

Product Liability

In 20 jurisdictions worldwide

Contributing editors

Harvey L Kaplan, Gregory L Fowler and Simon Castley



2015

GETTING THE
DEAL THROUGH

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Product Liability 2015

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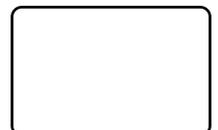


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Italy

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Civil litigation system

1 What is the structure of the civil court system?

In Italy there are three levels of courts: first-instance courts (justices of the peace and tribunals); second-instance courts (courts of appeal for judgments rendered by tribunals; tribunals for judgments rendered by justices of the peace); and then there is also the Court of Cassation (Supreme Court).

The justice of the peace courts have jurisdiction over legal actions up to the value of €5,000, damages caused by floating or vehicular traffic up to the value of €20,000 and some specific subject matters. Cases filed with the justice of the peace in which the amount claimed is less than €1,100 may be decided 'according to principles of equity', which means on a 'common-sense' basis. In these cases the justice of the peace may depart from the rules of law, provided that the principles of the legal system are respected.

Tribunals have first-instance jurisdiction over all cases not expressly allocated to other courts and second-instance jurisdiction over decisions issued by the justices of the peace.

Courts of appeals have first-instance jurisdiction over some specific matters and second-instance jurisdiction over decisions issued by the tribunals.

The Court of Cassation is at the top of the hierarchy. It is the court of last resort and its task is to ensure the consistent interpretation and application of the law. The court review is limited to issues regarding the interpretation and correct application of the law, as the court does not review any assessment of facts made by the judge in the trial.

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

Italy relies upon an adversarial judicial system. There are no juries in civil proceedings.

3 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?

A product liability action is governed by the same rules set forth by the Italian Code of Civil Procedure for ordinary proceedings.

A case begins with the plaintiff's writ of summons, which includes all the claims against the defendants. In the writ of summons the plaintiff must clearly state the type of relief sought (namely, claim for compensation for damage) and the facts and points of law supporting the claim.

The defendant's first pleading, whereby appearance is entered in the proceedings, must include any defence arguments and challenge to any fact and point of law indicated by the plaintiff at support of its claims. The said pleading has to be filed within the mandatory term of 20 days before the first hearing in case the defendant intends to raise a counterclaim, to join third parties in the proceedings or raise any 'strict' exception (any exception, procedural or on the merits, that cannot be raised by the judge) or all of these. Otherwise, the same pleading can be filed also at the first hearing.

At the first hearing, any of the litigants may request terms within which to file defensive briefs; namely, a first term of 30 days to amend claims and defence arguments already submitted; a second term of additional 30 days to file means or requests for evidence or both; and for a third term of an additional 20 days to oppose the counterparty's means or request of evidence or both.

The judge, who is not bound to apply the law indicated by the parties (iura novit curia principle), will then set a date for a hearing, during which the items of evidence requested by the parties and considered relevant and admissible will be gathered.

When the judge, after the conclusion of the evidence-gathering phase or even before, deems the case ready to be decided, he or she schedules a hearing to let the parties specify their conclusions. Following this, the parties are granted a term not longer than 60 days to file their final pleadings and a further term of 20 days to file their pleadings of reply. Alternatively, the judge can let the parties discuss the case orally at the above hearing or at a further hearing to be scheduled to this end. That, however, is not a very common option.

4 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 to begin a formal, ordinary lawsuit for product liability.

As a result of a very recent reform of the Italian procedural law, since 9 February 2015 for claims for payments of any amount between €1,100 and €50,000, before litigating in court parties to a dispute have to carry out negotiations in the presence of their attorneys at law to try to amicably settle their dispute (assisted negotiation). Assisted negotiation is not mandatory in the case of disputes arisen as per obligations set forth by agreements entered into by professionals and consumers. Since assisted negotiation was introduced into the Italian legal system only a few months ago, no relevant case law on its application has yet developed.

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

There are no mechanisms of summary dispositions available once proceedings are initiated.

Nonetheless, in appeal proceedings, at the first hearing court of second instance (for tribunals or courts of appeal, see question 1) an evaluation on the admissibility of the relevant writ of appeal has to be made, that considers the actual possibility that the relevant appeal is admissible (the filtering evaluation).

6 What is the basic trial structure?

Italian civil proceedings can be broadly divided into three phases:

- introductory phase - this is to assess the formal and procedural regularity of the proceedings, with regard to the parties (relevant legal standing and powers), jurisdiction of the court and all the other procedural issues that may prevent the case from reaching the subsequent phase. The court examines the requests for evidence and admits the requests it deems appropriate;
- evidentiary phase - the evidence admitted by the court is gathered, witnesses are examined and experts appointed by the judge render their opinions; and
- decision phase - this includes the evaluation of the collected evidence and of the arguments submitted by the parties. This leads to the final decision.

There is no distinction between pretrial and trial phases found in the common law system. The same judge presides over all three phases, which are

not formally divided; the judge sets the dates for the hearings, checks that there are no procedural flaws, rules on the requests of the parties, appoints experts and conducts and oversees the evidence-taking activities up to the final decision. Only the judge can question witnesses, putting to them questions previously submitted by the parties and accepted by the judge.

Normally, proceedings are not public. Access to court files is not permitted to third entities, not being party to the proceedings. Nonetheless, the hearing held for discussion of the case is open to the public. Further, the decision is publicly available.

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

Class action seeking for damage compensation is a mechanism fairly recently introduced in the Italian legal system, effective from 1 January 2010 in relation to wrongful events that have occurred since 15 August 2009. Since then, moreover, the relevant provisions have already been subject to partial modifications. At the moment a bill of law for further modifications of this procedural tool is under the evaluation of the Parliament (see question 36).

Class action consists of two phases: a first admissibility stage and a second liability and damage stage. An essential condition for admissibility is homogeneity of the rights claimed by the members of the group. Once the court, ruling in panel, declares the action admissible, publicity takes place, being the action based on an opt-in system.

The decision of the court is not a direct condemnation but rather sets the criteria to be used to calculate the amount to be paid to the consumers or, if possible, establishes the minimum amount to be paid to each consumer. The assessment of individual damages is then referred to a subsequent settlement or litigation.

Class action can be started by 'duly representative' consumers associations appointed by one or more consumers, in order to request compensation for damages or reimbursement in favour of consumers in the event of unlawful behaviour damaging a plurality of persons, including product liability.

8 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 average length of first instance proceedings, whose rules also govern product liability action, ranges from one to five years, depending mainly on the evidentiary means offered by the parties and admitted by the court and on the workflow of each individual court.

Evidentiary issues and damages

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

The law sets forth the preservation of documents for companies and professionals. Timing may vary depending on the nature of the documents.

No formal US-style discovery exists. Any party can ask the judge to order the filing of specific documents with the court.

Very limited pretrial activities are admitted to procure evidence (witness, ascertainment over the status of goods, technical experts) prior to the beginning of proceedings should there be a matter of urgency or the risk not to be able to procure the same evidence any more later on.

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

In the Italian civil law system considerable weight is given to written evidence. The basic principle is that oral testimony is allowed in cases where documents are either unavailable or unreliable. In practice, apart from unusual cases all evidence must be given verbally at the hearings and written statements are not allowed.

When the parties submit their requests for evidence, they must also include a list of people to be called to testify, along with the list of questions to the witnesses. The judge rules on the admissibility of both witnesses and questions. Only witnesses of fact can be admitted and no personal evaluation can be expressed by the witness; it follows that experts cannot be used as witnesses.

The parties are not entitled to question the witnesses directly and no formal cross-examination exists: it is only the judge who questions the witnesses, while the parties can suggest questions to the judge.

The parties cannot be witnessed. Upon request of the counterparty, however, each party or its legal representative can be summoned for a 'formal examination'. Formal examination is a kind of evidence aimed at achieving a confession. The party can be questioned only by the judge and only on the questions previously approved by the judge. The party cannot be forced to appear, but if he or she fails to appear or refuses to answer, the judge can consider the facts as admitted.

Moreover, the court can order the parties to appear in order to question them informally (free examination). During a free examination the party is not bound to answer, and the statements rendered are not considered as technical evidence.

Formal and free examinations are not used often, because the examination is not under oath and a possible lie would not be punished as perjury as the party is not – technically – a witness (principle of 'privilege against self-incrimination').

A party's 'oath' is a sworn statement affirming that one or more of the alleged facts is true. It is taken only upon the request of the opposite party, and the party requested to take the oath may also ask the other party to do the same. The oath, when taken, provides 'legal' evidence and conclusive proof of the facts. On the contrary, when the party requested to take the oath refuses to do so or fails to appear, the relevant facts are regarded as established. In practice, oaths are rarely used.

Writing witnesses in the form of depositions became recently admissible, albeit within strict limits depending on the nature of the matter, the agreement of the parties and the discretionary evaluation of the judge.

The court can rely only upon evidence provided by the parties, and must refrain from personally investigating facts deemed relevant to the case. Nonetheless, the judge is entitled to appoint one or more experts, in order to ground his or her decision in facts or circumstances of general knowledge and to call witnesses referred to by other witnesses during their testimony. The judge may ground his or her findings on certain particular items of evidence and disregard other items, provided that a logical and detailed explanation for this is given in the decision.

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

When the case requires specific technical knowledge, the judge may appoint, also upon a party's request, one or more experts (CTUs) to act as the judge's assistants and provide their technical opinions.

The CTU is selected among experts included in lists filed in court. Otherwise, the authorisation of the court president is necessary. The parties can oppose the appointment of the CTU on proper grounds, such as risk of impartiality and bias.

The CTU cannot make legal assessments, establish the existence of legal provisions or assess documentary evidence. Each party can appoint its own retained expert to work together with the CTU.

The CTU's expertise is carried out in writing and develops through a first filing by the expert of a draft report, to which parties' experts can reply in a given term, and ends by the filing of a final report, including comments on or remarks to the parties' experts notes. The expert can be summoned to the hearing to explain the outcome of his or her activity or to reply to the questions raised by the lawyers and by the parties' experts.

It is the judge's duty to evaluate the findings of all experts. The judge may disagree with the conclusions reached by the CTU, as long as he or she provides adequate grounds for this disagreement.

The parties may appoint experts even if the court does not appoint a CTU, and these experts can draft reports.

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

All damages, including both pecuniary and non-pecuniary damages, suffered by the injured party are recoverable.

For years, courts and scholars have made reference to four categories of damages:

- economic damages – these can consist of monetary damages (pecuniary loss incurred or loss of profits);
- biological damages – damages to the psychological and physical integrity of a person, directly related to his or her health;

- non-economic or moral damages – non-pecuniary damages (pain and suffering), which can be awarded only in the cases provided for by law (mainly in cases involving criminal offences); and
- existential damages – these are non-pecuniary damages ‘created’ by case law to compensate damages not covered by the moral damages rule. The category is relatively undefined, but according to the same case law can cover any event that negatively affects ‘quality of life’.

However, by a stand-out ruling in 2008 (No. 26972) the Joint Sections of the Court of Cassation maintained that non-pecuniary damages are compensable only in the cases provided for by law, namely in two sets of cases: cases in which compensability is expressly acknowledged (for example, in cases in which the tort is characterised by elements that make it amount to a criminal offence); and cases in which, although compensability of such kind of damages is not expressly provided for by any legal provision, the tort seriously prejudiced a personal right that is directly protected by the Constitution.

As a consequence of such a decision, damage defined as ‘existential’ is practically no longer compensable as an autonomous category of damages, while non-pecuniary damages must be compensated in full, but without duplications.

In Italy, decisions, even from the Supreme Court, do not consist of binding precedents and only have persuasive effect. In recent years, however, the trend of both high and lower courts is to follow the above interpretation.

The damage may also be proved on the basis of mere presumptions, but the damaged person remains burdened with the task to allege the factual elements from which the existence and the extent of prejudice may be gathered.

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

Italian traditional legal theories state that any damage not aimed at fully compensating the injured party for distress actually suffered (punitive, exemplary, etc) is not permitted. It should be noted that some scholars and some legal provisions, in specific areas, are to some extent in support of not strictly compensatory damages.

Litigation funding, fees and costs

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

An indigent party can access legal aid, provided that the claim is not clearly groundless. In order to obtain legal aid, the party must file an application to the local bar association. Thereafter, the court before which the proceedings are pending may cancel the legal aid if the income of the party is found to be above the threshold set by the law, or that the requirements provided by the law do not exist or if it deems that the party has acted or defended itself with malice or gross negligence. Legal aid includes lawyers’ fees and any other costs linked to the case. When legal aid is granted, some of the costs are anticipated by the state and others are waived. Legal aid is, however, not widespread, due to its limitation in admissibility and because – in general – litigation in Italy is not particularly expensive.

15 Is third-party litigation funding permissible?

Generally speaking, third-party litigation funding is permissible but not common.

16 Are contingency or conditional fee arrangements permissible?

Contingency or conditional fees have become admissible in the past few years. Accordingly, legal fees can be agreed as a percentage of the sum awarded to the represented party. Agreements have to be in writing. In any case, any form of transfer of credits in favour of the lawyers is still prohibited.

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

The court’s final decision also awards costs. As a general rule, the losing party has to pay both the expenses and the fees of the winning party; however, this does not mean that the winner will certainly recover all costs, as the court does not liquidate the effective costs incurred but determines the fees to be reimbursed on the basis of certain criteria as established by the

law. In accordance with these criteria, which have been quite recently modified and reviewed, fees have to be calculated having regard, basically, to the value of the claims and the activities carried out by the lawyers in each and every phase of the proceedings (ie, study of the case; introductory, evidence-gathering and ruling phases; and the enforcement procedure).

The court may also (wholly or partly) deny the recovery and settle the expenses under certain conditions, that is, when:

- it assesses that the costs to be reimbursed to the winning party are excessive or superfluous;
- all the parties are losing under some aspects of the final decision;
- there are serious and exceptional reasons to do so; and
- the case regards a new matter which has never been decided before by case law or the final decision departs from case law, establishing a principle which revises or overrules what has been established until then by the case law.

In any event, irrespective of the outcome of the proceedings the court may order one of the parties which by its conduct breached its duty of loyalty and probity in the same proceedings to reimburse the costs borne as a consequence of the same proceedings to the other party.

As a matter of fact, courts frequently deem it not appropriate for a company to recover costs against losing individuals.

Sources of law

18 Is there a statute that governs product liability litigation?

EU Directive No. 85/374 on product liability was implemented in Italy in 1988 by the Product Liability Act, as amended by Legislative Decree No. 25/2001 (the PLA). Further, Legislative Decree No. 115/95, implementing European Directive No. 1992/59, as amended by Legislative Decree No. 172/04, in turn implementing European Directive 2001/95, which introduced general obligations on product safety, to a certain extent supplements the PLA, imposing an obligation on manufacturers and producers to withdraw unsafe products from the market. All the above Acts were subsequently incorporated into the Consumer Code, enacted in 2005.

In general terms, the provisions of these Acts are a response to the difficulties that consumers had been facing in seeking damages caused by a defective product, relying on the ‘traditional theories of liability’, namely in contract or in tort, as the former implied that the action had to be laid against the party with which the consumer had signed a contract (usually the seller) and the latter implied the fault of the manufacturer, that had to be proven by the consumer.

On the contrary, the EU Directive and now the Consumer Code have provided a new kind of liability, which is strict, not fault-based, and can be claimed directly against the manufacturer, regardless of the existence or not of a contract between the latter and the consumer or user.

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

As discussed above, pursuant to most widespread case law, further to the Consumer Code, claimants may claim compensation on the basis of tort or contract liability, or both.

Tort is based on the ‘duty of care’ concept. The main rule establishes that: ‘Any person who wilfully or negligently commits an act causing another party to suffer unjust damages shall be required to pay compensation for such damages.’

Additionally, the Italian system provides for a strict liability, based on a presumption of liability on subjects who perform a ‘dangerous activity’, so that ‘whoever has caused injuries to others while performing dangerous activities (defined as dangerous by their nature or because of the type of instruments used to perform them), is required to pay compensation, if he or she is unable to prove that all measures that would have been suitable to avoid any injury have been adopted.’ The presumption of liability exempts the injured party from the burden of proving the fault of the allegedly liable party.

Contractual liability, based upon the breach of an obligation undertaken by one of the parties, relies on the general rule, according to which in the event of non-performance or imperfect performance of the contract (which includes the supply of a defective product), the seller and the lessor are liable to the buyer, leaseholder or user, unless they can prove that non-performance was owing to facts beyond their control. For contractual liability, compensation is limited to reasonably foreseeable damages at the time of entering into the contract.

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

The Consumer Code was put in place in 2005, to gather together and consolidate all the different provisions concerning consumers already in force in Italy. It consists of 146 articles divided into six parts:

- part I contains the 'general provisions' governing consumers' and users' rights. In particular, section 2 contains a list of consumers' rights (for example, the rights to protect health; to safety and quality of products and services; to adequate information and fair advertising; and to fairness, transparency and equity in contractual relationships);
- part II deals with consumers' education and information to the same in terms, for instance, of quality, price and risks, and advertising;
- part III contains the provisions regulating contracts signed by consumers;
- part IV concerns the quality and the safety of products, providing for, in particular, provisions on liability for defective products, legal guarantee of conformity and commercial guarantee for goods;
- part V deals with consumers' associations and their right to take legal action, including class actions, without preventing the consumer from suing. Consumers' associations are entitled to act in defence of consumers' health, safety and quality of goods and services, adequate information and fair advertising; and
- part VI contains final provisions, including provision establishing that consumers' rights cannot be waived and the consequent nullity of any agreement in this regard.

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

Pursuant to the Consumer Code it is the manufacturers' duty to ensure that products placed on the market are safe and grants the power to the relevant authorities to check the safety of products and to order or impose certain means aimed at preventing any possible damage.

Manufacturers can be sanctioned for the infringement of the provisions of the Consumer Code and may also be sentenced to imprisonment of up to one year.

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

There are no significant novel theories available to claimants. In general terms, theories on product liability litigation are still developing, also in connection with the quite recently introduced class action provisions.

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

In accordance with the Consumer Code a product is defective 'when it does not provide the safety a person can reasonably expect, taking into account all circumstances' or in the case of manufacturing defects, when it does not provide the safety normally provided by other category specimens. In assessing this standard, various factors are considered, including the manner in which the product was distributed and marketed, its clear features, the instructions and warnings provided; the reasonably foreseeable use of the product; and the time the product was put on the market.

Consumers' safety expectations are evaluated on the basis of a series of objective parameters, including price, technical rules (mandatory standards that the manufacturer or producer must comply with), any trial, test and present state of technical and scientific knowledge available at the date of distribution of the product. Finally, the reasonable use of the product is evaluated not in abstract terms but rather in relation to the users at whom the product is aimed (such as the foreseeable use of a toy for children).

Three types of defects are set forth under the Consumer Code: manufacturing defects (when the defect is the result of an error in production of an otherwise well-conceived product); design defects (when the defect is inherent to the project itself); and defects based on inadequate information (when the product is well conceived and produced, but it is dangerous as placed on the market without adequate information to users or consumers).

24 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?

The injured party bears the burden of proof with regard to the defect of the product, damage and causality.

A first trend of merit courts was to assume the existence of the defect by the damage caused. But said trend seems to be changed further to a decision of the Supreme Court, which can be now regarded as a benchmark in the matter (Court of Cassation judgment of 15 March 2007, No. 6007). Indeed, assuming a more severe approach, the Supreme Court ruled that the general rules on burden of proof set out in the Code have to be applied. As noticed above, Italian decisions, even from the Supreme Court, do not consist of binding precedents and only have a persuasive effect. Nonetheless, at the present time, the trend of both high and lower courts is to follow the interpretation at issue.

A fairly recent decision of a trial court (Court of Appeals of Brescia judgment of 2 February 2014) in which the relevant case was sent back by the Supreme Court to be decided again on the merits (Court of Cassation judgement of 8 October 2007, No. 20985) established that the injured party can meet its burden to prove the defect of the product by merely submitting evidence that the same product cannot be used safely, as could be legitimately expected. Thus, according to this decision, it is not necessary that the injured party indicates and detects the inherent vice due to the project or the manufacturing of the product at issue (in this case the defect regarded a breast implant which emptied out just two years after it was inserted).

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

The principle is that manufacturers shall be liable for damage caused by their products. Manufacturers, as described by the Consumer Code, include:

- the manufacturer of the product in the EU;
- anyone presenting itself as manufacturer by placing a name, trademark or other distinctive sign on the product, or anyone who reconditions the product;
- the manufacturer's representative when the manufacturer is not established in the EU, and importers when there is no manufacturer's representative established in the EU; and
- other parties included in the supply chain, insofar as their activities may affect the standards of safety of a product.

Suppliers may also be held liable, but only in the event that manufacturers have not been identified. Suppliers can be released from liability by allowing the identification of manufacturers.

26 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?

With reference to the standard of causation, the trend of the Supreme Court is to consider the threshold of probability in civil cases lower than that required in criminal cases and that consequently in the former cases causal chain can be determined on the logic of 'more probable than not'. Thus, according to the above, the relevant causal chain, for which wrongdoers shall be liable, is that related to consequences that are 'usually' produced by their actions, unless a new fact occurs in relation to which they have no duty or possibility to act (in compliance with the 'theory of causal regularity'). The law does not set forth the reversal of the burden of the proof, which is on the plaintiff.

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

As already stated, the Consumer Code requires the manufacturer and the distributor to place on the market a safe product and to ensure this foresees a general duty to carry out 'post-market controls' (testing the product, monitoring consumers' claims, etc) and a number of post-sales duties aimed at preventing damages that a defective product might cause. These may include the withdrawal of the product from the market, the recall from the consumers or users and provision of supplementary information aimed at making consumers aware of risks and instructing them on how to avoid damages. Manufacturers are also required to inform the authorities with jurisdiction of any of their products' defects or risks and cooperate with them in all activities aimed at preventing damage.

In turn, the authorities have the power to instruct manufacturers to withdraw or recall any product they deem to be faulty and to supplement information in order to prevent damage.

Limitations and defences

28 What are the applicable limitation periods?

The statute of limitation period is three years from the day on which the injured party becomes or should have become aware of the damage, the defect and the identity of the liable party and 10 years from the day on which the product was placed on the market.

If the action is based on the general tort provision, the statute of limitation period is five years from the consumer's awareness. In contract liability action the relevant period is 10 years, again from the consumer's awareness.

29 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?

Liability is excluded in the event that 'the scientific and technical knowledge available at the time the product was put on the market was not yet of such a kind as to allow the product to be considered faulty.' The Consumer Code confirmed this exemption, but some authors consider it tacitly revoked by the regulations governing product safety that impose post-selling obligations. The burden of the proof is borne by the defendant.

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

The fact that the product is in compliance with mandatory standards or requirements is a valid defence, as pursuant to the Consumer Code liability is excluded if the defect is owing to the compliance of the product with a mandatory law or a binding order.

According to commentators, this defence may be applied in the event the mandatory law or a binding order imposes specific conditions or formalities on the manufacturer, but not if the mandatory law or a binding order sets forth for minimum safety standards. In this case, compliance with such minimum safety standards does not amount to a valid defence.

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

Another exclusion of liability that has, in our experience, proved to be fairly effective is the contribution by the injured party. The Consumer Code allows for exclusion from compensation if the party, although aware of the defect and the related risks, voluntarily exposes himself or herself to risk of damage.

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

Decisions issued in first instance proceedings for product liability can be appealed by ordinary means before courts of second instance (for tribunals or courts of appeal see question 1).

Second instance courts can rule again on the merits of the case. As a general remark, new claims and new challenges are not admissible. New evidentiary means or requests cannot be admitted unless the court considers them essential to decide the case or the party proves that they could have not been submitted during first instance proceedings for reasons not attributable to the same.

Relevant decisions can in turn be challenged before the Supreme Court for reasons of law, but are not subject to further review on the merits.

Jurisdiction analysis

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

Although theories and case law on product liability are still developing, there does appear to be a good balance between the provisions governing product liability in terms of compensation of damages suffered by consumers and those aimed at preventing these damages, and in particular those enforcing post-sales duties and post-market controls.

Having said this, however, statistically the plaintiffs' lawyers still tend to rely on different law to tort liability. Consequently, the number of cases concerning product liability decided every year, albeit seemingly increasing, remains limited. The familiarity of the judiciary with this area of the law still has room for improvement. Differences, moreover, can be seen

between lower and higher courts, and also in different territorial areas around the country.

34 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?

Until the end of the 1960s, judges based manufacturers' liability on general tort rules. This solution was extremely detrimental to injured parties in that the burden of proving the manufacturer's fault lies with the injured party. Case law underwent a crucial transformation in the *Saiwa* case, decided in 1964. Here the judges made their decision on the basis of the criteria of objective liability and the fault of the manufacturer was assumed as culpa in re ipsa, namely, implicitly owing to the damaging nature of the product itself.

Further to the *Saiwa* case, judges began – although case law was far from uniform – to decide cases of product liability by presuming liability on the part of the manufacturer. In particular, from the 1980s onwards, case law began to refer to other rules to simplify the injured party's position, including article 2050 of the Italian Civil Code on dangerous activities, affirming that the expression 'dangerous activities' could also include the product as final result of the relevant activity. In this regard, case law on blood infection and drugs should be mentioned.

The PLA had limited application in Italy, as shown by the few rulings made, based specifically on this rule. In fact the first action was brought in 1991, known as the *Mountain Bike* case, concerning personal injuries due to the sudden breakage of the column supporting the front gear-shift of a mountain bike and the consequent detachment of the bicycle wheel.

Another well-known decision was issued by the Court of Cassation, which excluded the liability of the manufacturer in relation to a swing. The court held that: 'The manufacturer of a product that has caused damage shall be exempt from liability [...] when it is shown that the safety defect of the product was only manifested in relation to a method of use thereof that did not fall within the use that can be reasonably foreseen by the manufacturer.'

Two other significant decisions were issued in 2008 by the Joint Divisions of the Supreme Court, ruling on causation and on statute of limitation. The Joint Divisions have held that in civil litigation the existence of causation does not require a certainty beyond any reasonable doubt; rather, the criterion of 'more probable than not' applies. The Supreme Court also maintained that, when evaluating causality, judges must take into account whether the event could have been foreseen, in the sense that the harm resulting from an act or omission must be reasonably predictable on the basis of statistical or scientific criteria.

In this regard, it is also worth mentioning that the awareness of the risks or the relevant warnings turned out to be a winning defence argument in product liability litigation. With respect to warnings, some merit courts ruled on the relevant standard and clarified that the warning must be sufficiently explicit to enable the consumer to appreciate the particular hazard involved, especially where the hazard is likely to arise from normal use of the product.

This interpretation, moreover, was more recently confirmed by the Court of Cassation. In a case for compensation of damage caused by the use of sun tanning lotion with no sunscreen protection, the Supreme Court stated that the production could not be considered as 'defective' only because of its potential riskiness, as the liability of the manufacturer of a defective product could only be ascertained if the damage had been caused by said product when used 'in accordance with its normal use', namely, in accordance with the instructions and warnings provided for by the manufacturer (decision No. 25116 of 13 December 2010). This principle was subsequently followed by both higher and lower courts.

Notwithstanding the above, however, the courts continue to decide many cases of product liability on the basis of general rules provided by the Italian Civil Code, also after the PLA became effective.

This trend arguably relies on the outcome of decision C-52/00 of 25 April 2002 of the European Court of Justice, stating that:

The reference in article 13 of the Directive to the rights that an injured person may rely on under the rules of the law of contractual or non-contractual liability must be interpreted as meaning that the system of rules put in place by the Directive, which in article 4 enables the victim to seek compensation where he or she proves damages, the defect in the product and the causal link between such defect and the damages, does

Update and trends

Very recently the Court of Justice of the European Union issued a relevant decision for product liability litigation (CJEU judgment of 5 March 2015, Cases nos. 503 and 504 of 2013). The cases at issue regarded medical devices, pacemakers and defibrillators to be implanted in humans for therapeutic purposes. After these medical devices were placed on the market, the manufacturer acknowledged that they were defective and could be risky for the patients in whom they had been implanted. Owing to this risk, surgical interventions were recommended to remove the devices or more generally to adopt measures aimed at removing said risk. According to the decision, all the medical devices that had been placed on the market had to be considered defective – irrespective of whether or not anomalies in their functioning had actually been reported in the treated patients – since they did not provide the standard level of safety that consumers or patients may legitimately expect, also considering the peculiarity of the products at issue and the impact they could have on their lives. Thus, on the basis of this decision, the assessment of a potential defect of the medical devices belonging to the same group or manufacturing series rendered all said medical devices defective. Still according to this decision, the surgical intervention required to remove the defect in

the medical devices constitutes a personal injury to the consumers or patients which the manufacturer is liable for. Thus, the relevant costs are ultimately the manufacturer's responsibility.

It is foreseeable that this judgment will soon become a leading precedent, to be followed by courts in Italy ruling on matters of product liability. This case may also have an impact over the general recourse by consumers to product liability protection rather than to other kinds of legal protection based on tort or strict liability provided by Italian law.

Also, in the past few years, special attention has been dedicated, both by professionals and scholars, to class action. This mechanism of legal protection became available to consumers in Italy only recently, starting from 1 January 2010. In the five years since its introduction, recourse to class action has been limited. Almost 60 class action procedures have been initiated to date. Out of them, only a very few were admitted, positively passing the preliminary evaluation of the court in terms of certification. Recently a bill of law for the reform of the current class action procedure has been submitted to the Parliament. Should such reform take place, it may have a strong impact in determining the recourse to this kind of procedure and modifying present scenarios in product liability litigation.

not preclude the application of other systems of contractual or non-contractual liability based on other grounds, such as fault or a warranty in respect of latent defects [...] Article 13 of the Directive cannot be interpreted as giving the member states the possibility of maintaining a general system of product liability different from that provided for in the Directive. Indeed, on the basis of the above decision, the injured party can rely on different legal grounds rather than the PLA and Consumer Code.

No significant change, moreover, has been registered in this trend in the past 12 months.

35 Describe the level of 'consumerism' in your country and consumers' knowledge of, and propensity to use, product liability litigation to redress perceived wrongs.

Despite the legislative instruments available to injured parties, disputes concerning product liability do not have a wide, significant development. The increasing attention of consumers' associations to the matter may, however, determine new trends in the near future. Moreover, after an initial start-up period, seemingly needed to sharpen 'techniques', recourse to class action may become more common.

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

As already mentioned, litigation based on product liability claims is still developing in Italy. Law reforms introduced in the past few years may have

a role in speeding up such a development. These reforms include the introduction of a class action procedure and the possibility for clients to enter into contingency fee agreements with their lawyers, which had been previously inadmissible. Third-party funding (which is not prohibited but which at the same time is not regulated) may contribute.

Nonetheless, up to the present time, statistics show that the above mechanisms are still timidly approached by plaintiffs and that general awareness on their availability and potential effects is not mature yet.

On the subject of class action, since the introduction of this procedural tool in 2010 only about 60 class action procedures have been initiated and only a few of these procedures have actually been declared admissible. Moreover, in almost all these cases the relevant claims were rejected on the merits. In fact, the activities of consumer associations, which are themselves entitled to represent classes of consumers in relevant class action procedures, may become more and more decisive in bringing attention to the topic at issue and in promoting the same.

Very recently a bill of law for the reform of class action procedure has been submitted to Parliament; this bill of law is still under discussion.

According to said bill of law, some modifications to the present procedural framework should be applied aiming to favour recourse to class action as an effective tool for consumers to recover product liability damages. Inter alia, the reform at issue has the scope of increasing the number of cases for which class action procedure is applicable, to reduce costs for the plaintiffs to initiate or carry on class action procedures and provide economic advantages for lawyers representing and defending parties in class action procedures.



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