THE PRODUCT REGULATION AND LIABILITY REVIEW

Sixth Edition

Editors
Chilton Davis Varner and Madison Kitchens

THE LAWREVIEWS

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PREFACE

In today's global economy, product manufacturers and distributors face a dizzying array of overlapping and sometimes contradictory laws and regulations around the world. A basic familiarity with international product liability is essential to doing business in this environment. An understanding of the international framework will provide thoughtful manufacturers and distributors with a strategic advantage in this increasingly competitive area. This treatise sets out a general overview of product liability in key jurisdictions around the world, giving manufacturers a place to start in assessing their potential liability and exposure.

Readers of this publication will see that each country's product liability laws reflect a delicate balance between protecting consumers and encouraging risk-taking and innovation. This balance is constantly shifting through new legislation, regulations, treaties, administrative oversight and court decisions. But the overall trajectory seems clear: as global wealth, technological innovation and consumer knowledge continue to increase, so will the cost of product liability actions.

This edition reflects a few of these trends from 2018. Most notably, various jurisdictions continued to experiment with regulatory and procedural innovations that may augur increased exposure for product manufacturers. In 2018, the first collective action was brought under the Collective Redress Act in Japan, which joined the ranks of other nations (such as France and Belgium) that have newly embraced class adjudication. A draft law on class actions is currently under consideration by the Russian State Duma as well. In Europe, implementation efforts continued apace on the European Databank on Medical Devices, an initiative designed to strengthen market surveillance and transparency for medical devices. The EUDAMED Database is slated to be launched in March 2020, a mere two months prior to the deadline for medical device companies to recertify their products under the EU's new Medical Device Regulation. Meanwhile, as the incidence of product recalls has escalated globally, various jurisdictions in Asia are establishing new regulatory bodies to monitor product safety and respond to crises. For instance, the Singapore Food Agency is being formed to oversee food safety and security, while India has introduced the Consumer Protection Bill 2018, which will establish the Central Consumer Protection Authority and a broad mandate to protect consumer rights. Perhaps most notably, China has established the State Administration for Market Regulation, an institution housed directly under the State Council, that is responsible for ensuring product quality and safety and guiding the China Consumers Association.

Other novel challenges facing product manufacturers were spawned by judicial decision, rather than legislative decree. For example, France's Court of Cassation ruled that, when adverse reactions to a drug are severe enough relative to the expected benefits, the product

should be deemed 'defective,' regardless of whether the manufacturer provided express warnings about those side effects on the product label. Moreover, the Spanish Supreme Court ruled in favour of a plaintiff property owner who argued that damages caused by a metal pipe leak resulted from a manufacturing or design defect – rather than external causes – even though the piping had performed without incident for more than six years after installation. By placing the burden on the product manufacturer to rebut the presumption of a defect, the Court's opinion abrogated prior case law holding that the chain of causation is presumptively broken once sufficient time has elapsed since the product was placed into circulation. And in the United States, the Supreme Court is poised to decide a landmark pre-emption case that may provide valuable guidance to product manufacturers seeking to minimise their exposure to failure-to-warn claims arising under state law. Additionally, this edition highlights how certain countries' product liability laws have grappled with cutting-edge issues in the modern economy, including e-commerce innovations and the emergence of autonomous vehicles and artificial intelligence. Although these changes and trends may be valuable in their own right, they also create a need for greater vigilance on the part of manufacturers, distributors and retailers.

This edition covers 17 countries and territories and includes a high-level overview of each jurisdiction's product liability framework, recent changes and developments, and a look forward at expected trends. Each chapter contains a brief introduction to the country's product liability framework, followed by four main sections: regulatory oversight (describing the country's regulatory authorities or administrative bodies that oversee some aspect of product liability); causes of action (identifying the specific causes of action under which manufacturers, distributors or sellers of a product may be held liable for injury caused by that product); litigation (providing a broad overview of all aspects of litigation in a given country, including the forum, burden of proof, potential defences to liability, personal jurisdiction, discovery, whether mass tort actions or class actions are available and what damages may be expected); and the year in review (describing recent, current and pending developments affecting various aspects of product liability, such as regulatory or policy changes, significant cases or settlements and any notable trends).

Whether the reader is a company executive or a private practitioner, we hope that this edition will prove useful in navigating the complex world of product liability and alerting you to important developments that may affect your business.

We wish to thank all of the contributors who have been so generous with their time and expertise. They have made this publication possible. We also wish to thank our colleague Alex Gray, who has been invaluable in assisting us in our editorial duties.

Chilton Davis Varner and Madison Kitchens
King & Spalding
United States
March 2019

Chapter 9

JAPAN

Akihiro Hironaka, Yutaro Kawabata and Yui Takahata[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Japan is a civil law country and it has a unified national legal and court system under a single Supreme Court. National statutes are the main source of law for civil liability, but court precedents also play an important role in filling gaps and clarifying the meaning of statutes.

The core source of civil liability for product defects had been tort liability under the Civil Code, Law No. 89 of 1896 (CC). However, to mitigate difficulties faced by victims of defective products in establishing tort claims against manufacturers and other entities responsible for the product defects, the Product Liability Act, Law No. 85 of 1994 (the PL Act) was enacted to create strict liability (i.e., no proof of negligence for the defect is necessary) in product liability claims. Tort liability can also be pursued even if the claims under the PL Act are available to the victim.[2]

Multiple administrative statutes also play an important role in the area of product liability. The purposes of these administrative statutes are as follows:

a to prevent defective products from being distributed in the market (e.g., government approval and licensing systems);

b to prevent defective products in the market from causing damage or injury to consumers (e.g., recall and remedy systems); and

c to provide prompt and effective relief to consumers who have actually suffered losses from defective products (e.g., special measures or relief for losses from defective products and a compulsory insurance system).

II REGULATORY OVERSIGHT

National courts decide the civil liability of the responsible entities by applying the relevant provisions of the CC and the PL Act described in Section I. With respect to the administrative regulations, various administrative authorities oversee the safety of different categories of products as explained below.

i Food safety

The Food Sanitation Act, Law No. 233 of 1947, governs administrative matters to prevent the public health risks arising from human consumption of food. It is administered by

1 Akihiro Hironaka and Yutaro Kawabata are partners and Yui Takahata is an associate at Nishimura & Asahi.

2 PL Act, Article 6.

the Ministry of Health, Labour and Welfare (MHLW) and the Consumer Affairs Agency (CAA). This Act provides standards for methods of producing, processing, using, cooking or preserving food and additives, standards for the ingredients of food and additives, the mandatory labelling system for food and additives, and the procedures for investigating food poisoning causes and for reporting investigation results. In 2018, the Food Sanitation Act was revised to further ensure the safety of food, and introduced a sanitary monitoring system, called the Hazard Analysis and Critical Control Point, among other revisions.[3]

ii Drug safety

Drugs, quasi-drugs, cosmetics and medical-instruments are regulated by the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, Law No. 84 of 2013 (the PMD Act). The MHLW administers the PMD Act. The PMD Act provides the regulations concerning the labelling, manufacturing methods and false or exaggerated advertising of such products. It is necessary to obtain approval from the minister of the MHLW to manufacture and market drugs and quasi-drug ingredients covered under this Act.[4] The Pharmaceutical and Medical Devices Agency conducts safety tests of these products. It is expected that the PMD Act will be revised in 2019 at the earliest to further improve the system.

iii Industrial products safety

Regarding industrial products, an important statute providing applicable regulations is the Consumer Product Safety Act, Law No. 31 of 1973 (the CPS Act). The Ministry of Economy, Trade and Industry (METI) and the Consumer Affairs Agency (CAA) administer the CPS Act. The CPS Act provides a certification system called PSC marks, which mandates manufacturers of products that pose high risks to the lives and bodies of consumers to comply with technical standards determined by the government, and to put labels that satisfy national standards on such products.[5] If a product lacks such labelling, the government can order certain measures to be taken, including the collection of the products.[6] If a product has caused a serious accident, the manufacturer and importer of the product must report it to the CAA.[7] The CAA may then announce the incidents to the public, if it deems it necessary.[8] The CPS Act also provides certain measures to prevent accidents from prolonged use of products.[9] Incidents that are not serious must be reported to the National Institute of Technology and Evaluation (NITE).

Other relevant important statutes are as follows: (1) the Electrical Appliances and Materials Safety Act, Law No. 234 of 1961; (2) the Act on the Securing of Safety and the Optimisation of Transaction of Liquefied Petroleum Gas, Law No. 149 of 1967; and (3) the Gas Business Act, Law No. 51 of 1954. The METI also administers these Acts. These Acts provide certification systems similar to PSC marks under the CPS Act.

3 Law No. 46 of 2018. The new law will be in force within one, two or three years, depending on the revised items, from the publication of the revision.

4 PMD Act, Article 14(1).

5 CPS Act, Article 4(1).

6 id., Article 32.

7 id., Article 35(1).

8 id., Article 36(1).

9 id., Article 32-2 et seq.

iv Vehicle safety

The Road Transport Vehicle Act, Law No. 185 of 1951 (the RTV Act), provides measures to secure the safety of vehicles. The Ministry of Land, Infrastructure, Transport and Tourism (MLIT) administers the RTV Act. The RTV Act requires that users of the vehicles maintain mandatory safety standards that are issued by the MLIT under the RTV Act[10] and also provides recall systems for manufacturers and importers of vehicles, tyres and child restraint seats that do not satisfy the mandatory safety standards.[11]

v The Consumer Safety Act and the Consumer Affairs Agency

The administrative regimes explained above, depending on the category of the products, had a shortfall by which defective products were not regulated because they inadvertently were not covered by the existing regimes. In response, in 2009 the government enacted the Consumer Safety Act, Law No. 50 of 2009, and created the CAA, to comprehensively administer matters for the protection of consumers, including protection from defective products. Under the Consumer Safety Act, when the national or local government, or another relevant government entity, is informed that a serious accident has occurred, the person in charge at these entities must immediately notify the CAA of the accident.[12] The CAA then collects information on the accident and responds with responsive measures.[13]

III CAUSES OF ACTION

The PL Act defines the term 'product' as a movable item that is manufactured or processed.[14] Therefore, no processed agricultural products are subject to the PL Act.

The PL Act applies to manufacturers, processors and importers (collectively, the manufacturers).[15] The PL Act also applies to any person who provides his or her name, trademark or other indication on a product as its manufacturer, and any person who provides his or her name, trademark or other indication on a product that misleads others into believing that he or she is its manufacturer.[16] The PL Act further applies to any person who provides his or her name, trademark, or other indication on a product and who holds him or herself out as a substantial manufacturer of a product in light of the manner and other circumstances under which the product is manufactured, processed, imported or sold.[17] The PL Act will not provide a cause of action against distributors or sellers of a product if those persons are not an entity specified above. Therefore, civil claims against distributors and sellers of a defective product (i.e., entities that may owe direct contractual liability to the consumers) must be brought on grounds of the warranty of defects, breach of contract or tort under the CC.

10 RTV Act, Article 40 et seq.
11 id., Articles 63-2 and 63-3.
12 Consumer Safety Act, Article 12(1).
13 id., Article 13 et seq.
14 PL Act, Article 2(1).
15 id., Article 2(3)(i).
16 id., Article 2(3)(ii).
17 id., Article 2(3)(iii).

To prove liability under the PL Act, a plaintiff must establish:

a a defect in the product;

b damage to life, body or property; and

c causation between the defect and the damage.[18]

'Defect' is defined under the PL Act to mean a lack of safety that the product ordinarily should possess, taking into account the nature of the product, the ordinarily foreseeable manner of use of the product, the time the product was delivered and other circumstances concerning the product.[19] 'Defect' above is interpreted to include the following three types: defect in manufacture, defect in design and defect in instructions or warnings. As mentioned above, it is said that the PL Act creates strict liability. However, it is noted that the Supreme Court of Japan denied the defective instructions or warnings in *re Iressa*, where a Japanese subsidiary of a UK pharmaceutical company was sued for an alleged defect in its drug, stating that it was unforeseeable that 'Iressa had the side effect of causing interstitial pneumonia which could rapidly become severe.'[20]

In Japan, there are no general administrative or criminal procedures for the government to bring a claim seeking remedies for personal injury or property damage against the manufacturer, distributor or seller of a product.

Conflict-of-law issues often arise in cross-border product liability cases. Japanese courts determine the applicable law by applying the Japanese code concerning conflict-of-law rules, entitled the Act on General Rules for Applications of Laws, Law No. 78 of 2006 (AGRAL). The AGRAL provides a general rule that where a claim against a manufacturer, processor, importer, exporter, distributor or seller of a product arises from a tort involving injury to life, body or property caused by a defect in the product that is delivered, the formation and effect of the claim shall be governed by the law of the place where the victim received delivery of the product.[21] However, the application of the general rule would be inappropriate especially where the manufacturer (or other entities mentioned above) could not have foreseen the distribution of a product in a particular market. Accordingly, to ensure foreseeability regarding the applicable law, the AGRAL provides an exception to the general rule that if delivery of the product at a certain place is ordinarily unforeseeable, then the law of the principal place of business of the manufacturer (or other entities mentioned above) shall apply.[22]

IV LITIGATION[23]

i Forum

Product liability civil claims are determined by professional judges in national courts. No jury system exists for civil litigation.

18 id., Article 3.

19 id., Article 2(2).

20 *X v. AstraZeneca K.K.*, 67 Minshû 899 (Sup. Ct., 12 April 2013).

21 AGRAL, Article 18.

22 id.

23 For general explanations on Japanese civil procedure, see Yasuhei Taniguchi, et al. eds., *Civil Procedure in Japan* (3rd edn) (Juris Publishing, 2018), to which Akihiro Hironaka, one of the authors of this chapter, is a contributor.

Alternative dispute resolution (ADR) procedures also play an important role in resolving civil product liability claims in Japan. Some industries have established their own 'product liability centres' intended to resolve product liability civil claims through ADR. For example, the Electric Home Appliances PL Centre and the Automotive Dispute Resolution Centre are two such institutions. Furthermore, the National Consumer Affairs Centre of Japan also manages an ADR procedure that deals with product liability matters.

ii Burden of proof

During civil proceedings, plaintiffs must prove each required element of a product liability claim. With respect to the issue of how much proof is necessary for the judges to be persuaded (the degree of proof), in *Miura v. Japan*, a medical malpractice case, the Supreme Court of Japan has defined the required degree of proof.[24] In that case, the Supreme Court found causation of a patient's injury owing to the negligence of a doctor based on the following standard: 'Proving causation in litigation, unlike proving causation in the natural sciences (which permits no doubt at any point), requires proof of a high degree of probability that certain facts have induced the occurrence of a specific result by taking into necessary and sufficient account that the judge has been persuaded of the truthfulness to a degree where an average person would have no doubt.' It is difficult to express the required degree of persuasion using a numerical formula under the standard of 'proof of a high degree of probability'. It is certainly higher than a preponderance of evidence, but less than beyond reasonable doubt.

iii Defences

If a claim is brought under the PL Act, the defendant may be exempt from liability if the defendant successfully proves that the defect in the product could not have been discovered given the state of scientific or technical knowledge at the time the product was delivered (this is called a 'development risk' or 'state of the art' defence).[25] Furthermore, where the product is used as a component or raw material of another product, the manufacturer of the component or raw material that is named as the defendant may be exempt from liability if the defendant successfully proves that the defect has occurred primarily owing to compliance with the instructions concerning the design given by the manufacturer of the finished product, and the defendant is not negligent with respect to the occurrence of the defect.[26]

In addition, the PL Act provides for limitations of the period in which a claim under the PL Act will extinguish:

a if the victim does not exercise his or her claim within three years of the time when he or she becomes aware of the damage and the party liable for damages; or

b 10 years have elapsed from the time the product was delivered.[27]

This 10-year period is calculated from the time of the occurrence of the damage if the damage is caused by substances that become harmful to human health when they accumulate in the body, or if the symptoms that represent the damage appear after a certain latent period.[28] As

24 *Miura v. Japan*, 29 Minshû 1417 (Sup. Ct., 24 October 1975). See also X v. Y, 1724 Hanrei jihô 29 (Sup. Ct., 18 July 2000).

25 PL Act, Article 4(i).

26 id., Article 4(ii).

27 id., Article 5(1).

28 id., Article 5(2).

for tort claims under the CC, the prescription period is three years from the time the victim becomes aware of the damage and the identity of the perpetrator.[29] A tort claim also cannot be brought when 20 years have elapsed from the time of the tortious act.[30]

The prescription period for the claim under the PL Act explained above was revised when the Civil Code was overhauled in 2017, and the revision will be implemented in 2020. The revision has extended the prescription period for a right to seek damages when the defect in the product infringes upon life or body, which was originally three years, to five years.[31] The revised prescription period explained above is not applicable where the original three year period has passed at the time the amended law is implemented in 2020.[32]

Comparative negligence is available with respect to the determination of the amount of damage to be compensated and can be asserted in defending a product liability claim either under the PL Act or as a tort under the CC.[33]

Compliance with applicable regulations is considered one of the important factors in determining whether there is a defect in a product; however, non-compliance or compliance with applicable regulations by itself will not automatically give rise to liability or preclude liability.[34]

In a majority of US states, the 'learned intermediary doctrine' has been recognised. The 'learned intermediary doctrine' means that a manufacturer of prescription medications and devices is released of its duty to warn users of the risks associated with its products, by warning the prescribing physician of the proper use and risks of the manufacturer's product. The Supreme Court, in *re Iressa*, in denying the defective instructions or warnings, stated that 'it was known at least among physicians engaged in anti-cancer therapy targeting lung cancer that when interstitial pneumonia occurred owing to the administration of these drugs, including anti-cancer drugs, it could be fatal'.[35] This ruling of the Supreme Court is similar to the 'learned intermediary doctrine' above, in that the Court considered the knowledge of the addressee of the information in determining the defective instructions or warnings in the product.

iv Personal jurisdiction

No provision for product liability claims

The Code of Civil Procedure, Law No. 109 of 1996 (CCP), provides a set of both domestic and international jurisdiction rules applicable to litigation in Japanese courts, but it does not include an express provision for product liability claims. Under the prevalent view, product liability claims are classified as tort claims for the purpose of determining their jurisdiction. With respect to international jurisdiction of tort claims, the CCP provides that the Japanese court has jurisdiction if the place where the tort took place is located in Japan, unless the result of a wrongful act committed in a foreign country occurred in Japan and the occurrence

29 CC, Article 724.

30 id.

31 The revised PL Act, Article 5(2).

32 Act for the Establishment of Laws and Regulations Necessitated by the Entry into Force of the Act for Partial Revision of the Civil Code (Law No. 45 of 2017), Article 97(1).

33 id., Article 722(2).

34 See Economic Planning Agency, Consumer Policy 1st Division, Chikujyô Kaisetsu Seizôbutsu Sekininhô 72-73 (Shôjihômu Kenkyûkai, 1994).

35 *X v. AstraZeneca K.K.*

of such a result in Japan was ordinarily unforeseeable.[36] The jurisdiction of international product liability claims will be determined pursuant to this provision. The stream-of-commerce doctrine, discussed in the US courts, was not introduced when the CCP was revised in 2011 to include international jurisdiction provisions.[37]

The place where the tort took place

This phrase generally includes the place of the wrongful act and the place of the result. The place of the wrongful act includes the place where the product was manufactured. Unless advertisement on the internet constitutes part of the wrongful act, the act by itself does not constitute the basis for the jurisdiction of Japanese courts. On some occasions, allowing international jurisdiction at the place of the result will cause substantial difficulties for the defendants. In such circumstances, the prevalent view recognises exceptions where Japanese courts do not have international jurisdiction over the defendants.

The place of secondary loss or economic loss

Whether the place of secondary loss or economic loss is included in the 'place of the loss' has also been discussed in Japan. If it is included, courts within the consumers' place of residence will almost always have jurisdiction over the product liability claim and the result will be too harsh for businesses. Therefore, some lower court decisions have rejected this theory.[38]

v Expert witnesses

The CCP has a set of provisions providing procedures for the examination of court appointed expert witnesses. Where the issues to be determined by judges are highly specialised and difficult to determine, the court can appoint expert witnesses to assist fact finding by the judges.[39] After an expert witness has provided his or her opinion to the court in writing or orally, both parties have an opportunity to examine the expert witness before the judges for the purpose of impeaching an unfavourable opinion, or to restore the credibility of a favourable opinion. A court may, when it finds it necessary, request that a Japanese or foreign government agency or public office, or a juridical person that has adequate equipment, give its expert opinion.[40]

In Japanese litigation practice, parties to a litigation frequently find their own private experts and have them author expert opinions addressed to the court. The parties may also request to examine experts before courts. Technically speaking, these private experts are classified as 'witnesses' rather than 'expert witnesses' under the CCP, because they are not appointed by judges. However, these private experts also perform an important role.

The court may require assistance from experts not only for fact-finding, but also in the process of clarifying issues and conducting proceedings efficiently. To enable the court to obtain such assistance, the court may appoint an expert commissioner in the proceedings.[41]

36 CCP Article 3-3(viii).

37 Law No. 36 of 2011.

38 *Nihon Yūsen K.K. v. London Steamship Owners' Mut. Ins. Ass'n Ltd*, 31 October 2006, 1241 Hanrei taimuzu 338; *Greenlines Shipping Co Ltd v. California First Bank*, 525 Hanrei taimuzu 132 (Tokyo Dist. Ct., 15 February 1984).

39 See CCP Article 213.

40 id., Article 218(1).

41 id., Article 92-2(1).

vi Discovery

No extensive discovery system (as in the United States) exists in Japan and only limited discovery is permitted. The Japanese discovery system explained below is far from being an effective tool for litigants to request useful evidence from the other party or third parties.

Request for document production order

The party may request a document production order (DPO) against the other party or third parties. The CCP provides that the possessors of the documents shall not refuse to produce the documents in the following circumstances:

a (1) as a party, the possessor has cited the document in his or her arguments in the action; (2) the party applying for the DPO was otherwise entitled under the law to possess or inspect the document; (3) the document was executed for the benefit of the petitioner; or (4) the document was executed with respect to a legal relationship between the petitioner and the possessor; and

b the document does not fall under any exemptions provided in the CCP.[42]

The exemptions provided for in (b) above are as follows:

a a document containing information with respect to which the possessor would have the right to refuse to testify, as self-incriminating or incriminating one's family;

b a document containing a secret in relation to a public officer's duties;

c a document containing professional secrets, including documents obtained by lawyers and doctors through performance of their duties;

d a document containing technical secrets or secrets useful for occupations;

e a document held by the possessor exclusively for his or her own use; and

f a document relating to criminal proceedings or juvenile delinquency proceedings.

Courts may decide not to examine documentary evidence if they deem it to be unnecessary,[43] and courts are strict when considering the necessity for issuing the DPO. If the court finds that the fact that the party seeks to establish a DPO is unnecessary for resolution of the dispute, the court will decline to issue the DPO.

Japanese evidence law does not have strict rules on excluding evidence (as in the United States) where there is a danger of the evidence being unfairly prejudicial, confusing the issues, misleading the judges, etc. Therefore, whether a judge orders the DPO regarding 'other similar incidents' of a product defect, for example, depends on the judge's interpretation of the 'necessity' of such evidence to decide the issues in the case before him or her. Two of the authors had an actual case where the court was convinced and declined to issue the DPO.

Interrogatory

A party, before the lawsuit is instituted, or while the lawsuit is pending, may inquire with the opponent to request information regarding the matters necessary for preparing allegations or proof.[44] This system is analogous to the US interrogatory, but this is not frequently used in Japan in practice.

42 id., Articles 220(i)–(iv).

43 id., Article 181(1).

44 id., Articles 132-2, 163.

Deposition

No deposition of parties, witnesses or experts exists in Japan.

Evidence preservation proceedings

If the party establishes that any circumstances exist where it will be difficult to examine evidence, including where the other party may spoil the evidence, it may request that the court issue an order to preserve the evidence.[45] The order is granted for an *ex parte* hearing of the petitioner and the other party is notified of such an order only an hour or an hour and a half before the judge executes the preservation order, which is issued to avoid another party spoiling the evidence.

vii Apportionment

When multiple entities are involved in a product liability case, the entities are jointly and severally liable for liability under the PL Act or in tort. A named defendant that has compensated the victim in excess of the damages that it is required to bear may seek indemnification from other entities. The portion of the burden that should be borne by each entity is determined on a case-by-case basis, considering the fair burden of damages and taking into account various circumstances such as the situation in which the act occurred and the connection between the act and the damage.[46]

Under Japanese law, the successor of an entity, for example, by way of merger, will be liable for its predecessor's liability.

viii Mass tort actions

In Japan, there is no legislation creating a US-style class action for a mass tort. In practice, plaintiffs bringing mass tort actions have been solicited through announcements on the internet and by other methods. However, a new law relating to mass tort actions was promulgated in 2013: the Act on Special Measures Concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers, Law No. 93 of 2013 (the Collective Redress Act). The Act was implemented on 1 October 2016 and organisations certified by the Prime Minister of Japan pursuant to the Consumer Contract Act, Law No. 61 of 2000 (the certified organisations) may bring a claim in relation to consumer contracts against business operators for recovery of damages suffered by consumers with respect to:

a performance of a contract;
b unjust enrichment;
c a claim for damages owing to breach of contract;
d warranty against defects; and
e a claim for damages arising out of tort.[47]

As explained above, the Civil Law was overhauled in 2017 and will be implemented in 2020. Owing to this overhaul, warranty against defects claims, explained in (d) above, was eliminated from the list, as such claims are merged into claims for damages owing to breach of contract in the revised Civil Code. However, damage to property other than the subject

45 id., Article 234.

46 See Economic Planning Agency, Consumer Policy 1st Division, footnote 31, at 128.

47 Collective Redress Act, Article 3(1).

matter of the consumer contract, lost profits, personal injury, pain and suffering are expressly excluded from the scope of a claim that can be brought under the Collective Redress Act.[48] The Collective Redress Act adopts a two-stage process. This legislation is modelled after the Brazilian class action system, and it adopts a European type opt-in method. It is opposed to a US-style opt-out method.

As explained above, the proceedings provided in the Collective Redress Act are a two-stage process. During the first stage, the certified organisation files a lawsuit with the court against a business operator for a declaratory judgment, with respect to property damage suffered by numerous consumers in relation to a consumer contract, on whether the business operator owes an obligation to pay monies to the consumers owing to common factual cause or common legal cause. Issues that would be decided during this first stage are: validity of contracts between consumers and the business operator; illegality of the acts conducted by the business operator; and the intent or negligence of the business operator. The result of the first stage proceedings binds the consumers who participate in the second stage proceedings explained below. This declaratory judgment at the first stage is appealable.

If the court finds that the business operator is liable or that the business operator has acted illegally and makes a decision upholding a claim during the first stage, the same certified organisation then files a proceeding to commence the second stage, in which consumers may participate (i.e., opt-in). During the second stage, following the denial and admission process by each party, the specific amount of compensatory damages for each consumer will be determined by the court's summary ruling only by documentary evidence. The party or relevant consumer who objects to the court's summary ruling may make an objection to request a formal judgment process from the court, and the compensatory damages will be determined in the formal judgment process. After the determination of the specific amount of compensatory damages for the consumer become final, the certified organisation collects monies from the business operators and the monies collected will be distributed to each consumer. As explained above, in this process, certified organisations have a significant role, and, as of January 2019, there are three certified organisations under the Collective Redress Act.

ix Damages

Recovery for economic damage, including lost profits and non-economic damage such as pain and suffering, is permitted in product liability cases under Japanese law, regardless of whether the claim is for breach of contract, tort or under the PL Act. In general, the remedy for damage is monetary compensation.[49] The amount of damages is determined by the judge because no jury system exists in Japan as explained in Section IV.i. There is no law limiting the amount of damages that may be ordered. Japanese law does not allow punitive damages. Punitive damages awarded in foreign litigation or arbitration will not be recognised in Japan because they infringe upon the public policy of Japan.[50]

48 id., Article 3(2).

49 CC, Article 722(i), 417.

50 For punitive damages awarded in a foreign court, see *Northcon I, Oregon Partnership v. Mansei Kôgyô Co Ltd*, 51 Minshû 2573 (Sup. Ct. 11 July 1997).

The PL Act limits its application to claims for damage arising from the infringement upon life, body or property caused by the defect in the product. Damage that occurs only with respect to the defective product is excluded from the scope.[51] However, such damage can be pursued in claims under the PL Act together with other types of damage.

With respect to criminal liability, if death or injury is caused because of a failure to exercise due care in pursuit of social activities, a criminal penalty may be imposed under the Penal Code, Law No. 45 of 1907.[52]

V YEAR IN REVIEW

Over two years have passed since the Collective Redress Act came into force on 1 October 2016. The CAA is interested in making this system functional; therefore, it convened a study group of experts, including consumer group representatives, a scholar who is a retired judge, and a certified public accountant to discuss the methods to support these organisations. The methods of support being discussed by the government include:

a information support regarding consumer damages;

b financial support by letting the certified organisations utilise grants or crowdfunding; and

c support for security deposits by third parties on behalf of the certified organisations in the provisional attachment proceedings.

With the implementation of the Collective Redress Act, small claims that have not been pursued by consumers owing to the burden on the individual bringing the claim were expected to be sought by the certified organisations, and there was the possibility that lawsuits relating to product liability would increase in number. However, for now, the impact of the implementation of the Collective Redress Act seems slight and concern over litigation under the Collective Claims Act is not yet significant. First, damage to property other than the subject matter of the consumer contract (i.e., lost profits, personal injury, pain and suffering) is expressly excluded from the scope of claims that can be brought under the Collective Redress Act, and punitive damages like those in the United States cannot be sought through Japanese litigation. Therefore, the motivation for plaintiffs is relatively slight. Second, the scope of claims under the Act is limited to claims based on consumer contracts executed after 1 October 2016, and it may take some time before disputes arise based on the contracts on which parties can file a lawsuit under the Act.[53] Third, dissemination of the procedure of the Act to the public may not be sufficient.

However, the first collective action under the Collective Redress Act was finally filed with the Tokyo District Court in December 2018, over two years after the implementation of the Collective Redress Act. A certified organisation, the Consumer Organization of Japan (COJ), filed the action against Tokyo Medical University (TMU), alleging that TMU treated the following categories of candidates, among others, in an unlawful fashion: females, candidates who did not apply immediately after graduation from Japanese high schools (e.g., candidates who did not pass in the previous year or years) and graduates of foreign high schools. The COJ claimed damages including examination fees, travel and lodging expenses for taking the

51 PL Act, Article 3 proviso.

52 Penal Code, Article 211.

53 Supplementary Provisions to Collective Redress Act, Article 2.

entrance exam. The COJ argued that adjusting grades without explaining such adjustment in advance to the candidate is tortious, and, alternatively, the adjustment itself is tortious and breaches the contract with the candidates. Depending on the result of the case, the tendency for the Collective Redress Act to remain underutilised may change.

Although the implementation of the Collective Redress Act has not yet had a significant impact on business operators, this does not mean that product safety can be addressed easily. Japanese consumers are very sensitive about product safety. If a business operator distributing products in Japan fails to take appropriate measures to address product safety issues, its reputation may be seriously harmed. If a business operator receives an objection from a consumer or a certified organisation, the business operator should consider carefully whether it should accept responsibility, to avoid reputational damage in the long run, or compensate consumers proactively before they file lawsuits, to reduce the reputation risk for the immediate future, as well as the potential time and cost of litigation against consumers.

Appendix 1

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Akihiro Hironaka has been a partner of the dispute resolution group of Nishimura & Asahi since 2007. He has extensive experience dealing with large-scale and complex disputes, including representations of foreign and Japanese vehicle manufacturers and pharmaceutical companies in defending important product liability lawsuits. Mr Hironaka also successfully represented a foreign corporation in an international arbitration involving an alleged defect in the design of a foreign factory. Furthermore, he successfully represented a major foreign corporation in a cross-border M&A dispute involving a breach of representations concerning numerous product defects. Mr Hironaka is a graduate of the University of Tokyo (LLB, 1993) and Harvard Law School (LLM, 2003), and is admitted to the Bars of Japan and New York. He served as a Japanese district court judge from 1998 until 2000 and worked at Arnold & Porter (Washington, DC) from 2003 to 2004. Mr Hironaka has authored numerous publications concerning dispute resolution, including Yasuhei Taniguchi et al. (eds.), *Civil Procedure in Japan, Third Edition* (contributor, Juris Publishing) and *International Arbitration and Corporate Strategy* (co-editor and author, Yûhikaku). He is an individually ranked lawyer in the category of dispute resolution with *Chambers Global 2019/Asia-Pacific 2019* and in the categories of litigation/product liability defence/arbitration in *Who's Who Legal: Japan 2018*.

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