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The International Comparative Legal Guide to:
Product Liability 2011

A practical cross-border insight into product liability work

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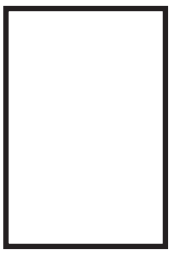

General Chapters:

Country Question and Answer Chapters:

Continued Overleaf

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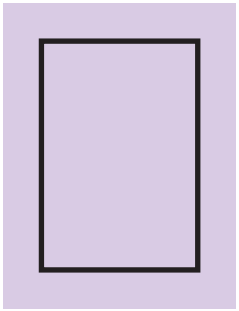

Country Question and Answer Chapters:

EDITORIAL

Welcome to the ninth edition of *The International Comparative Legal Guide to: Product Liability*.

This guide provides the international practitioner and in-house counsel with a comprehensive worldwide legal analysis of the laws and regulations of product liability.

It is divided into two main sections:

Fifteen general chapters. These are designed to provide readers with a comprehensive overview of key product liability issues, particularly from the perspective of a multi-jurisdictional transaction.

Country question and answer chapters. These provide a broad overview of common issues in product liability laws and regulations in 31 jurisdictions.

All chapters are written by leading product liability lawyers and we are extremely grateful for their excellent contributions.

Special thanks are reserved for the contributing editors, Ian Dodds-Smith of Arnold & Porter (UK) LLP and Michael Spencer QC of Crown Office Chambers, for all their assistance.

Global Legal Group hopes that you find this guide practical and interesting.

The *International Comparative Legal Guide* series is also available online at www.iclg.co.uk

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Chapter

Spain

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

In Spain, Article 128 of the Spanish Royal Legislative Decree 1/2007 Consumers Act ("Consumers Act") provides that the strict product liability system shall exist alongside the contractual or tort liability systems.

The liability of the manufacturer is designed as an *objective* or strict liability, since concurrence of fault is not necessary. The features of such a liability system are i) relativity, since there are a number of defences and the manufacturer is not always held liable, ii) limitations in time, for there are time limits on issuing proceedings, and iii) mandatory inclusion, for liability cannot be waived or limited in a contract or agreement between two parties.

Civil liability arises only when three requisites concur: a defect or fault in the product; the existence of damage; and a causation relation between them both. It is not necessary, therefore, that there is fault on the part of the manufacturer or supplier, and the Consumers Act makes no reference to fault.

According to both the Consumers Act and the Spanish Supreme Court doctrine, a product is defective if it does not offer the safety it was expected to have, taking into account all circumstances but specially i) its presentation, ii) the use one could reasonably expect of it and iii) the moment of its commercial launch. The moment of its commercial launch is the most relevant part of the legal concept of a defective product: only a product placed in the market can be considered as defective. An intrinsically faulty product is not defective in the terms of the law if it is not available in the market.

A defect may have its origin in the product's design or project, in its production or it may be based on the information it provides (unclear guidelines or imprecise operation instructions or warnings).

Damage is an essential requisite. Bodily injury or death, as well as economic damage to property other than the defective product, are covered. The damaged property has to be objectively devoted to private use or consumption and has to have been used for this purpose principally by the injured person; the Consumers Act is not applicable to products sold for resale.

The third element, causation, is a bridging concept between the defect and the result; damage must be a consequence of the product's defect. The Supreme Court has interpreted the various theories on causation in civil liability. To summarise, to find the existence of causation, a precise and direct link between the defect (cause) and the damage (effect) is needed. If this link cannot be established, causation will not exist, despite the proven existence of a defect and a loss.

In Spain, the distinction between contractual and extra-contractual (tort) liability may be summarised as follows: a claim concerning material or property damages affecting the acquired product itself shall be considered contractual, whilst a claim for personal injury or property damages not affecting the product, as well as positive damages and loss of profits (in Spanish: *daño emergente y lucro cesante*, both of which are economic nature), shall be considered extra-contractual (law of tort).

Contractual liability is regulated by arts. 114 *et seq.* of the Consumers Act and by art. 1484 *et seq.* of the Civil Code (liability for hidden defects).

Tort liability is based on art. 1902 of the Civil Code (damage caused by negligent or wilful misconduct).

Breach of statutory obligations will lead to potential administrative sanctions as well as the obligation to compensate the damages caused.

1.2 Does the state operate any schemes of compensation for particular products?

According to the Consumers Act, the state has operated schemes of compulsory insurance of civil liability for traffic of motor vehicles, compulsory insurance for travellers, and compulsory insurance for recreational or sportive boats.

Funds for liability regarding health problems have also been put in place.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

The rule provides that the manufacturer and the importer will be liable. The legal concept of manufacturer includes i) the producer of a finished product, ii) the producer of any element integrated into a finished product, iii) the producer of raw material, including agriculture and livestock products, and iv) any person presenting itself to the public as the producer, by placing its name, company name, trademark or any distinctive mark whatsoever on the product or its packaging. Hence, the legal concept of manufacturer includes not only the real producer but also the apparent one.

An importer is defined as the person who, in the exercise of a professional activity, introduces a product in the EU for its sale, rent, leasing or any other form of distribution whatsoever. An importer is liable just like the manufacturer. On the other hand, a person importing goods from the EU or the AELC will be considered, accordingly, a mere supplier.

A supplier is any person who supplies or makes the product available. He has in principle a reduced liability compared to the manufacturer and the importer but if the supplier acts knowing that the product it supplies is defective his liability can become equal to that of the manufacturer/importer. If he were held liable, the supplier is entitled to bring an action to recover damages from the manufacturer or importer.

The nature of the liability system laid down by the Consumers Act is joint and several liability. The injured party has the option to bring an action against the manufacturer, the importer, the supplier or the retailer. However, the injured party cannot join all these operators to the action unless he is able to prove that they all concurred in the production of the damage.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Despite civil law not providing a specific provision obliging the recall of products, there may be an obligation to recall products according to an administrative procedure if the authorities so require, or as a consequence of an injunction granted as an interim measure of a lawsuit.

Royal Decree 1801/2003, dated 26 December 2003 ("RD 1801/2003") establishes follow-up and recall obligations.

According to the general principle of consumer safety, all products sold in Spain must, when used under normal conditions, present the level of safety which one may legitimately expect and not endanger the health of persons. The person responsible for marketing a product has the duty to take the necessary measures to be kept informed of any risk that its product may create and, where necessary, recall the product that may endanger consumers from the market. Failure to recall a defective product constitutes a fault, which may give rise to an action for compensation should the other conditions of liability be fulfilled.

Producers and distributors shall immediately notify the competent authorities in their region (*Comunidades Autónomas*) if they are aware that their product is dangerous. Failure to notify the authorities will be taken into account in any civil, administrative or criminal proceedings concerning the product.

Finally, it is of note that the "RAPEX" (EU Rapid Information System) allows for the notification in one Member State of a defect or danger to be relayed to all Member States if the product has been marketed in other EU Member States.

1.5 Do criminal sanctions apply to the supply of defective products?

The Criminal Code covers (arts. 360 *et seq*.) offences against public health, in which, among others, criminal liability is established for the supply of defective products, whose harmful effects may constitute grounds for such liability. It distinguishes between products which are medicines, food or other kinds of products.

The manufacturer, distributor or seller of the products may be deemed liable, as long as those products do not fulfil the legal prescriptions regarding their composition (e.g. adulterated products) and lead to harmful results for the purchaser of such products. The affected –irrespective of the criminal liability- may also be entitled to civil damages, which arise from the criminal liability.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The injured party has the burden of proving the defect, the damage and the causality. This clearly shows that the liability system laid down in the Consumers Act has a relative and objective nature. The doctrine of the higher courts also refers to it as "special closed liability". Of the three requisites, the most difficult to prove is the defect, which may derive from an action or negligent omission. Once a defect is proven to exist, the applicable law is the Consumers Act, otherwise the norms of the Civil Code (art. 1902) will apply.

To avoid liability, the manufacturer has to prove that the use of the product by the injured party was incorrect. The Supreme Court in its decision STS 10.06.02 found the parents of a three-year-old child who died after eating a sweet negligent for allowing the child to eat it and therefore lowered the penalty that lower courts had imposed upon the importer of the sweet on the grounds of not warning that such a sweet could be dangerous for small children.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The general principle in the civil liability system states that the claimant bears the burden of proof, regarding the link between the defendant's behaviour and the injury suffered by the claimant, which must bring evidence of being a direct and immediate effect of the defendant's conduct. In other words, the claimant must prove that the defendant's behaviour was enough to cause the injury.

Sometimes, however, due to special circumstances, the activity performed by the defendant or even if there have been different agents intervening in the final injury, it becomes very difficult to discern the link between the defendant's conduct and the injury suffered. In some cases, courts have awarded damages to a claimant who could prove the damage and the fault in the product, under the presumption that the link existed.

To do so, case law has provided different theories regarding causation, namely:

The "equivalent condition" (the cause of the cause is the cause of the injury caused). In a series of acts resulting in an injury, all acts, from the first act to the last, directly causing the injury would be deemed as the causation of the injury. This theory is also known as the *conditio sine qua non* theory when only the act whose absence would determine the lack of injury is taken into account. These theories have been finally rejected by Spanish courts because it may lead to disproportionate results if the claimant had to prove the exact ratio of liability against each agent acting within the aforementioned series of acts.

There is also the so-called "proximate causation" theory, according to which the act considered to be linked to the injury would only be the one previous to the injury. This theory has also been rejected due to its simplicity and the fact that it may not fit in all cases.

The theory known as "efficient cause" deems the act that has enough entity to cause the injury as being directly linked to the injury. However, this theory includes an indeterminate legal concept, since it may become very difficult to determine which act had enough entity to cause the injury.

The most accepted theory is the "adequate cause", according to which the conduct (in our case, the defect of the product) will be considered as directly linked to the injury if it led logically and reasonably to conclude that there would be an injury.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

As mentioned above, Spanish law requires causation as the mechanism to attribute and, at the same time, limit liability. However, court practice resolves the problem of causation in cases where the damage has been caused by a non-determined member of a group by means of the joint liability of all members (see decision STS 8.2.1983, STS 13.9.1985 and STS 8.7.1988). In each case, there was just one injured party who brought an action against all possible tortfeasors. Therefore, market-share liability does not apply.

Notwithstanding, some authors believe that market-share liability may also be applicable under Spanish law, both in the field of product liability and environmental liability. They maintain that market-share liability would be admissible in cases where the manufacturer of the defective product is capable of identification by its membership of the group, although his exact identity is impossible to discover (''relative indetermination'').

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

We must firstly consider that under Article 137 of the Consumers Act, the information regarding the use and/or risks of the product are specially incardinated in the safety measures the consumer has the right to receive with the product itself. Consequently, the lack of the appropriate information, warnings or advice of potential dangerous effects or the correct use of the product might be considered as a defect of the product.

Under articles 12 and 18 of the Consumers Act, irrespective of the specialities a given product might have to fulfil, all products addressed to consumers must contain enough, truthful and efficient information regarding: the name and address of the manufacturer; the nature, composition and purpose of the product; the quality, quantity, category, common or commercial denomination, if relevant; the manufacturing or supply date and, when legally required, the expiration date; the instructions or indications about the correct use of the product; and warnings and foreseeable risks.

The Judgments of the Court of Appeal in Madrid of February 10, 2009 and in Barcelona of March 16, 2009 and April 18, 2008 insist on the fact that the lack of the complete information in the product's instructions or prescriptions (e.g. medicines), irrespective of the existence of a learned intermediary, are a defect of the product itself and its safety requirements and, therefore, result in the product being defective under article 137 of the Consumers Act.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Concerning product liability, the Consumers Act establishes that the manufacturer may be exonerated from his liability in the following circumstances:

- The subjective defence, where the defendant states:
  - (1) that he did not put the product into circulation; or
  - (2) that the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business.
- The defence for cases where the defect cannot be attributed to the defendant. This kind of defence is available when (1) having regard to the circumstances, it is likely that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards, (2) the defect is due to the compliance of the product with mandatory regulations issued by the public authorities, (3) that the state of the scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the detection of the defect - the ''development risk defence'' or (4) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.

Additionally, the manufacturer may also be totally or partially exonerated from his liability if, according to the circumstances of the case, the damage is due to a defect of the product as well as the fault of the victim or the act of a third party for which the victim is responsible. Article 140.2 of the Consumers Act provides that the manufacturer of a component of the finished product will not be held liable if he proves that the defect is due to the design of the product to which it has been incorporated or due to the instructions given by the producer.

Another element of exoneration or limitation of liability is *force majeure*, which fully exonerates the manufacturer's liability. *Force majeure* may result from the fault of the victim or the act of a third party as well. As far as contractual liability is concerned, parties may in their contract exclude some events from being considered as *force majeure* (e.g. strikes).

Contractual liability may be excluded or limited by including the corresponding clause in a contract. However, damages caused as a result of wilful misconduct or gross negligence of the manufacturer may not be limited nor excluded contractually.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Art. 140.1.e) of the Consumers Act sets out the rule for the

development risk defence. However, this defence strategy may not apply in the fields of medicine and food law.

The manufacturer may present a defence in the case of manufacturing defects alleging that the state of knowledge at that time prevented the fault from being discovered. In the case of design defects, the manufacturer may deny liability by contending that it was not possible at the relevant time to choose a more secure solution. In the case of insufficient warnings or instructions, the defendant may use the defence of state of knowledge which made it impossible to identify the risk in question.

The defendant has to explain and prove the development risk. The evidence has to refer to the fact that the state of scientific and technical knowledge at the time of placing the product into circulation did not make it possible to discover the fault.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

This possible defence is set out in art. 140.1.d) of the Consumers Act. The exoneration of liability established in this section is only in reference to the binding legal norms which oblige the manufacturer to a total and absolute commitment to the fulfilment or omission of certain actions (statutory norms). The defendant, however, cannot plead observance of legal norms which are subject to the disposition of the parties (*jus dispositivum*) as these are characterised by the voluntary nature of their fulfilment, or of professional standards or generally applicable rules. Compliance with the latter shall not constitute a defence.

In any case, it is for the manufacturer to prove compliance with the statutory norms.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

A judgment which has been rendered in proceedings initiated by an individual does not have legal force in relation to a third-party plaintiff. The *res judicata* principle only applies as regards the admissibility of an action, where a final decision has already been rendered in a previous proceeding with an identical subject matter. It is not considered as an identical subject matter if the persons in the two proceedings are not identical, amongst other things. Additionally, a judgment which was handed down in a class action suit does not gain legal force in relation to compensation claims which can be initiated by individual consumers.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

According to art. 140 of the Consumers Act, the manufacturer of a component or a defective product can only be exonerated if he or she can prove that the defect was due to the conception of the product as a whole.

Otherwise, the conduct of a third party does not exonerate the liable person *vis-à-vis* the injured person, but only gives that party the possibility to seek redress from the person to whom the defect is attributable afterwards in order to recover the amounts paid as damage by means of a subrogation action, within the term of one year.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Under art. 145 of the Consumers Act, the exclusive or partial negligence of the injured or damaged party in the course of events leading to the injury may totally or partially exonerate the liable party of its duty. The extent of such exoneration will depend on how the injured or damaged party's conduct helped the causation of the injury and will need to be analysed on a case-by-case basis.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

In Spain there are no special provisions regarding the appointment of the pronouncing court concerning liability for defective products. The first instance court is, as in all civil claims, the *Juzgado de Primera Instancia*, which consists of a single judge. Neither a jury nor a panel of judges exists at first instance.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The court rules on the basis of its own and independent evaluation of evidence without the support of a technical specialist. Thus, the judge rules according to the evidence as it is presented in the taking of evidence. The judge may, however, ask for an independent expert witness to appear, but he is not bound to his technical assessment of the case.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Class actions were introduced to the Spanish legal system by sections 6.1.7, 7.7, 11, 13.1, 15, 78.4, 221, 222.3, 256.1.6 and 15 of the Act 1/2000, of Jan. 7th, of Civil Procedure ("Act of Civil Procedure" or "LEC").

By this means, consumer protection organisations or groups are able to sue for compensation on behalf of a group of people who are affected by the same injurious event. Claims which are made within the framework of a class action can be on the basis of contractual and non-contractual relationships. Liability in tort may also be established by means of a class action, in criminal proceedings as well as civil actions.

In the case of a class action, the principle of publicity of class actions is applicable, according to section 15 LEC. Generally, in the first stage of proceedings all those potentially affected are informed of the action by an announcement to be published by the court. Here it is necessary to distinguish between two types of class actions:

- Class actions according to section 11.2 LEC (specified or easily specified persons affected). The persons affected can join the action at any time, though they join the proceedings

at the point reached and are prevented from taking those steps which have already been carried out in the proceedings. The appeal by the court does not suspend the course of the action.

- Class actions according to section 11.3 LEC (unspecified or not easily specified persons affected). The appeal by the court suspends the action for a period of up to a maximum of two months. On expiry of the statutory period the entry to the action is no longer admissible, however the persons who have not joined are able to assert their rights with reference to the issued judgement at a later date.

In the case that a class action in the sense of section 11.2 LEC is carried out for a specified or easily specified group of people, section 15.2 LEC requires that the plaintiffs be previously notified of all persons affected by the filing of the action. This notification does not replace the later appeal of the court to the persons affected.

The judgment is handed down according to section 221 LEC following the conclusion of the suit. The judgment is on the basis of whether the damaging event is to be ascribed to the defendant and whether the claimed damages of the affected persons are to be attributed to the damaging event. The individual identification of the compensation creditor is mainly dependent on its appropriateness when establishing the persons affected. If specified consumers have filed an action, the judgment has to expressly and separately decide on the claims of the respective plaintiffs.

A judgment which sets a definite compensation for a specific consumer represents an enforceable title. If the judgment does not refer to individually specified consumers, but only demonstrates the data, characteristics and requirements to which each claim is entitled, the affected persons are considered as being individualised and the compensations set respectively in the execution proceedings according to section 519 LEC.

In Spain, class actions are not commonly brought.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Spanish law distinguishes between three groups which can be actively legitimised for class actions: (1) groups of affected persons; (2) consumer protection organisations; and (3) corporations legally founded for the defence and protection of consumers.

- The right of action for groups of affected persons is set out in section 6.1.7 LEC. It is necessary that the individuals who make up the group of persons affected by an event are specified or easily specified. Furthermore, the group has to be made up of the majority of the affected persons. The group of affected persons is only legitimised to sue if the members of the group are exactly specified or easily specified and are able to exercise section 11.2 LEC, i.e. the so-called "*intereses colectivos*", collective interest.
- Consumer protection organisations always have the right of action according to section 6.1.3 LEC, no matter whether they exercise the interests of an easily specified group of people (section 11.2 LEC) or of a group of persons which may be specified only with difficulty (section 11.3 LEC). In the latter case the law talks of the so-called "*intereses difusos*", diffuse interests.
- In the case of a group of affected persons being specified or easily specified, section 11.2 LEC gives capacity to sue to those corporations which were founded for the defence and protection of consumers.

4.5 How long does it normally take to get to trial?

The time it takes to get to trial depends on various factors. In case of an individual plaintiff, the action can be filed immediately after the injurious event as long as the facts of the case have been gone through entirely.

If it is necessary to form consumer groups as in the case of a class action in the sense of section 11 LEC, it can take several months before actual proceedings take place.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The court can try certain preliminary matters of proceedings (right of action and power of representation, res judicata or pendency, necessary joinder of parties, formal defect of the action) which refer to legal matters.

The only preliminary matter which does not refer exclusively to legal matters concerns the jurisdiction over the subject of the court, which has to be legally determined on the basis of the declinatory plea. Issues of fact cannot be decided in preliminary instances.

4.7 What appeal options are available?

In proceedings of liability for defective products, the same means of legal redress are available to the parties as in other contentious proceedings.

In principle, these are the right of appeal ("*apelación*") and of appeal to the Supreme Court (*casación*) (their admissibility is bound to certain requirements, e.g. the amount of the sum of appeal must be at least €150,000, and the legal significance of the matter or the possible breach of a principle of proceedings must be relevant to the Constitution).

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

On the one hand, the parties may present their own expert's report in order to meet the burden of proof as to their responsibility. The judge can, on the other hand, on the petition of the parties ask for an independent expert to appear. The report is limited by the examination of evidence. The expert is not allowed to introduce new facts to the proceedings, although he can reconstruct facts or their causes on the basis of his expert knowledge. It is also possible that the expert provides a statement on a future course of facts or damages.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

No. In general terms, there is no pre-trial deposition.

Expert reports must be filed together with the respective pleadings. They must be requested by the parties prior to the preliminary hearing.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

Before the legal proceedings are commenced, no documentary evidence has to be disclosed. The defendant may however be obliged to present certain documents before the proceedings begin in order to protect evidence; third parties may likewise be requested by the judge to disclose documents if considered essential for the case.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

In principle submission clauses in contracts where consumers are involved are deemed null and void.

However, arbitration submission clauses will be allowed as long as they refer to the consumers' arbitration system, usually dealt through administrative entities, either in the contract (through arbitration clauses) or later, when the conflict has arisen. In the consumer's arbitration system the parties are requested to resort to mediation to resolve their conflict prior to arbitrating.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

The rights to claim for product liability are subject to several time limits, depending on the action being brought.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

The right to claim for product liability comes under the statute of limitations after three years. According to section 143 of the Consumers Act, the time in which the action becomes statute-barred depends on a) the point in time when the injured party suffered the damage or the damage occurred, and b) the point in time when the injured party comes to know the identity of the person responsible.

Action of redress against the remaining parties responsible for the damage by the party who has paid compensation to the injured party becomes statute-barred after one year.

Apart from the three-year statutory period for the claim, the Consumers Act also states that liability expires (and any claim becomes inadmissible) once the product which caused the damage has been in circulation for more than 10 years, unless the injured party has initiated court proceedings against the manufacturer in the interim.

These statutory limitation regulations are applicable to the strict liability for defective products.

To fault-based liability, the general rules for statutory limitations apply. Actions on contractual liability are barred after 15 years. Actions on tort liability are barred after one year from the time the victim had knowledge of the injury.

The statutory limitation as well as the expiration of a claim are independent of the age or other circumstances of the claimant.

The statutory limitation has to be plead, explained and proven by the defendant. However, the expiration of a claim has to be taken into consideration *ex officio*. The judge has no discretionary powers regarding the evaluation of the statutory limitation or the expiration of a claim.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

According to art. 143 of the Consumers Act, the time bar for this kind of action begins as soon as the injured or damaged party suffers the injury or is aware of the consequences, as long as the liable person is known.

Therefore, fraud or concealment intended to prevent the consumer from knowing who the liable person is will affect the commencement of the time bar.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

The most commonly used remedy is, undoubtedly, monetary compensation. Nevertheless, the Consumers Act establishes an action addressed to obtain an injunction to cease on the practice against the Consumers Act (e.g. abusive clauses, supplying defective products).

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The liability system laid down in the Consumers Act covers damages caused to property or products other than the defective product itself as well as personal injury and death (see section 1). Damages to the product itself are excluded. In relation to damage to property, a franchise of €390.66 will be deducted.

The limit for the producer's liability for death or bodily damage caused by identical products with the same defect, is set at €63,106,270.96 (art. 141 Consumers Act).

Other damage such as moral damages and other property damages and losses are excluded from the scope of the Consumers Act, therefore only being recoverable according to the principles of general civil law.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Damages in respect of the cost of medical monitoring when the product is yet to malfunction are not recoverable according to the current state of Spanish law and jurisprudence.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Under Spanish law, punitive damages are not recoverable. The law of tort in Spain plays no sanctioning role at all. Most authors agree that tort law cannot tie in with punitive, criminal or administrative law.

In contrast, a liquidated damages clause may be included in a contract to provide for a total amount of damages (which may

exceed or limit the amount of damages resulting from a breach of contract), which nonetheless may be increased or reduced by the judge.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

The Consumers Act lays down a maximum of €63,106,270.96 for recoverable damages as a manufacturer's global liability for death or personal injury caused by identical products causing the same defect.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Parties have the power to finish proceedings, by means of an agreement, at any moment before proceedings are pending for the issue of a judgment.

Those agreements may be approved by the court, in which case they will be directly enforceable in case of breach. However, this approval is not compulsory. There are no special rules for the settlement of groups/class actions.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

In case any authority has paid any costs that have arisen from surgery or medical treatments, unemployment, etc., it would be entitled to claim against the person or entity whose conduct led to the injury allegedly caused.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

a) The successful party may be able to recover the procedural costs from the losing party (i) if all claims made by the successful party are accepted, (ii) if all claims brought by the losing party are rejected, and (iii) provided that the court does not find that the case raised serious factual or legal doubts. The recoverable incidental expenses can be, e.g. the translation costs, the experts' fees, the witnesses' expenses, the counsels' fees and proctor's fees.

b) Any other legal costs incurred by a party, such as the legal fees when they are freely determined between the lawyer and his or her client, are generally not recoverable.

c) Court fees are not recoverable.

7.2 Is public funding e.g. legal aid, available?

Rules for Legal Aid were established in the Act 1/1996, of Right to free legal aid. Persons, who do not have an income beyond a certain limit fixed by law, may apply for free legal advice without the need to pay lawyer's fees. These expenses are covered by the State. Even non-profit-associations may claim this right. In the case of consumer associations this is particularly important.

7.3 If so, are there any restrictions on the availability of public funding?

The family income of the person making the request must not be higher than twice the statutory minimum wage in order to claim legal aid.

Moreover, it is not awarded in order to pursue personal rights or claims.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fee arrangements ("*quota litis*") have been forbidden in Spain until very recently. The Spanish Supreme Court rendered a decision on 2008, which allowed for strict contingency fee arrangements.

Success fees were, nevertheless, admissible.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Spanish law does not provide rules regarding the third party funding of claims. Therefore, we must assume it is not a forbidden practice to fund injured/damaged persons' claims.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Spain.

It is relevant to underline the recent Spanish Supreme Court's Judgment dated December 9, 2010, regarding a case of various women all over Spain who claimed for damages to a company providing breast prostheses. The British Medical Devices Agency issued a communication recommending all those women who had breast prostheses implants to have them preventively extracted, due to the potential danger the prostheses could entail in the long term. The ground for such communication –also adopted by the Spanish Medical Authorities- was the use of soya oil as a filling, which caused the deterioration of the prostheses because of its toxicity. The manufacturer preventively halted the production of those breast prostheses since it could not ascertain the falseness of such suspicions, as the proper studies were not performed, according to the British Medical Devices Agency.

The Supreme Court, even though no woman was intoxicated and the implants were duly extracted, understood the products were defective, for the following reasons:

- The lack of proper studies regarding the risks the use of the product may cause entails the consideration of the product as defective, since the safety defect does not only include those risks derived from the product's toxicity or dangerousness, but also from the lack of the necessary verifications to exclude those risks, which entails a risk itself.
- Injuries caused to the affected women derived directly from the lack of safety of the product, since the premature extraction was not a risk which the affected women had to

assume for the use of breast prostheses, which had to present an appropriate level of safety and stability guaranteed by the necessary previous studies.

- The defendant could not bring evidence that the lack of the proper studies was due to the state of scientific and technical knowledge.
- Although stability is an intrinsic quality of products such as breast prostheses safety requirements, which have to be surgically implanted/extracted, the need of periodic renewal of implants cannot be compared to the need of their extraction to prevent the toxicity of their components from damaging the persons affected.

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