the Australian Capital Territory (ACT) requires the claimant of a personal injury claim to provide a potential respondent with a notice of their claim (in the approved form), which includes brief particulars and copies of any documents directly relevant to a matter in issue in the claim. The respondent must respond to the notice of claim, acknowledging whether it is in fact the proper respondent to claim or whether it has knowledge of who may be the proper respondent to the claim. If the respondent on whom the notice of claim was served is the proper respondent to the claim, they have an obligation to provide the claimant with copies of all documents in its possession that are directly relevant to a matter in issue in the claim. There is then an obligation on the respondent to attempt to resolve the dispute by making an offer of settlement or counteroffer to any offer made by the claimant. Queensland has a very similar pre-action procedure provided for by the Personal Injuries Proceedings Act 2002 (QLD), except that, in addition to the obligations of the parties outlined above for the ACT, parties in Queensland must also attend a compulsory

settlement conference before formal proceedings are commenced. South Australia also has pre-action procedures which the parties are required to comply with before commencing formal proceedings in relation to most claims.

Non-compliance with the various pre-action procedures may mean that the claimants cannot commence or continue proceedings until those pre-action requirements have been complied with. Furthermore, non-compliance may result in the court awarding costs reasonably incurred because of the non-compliance, against the non-complying party, once proceedings are commenced.

2.6 Rules for Preservation of Evidence in Product Liability Claims

The general rule is that documents must be preserved as soon as there is a reasonable anticipation or reasonable contemplation of litigation. The definitions of document are extremely broad and extend to information in many forms, and to the product itself. The rule first existed at common law, where it is expressed as an offence involving perverting the course of justice. In most Australian jurisdictions, the common law offence has now been supplemented or replaced by statute. For example:

- the Crimes Act 1914 (Cth) contains an offence for the destruction of “a book, document or thing of any kind” which “is, or may be, required in evidence in a [federal] judicial proceeding”, provided the intention is to prevent the book, document or thing from being used in evidence (Section 39) – it is sufficient that there is a reasonable possibility that proceedings would be brought; and
- the Crimes Act 1958 (Vic) contains an offence for the intentional destruction/concealment of a “document or other thing of any kind” which “is, or is reasonably likely to be, required in evidence in a legal proceeding” (Section 254).

The relevant intention here is the “intention of preventing it from being used in evidence in a legal proceeding” – this offence applies to a legal proceeding that is in progress or is to be, or may be, commenced in the future.

Depending upon the jurisdiction, penalties include up to five years’ imprisonment, significant fines and the ability of the court to strike out affected parts of the defence of a contravening party. Lawyers who advise their clients to act contrary to the obligations in legislation may also face sanction and penalties.

From a procedural perspective, if documents that were relevant to litigation are no longer available because of steps taken by a party who was aware of, or should have been aware of, actual or likely proceedings, that may result in that party’s claim or defence being struck out, to the extent that the documents would have been relevant to that claim. It may also result in adverse inferences being drawn against the party about the content of the documents, which can then be used as a basis to make findings of fact against the non-producing party.

2.7 Rules for Disclosure of Documents in Product Liability Cases

The rules of the court in which a claim is commenced outline the applicable requirements with respect to discovery. While these rules are similar across the various Australian jurisdictions, there are nuances between the courts. To assist the parties, the Australian courts have published Practice Notes and directions that provide further guidance, such as in relation to the court’s expectations with respect to the parties’ approach to discovery. Use of technology is actively encouraged by all courts in discovery, and many provide suggested protocols for exchanging documents with technological assistance.

Generally speaking, the practice of Australian courts is to try to actively manage the discovery process so as to keep the level of discovery proportionate to the complexity of the issues in proceedings and the amount that is at stake.

In personal injury proceedings, in most courts, documentary discovery is only available with the court’s leave. Before making discovery orders, a court must be satisfied that the discovery sought is necessary and will assist the resolution of proceedings as quickly and efficiently as possible. Courts will generally not grant discovery requests that are expansive or may be “fishing” expeditions. The additional guidance provided by Australian courts via practice notes and directions emphasises the courts’ expectation that parties to proceedings will take all steps necessary to reduce the burden of discovery.

Subpoenas may also be used to obtain documents that are relevant to issues raised in a proceeding but are held by a third party. As with discovery, in many courts a party must approach the court to request leave to issue a subpoena, and must demonstrate to the court that the subpoena has a legitimate forensic purpose. A subpoenaed entity will also have an opportunity to object to the scope or timeframe of a subpoena.

2.8 Rules for Expert Evidence in Product Liability Cases

Expert evidence is typically an important part of the evidence in product liability cases, in respect of questions of both liability and quantum. This is because they often involve complex, technical questions regarding products, standards and the scientific state of the art.

Experts must be independent, and have a duty to assist the court rather than to advocate on behalf of the party that calls them. Powers do exist for courts to appoint their own experts or refer particular matters to referees. Increasingly,

the use of these powers is being explored by Courts in Australia in complex product liability cases.

The duties of expert witnesses are usually set out in the court rules or practice notes (in addition to the common law). For example, the Federal Court of Australia's Expert Evidence Practice Note (GPN-EXPT) states that any expert witness retained by a party for the purpose of preparing a report or giving evidence should, at the earliest opportunity, be provided with a copy of the Practice Note, the Harmonised Expert Witness Code of Conduct and all relevant information (whether helpful or harmful to that party's case) so as to enable them to prepare a report of a truly independent nature. Experts must also set out the basis for their opinions, and acknowledge that they have complied with their obligations under the Practice Note.

Most courts also have rules that prohibit the evidence of any expert from being relied on unless the expert has served a written report well before the date for trial.

In addition, product liability cases often involve a court-ordered process for the evidence of experts in the same field to be given concurrently – ie, the experts for all parties in the same discipline will be sworn in together to give their evidence. It is also usual for a conferral process to be ordered in advance of the experts giving evidence so that they can produce a joint report which details the areas of agreement and disagreement, and the reasons for that disagreement.

2.9 Burden of Proof in Product Liability Cases

Under the law of contract, negligence and the majority of provisions in the Australian Consumer Law, the claimant bears the onus of proving

the elements of their claim on the balance of probabilities.

2.10 Courts in Which Product Liability Claims Are Brought

Claimants may bring product liability claims in either the Federal Court or state or territory courts. Each state and territory has either two or three levels of court: a magistrates or local court, a district or county court and a Supreme Court. The Federal Court has the Federal Circuit Court, the Federal Court and the Full Court of the Federal Court.

There are jurisdictional limits for lower courts, which vary from state to state (they are usually in the range of AUD750,000 to AUD1 million for the district courts). The Supreme Court of each state and territory has unlimited jurisdiction (subject only to other laws that may separately restrict the quantum of damages payable for certain types of claims, including personal injury claims). Most product liability litigation of any complexity will be brought in either a state or territory Supreme Court or the Federal Court.

Civil juries are very rare in Australia, so in practice most product liability cases are heard by a judge alone. The usual practice in Australia is for a single judge to sit at first instance and a panel of three or more judges at appellate level.

All civil litigation in Australia is adversarial in nature. Individual parties present their evidence to the judge and make submissions on the law. After consideration of all the materials presented, the judge makes findings of fact and law.

2.11 Appeal Mechanisms for Product Liability Claims

In virtually all jurisdictions, unsuccessful parties have the right to appeal a judgment of a trial judge. The applicable appeal procedure is dictated by the jurisdiction in which the trial took

place. In the case of interlocutory judgments, it is generally necessary for the unsuccessful party to apply for leave to appeal (from the original deciding judge). Appeals are typically raised on a particular question of law, but it is not unusual for some of the evidence presented at trial to be reviewed in the course of an appeal.

Parties who are unsuccessful on appeal to the Full Court of the Federal Court or a state or territory court of appeal may seek leave to appeal to the High Court, Australia's highest appellate court. There is no automatic right to have an appeal heard by the High Court. The party wanting to appeal must convince the High Court in a "special leave" hearing that the issues in dispute are sufficiently important or that the potential for miscarriage of justice is sufficiently great to justify the appeal being heard by the High Court. Once a matter has been determined by the High Court there is no further appeal, and the decision is binding on all other Australian courts.

Appeals in most Australian courts are by way of rehearing, meaning that the court has the power to consider all of the evidence anew. However, no new evidence may be put before the appellate court unless that court grants leave. It is extremely rare for such leave to be granted in civil matters.

Timeframes

In the Full Court of the Federal Court, appeals from final judgments must be filed and served within 28 days of the trial decision. Timeframes for state and territory courts of appeal vary based on jurisdiction but are all of a similar order.

2.12 Defences to Product Liability Claims

Negligence

The following defences may be available to a claim in negligence:

- voluntary assumption of risk;
- contributory negligence; and
- the learned intermediary defence.

Voluntary assumption of risk is when a plaintiff consciously decides to take responsibility for injury, loss or damage. In establishing this defence, the defendant must show that the plaintiff properly perceived and appreciated the danger, and voluntarily chose to accept the risk. Contributory negligence may be relied upon when the plaintiff has contributed to their own injury by failing to meet the standard of care for their own safety. Typically, contributory negligence will result in apportionment of damages according to the degree of fault, but may be a complete defence in some jurisdictions.

The learned intermediary defence has not yet been applied in Australian courts, but the existing common law principles would accommodate its use.

As above, the introduction of various Civil Liability Acts has led to additional specific statutory defences relating to certain types of claims. For example, the state of New South Wales has introduced complete defences where:

- harm was suffered as a result of the materialisation of an inherent risk (unavoidable by the exercise of reasonable care and skill) or an obvious risk (obvious to a reasonable person);
- the conduct was widely accepted at the time by peer professional opinion as competent professional practice;
- the defendant is a good Samaritan or volunteer exercising reasonable skill and care; or
- the defendant is a public or other authority (in certain cases).

Australian Consumer Law

In cases where a safety defect was not discoverable within the limitations of science and tech-

nology at the time of distribution, the manufacturer or supplier may rely on the “state of the art defence”, also known as the “development risk defence”. To rely on this defence it must be established on the balance of probabilities, and the claim in question must be in relation to the Australian Consumer Law provisions relating to defective products.

Another defence to an action based on a safety defect may be claimed in circumstances where the defect is brought about by compliance with a mandatory standard. A mandatory standard is a standard for goods or anything relating to the goods which, under law, must be complied with when goods are supplied, and which carries a penalty for non-compliance. This defence cannot be claimed in relation to statutory requirements for goods to achieve a minimum standard.

Manufacturers are also entitled to claim a defence where the defect alleged did not exist when the goods were supplied by the manufacturer. Similarly, if an entity is only responsible for the manufacture of a component of the product, that entity will be able to claim a defence against actions for claims relating to safety defects in the finished product.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Adherence to regulatory requirements is a relevant consideration in product liability cases in Australia, although it does not operate as a complete defence to such claims. In this respect, please see **2.12 Defences to Product Liability Claims**. Unlike the United States of America, there is no “pre-emption” defence in Australia. Compliance with applicable regulatory requirements or mandated standards will be a relevant factor considered by the courts in actions for negligence and under the statutory warranty or guarantee provisions of the Australian Consumer Law, but the fact that a product had its safety

assessed by a regulator as part of a process of granting a licence to sell that product in Australia does not preclude a product liability claim being brought in respect of it.

2.14 Rules for Payment of Costs in Product Liability Claims

Australia has a loser pays costs system. The precise rules that apply to calculate the costs payable by an unsuccessful party to a successful one vary from jurisdiction to jurisdiction, but are generally calculated on a party/party basis, which means that only some parts of the work undertaken are recoverable (meaning that in the ordinary course the costs recovered are only a portion of the costs incurred). However, solicitor/client or indemnity costs, which would be close to the total costs incurred, may be awarded in some circumstances, particularly if a party formally rejected a settlement offer and then failed to do better than that offer at trial.

The approach taken to calculating costs differs from jurisdiction to jurisdiction. Some jurisdictions have a scale of costs, which specifies (and limits) the amount a successful party may recover from the unsuccessful party for tasks undertaken during the course of litigation (such as the drafting of correspondence or electronic document management). Other recoverable costs include court filing fees and other out-of-pocket expenses. In other jurisdictions, an assessment is made as to the reasonableness of the costs incurred.

Depending on the type of proceeding commenced, more particular rules may apply in relation to costs. For example, in representative proceedings or class actions, statutory provisions restrict costs orders being made against class members, other than those who commenced the proceedings.

2.15 Available Funding in Product Liability Claims

Australia has a well-established litigation funding industry. Although the exact number is unknown, in December 2020 the Parliamentary Joint Committee on Corporations and Financial Services indicated that 22 litigation funding companies were known to be operating in Australia (14 of which were foreign owned or based overseas, and six of which were Australian owned or based).

Litigation funding arrangements typically involve a funding agreement between the funder and claimant, a retainer agreement between the lawyer and claimant, and an agreement between the litigation funder and lawyer, which sets out the terms on which the funder agrees to pay the costs of the litigation. However, the models of litigation funding are evolving and the law in this area is also changing.

At the core of such litigation funding arrangements is an arrangement whereby the litigation funder promises to pay the legal costs and disbursements of the litigation, and to meet any adverse costs order, in exchange for which the claimant promises to pay the funder a percentage of any compensation they receive.

Such arrangements are very common in Australian class actions, although less common in product liability class actions than in other forms of class actions. Approximately three quarters of funded class actions are shareholder or investor class actions.

Litigation funding is an area of rapid reform and development in Australia. In 2020, the previous exemption for litigation funders from the operation of the certain provisions of the Corporations Act 2001 (Cth) was removed. Litigation funders are now required to hold an Australian Financial Services Licence and funding arrangements may

be regulated as managed investment schemes under that legislation.

Shortly thereafter, in 2021, a litigation funder and five lawyers were found by the Supreme Court of Victoria to have engaged in a fraudulent scheme, which was designed to claim more than AUD19 million in legal costs and funding commission from a settlement sum in a class action. It can be expected that further legislative reforms will result from this egregious case.

Australian lawyers are permitted to enter into “no win no fee” arrangements and, in the case of such arrangements, to charge an uplift on their fees of up to 25% in the event of success. They are not otherwise permitted to charge contingency fees, except in class actions in the Victorian Supreme Court where the Court approves the arrangement. (see further discussion in **3.1 Trends in Product Liability and Product Safety Policy**).

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

There are five Australian courts that have a class action procedure (referred to as a representative proceeding): the Federal Court of Australia and the Supreme Courts of New South Wales, Queensland, Tasmania and Victoria. The class action procedure is often used in product liability claims.

The rules governing representative proceedings are largely identical in each of the five jurisdictions. In order to bring representative proceedings, there must be seven or more persons who have claims against the same legal person, arising out of the same, similar or related circumstances and giving rise to a substantial common issue of law or fact. However, it is not necessary for at least seven persons to be individually iden-

tified, nor is there are requirement, as in many other jurisdictions, that the common issues predominate over those which are not common.

Australian representative proceedings are “opt out”, meaning that all persons who fall within the group definition will be bound by the outcome of the proceedings unless they choose to opt out. Unlike many other jurisdictions, there is no certification requirement for Australian class actions, meaning that once a class action that meets the basic requirements is commenced, a class action is on foot unless the defendants can convince the court that representative proceedings are an inappropriate vehicle for the dispute in question. Class actions in Australia are very rarely “declassified” in this manner.

2.17 Summary of Significant Recent Product Liability Claims

In recent years, Australia has seen a number of class actions concerning product liability claims. A selection of those cases is included below.

ASR Hip Replacement Class Action

In 2011, an action was jointly brought by Shine Lawyers and Maurice Blackburn Lawyers on behalf of Australians implanted with the defective ASR hip device, after a worldwide recall was announced. In March 2016, the parties reached a conditional agreement to settle the class action for AUD250 million, an agreement that was subsequently approved by the Federal Court.

Bayer Essure Class Action

In July 2019, a representative proceeding was commenced by Slater & Gordon on behalf of women who are alleged to have suffered injury as a result of using the Essure Contraceptive device. The action is still in the early stages.

Combustible Cladding Class Action

More recently, two class actions have been commenced by William Roberts Lawyers, funded by

IMF Bentham, on behalf of owners of buildings who have suffered or will suffer financial loss due to the need to remove and replace Alucobond PE and Vitrabond PE combustible cladding products. The claimants seek to recover the cost of rectification, loss of property value and the legal cost of experts from the product manufacturers. Both actions are still in their early stages.

Mesh Implant Class Action

In 2012, a representative proceeding was commenced by Shine Lawyers on behalf of Australian women who alleged injuries as a result of implanted pelvic mesh implants. The first instance trial in the pelvic mesh class action was held in the Federal Court of Australia in 2017. Judgment was delivered in late 2019 in favour of three applicants. An appeal in respect of the trial judgment was heard by the Full Court of the Federal Court in February 2021, with judgment delivered in March 2021 in favour of the three applicants. The appellants sought special leave to appeal to the High Court of Australia. This application was rejected in November 2021. Numerous class action have been filed on behalf of women not captured in the original proceedings against other manufactures of pelvic mesh.

Roundup

Three competing class actions were commenced in 2019 and 2020 in relation to the weedkiller, Roundup. In June 2020, the Federal Court ruled that the latest of those class actions (commenced by Maurice Blackburn) ought to proceed, in preference over the competing claims. The matter is presently listed for hearing in 2023.

Philips Ventilator Machines Class Action

In October 2021, a representative proceeding was commenced by Carbone Lawyers in relation to alleged safety defects in certain sleep apnoea machines. The action is still in the early stages.

Further Claims

In addition, there have been a number of highly contentious toxic tort class actions relating to bushfires and floods, some of which resulted in significant multimillion-dollar settlements.

Separately, the ACCC has also been active in recent years, particularly in its oversight of product recalls and allegedly unsafe products.

3. RECENT POLICY CHANGES AND OUTLOOK

3.1 Trends in Product Liability and Product Safety Policy

The maximum penalties for breach of the Australian Consumer Law, as set out in **1.5 Penalties for Breach of Product Safety Obligations**, were introduced as a result of amendments that took effect on 1 September 2018 and substantially increased the penalties available (the previous maximum corporate penalty for a breach of the Australian Consumer Law was AUD1.1 million). The amendments introduced, for the first time in relation to product safety breaches, the potential for penalties linked to benefit from either the breach or corporate turnover.

Even apart from these amendments, the penalties being imposed by courts for breaches of the Competition and Consumer Act 2010 (Cth) (including but not limited to those relating to product safety breaches) have been steadily increasing with a new high being set by the AUD125 million penalty mentioned in **1.5 Penalties for Breach of Product Safety Obligations**. This trend is expected to continue with the application of the new penalty regime to conduct that occurred after 1 September 2018:

- an entertainment company being fined AUD7.5 million for making misleading claims

on its website relating to the reselling of tickets to live music or sporting events.

- in May 2021, a telecommunication provider was ordered to pay AUD50 million in respect of unconscionable conduct in its dealing with more than 100 Indigenous consumers across Australia;
- in June 2021, an energy retailer was ordered to pay AUD1.2 million in penalties and to pay consumer redress in respect of false or misleading representations that it made in selling electricity plans to consumers; and
- in April 2022, a company operating an online hotel booking site was ordered to pay AUD44.7 million in respect of misleading representations in its advertisements about hotel room rates.

Class action procedure, in particular as it relates to litigation funders, has been the subject of considerable activity by the court and the federal legislature. The following are of particular relevance.

- In January 2019, the Australian Law Reform Commission (ALRC) tabled to Parliament its report on class actions: Integrity, Fairness and Efficiency—An Inquiry into Class Action Proceedings and Third-Party Litigation Funders.
- In December 2019, the High Court held that neither the Federal Court nor the NSW Supreme Court has the power to make common fund orders (which enabled funders to obtain a commission from group members who had not signed a funding agreement), at least at an early stage of proceedings.
- In April 2020, the NSW Court of Appeal held that the NSW Supreme Court did not have power to make an order closing an otherwise open class in order to facilitate a mediation.
- In August 2020, the Corporations Regulations 2001 (Cth) were amended to subject litigation funders to regulatory regimes relating to managed investment schemes and the supply of

financial products from which they had previously been exempt. Central to the changes is the requirement that litigation funders must now hold an Australian Financial Services Licence.

- In December 2020, the Federal Government Joint Committee on Corporations and Financial Services published a report titled *Litigation Funding and the Regulation of the Class Action Industry*. The report made 31 recommendations for further legislative and procedural reform across class actions and litigation funding.
- In October 2021, the Australian government responded to these recommendations, making its priorities:
 - (a) ensuring that Australians receive a fair and proportionate amount of any class action settlement or judgment, and reducing the windfalls gains made by litigation funders – draft legislation has been proposed to this effect;
 - (b) expanding the regulation and supervision of litigation funders;
 - (c) ensuring that “economically inefficient class actions” are not detrimental to Australia’s economic recovery from COVID-19;
 - (d) enhancing the Federal Court’s powers to protect class members and regulate class actions; and
 - (e) consideration of whether the Federal Court ought to have exclusive jurisdiction for class actions commenced under the Corporations Act 2001 (Cth) and the Australian Securities and Investments Commission Act 2001 (Cth).

At the same time, the Australian government proposed amendments to the Corporations Act which would significantly curtail the ability of litigation funders to operate in Australia and place a cap on their maximum recovery from class actions. However, that legislation was referred

to a Senate committee for further consideration and with the change of government following the May 2022 election, is unlikely to move forward in its present form.

In relation to product liability, the current product liability regime remains relatively unchanged since its introduction in 2011 as part of the Australian Consumer Law. However, class actions are now a significant driver of a number of different forms of litigation, including product liability litigation.

3.2 Future Policy in Product Liability and Product Safety

In March 2017, Consumer Affairs Australia and New Zealand published the report of its review of the Australian Consumer Law. The report made a number of recommendations in relation to amendment of the Australian Consumer Law, some of which (for example, the increased penalties described in **3.1 Trends in Product Liability and Product Safety Policy**) have already been implemented. However, one that has not been implemented is the recommendation that Australia should introduce a general safety provision that imposes an obligation on suppliers in Australia to ensure the safety of a product before it enters the market, and that imposes penalties on suppliers in accordance with the new penalty regime for failing to do so.

The ACCC is actively promoting this recommendation. In March 2019, the Chairman of the ACCC delivered a speech in which he advocated for the introduction of the general safety obligation. At the same time, the Minister responsible for the ACCC indicated that Consumer Affairs Australia and New Zealand was drafting a consultation regulatory impact statement in respect of such a proposal. However, these calls have not been repeated and the impact statement has not been published. This may be due to the

COVID-19 pandemic causing different priorities to arise.

In 2019 the ACCC also identified raising awareness of consumer safety hazards with interconnected devices as a product safety priority. The ACCC has a web page devoted to providing guidance to consumers in relation to such issues, but there have otherwise not been outcomes of the 2019 priority. However, in March 2021 the TGA published a guidance document dealing with cyber security for medical devices which among other things states that a failure to adequately address cyber security risks associated with a connected medical device may be a breach of the Essential Principles with which all medical devices are required to comply.

From a product liability perspective, much will depend upon developments in relation to the funding of class actions. In addition to the focus on litigation funders mentioned above, the Victorian Parliament passed legislative changes in 2020 permitting lawyers to charge, under some circumstances, percentage-based contingency fees in class actions before the Victorian Supreme Court.

The degree to which the Parliamentary Joint Committee's recommendations are given effect, as well as the related impacts of the Victorian reforms, could fundamentally change the product safety and product liability landscape in Australia.

3.3 Crisis Management/Situations/ Business Disruption and Product Liability and Product Safety Laws

The COVID-19 pandemic has not resulted in changes to Australia's product liability or product safety laws. However, the ACCC has published guidance on its product safety website for both businesses and consumers in relation to precautions which should be taken to ensure

product safety during the pandemic. It has also published specific guidance in relation to certain types of products (these include, at the time of writing, hand sanitiser, face masks and bidet products).

In addition, the TGA, which is responsible for approving therapeutic goods for supply in Australia, has taken a range of steps to facilitate access to medicines and medical devices which are important in stopping the spread of or treating COVID-19, as well as to prevent suppliers from taking advantage of the pandemic. This has included the granting of exemptions from the usual registration requirements for certain classes of products (including hand sanitiser, domestically manufactured ventilators and certain types of testing kits), streamlining the registration process for other products (including provisional approvals for a number of antiviral medications), issuing guidance about the regulatory requirements for certain products and fining companies who have sought to take advantage of the pandemic to advertise products for uses for which they are not approved. Throughout 2020–22, the TGA have been conducting post-market reviews of facemasks and COVID-19 point-of-care tests to verify whether products that have found their way to market during the pandemic meet the requirements of the regulations.

Significant additional requirements and guidance have also been published by various regulators including the health departments and SafeWork Australia.

None of the measures introduced in relation to the pandemic limit manufacturers' and suppliers' exposure to liability under the product liability laws described in this chapter. Indeed, the speed with which some products have come to market and the high degree of their take up may actually increase product liability risk. We

also expect that as the immediate threat of the pandemic recedes, regulators will actively scan the market for unsafe products which may have found their way into the market. The TGA's post-market reviews are an example of this type of regulatory activity.

In mid to late March 2020 most Australian courts either ceased face-to-face hearings entirely or significantly limited their use. While courts in 2022 have gradually resumed face-to-face hearings, audio-visual links will likely continue to be used more widely than before, particularly for case management hearings where they have been shown to be very efficient.

Clayton Utz is an independent Australian firm established in 1833, with more than 180 partners and 1,300 employees across six offices, and one of the largest commercial litigation practices in Australia, including a specialist five-partner product safety and product liability team. The firm handles the most complex, significant and high-profile matters, for clients

including many of Australia's top financial institutions, multinational corporations operating in a range of sectors, and state and Australian government departments and agencies. Clayton Utz is also a global leader in pro bono, with one of the largest pro bono practices of any law firm outside of the USA.

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The Clayton Utz logo, consisting of the words "CLAYTON UTZ" in white, uppercase, sans-serif font, centered within a solid black rectangular background.

CLAYTON UTZ

Trends and Developments

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Clayton Utz see p.29*

ACCC and TGA Action on COVID-19 Advertising

At the commencement of the COVID-19 pandemic both the Australian Competition and Consumer Commission (the ACCC) and the Therapeutic Goods Administration (the TGA) adopted a swift, strict stance on any advertising that referenced COVID-19.

Because COVID-19 is a “serious disease” under the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021, any advertising which includes references to COVID-19 is a “restricted representation” and required TGA approval.

Early action taken by the TGA and the ACCC indicated to both traditional medical companies and retailers that representations regarding COVID-19 would be face serious consequences from multiple regulators.

Lorna Jane’s false claims of anti-COVID-19 activewear

The popular Australian clothing manufacturer Lorna Jane learned this after both the TGA and ACCC took action over their line of “Anti-virus Activewear”.

Lorna Jane advertised that the products had been treated with “LJ Shield”, a substance that purportedly eliminated virus pathogens, including COVID-19, on contact with the fabric. The brand allegedly represented that the product would therefore protect wearers from the virus and help stop its spread.

Initially, Lorna Jane was issued three infringement notices by the TGA, totalling fines of

AUD39,960. The TGA alleged that the advertising of the LJ Shield garment treatment included therapeutic claims, being that it eliminated and protected against viruses including COVID-19. Under the Therapeutic Goods Act 1989 (Cth) (TG Act), any goods about which therapeutic claims are made must be registered on the Australian Register of Therapeutic Goods (ARTG) before they can be legally sold or advertised. The Lorna Jane products were not. The TGA also penalised Lorna Jane for the representations made in relation to COVID-19, which fall into the category of “restricted claims” and require the TGA’s prior approval to be made. Finally, Lorna Jane’s representations that the products were “safe, harmless or without side-effects” were also found to be in breach of the TG Act.

The ACCC separately alleged that Lorna Jane’s advertising claims were misleading on the basis that the clothing could not in fact eliminate the virus, protect wearers from infection, or prevent the spread of the virus. The ACCC alleged that there was no scientific basis for the representations at the time they were made.

In July 2021, the Federal Court ordered Lorna Jane to pay a penalty of AUD5 million for making false and misleading representations to consumers, and engaging in conduct liable to mislead the public.

Other advertising claims related to COVID-19

The TGA has remained vigilant in policing advertising claims regarding COVID-19 that alleged unproved therapeutic benefits, for example:

- celebrity chef Pete Evans was fined AUD25,200 for a Facebook live-stream in

which he allegedly made restricted representations, and for allegedly making therapeutic claims in relation to a product that was not ARTG-listed on his website (in May 2021, a further AUD79,920 in fines were issued to Mr Evans for continued advertising of therapeutic goods not entered in the ARTG, along with a direction to cease this conduct);

- fines against individuals for advertising ivermectin and zinc lozenges to treat COVID-19; and
- fines against individuals for advertising of hydrogen peroxide as a treatment for COVID-19.

Outside of the Lorna Jane matter, a large proportion of TGA action in relation to restricted representations regarding COVID-19 has been directed at individuals. Under the current legislative scheme civil penalties for individuals can be up to AUD1.05 million. The possible civil penalties and the proportion of individual enforcement action being taken marks a high-water mark in TGA regulatory action against individuals, in an area that is normally dominated by (generally sophisticated) corporate entities.

Reforms to the TG Act

This enforcement activity has occurred against the background of a suite of reforms to the TG Act that introduced:

- an improved complaints handling process regarding therapeutic goods advertising;
- stronger compliance and enforcement powers; and
- graduated penalties depending on the seriousness of the offence.

The full force of those amendments was felt in *Secretary, Department of Health v Peptide Clinics Australia Pty Ltd* [2019] FCA 1107, in which the Federal Court ordered penalties of AUD10 million for advertising prescription medication

(not related to COVID-19) on Peptide Clinic's website, Facebook, Instagram and via telephone.

However, as the COVID-19 vaccine roll-out in Australia progressed, and following the provisional approval of a number of anti-viral medications for the treatment of COVID-19, the TGA has also recognised that many advertisers (both of therapeutic goods and more broadly) wish to assist in disseminating public health messages regarding COVID-19.

Accordingly, the TGA has given its permission to advertisers to refer to COVID-19 in the context of advising individuals to seek health advice. It is also acceptable to use general statements that are understood as referring to COVID-19, such as "stay at home if you are unwell" even without a specific reference to COVID-19.

Presumably in an effort to increase the take-up of anti-viral medication by the Australian public (which has been sluggish), in May 2022 the TGA also permitted representations to be made that relevant COVID-19 treatments are available for supply on prescription from a particular pharmacy or other dispenser. That permission is not limited in its application, and so would permit (for example) a local pharmacy to advertise that it has a provisionally approved anti-viral available when that medication is in stock.

Sponsors and advertisers in Australia are thus presently required to walk the line between being encouraged to contribute to the national "public health messaging", and not stepping outside the bounds of the small number of permissions issued by the TGA in respect of advertising.

Litigation Funding in Australia – Banksia and Litigation Funding Reform

In October 2021 the Australian class actions world was rocked by his Honour, Justice Dixon's

decision in *Bolitho v Banksia Securities Ltd* (No 18) (remitter) [2021] VSC 666 – a case that will have lasting implications for the conduct of class actions, the Australian legal profession and the scrutiny of litigation funders in Australia. It has been described by Justice Dixon at [92] of the judgment as “one of the darkest chapters in the legal history of this State”.

Justice Dixon found that a litigation funder and five lawyers (the fraudulent parties) had engaged in a fraudulent scheme, with the intention of claiming more than AUD19 million in allegedly incurred legal costs and funding commission from the settlement sum in a group proceeding involving around 16,000 (largely elderly) investors in a failed company.

In addition to ordering that the fraudulent parties pay damages of AUD11,700,128 to group members, plus indemnity costs (estimated to exceed AUD10 million), Justice Dixon made a number of personal orders directed at removing the (very senior) barristers involved in the scheme from the Supreme Court’s roll of practitioners and requiring other participants to show cause as to why they ought not be removed. The central architect of the scheme, Mr Mark Elliot, had died during the proceedings, and no show cause orders were made in his regard.

The case began in 2018 when the litigation funder Australian Funding Partners Limited (AFP) made an application for reimbursement of AUD5.2 million in legal costs and AUD14.1 million in litigation funding commission (AUD19.3 million in total) out of a settlement of AUD64 million.

However, two group members were not satisfied that those claims were proportionate or legitimate and appealed the original approval, resulting in the appointment of appropriate con-

tradictors. Their belief that something was amiss ultimately led to exposure of the scheme.

However, two group members were not satisfied that those claims were proportionate or legitimate and appealed the original approval, resulting in the appointment of appropriate contradictors. (A contradictor is a lawyer appointed by a court to argue against an outcome sought by a party in circumstances where that outcome is not opposed. It is becoming increasingly common to appoint contradictors in class action settlement hearings to represent the interests of absent class members.) Their belief that something was amiss ultimately led to exposure of the scheme.

Justice Dixon found that AFP was a shell company, and that the sequence of events in the fraud had been:

- Mr Elliot had been both the managing director of AFP and the principal solicitor at Elliot Legal;
- an early decision by Justice Ferguson had found he was conflicted in acting both as funder and solicitor in the proceedings;
- to circumvent this ruling, Mr Elliot appointed a “post-box” solicitor to create the appearance of an independence;
- the fraudulent parties demanded that the other parties agree to settlement terms that were adverse to the interests of group members, including the original claim by AFP of AUD19.3 million; and
- the fraudulent parties then backdated costs agreements and invoices, to make it appear as if the claimed fees were legitimately incurred, and misled an expert costs lawyer to support the costs claimed.

Effects of the Banksia decision

It is highly likely that the Banksia decision will cause Australian courts to scrutinise the costs

and commission claims made by lawyers and litigation funders running class actions. In addition, the Banksia decision was handed down at the end of a substantial period of policy consideration and activity regarding class actions reform, notably:

- in January 2019, the Australian Law Reform Commission (ALRC) had tabled to Parliament its report on class actions – Integrity, Fairness and Efficiency—An Inquiry into Class Action Proceedings and Third-Party Litigation Funders; and
- in December 2020, the Federal Government Joint Committee on Corporations and Financial Services published a report titled Litigation Funding and the Regulation of the Class Action Industry – the report made 31 recommendations for further legislative and procedural reform across class actions and litigation funding.

It was expected that these two reports would form the basis of policy and legislative development in class actions for a considerable period to come.

Nine days after Banksia, in October 2021, the Australian government responded to these reports (the “response”). Acknowledging Banksia, the response stated that “the Government has already taken action, and will continue to take action, to address these concerning litigation funding practices”.

Most notably, at the time when AFP was incorporated the Corporations Regulations 2001 (Cth) exempted litigation funders from the usual requirement that financial service providers hold an Australian financial services licence. That position has now changed, and as of August 2020, the Corporations Regulations 2001 (Cth) were amended to subject litigation funders to regulatory regimes relating to managed invest-

ment schemes and the supply of financial products from which they had previously been exempt. Central to the changes is the requirement that litigation funders must now hold an Australian Financial Services Licence.

Other priorities in the response addressed towards litigation funders are reforms to ensure that Australians receive a fair and proportionate amount of any class action settlement or judgment, and to reduce the windfalls gains made by litigation funders. Draft legislation has been proposed to this effect which would:

- introduce a rebuttable presumption that at least 70% of the gross proceeds ought to be returned to group members;
- require funding agreement to include a complete indemnity against adverse cost orders against the representative plaintiff;
- require litigation funders to provide security for costs in an enforceable manner; and
- provide courts with the power to make costs orders against litigation funders

A number of other proposed reforms go towards enhancing court powers in respect of litigation funders, and permitting the interrogating of litigation funding agreements. For example, the government has committed to engage with the Federal Court regarding the appointment of a litigation funding fees assessor, with experience in market capital or finance.

In late 2021 some of the changes proposed in the response were put before the Australian Parliament in a bill to amend the Corporations Act. A number of those changes were contentious and the bill was referred to a Senate committee for review. In February 2022 the Senate committee’s report endorsed the bill, but a minority report raised significant questions as to whether the proposed reforms were permitted under the

Constitution and also whether they went too far in impairing access to justice.

In May 2022, a change of government occurred in Australia when the Labor Party won the Australian Federal Election. It now seems unlikely that the bill will proceed in the form originally proposed. However, class actions and litigation funding reform are likely to remain topics of significant interest and debate both in court and at a policy level.

AUSTRALIA TRENDS AND DEVELOPMENTS

Contributed by: Greg Williams, Alexandra Rose and Caitlin Sheehy, Clayton Utz

Clayton Utz is an independent Australian firm established in 1833, with more than 180 partners and 1,300 employees across six offices, and one of the largest commercial litigation practices in Australia, including a specialist five-partner product safety and product liability team. The firm handles the most complex, significant and high-profile matters, for clients

including many of Australia's top financial institutions, multinational corporations operating in a range of sectors, and state and Australian government departments and agencies. Clayton Utz is also a global leader in pro bono, with one of the largest pro bono practices of any law firm outside of the USA.

AUTHORS



Greg Williams has more than 20 years' experience in Australia's premier product safety and product liability practice. He has defended product liability claims and class actions involving

pharmaceuticals and medical devices, financial services and automobiles, and advises on product safety and regulatory issues. He is a member of the International Association of Defense Counsel, and also has a master's degree in biochemistry.



Alexandra Rose is a partner in the product liability team, whose practice centres around the defence of major disputes, including class actions, which often involve complex expert

and scientific issues. Her product liability advisory practice includes product labelling and consumer law advice, proactive risk management, crisis management and remediation. Alex's sector expertise includes a particular interest in the issues affecting pharmaceutical, medical device and health technology clients. She is a member of the Defense Research Institute (DRI).

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Caitlin Sheehy is a senior associate in the Clayton Utz product liability team and an experienced commercial litigator who acts in complex product liability litigation, including class

actions. She has represented Australian and overseas pharmaceutical and medical device clients in both contentious and advisory matters, including in relation to regulatory issues, advertising and labelling requirements, and product safety and recall issues.

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