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Product Liability

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Law Business Research

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Japan

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Civil litigation system

1 The court system

What is the structure of the civil court system?

All judicial power is vested in the Supreme Court and lower courts such as the high, district, family and summary courts. Summary courts have jurisdiction over proceedings where the contested amount does not exceed ¥1.4 million. District courts hear appeals from summary courts and are also courts of first instance for all matters with a contested amount in excess of ¥1.4 million and litigation involving property. Family courts have jurisdiction over non-monetary family law claims. Appeals from the district and family courts are heard by the high courts. The Supreme Court hears appeals on certain matters from the high courts.

2 Judges and juries

What is the role of the judge in civil proceedings and what is the role of the jury?

Japanese civil litigation is adversarial in nature and it does not involve a jury. Judges make findings of fact, apply the law and deliver judgments on whether the claim of the plaintiff should be allowed or not. Judges rely on the factual information provided to the court by the parties and will not generally collect information themselves. Judges also control procedural issues such as deciding the timeline and schedule for the case, the admissibility of evidence, etc.

3 Pleadings and timing

What are the basic pleadings filed with the court to institute, prosecute and defend the product liability action and what is the sequence and timing for filing them?

An action shall be filed by submitting a complaint to the court. A complaint shall contain the following facts to provide the court with sufficient information to decide the course of the case:

- the parties;
- the object of the claim (namely, the nature of the relief claimed, such as demand for payment of a certain amount of money);
- the statement of claim (namely, the facts to specify the claim);
- the fundamental facts from which the claim arises in law;
- the substantial evidentiary facts; and
- the necessary evidence in the plaintiff's possession, including documentary evidence.

It is the plaintiff's responsibility to specify the content of the claim and the claim amount.

After the filing of the complaint, the court clerk will verify the correctness of the complaint form and the stamp duty paid in relation to the complaint (the amount of stamp duty corresponds to the contested amount). The clerk will then contact the plaintiff or the plaintiff's attorney and will determine the date of the first oral hearing according to the availability of the plaintiff or the plaintiff's attorney.

The court will then send a summons together with the complaint to the defendant by post. Before the hearing, the defendant has to file a written answer. A written answer shall contain the following:

- statements of the answer to the object of claim;
- concrete statements of admission or denial of the facts stated in the complaint and facts in support of defence; and
- statements of material facts related to the facts stated in the complaint or the facts in support of defence and evidence for the respective grounds that require proof where necessary.

In cases where it is not possible to include the aforementioned statements in the written answer due to unavoidable circumstances, a brief containing these statements shall be submitted promptly after submitting the written answer. Copies of important documentary evidence are to be attached to a written answer where evidence is required. Where it is not possible to attach such copies of important documentary evidence due to unavoidable circumstances, the copies shall be submitted promptly after submitting the written answer.

4 Pre-filing requirements

Are there any pre-filing requirements that must be satisfied before a formal lawsuit may be commenced by the product liability claimant?

There are no pre-filing requirements for civil litigation generally. In practice, however, a claimant often sends a content-certified letter, stating the material issue and asking for some action to be taken, to the defendant.

5 Summary dispositions

Are mechanisms available to the parties to seek resolution of a case before a full hearing on the merits?

There are no statutory mechanisms that allow parties to seek resolution of a case before a hearing on the merits. However, a claim that lacks certain prerequisites shall be deemed unlawful, and the court, by a judgment, may dismiss such a claim without holding a full hearing on the merits (see article 140 of the Code of Civil Procedure (CCP) (Act No. 109 of 1996, as amended)). The following are examples of such prerequisites: the valid service of a complaint, the non-filing of overlapping claims, the parties have the ability to bring proceedings in their own names, the court has jurisdiction, and the claim contains the benefit of bringing such a suit or person eligible to be pursued in the litigation.

6 Trials

What is the basic trial structure?

Court hearings are held periodically to determine the substantial issues and prepare the trial. In many cases preparatory hearings are held in chambers, where judges might ask the counsel questions to clarify the parties' positions. After determining the substantial con-

tested issues, the court will run a trial and permit the conduct of witness examination if it deems it necessary.

When a party requests for witness examination to be conducted, the requesting party's witness statement shall be submitted as evidence prior to the witness examination to facilitate the counterparty's preparation for the cross-examination, unless it is difficult for the requesting party to submit such statement (for example, where the witness is hostile). After the witness examination, each party will submit its closing brief to facilitate the court's final deliberation and judgment.

7 Group actions

Are there class, group or other collective action mechanisms available to product liability claimants? Can such actions be brought by representative bodies?

Class actions are currently not allowed under Japanese law; accordingly, each person needs to be a plaintiff (although there is no restriction on the number of the plaintiffs named in one complaint). However, a bill for the introduction of a class action procedure, which will enable a qualified consumer organisation which has received the recognition of the prime minister to file a lawsuit in which common questions of liability will be assessed, was approved in a Cabinet meeting on 19 April 2013 (see question 36).

Under the CCP, each person can individually appoint any other person who shares the common interest as a plaintiff in such litigation (CCP article 30).

8 Timing

How long does it typically take a product liability action to get to the trial stage and what is the duration of a trial?

The first court hearing will typically be held within 40 to 60 days after the filing date by the decision of the court. After that, court hearings or preparatory proceedings will be held once a month, or once every few months. The examination of the witnesses, if necessary, the closing brief, final oral proceedings and the judgment then follow.

On average, judgment in the first instance is rendered one-and-a-half or two years following the filing of the complaint in ordinary cases which involve witness examinations. For product liability cases, it takes on average 32 months before final judgment will be received.

Evidentiary issues and damages

9 Pretrial discovery and disclosure

What is the nature and extent of pretrial preservation and disclosure of documents and other evidence? Are there any avenues for pretrial discovery?

There is no general discovery or disclosure. However, pre-trial preservation of evidence and some avenues for pre-trial 'request for information' do exist (there are various specific exceptions, such as when trade secrets or private secrets are involved) as follows:

- preservation of evidence (CCP article 234): where a court concludes that it would be difficult to examine evidence unless a prior examination of evidence is conducted (for example, where there is a risk that such evidence will be altered or discarded), it may permit the conducting of an examination of evidence upon petition. This procedure is typically used for clinical records where a medical accident happened;
- inquiry prior to filing an action (CCP articles 132-2 and 132-3): where a person who intends to commence legal action has given advance notice of the same to a prospective defendant, the giver of the advance notice may make an inquiry with the prospective defendant regarding matters necessary for the preparation of the advance notifier's allegations or evidence. The recipient of the advance notice may also make an inquiry with the advance notifier for purposes of preparing its allegations or evidence. This procedure of making inquiries is not typically practised in Japanese lawsuits;
- disposition for the collection of evidence prior to the filing of an action (CCP article 132-4): if an advance notifier or a recipient of an advance notice has difficulty collecting any evidence necessary for proving its case, the court may make dispositions such as commissioning to send a document or commissioning of examination upon petition before the filing of the action. Please note that such dispositions are not typically practised in Japanese lawsuits;
- request for information (Attorney Act (Act No. 205 of 1949) article 23-2): a qualified attorney may request the bar association to which he or she belongs to make inquiries with public offices or private organisations regarding information necessary for a case for which he or she has been retained. The bar association will make such inquiries unless it finds such request to be inappropriate. Notwithstanding this, information may be withheld by the its holder, especially if the information requested is private and confidential;
- inquiry to an opponent (CCP article 163): a party may, when a suit is pending, request for its opponent to make inquiries regarding matters necessary for preparing its allegations or evidence;
- commission to send a document (CCP article 226): a party may request the court to commission the holder of a document to send such document to it;
- commission of examination (CCP article 186): government agencies, public offices, foreign government agencies, foreign public offices, schools, chambers of commerce, securities exchanges or any other organisations (such as hospitals or employers of victims in a suit) may be commissioned by a court to conduct a necessary examination and report the result to the court; and
- document production order (CCP articles 220 to 225): a party can request the court to order the holder of a document to submit the same to the court if such holder has an obligation (under CCP article 220) to produce the document in court and it is necessary to a suit for that document to be examined. If the holder of the document, who is a party to the case, does not comply with such a court order, or has discarded the document with the intention of disrupting the proceedings, the court may rule that the petitioner's allegations regarding the contents of the document are true.

10 Evidence

How is evidence presented in the courtroom and how is the evidence cross-examined by the opposing party?

Witnesses give oral evidence regarding the facts they have personally experienced that are related to the subjects to be proved. The examination of a witness proceeds with direct examination by the requesting party, cross-examination by the opposing party and supplemental examination by the judge. The opposing party cross-examines the witness about matters raised previously in the direct examination and any matters related thereto, and also matters concerning the credibility of the testimony (Rules of Civil Procedure (Rules of the Supreme Court No. 5 of 1996, as amended) article 114). If the opposing party wants to bring up matters which the requesting party will not raise, the opposing party can do so by filing a request for examination as well.

Although it is not necessary in all cases, the court will often instruct the parties to submit written statements, prior to trial, containing the principal facts to be attested to from each person who is to give evidence as a witness. Written statements help the court to understand what a witness is going to prove, facilitate the opposing party's preparation for cross-examination and contribute to improving the quality of examination.

The court decides a plan for witnesses' examination in light of the parties' motions, the allegations, and the written statements. The plan includes the persons to be examined, the order of witnesses, and the allotted examination time for each witness.

11 Expert evidence

May the court appoint experts? May the parties influence the appointment and may they present the evidence of experts they selected?

Generally, presentation of expert testimony is arranged only at the request of the parties to a suit. However, the court sometimes takes the view that expert testimony is necessary and may request the parties to arrange for expert testimony to be presented. An expert witness shall be designated by the court at its discretion (CCP article 213). The court usually determines who is to be an expert after consulting with parties. Expert witnesses state their opinions either in writing or orally as determined at the discretion of the court (CCP article 215).

Where the court has an expert witness state their opinions orally, the opinion will be stated first, followed by questioning from the judge, the requesting party and the opposing party (in that order) (CCP article 215-2).

If the parties choose to present their own expert evidence, the parties may present an expert's written opinion as documentary evidence. At the opposing party's request, the expert may be examined as a witness so that the opposing party can conduct a cross-examination in order to challenge the written opinion. Sometimes, the court may arrange for further expert testimony to be presented after both parties present their respective experts' written opinions as documentary evidence.

In addition, after hearing the opinions of the parties, the court may have a technical adviser participate in the court proceedings in order to provide explanations on various technical aspects thereto (CCP article 92-2). However, practically speaking, technical advisers are not frequently used in product liability lawsuits.

12 Compensatory damages

What types of compensatory damages are available to product liability claimants and what limitations apply?

There is no specific limitation regarding the types of compensatory damages under the Civil Code (Act No. 89, of 1896, as amended) or the Product Liability Act (PLA) (No. 85, of 1994, as amended) (see question 18). Therefore, any compensable damage incurred by the victim, whether direct or indirect, physical, psychological or economic, can be covered, if there is legally sufficient causation.

13 Non-compensatory damages

Are punitive, exemplary, moral or other non-compensatory damages available to product liability claimants?

No punitive, exemplary, moral or other non-compensatory damages are available under either express provisions or court cases.

Litigation funding, fees and costs

14 Legal aid

Is public funding such as legal aid available? If so, may potential defendants make submissions or otherwise contest the grant of such aid?

The Japan Legal Support Centre (JLSC), which is a public corporation established according to the framework of an incorporated administrative agency under the Comprehensive Legal Support Act (Act No. 74 of 2004), may provide financial support to a claimant to cover the claimant's legal fees (including but not limited to attorneys' fees. The claimant is required to repay such funding to the JLSC, although the amount to be repaid may be reduced or the repayment date may be postponed, depending on the financial circumstances of the claimant. Pursuant to a party's petition, the court may also exempt the party from the payment of court costs or from the requirement to provide security for court costs (CCP article 83(1)). However, this discretion of the court does not extend to other costs, such as attorneys' fees.

Potential defendants can make submissions or contest the grant of aid under CCP.

15 Third-party litigation funding

Is third-party litigation funding permissible?

There are no specific regulations regarding third-party litigation funding where a third party funds a claimant's action against the defendant in return for a share of the damages. Article 73 of the Attorney Act stipulates that no person shall engage in the business of obtaining the rights of others by way of assignment and enforcing such rights through lawsuits, mediation, conciliation or through any other means. The scope of such prohibition is unclear. However, it would be deemed a violation of the Attorney Act if a party repeatedly obtains the rights of others and enforces such rights in Japan.

16 Contingency fees

Are contingency or conditional fee arrangements permissible?

There are no specific limitations or restrictions under the rules or laws, including the rules of the Japan Federation of Bar Associations. However, in practice, no win, no fee arrangements are rare in Japan.

17 'Loser pays' rule

Can the successful party recover its legal fees and expenses from the unsuccessful party?

In principle, the unsuccessful party bears the court costs, including filing fees for an action or fees for the presentation of expert testimony (CCP article 61). Where the court has not ruled entirely for the claimant or defendant, the court may allocate the court costs to the parties at its discretion (CCP article 64). Attorneys' fees are not part of court costs. However, in tort cases (which include PLA cases), the court can include a certain portion of the claimant's attorneys' fees (typically amounting to 10 per cent of damages) as part of the damage that the claimant has suffered.

Sources of law

18 Product liability statutes

Is there a statute that governs product liability litigation?

The PLA, which came into force from July 1995, governs product liability litigation along with the Civil Code. The liability under the PLA can be regarded as 'strict' liability as, by replacing 'negligence' with the existence of 'defect', victims are not required to prove the negligence of the manufacturer as defined in question 25. However, victims still have to prove the defect and the other conditions for tort liability (namely, the existence of damage and the causation between defects in the product and the damage) to claim the damage under the PLA. The PLA is notable for its protection of not only individuals but also corporations.

19 Traditional theories of liability

What other theories of liability are available to product liability claimants?

Along with liability under the PLA, victims may make claims in tort or for contract liability under the Civil Code. Liability in tort under the Civil Code is regarded as fault-based liability.

20 Consumer legislation

Is there a consumer protection statute that provides remedies, imposes duties or otherwise affects product liability litigants?

The Consumer Products Safety Act (CPSA) (No. 31, of 1973, as amended) stipulates that where an accident has occurred in relation to a consumer product, any person engaging in the manufacture or import of that consumer product shall investigate the cause of the accident, and where necessary to address any danger in relation to such products, endeavour to recall the product or take other measures to address any danger in relation to the product (CPSA article 38(1)). Under the CPSA, where an accident has occurred as a result of defects in a consumer product, or serious danger has arisen or is imminent to general consumers, the minister of economy, trade and industry may, if he or she finds it particularly necessary to prevent the occurrence and increase of such danger, order a person engaging in the manufacture or import of the consumer product to recall the consumer product or to take such other measures necessary to address the danger (CPSA article 39(1)). Violation of such a ministerial order is punishable by imprisonment for a term not exceeding one year with prison labour, a fine not exceeding ¥1 million, or both (CPSA article 58 (iv)). If the representative or agent, employee or other worker of such manufacturer or importer violates such a ministerial order with respect to the business of the manufacturer or importer, the offender, together with the manufacturer or importer is punishable by a fine not exceeding ¥100 million (CPSA article 60 (i)).

In addition, certain specific products are regulated exclusively by the following laws instead of the CPSA: automobiles by the Road Tracking Vehicle Act (No. 185, of 1951, as amended); medicines, cosmetics and medical appliances by the Pharmaceutical Affairs Act (No. 145, of 1960, as amended); and food, additives and the like by the Food Sanitation Act (No. 233, of 1947, as amended).

21 Criminal law

Can criminal sanctions be imposed for the sale or distribution of defective products?

There are no clauses in the PLA or the Civil Code that impose criminal sanctions on the sale or distribution of defective products.

However, laws concerning specific types of products (the Food Sanitation Act, for example) (see question 20) have penalty provisions applicable to non-compliance with the respective laws, some of which are related to the sale and distribution of defective products.

22 Novel theories

Are any novel theories available or emerging for product liability claimants?

There are no apparent or obvious novel theories regarding product liability cases in Japan at present.

23 Product defect

What breaches of duties or other theories can be used to establish product defect?

Defect is defined as 'a lack of safety that the product ordinarily should provide, taking into account the nature of the product, the ordinarily foreseeable manner of use of the product, the time when the manufacturer, as defined in question 25, delivered the product, and other circumstances concerning the product' (PLA article 2(2)).

24 Defect standard and burden of proof

By what standards may a product be deemed defective and who bears the burden of proof? May that burden be shifted to the opposing party? What is the standard of proof?

A product may be deemed defective where there is a lack of safety that the product ordinarily should provide (see question 23). Any factor related to the product is considered in this standard, including the nature of the product, the ordinarily foreseeable manner of use of the product, and the time of delivery. The defect must exist at the time the product is delivered.

The claimant bears the burden of this proof under the PLA. However, a court may lower the burden of proof regarding the existence of a defect, depending on the parties involved (for example, in the instance of a consumer acting against a large corporation), the nature of the product (such as the complex operational functions of a product) and the ordinarily foreseeable manner of use of a product.

25 Possible respondents

Who may be found liable for injuries and damages caused by defective products?

The liable actors under the PLA are:

(i) any person who manufactured, processed, or imported the product in the course of trade (actual manufacturer);

(ii) any person who provides their name, etc, on the product as the actual manufacturer of such a product, or any person who provides the representation of their name, etc, on the product thereby misleading others into believing that they are the actual manufacturer; and

(iii) apart from any person mentioned in item (ii), any person who provides any representation of their name, etc, on the product that, in light of the manner concerning the manufacturing, processing, importation or sales of the product, and other circumstances, holds themselves out as its substantial actual manufacturer (collectively defined as the 'manufacturer' in PLA article 2). ('Person' encompasses both natural persons and corporate entities.)

Therefore, the manufacturer and importer can bear liability under the PLA, but a distributor or seller is not included unless it falls into (ii) or (iii) above.

26 Causation

What is the standard by which causation between defect and injury or damages must be established? Who bears the burden and may it be shifted to the opposing party?

The standard for causation is whether the causation between the defect and injury or damages is legally sufficient. The standard of proof of causation under the PLA is the same as that under the Civil Code. Essentially, the complainant bears the burden to establish causation.

27 Post-sale duties

What post-sale duties may be imposed on potentially responsible parties and how might liability be imposed upon their breach?

The following are examples of post-sale duties imposed by specific laws and regulations:

- duty to report: manufacturers or importers are required to report to the Consumer Affairs Agency (CAA) (CPSA article 35(1)) any known serious accidents caused by their products. Where manufacturers or importers fail to comply, the CAA may require them to develop a system necessary for collecting, managing and providing information concerning serious product accidents (CPSA article 37). Violation of such orders is punishable by imprisonment with prison labour or a fine, or both (CPSA article 58(v)). The CAA should make public the information regarding serious product accidents after receiving such report, or where they otherwise come to know of the occurrence of the accidents, if it finds it necessary (CPSA article 36);
- duty to investigate and recall a product: the CPSA stipulates that manufacturers or importers must investigate the cause of product

accidents and, if necessary, take preventive measures (CPSA article 38). In serious cases, the authority may order the manufacturers or importers to recall products or to otherwise take hazard prevention measures (Hazard Prevention Order; CPSA article 39(1)). Violation of such orders is punishable by imprisonment with prison labour or a fine, or both (CPSA article 58(iv));

- duty to record and to give supplementary warnings: under the Long-term Use Consumer Product Safety Inspection System (the System) (CPSA article 32-2, etc), manufacturers or importers of certain products with a high likelihood of causing serious accidents over time, should:
  - prepare a list of the product holders;
  - establish, label and explain the design standard-use period and inspection period;
  - notify holders of the need for an inspection of the product six months before commencement of the inspection period; and
  - conduct an inspection of the product upon request. Failure to give notification under article 32-2(1) is punishable by a fine; and
- duty to attach warning labels: the labelling system applies to certain products (including air conditioners and cathode ray tube televisions) with high rates of accident report due to deterioration over time (the Electrical Appliances and Materials Safety Act (No. 234, of 1961, as amended) and its ordinance).

In addition, there are some (criminal and civil) judgments where the court held the manufacturer liable due to its failure to conduct a recall. Generally speaking, the manufacturer has a duty to conduct a recall or other appropriate measures when it can foresee that the accidents will occur widely.

Limitations and defences

28 Limitation periods

What are the applicable limitation periods?

The right to demand compensation for damage based on the PLA is extinguished if:

(i) the victim does not exercise such right within three years from the time the victim becomes aware of the damage and the identity of the party liable for the damage; or

(ii) 10 years have elapsed from the time the manufacturer delivered the product (PLA article 5(1)).

Notwithstanding this, it should be noted that the 10 years in (ii) is calculated from the time of the occurrence of the damage, where such damage is caused by substances that become harmful to human health as a result of accumulation in the body, or where the symptoms indicative of such damage appear only after a certain latent period (PLA article 5(2)).

The right to demand compensation for damage based on tort under the Civil Code is extinguished if:

- the victim does not exercise such right within three years from the time the victim becomes aware of the damage and the identity of the defendant; or
- 20 years have elapsed from the time the tortious act was committed (Civil Code article 724).

The right to demand compensation for damage due to breach of contract under the Civil Code is extinguished if the victim does not exercise that right within 10 years from the time the victim was eligible to exercise that right. Where the contract falls within the definition of 'commercial transactions' under the Commercial Code of Japan (Act No. 48 of 1899), which is typical of product liability cases, the period of 10 years will be reduced to five years.

The right to demand compensation for breach of a seller's warranty against defects (Civil Code article 570) is extinguished if the victims do not exercise such right:

(i) within one year from the time when the victims become aware of the defect; or

(ii) within 10 years of the delivery of the product. Please note that in cases of a sale between 'traders' under the Commercial Code, the buyer must generally examine the products and dispatch notice of any defect to the seller immediately after discovering it.

With regard to item (ii), the period of 10 years may be reduced to five years if the contract falls within the definition of 'commercial transactions' under the Commercial Code.

29 State-of-the-art and development risk defence

Is it a defence to a product liability action that the product defect was not discoverable within the limitations of science and technology at the time of distribution? If so, who bears the burden and what is the standard of proof?

It is stipulated as a defence in the PLA that the manufacturer will be exempted from product liability if it proves that the defect in the product could not have been discovered given the state of scientific or technical knowledge at the time when the manufacturer delivered the product (PLA article 4). Practically, however, this defence is very difficult to prove.

30 Compliance with standards or requirements

Is it a defence that the product complied with mandatory (or voluntary) standards or requirements with respect to the alleged defect?

No. This is because product liability law (regulation after the accident) and product regulation (pre-regulation to prevent the accident) are independent from one other. Accordingly, compliance with standards or requirements is not a defence for a manufacturer under the PLA. However, compliance with standards or requirements would be an important factor when determining whether there is a defect in a product.

31 Other defences

What other defences may be available to a product liability defendant?

Examples of some defences that a product liability defendant can use are as follows:

(i) the court may decrease the amount of compensation in consideration of the negligence of a victim (contributory negligence) (Civil Code article 722(2));

(ii) the defendant may claim that the amount of profit that the plaintiff gained or the amount of expenses that the plaintiff has ceased to incur in relation to the tortious action (such as the cessation of incurrence of living expenses where a victim has died) should be deducted from the amount of compensation;

(iii) the court can allow a decrease in the amount of compensation payable due to a victims' pre-existing conditions prior to them suffering damage (such as a specific chronic disease) by a wide interpretation of contributory negligence; and

(iv) the defendant is not liable under the PLA if it proves that where the product is used as a component or as a raw material of another product, the defect occurred primarily because of compliance with the instructions concerning the design of that other product given by the manufacturer of that other product and the defendant was not negligent with respect to the occurrence of such defect (PLA article 4).

It should be noted that in certain legal precedents, the amount of compensation was cut by 70 per cent or 80 per cent due to contributory negligence (item (i)). It should also be noted that a defence under item (iv) is very difficult to prove in practice.

Update and trends

As mentioned in question 34, there have been notable lawsuits in which the court has dismissed the plaintiffs' claims, especially the case concerning the supposedly defective lung cancer treatment (Iressa) which allegedly caused plaintiffs (or their families) to develop interstitial lung disease.

AstraZeneca started to import and distribute Iressa with the approval of the Health, Labour and Welfare Ministry in July 2002. As there had been no effective treatments with respect to lung cancer before Iressa appeared, at the beginning of its distribution, the media popularised the drug as a 'dream treatment with few side effects'. On the other hand, there was a statement fourth from the top of the section entitled 'Significant side effects' in an annexe attached to Iressa that stated: 'Interstitial Lung Disease (unknown frequency): As interstitial lung disease may develop, observations should be made. The treatment should be discontinued and adequate measures should be taken if any abnormalities appear.'

Certain patients who had taken Iressa developed interstitial lung disease, and some of them died. In 2004, the victims their families filed two lawsuits against AstraZeneca and the government in Tokyo and Osaka. They claimed that they or their families developed interstitial lung disease because of defects in design, defects related to the absence or inadequacy of a warning label and advertisements exaggerating the safety of Iressa without pointing out its supposedly fatal side effects.

In 2011, both the Tokyo District Court and the Osaka District Court partially granted the claims of the victims under the PLA and ordered AstraZeneca to make compensation payments to the victims. The Tokyo District Court concluded that there were defects related to the absence or inadequacy of a warning label, pointing out the following reasons:

- there were no sections entitled 'Caution' related to the side effect;
- there were no statements regarding the side effect which caused interstitial lung disease in any section other than the section entitled 'Significant side effects'; and
- the statement concerning interstitial lung disease was fourth, not first, from the top of the relevant section in the annexe.

The court also stated that it was difficult for doctors who used Iressa to immediately understand that Iressa had the potentially fatal side effects for the above reasons. Both the victims and AstraZeneca appealed to the Tokyo High Court and the Osaka High Court, respectively.

The Tokyo High Court and the Osaka High Court overturned the earlier decisions and dismissed the claims of the victims, concluding that there were no defects related to the absence or inadequacy of a warning label in 2011 and in 2012, respectively. On 12 April 2013, the Supreme Court rejected the victims' appeals and upheld decisions reached by the two high courts. With regard to the lawsuit in Tokyo, the Supreme Court stated as follows: whether the defect related to the absence or inadequacy of a warning label depends on whether or not an annexe attached to medicinal chemicals includes adequate information with regard to side effects. The adequacy of the information should be judged in the light of whether or not the foreseeable risk of the side effects had been disclosed appropriately, considering factors such as:

- the nature and extent, including frequency, of the side effects;
- the knowledge and ability of the doctors and patients that are assumed to be the users based on the effect of the medicinal chemicals; and
- the appearance and format of warnings regarding the side effects in the annexe.

32 Appeals

What appeals are available to the unsuccessful party in the trial court?

Judgments of the district court can be appealed to the high court and then to the Supreme Court. The grounds for appeal from the district court to the high court are both error-in-law and error-in-fact. The Supreme Court will hear appeals from the high court on grounds of error in interpretation of (and other violations of) the Constitution. In addition, violations of civil procedure rules, such as error in jurisdiction, lack of reasoning, etc, will also give rise to a right of appeal to the Supreme Court. Petitions to the Supreme Court are also available, which gives the Supreme Court discretion to accept cases if the judgment being appealed is contrary to precedent or contains significant matters concerning the interpretation of laws and ordinances.

Jurisdiction analysis

33 Status of product liability law and development

Can you characterise the maturity of product liability law in terms of its legal development and utilisation to redress perceived wrongs?

Product liability law as embodied in the PLA can be regarded as mature enough to redress perceived wrongs; it has been almost 17 years since the PLA was enacted, and it is based on the theory developed and refined by the courts in the course of deciding major product liability cases since the 1970s.

34 Product liability litigation milestones and trends

Have there been any recent noteworthy events or cases that have particularly shaped product liability law? Has there been any change in the frequency or nature of product liability cases launched in the past 12 months?

Recent noteworthy events and cases that have particularly shaped product liability law in Japan include the following:

- Panasonic gas fan heaters and Paroma gas water heaters manufactured in the 1980s deteriorated over time and caused many carbon monoxide intoxication accidents, resulting in 30 casualties over 20 years. These cases led to the Long-term Use Consumer Product Safety Inspection System (see question 27). Paroma has been sued by the victims' families in product liability litigation at four district courts; two cases were settled in January 2010 and August 2012 with the company making payments. Also, the Tokyo District Court granted part of the claims in December 2012 and the judgment became final and binding. A past chairman and a manager accused of causing death or bodily injury through negligence in the conduct of their occupation were found guilty by the Tokyo district court in a criminal litigation in May 2010.
- A 21 month-old child choked on *konjac* jelly (which is harder than typical jelly) and died. The victim's parents filed a lawsuit against the manufacturer of *konjac* jelly. On 17 November 2010, the branch of the Kobe District Court dismissed the claim stating that *konjac* jelly met the safety standards that analogous products should have and that there were no defects in respect of the design and warnings regarding *konjac* jelly. On 25 May 2012, the Osaka High Court rejected the appeal of the parents. In this case, the victim had consumed *konjac* jelly (given to him by his grandparents) despite there being warnings on the packaging that the product was *konjac* jelly (as opposed to typical jelly), and should not be consumed by children or the elderly due to the risk of suffocation. There have been similar cases where customers have not used or consumed products correctly and such misusage could be a critical issue in certain lawsuits.
- Since April 2012, 39 lawsuits based on the PLA have been filed, in district courts all across Japan (according to the National Consumer Affairs Centre (NCAC) of Japan). The plaintiffs in these lawsuits sued Yuuka, Phoenix and Katayama Chemical, claiming that they had developed wheat-dependent exercise-induced anaphylaxis due to using certain soap. Yuuka sold the soap and

Phoenix manufactured it. Katayama Chemical manufactured and sold Glupearl 19S, which is a component in the soap and the substance which caused the disease. None of these lawsuits has yet been concluded.

- Certain patients who had taken a lung cancer treatment (Iressa) developed interstitial lung disease and some of these patients died. In 2004, the victims and their families filed two lawsuits in Tokyo and Osaka against the company, AstraZeneca, which imported and distributed the drug, and the government. In the lawsuits, they claimed that they or their family developed interstitial lung disease because of defects in design, defects related to the absence or inadequacy of a warning label and advertisements exaggerating safety without pointing out the fatal side effects of the drug. On 12 April 2013, the Supreme Court rejected the plaintiffs' appeals and upheld lower court decisions which had dismissed the claims. For more details, see 'Update and trends'.

35 Climate for litigation

Please describe the level of 'consumerism' in your country and consumers' knowledge of, and propensity to use, product liability litigation to redress perceived wrongs?

The number of filings under the PLA has consistently been around 10 cases a year since its entry into force. Lack of punitive damages and discovery-like evidence rules might have some effect on why this number is less than that expected at the time of the PLA's enactment. However, it is also true that the level of consumerism and consumers' knowledge in relation to recovering damage have been enhanced. The government's pro-consumer policy finally established the CAA and a new data bank for consumers (the Data Bank System for Accident Information). There are also multiple public and private institutions that support consumers by conducting consultations, alternative dispute resolutions, etc, including the NCAC, a national core institution working together with local consumer centres; local consumer life centres, which are accessible first contacts established by local governments; and product liability centres, which are complaints-resolution entities set up by industrial groups.

36 Efforts to expand product liability

Please describe any developments regarding 'access to justice' that would make product liability more claimant-friendly.

A bill for the introduction of a class action procedure, which will enable a qualified consumer organisation which has received the recognition of the prime minister to file a lawsuit in which common questions of liability will be assessed, was approved in a Cabinet meeting on 19 April 2013. In applying this procedure, a court judges first whether or not a defendant is liable to a considerable number of consumers based on common factual or legal causes. Then, the court determines the amount of the claims which each of consumers filed, respectively.

Although this new class action procedure will be applied to a lawsuit based on the general tort principles under the Civil Code, it will not be applied to claims based on the PLA. Further, it will only be available where the claimed losses are economic losses related to consumer contracts (for example, refund of the purchase price of defective goods), and will not be available in respect of other types of loss, such as physical injury (for example, injury or death caused by a defective product).

This class action procedure will become effective within three years of the promulgation of the Act stipulating this procedure provided, however, that it will not be applied to claims regarding contracts entered into or wrongful acts conducted prior to the promulgation.

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