The Product Regulation and Liability Review

Editors
Chilton Davis Varner
and Bradley W Pratt

Law Business Research

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CONTENTS

EDITORS' PREFACE

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

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

This edition reflects some of these trends. For example, Turkey has recently enacted a new consumer protection law aimed at protecting consumers in commercial transactions and expanding available remedies. In South Korea, new legislation has been proposed to permit consumer class actions and to lower a plaintiff's burden of proof in product liability cases. Australia has experienced a renaissance in product liability litigation due to a relatively plaintiff-friendly class-action regime and the emergence of litigation funding companies. And, in the United States – traditionally a consumer-friendly nation – private lawsuits show no signs of abating, while state and federal governments take an increasingly aggressive role in enforcing strict safety and manufacturing standards. Although these changes and trends may be valuable in their own right, they also create a greater need for vigilance on the part of manufacturers, distributors and retailers.

This edition covers 15 countries and provides a high-level overview of each jurisdiction's product liability framework, recent changes and developments, and a look forward at expected trends. Each chapter contains a brief introduction to the country's product liability framework, followed by four main sections: Regulatory Oversight

(describing the country's regulatory authorities or administrative bodies that oversee some aspect of product liability); Causes of Action (identifying the specific causes of action under which manufacturers, distributors or sellers of a product may be held liable for injury caused by that product); Litigation (providing a broad overview of all aspects of litigation in a given country, including the forum, burden of proof, potential defences to liability, personal jurisdiction, discovery, whether mass tort actions or class actions are available, and what damages may be expected); and the Year in Review (describing recent, current and pending developments affecting various aspects of product liability, such as regulatory or policy changes, significant cases or settlements, and any notable trends).

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

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

Chilton Davis Varner and Bradley W Pratt
King & Spalding
United States
April 2014

Chapter 7

FRANCE

Christophe Hénin[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Before the adoption of the Product Liability Directive No. 85/374/EEC (the Directive), French jurisdictions used to implement general civil liability, whether tortious, based on Article 1382 of the French Civil Code (FCC),[2] or contractual, based on Article 1147 of the FCC.[3]

The Directive was adopted in the European Union on 25 July 1985 to protect consumers against damages caused by defective products. It allows injured persons to seek compensation with regard to defective products put into circulation within the internal and single market. Companies are then required to deliver products free from defect or danger to users (i.e., products that offer the level of safety that can reasonably be expected). EU Member States were required to implement the Directive by 30 July 1988. As the French Republic failed to transpose the Directive within the time frame imposed, the Commission opened infringement proceedings under former Article 171

1 Christophe Hénin is a partner at Intuity.

2 Article 1382 of the FCC: 'Every act whatever of man that causes damage to another obliges him by whose fault it occurred to repair it.'

3 Article 1147 of the FCC: 'A debtor shall be ordered to pay damages, if there is occasion, either by reason of the non-performance of the obligation, or by reason of delay in performing, whenever he does not prove that the non-performance comes from an external cause which may not be ascribed to him, although there is no bad faith on his part.'

of the EC Treaty[4] against France, following the 13 January 1993 ruling by the European Court of Justice (ECJ).[5]

Notwithstanding such a default of the French Republic, the French jurisdictions decided *proprio motu* to interpret the existing general civil liability framework in the light of the Directive provisions. In a ruling dated 3 March 1998,[6] the French Supreme Court applied the Directive provisions and dismissed the provisions of the FCC.

Finally, on 19 May 1998,[7] France transposed the Directive, and the FCC has included an exhaustive set of regulations in this respect: the new Title IV bis, 'Liability for defective products' (Articles 1386-1 to 1386-18), just after the chapter relating to general civil liability rules. It should be noted, however, that in 2002,[8] the ECJ ordered the French Republic to amend its existing law which incorrectly transposed the Directive. The ECJ ruled that the French legislation that exposed suppliers and distributors to legal claims on the same basis as producers was illegal. Again, in 2006,[9] the ECJ ordered France to pay a fine because of its failure to take the necessary measures to fully comply with the previous judgment of 2002.[10]

On 17 March 2014, the French parliament adopted Law 2014-344, which introduces into French law the class action mechanism,[11] a mechanism that will deeply modify the economic and industrial power struggle in France, even though the health and environment sectors have been temporarily excluded from the scope of the law. However, the government has clearly stated that these sectors will be included in 2014.[12]

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4 Article 171 of the EC Treaty: 'If the Court of Justice finds that a Member State has failed to fulfil an obligation under this Treaty, the State shall be required to take the necessary measures to comply with the judgment of the Court of Justice.'

5 ECJ, 13 January 1993, *Commission of the European Communities v. French Republic*, Case C-293/91.

6 Supreme Court, civ I, 30 July 1998, *Laboratoires Léo v. M. Scovazzo*, No. 96-12078.

7 Law No. 98-389 of 19 May 1998 on Product Liability.

8 ECJ, 25 April 2002, *Commission of the European Communities v. French Republic*, Case C-52/00.

9 ECJ, 14 March 2006, *Commission v. France*, Case C-177/04.

10 The ECJ, in a ruling of 14 March 2006, *Commission v. France*, Case C-177/04 stated that, 'by continuing to regard the supplier of a defective product as liable on the same basis as the producer where the producer cannot be identified, even though the supplier has informed the injured person within a reasonable time of the identity of the person who supplied him with the product, the French Republic had not taken the all necessary implementing measures set out in the judgment of 25 April 2002.'

11 Official Journal of the French Republic, 18 March 2014, No. 0065, p. 5,400. It is important to note that the French Constitutional Council in its Decision No. 2014-690 DC dated 13 March 2014 decided that the class action mechanism does not breach any constitutional rules and principles.

12 Article 2 of the Law.

II REGULATORY OVERSIGHT

In France, the Directorate-General for Competition, Consumer Affairs and Prevention of Fraud (DGCCRF) is heavily involved in the prevention of accidents occurring in everyday life and has, in this regard, a general competence to deal with matters of safety of industrial products. It also publishes a list of notices of product recall and several reporting forms of risk products for professionals.

There are also several authorities that have specific expertise in certain industrial sectors.

For instance, the French Agency for Food, Environmental and Occupational Health Safety (ANSES) essentially contributes to ensure health and safety in the areas of environment, labour and food. More specifically, it helps to ensure the protection of the health and welfare of animals, the protection of plant health, and the assessment of food quality, food safety and nutritional properties. It also has competence over veterinary medicinal products. In its field of competence, the Agency, at the request of other public and administrative authorities, may provide the relevant expertise as well as the scientific and technical support necessary for the development of laws and regulations.

In the health products sector, as a second example, it should also be noted that in accordance with the EU directives, the conditions for granting a marketing authorisation for medicinal products for human use (for innovated products as well as for generics), either nationally or through the European centralised or decentralised procedure, are contained and detailed within the French Public Health Code (PHC).[13] In this regard, the French National Agency for Medicines and Health Products Safety (ANSM) plays a key role. Indeed, applications for marketing authorisation are submitted to the ANSM, which scientifically assesses the marketing authorisation file according to scientific criteria regarding quality, safety and efficacy. A new product must provide a benefit/risk ratio at least equivalent to the existing products. The application is thus reviewed by the committees of the Agency (and in particular by the commission in charge of the initial assessment of the benefit/risk balance of the health products) if a deeper examination and a supplementary peer opinion for such a case is required. Three outcomes can arise: a favourable opinion, a request for further information or an unfavourable opinion. Once the marketing authorisation has been granted, manufacturers must comply with a set of rules set out by EU directives,[14] and by the PHC under Article L.5121-9-2 et seq.[15]

13 Articles L.5121-8, L.5121-10, R.5121-5 and R.5121-21 et seq. of the PHC.

14 Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010, amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

15 Article L.5121-9-2 of PHC provides that 'the undertaking or the operator of a medicinal product shall immediately inform the ANSM of the withdrawal or restriction imposed by the competent authority of any country in which the product is marketed, and of any other new information which may affect the assessment of the benefits and risks of the medicinal product or the product concerned. Where appropriate, the ANSM conducts immediate reassessment of the risk-benefit balance of that product and of all products with the same mechanism of action or a similar chemical structure'.

The manufacturer of medicinal products for human use must also comply with the good manufacturing practices (GMP)[16] laid down with the intention of providing minimum requirements that a manufacturer must meet while manufacturing these products, in order to ensure that they are in compliance with requirements of safety, quality and efficacy included in the drug master file. It is also relevant to note that, downstream, good distribution practices (GDP)[17] shall also be observed. The safety of medicinal products is thus ensured by the ANSM, which has a general competence, under certain circumstances, to suspend or withdraw a marketing authorisation[18] or to order the recall of any lot or batch of a medicinal product,[19] as well as to carry out an inspection on the manufacturing site.

III CAUSES OF ACTION

As defined by general French civil liability rules,[20] the producer is liable for any loss or damage caused by a defective product put into circulation, whether or not the producer has a contract with the injured person. In order to make a claim against the producer, the injured person must prove an actual damage, a defect of the product, and a causal link between the defect and the damage.[21]

Pursuant to Article 1386-4 of the FCC, a product is defective 'when it does not provide all the safety that can be legitimately expected from it'. French case law has had several opportunities to define the content of a 'defect'. It should be noted, for instance, that the fact that certain active ingredients for therapeutic use are dangerous do not characterise *de jure* the defectiveness of the product.[22] Similarly, the defectiveness of a medicinal product cannot be inferred from the simple fact that the medication triggered the damage alleged by the patient, or from the fact that the marketing authorisation

16 Volume 4 of 'The rules governing medicinal products in the European Union' contains guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use laid down in Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC and 91/412/EEC respectively.

17 Ibid.

18 Article L.5121-9 of PHC.

19 Article L.5312-1 of PHC.

20 Article 1386-1 and following of the FCC.

21 Article 1386-9 of the FCC.

22 Supreme Court, civ I, 05 April 2005, No. 02-11.947 and 02-12.065, See Article of Christophe Hénin and Anne-Catherine Maillols, 'La responsabilité des médicaments: à la recherche d'un équilibre entre rigueur et pragmatisme' (Medicinal products liability: looking for a balance between rigour and pragmatism), *Les Petites Affiches*, 21 June 2005 No. 122 pp. 9–15.

listed the possible defect as an adverse reaction.[23] On the contrary, such a listing provides the consumer or patient 'the safety that can be legitimately expected from the product'.[24]

Concerning the causal link between the defect and the damage, at first, the French jurisdictions required an actual, direct and certain causal link. The certainty of the causal link should be understood as a scientifically proven causal link between the defectiveness of the product and the occurrence of the injury.[25] However, patients were facing some major difficulties in providing the necessary scientific evidence to prove the causal link between their damages and the defect of the product. Therefore, the actual case law has admitted 'proof by presumption', when these presumptions are 'serious, precise and concordant'. Several elements form the basis of the judges' assessment, such as the fact that the product, under the acquired scientific data, could be a material cause of the damage, the time between the occurrence of the damage and the medication, and the absence of other causes that could explain the occurrence of the injury to the patient.[26]

The victim could also bring criminal legal proceedings against the manufacturer, either by summoning him to appear before the criminal court or by filing a criminal complaint with an application to join in the proceedings. The public action aims to have the criminal offence publicly determined and punished. But, a victim who has been 'personally' harmed by the criminal offence and who seeks compensation may start a civil action,[27] which may be brought before the same criminal court.[28] For example, if the patient dies as a result of the medication, the manufacturer may be sued for manslaughter[29] or for an active or passive deceptive product.[30]

23 Supreme Court, civ I, 24 January 2006, No. 03-19.534, *Société Aventis Pasteur MSD v. Mme X et autres*.

24 Supreme Court, civ I, 24 January 2006, No. 02-16.648, *Société les Laboratoires Servier SA v. Mme X et autres* – See Article of Christophe Hénin and Anne-Catherine Maillols, 'La responsabilité du fait des médicaments: nouveautés et exigences' (Medicinal product liability:innovations and requirements), *Décideurs*, April 2006, No. 74–75, p. 166.

25 Supreme Court, civ I, 23 September 2003, No. 01-13.063, *Laboratoires GSK*.

26 Court of Appeal, Versailles, 25 November 2005 No. 04/03953, *Laboratoires GSK*. See also Article of Christophe Hénin and Anne-Catherine Maillols, 'La responsabilité du fait des médicaments: de quelques rappels nécessaires sur ses fondements et conditions' (Medicinal product liability: a necessary recall of the conditions and the basis of liability), *Les Petites Affiches*, 19 May 2006, No. 100, pp. 6–20.

27 Article 2 of the French Code of Criminal Procedure (CCP).

28 Article 3 of the CCP.

29 Article 221-6 of the French Criminal Code (CRC).

30 Article 213-2 of the Consumer Code (COC). A product shall be actively deceptive whenever the allegations, for example, apposed to the leaflet and/or to the immediate or outer packaging do not exactly correspond to the technical or marketing authorisation file. The same product could also be passively deceptive whenever relevant information in order to protect public health is missing.

IV LITIGATION

i Forum

In France, product liability claims are usually brought before civil and criminal courts. However, there do exist alternative procedures in certain cases. For example, within the health-care sector, the Law of 4 March 2002[31] establishes an autonomous alternative compensation scheme in relation to medicinal liability. The aim is to resolve the difficulties encountered by victims of serious medical accidents, such as iatrogenic disorders,[32] or of a defective medicinal product, by allowing them to obtain quick and easy access compensation.

In this regard, the National Compensation for Medical Accidents Office (ONIAM) was established in order to compensate victims of therapeutic hazards, medical accidents, iatrogenic diseases and nosocomial infections.

Thus, pursuant to Article L.1142-4 et seq. of PHC, the victim of a medical accident may refer to the Commission for Conciliation and Compensation (CCI). Depending on the seriousness of the injury,[33] this procedure aims at reaching a conciliation or an amicable settlement. The procedure of conciliation applies to an injured person the seriousness of whose injury is below the damage threshold considered as serious, whereas the procedure of amicable settlement applies when the injury is above the threshold of seriousness.

The President of the CCI acknowledges receipt of the request and shall require any missing documents. When the file is complete, the Commission has a period of six months to issue its opinion.

If the application is deemed admissible, the President of the CCI shall appoint an expert or a body of experts, and set a deadline for submission of the expert report. Then, a copy of this report is sent to each party, who is summoned before the CCI and may be assisted or represented by a person of their choice. Following the meeting, the Commission shall issue a notice signed by the President and sent to the parties, which is accompanied by documents required for an offer of compensation.

If the parties concerned disagree on the compensation proposed, the case shall then be brought before the regular courts.

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31 Law of 4 March 2002 No. 2002-303 concerning the patients' rights and the quality of the national health system.

32 Disorder or adverse effect resulting from the medical treatment, due to the use of medicinal product or to the intervention of a health-care professional.

33 Article D.1142-1 of PHC:
the threshold of seriousness is determined by the following criteria:
- the damage must have caused permanent damage to physical and mental integrity above 24%;
- or have resulted in a work disability or temporary functional deficit of at least 6 consecutive months, or 6 months on a non-consecutive 12-month period.

ii Burden of proof

It is particularly obvious that questions and procedural issues relating to the burden of proof are seen by the different parties to be of real practical significance.

Pursuant to Article 145 of the French Code of Civil Procedure (CPC), it is possible, prior to any trial, to obtain the necessary and relevant information, to establish proof of the facts or request the admissible investigation measures – including upon request.

The plaintiff may ask the judge to appoint an expert to draft an expert's report, on the condition that a legitimate reason for doing so is given. The assessment of whether or not a reason is legitimate requires examination in particular of the utility of the measure sought in regard to the further litigation,[34] and the relevance of the investigations requested.

Conversely, such a measure will be refused if it is considered 'unnecessary'. Thus, the judges refuse to order an expert to issue a report when they consider that there is sufficient evidence to rule, or when the measure sought is not likely to enable them to settle the dispute.[35]

Furthermore, on the basis of established practice and case law, judges consider that if the action based on the future litigation is time-barred, there is no legitimate reason to order the measures sought on the basis of Article 145 of the CPC.[36] In practice, Article 145 of the CPC is frequently used to seek an expert report in order to clearly establish the existence of the damage and its extent.

Concerning the burden of proof in regard with the defect of the product, pursuant to Article 1386-4 of the French Civil Code a product is defective 'when it does not provide all the safety that can be legitimately expected from it'.[37]

Article 1386-4 also provides that the safety of a product, which can be legitimately expected, has to be assessed through all the circumstances concerned, including the presentation of the product, the reasonably expected use of the product and the time when the product was put into circulation. A product shall not be considered defective for the sole reason that a better product has been subsequently put into circulation.

The burden of proof in relation with the causal link between the damage and the defect of the product concerns the certainty of the causal link. The French jurisdictions previously required a direct and certain causal link, but judges now admit 'proof by presumption' when these presumptions are 'serious, precise and concordant'.[38] The French courts definitively acknowledge that mere non-concordant presumptions cannot

34 Tribunal of First Instance, Rouen, Referee's Order of 6 December 2001, *Laboratoire Bayer v. X*, Tribunal of First Instance, Toulouse, Referee's Order of 11 December 2003, *Société Aventis Pasteur MSD v. Carine Barbier*.

35 Supreme Court, com, 17 March 1987, No. 85-11.130; Supreme Court, com, 18 February 1986, No. 84-10.620; Court of Appeal, Paris, 17 December 2003 No. 2003/13837.

36 Court of Appeal, Paris, 26 September 2012 No. 11/23165; Court of Appeal, Paris, 11 October 2012, No. 11/23194.

37 See Section III, *infra*.

38 See Section III, *infra*.

establish the existence of a causal link, no more than a mere possibility of a causal link.[39] However, judges clarified that the genetic predispositions or the previous state of health of the victim prevents the characterisation of a causal link between the medication and the damage suffered.[40]

iii Defences

As mentioned above, 'the safety that can be legitimately expected from the product' is notably assessed in the light of the product's presentation. Indeed, this information will influence the legitimate expectation of the user about the safety of the product, and must therefore be regarded as inseparable from the product in the assessment of the defectiveness. In this respect, the more information provided to consumers, the lower the chances of characterising the defect of the product. Therefore, concerning medicinal products, pharmaceutical companies have a strong incentive to provide exhaustive information in the summary of the product characteristics (SPC) and in the package leaflet.

Another legal defence may consist in contesting the causal link between the damage and the defect of the product, with the support of the world scientific literature related to the occurrence of the disease. This literature can help prove that the product, under the acquired scientific data, could not be a cause of the damage suffered.[41]

Moreover, Article 1386-11 of the FCC provides several grounds of exoneration for the manufacturer. The producer or the distributor cannot be found liable if he proves that he did not put the product into circulation, or that the product was neither manufactured by him for sale or any form of distribution. He can also argue that the defect is due to compliance of the product with mandatory regulations issued by the public authorities.

Finally, the manufacturer can also prove, alternatively or in addition, that the defect that caused the damage did not exist at the time the product was put into circulation, or that the state of scientific and technical knowledge at the time the product was put into circulation did not allow the manufacturer to discover or identify the defect concerned.

The ECJ clarified that the state of scientific and technical knowledge must be examined through an objective assessment of the most advanced level of knowledge, regardless of the industrial sector concerned.[42]

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39 Supreme Court, civ I, 23 September 2003, *Laboratoire GlaxoSmithkline v. Mme Morice*; Supreme Court, civ II, 31 March 1983, bull, civ, 1983 II, 89.

40 Supreme Court, civ II, 17 January 1990, No. 88-17.631 ; Supreme Court, civ I, 22 January 1991, Bull civ I No. 30.

41 See, for example, Tribunal of First Instance, Nanterre, 13 February 2014, *Leleux v. Zambon France*.

42 ECJ, 29 May 1997, *Commission of the European Communities v. United Kingdom of Great Britain and Northern Ireland*, Case C-300/95.

iv Personal jurisdiction

Article 1386-6 of the FCC provides that a producer of a finished product shall be defined as the producer of any raw material or of any component part and any other person who, by attaching his name, trademark or other distinguishing feature on the product presents himself as the producer.

Without prejudice to the liability of the producer, any person who imports into the European Union a product for sale, hire, leasing or any form of distribution in the course of his business is deemed to be a producer and shall be responsible as a producer.

In addition, where the producer of the product cannot be identified, each supplier of the product is treated as a producer unless he informs the injured person of the identity of the producer or of the person who supplied him with the product within three months from the date the victim notified the claim.[43] In this respect, Article 1386-16 of the FCC provides that the rights conferred upon the injured person against the producer expire 10 years from the date the product was put into circulation, unless the injured person has, in the meantime, brought a case against the producer.

Moreover, Article 1387-17 adds that a limitation period of three years applies to proceedings for the recovery of damages. The limitation period begins to run from the day on which the plaintiff became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.[44]

Where the product is manufactured in a foreign country and sold in the French jurisdiction, this sale within the French territory is sufficient to expose the manufacturer or producer to liability before the French jurisdictions. Indeed, Article 14 of the FCC states that the foreign party may be summoned to appear before the French courts for the enforcement of the obligations contracted either in France or in foreign countries, with a French citizen. In addition, and more substantially, Article 5 of the EU Regulation No. 44/2001 of 22 December 2000, on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters,[45] allows and recognises the French jurisdiction, especially when the damage is suffered in France.

French criminal law is also applicable to offences committed within the French jurisdiction. A criminal offence shall be deemed to be committed within the French

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43 See, also, ECJ, 9 February 2006, *Declan O'Byrne v. Sanofi Pasteur MSD*, Case C-121/04; ECJ, 2 December 2009, *Aventis Pasteur v. OB*, Case C-358/08.

44 Court of Appeal, Grenoble, 27 June 2011, *Robveille v. GlaxoSmithKline*; Court of Appeal, Toulouse, 24 January 2012, *El Hannoui v. GlaxoSmithKline*; Court of Appeal, Paris, 4 September 2012, *Bitton v. Sanofi-Aventis France*; Court of Appeal, Paris, 26 September 2012, *MSD France v. Bitton*; Court of Appeal, Paris, 11 October 2012, *Blouzat v. Sanofi Aventis France*; Court of Appeal, Rennes, 23 January 2013, *Raoul v. GlaxoSmithKline*; Tribunal of First Instance, Versailles, 4 April 2013, *Devoucoux v. Sanofi Pasteur MSD*; Court of Appeal, Versailles, 12 September 2013, *Sophie X v. GlaxoSmithKline*; Tribunal of First Instance, Nanterre, 13 February 2014, *Leleux v. Zambon France*.

45 JOUE, L-12/1, 16 January 2001 – See also, from the 1 January 2015, EU Regulation No. 1215/2012 of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, JOUE, L-351/1, 20 December 2012.

territory as long as one of the facts constituting the offence concerned is located within France. French criminal law is also applicable whenever the victim is of French nationality at the time of the offence, regardless of whether the crime was committed by a French national or a foreign national, and even if the offence took place outside the French jurisdiction.[46]

v Expert witnesses

In proceedings before the civil courts, as mentioned in Section IV.ii, *supra*, Article 145 of the CPC is frequently used by French judges in practice, in order to obtain an expert report which shall identify the damage, its extent and the existence of a causal link between the damage suffered and the alleged defect of the product.

Both parties are permitted to retain industry or subject-matter experts as a part of their defence. The victim can present an expert from his insurer, for example, while pharmaceutical companies, for instance, could use an expert report compiled by their own experts as part of their defence.

The French criminal courts also permit testimonies or evidence from expert witnesses, including during procedures connected with a crime where a jury is mandatory.

vi Discovery

One of the main differences between the rules of procedural law in common and civil law systems lies in the faculties that correspond both to the parties and to the judicial authority in the application of discovery in finding material evidence. Indeed, in civil law systems, there is no need to apply discovery, given that proceedings tend to be written rather than oral, and therefore there is no tacit or strategic advantage to be gained from applying the element of surprise. Even though a phase similar to that of pretrial (beginning with the allegations or pleading) does exist in civil law systems, the investigative powers offered to the parties are minimal when compared with those corresponding to the parties in common law systems. In this regard, there are no such available discovery methods regarding product liability cases before the French jurisdictions.

vii Apportionment

In situations where several persons are liable for the same damage, the protection of the consumer requires that the injured person should be able to claim full compensation for the damage from any one of them.

A fair apportionment of risk between the injured person and the producer or the distributor implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances. Therefore, the liability of the producer remains unaffected or may be reduced by acts or omissions of other persons having contributed to cause the damage. The contributory negligence of the injured person may also be taken into account to reduce or disallow such liability.

46 Article 113-2 and 113-7 of the FCC.

viii Mass tort actions

As mentioned in Section I, *supra*, Law No. 2014-344 was adopted by the French parliament on 17 March 2014 and embraces class actions.

Therefore, the French class action model will enable an accredited association, for the defence of representative consumers at the national level, to sue companies before a civil court in the name of several plaintiffs in order to obtain compensation for the damages suffered by individual consumers placed in a similar situation (i.e., a situation that has a common cause and failure by a professional or company to fulfil its legal and/or contractual obligations).[47]

ix Damages

The damages potentially recoverable against the manufacturer for product liability mainly concern the impairment of physical integrity (death or injury), and all the resulting damages whether or not they have economic consequences. Damages can include medical or pharmaceutical expenses, expenses related to requiring assistance from a third person, moral prejudice (pain and suffering, compensation for disfigurement and loss of amenity), direct material prejudice (work disability), and indirect material prejudice (revenue loss of subsidies). They also include the damage to goods and property (damage resulting from the destruction or deterioration of goods, economic damages, operating losses, loss of use, loss of profit, expenses caused by the damage to goods, etc.).[48]

In French civil law, damages are strictly limited to compensation. For this reason, punitive damages are not used since they are deemed to be in contrast with the principle of compensation, which has been promoted as a fundamental and mandatory principle governing the civil liability system.

However, there may be criminal penalties in certain circumstances. For example, if a victim of a defective product dies, as mentioned above, the manufacturer may be sued for manslaughter.

As an example, the maximum penalty for manslaughter, pursuant to Article 221-6 of the FCC is three years' imprisonment as well as a €45,000 fine. If a prudential obligation has been voluntarily breached the maximum penalty increases to five years' imprisonment and a €75,000 fine. Pursuant to Article 222-19 of the FCC, the maximum penalty for unintentional impairment to physical integrity is two years' imprisonment as well as a €30,000 fine. If a prudential obligation has been voluntarily breached, the maximum penalty increases to three years' imprisonment and a €45,000 fine.

47 Article L.423-1 to L.423-26 of the COC.

48 Damages resulting from injury to the product itself are excluded from product liability, but may be apprehended by the guarantee against hidden defects (Article 1641 et seq. of the FCC). Damages resulting from non-compliance of the good to the intended use are subject to the obligation of conformity (Article L 211-1 et seq. of the COC).

V YEAR IN REVIEW

In France, and in particular within the health-care sector, litigation has increased considerably in the past two years, and should be reinforced by the adoption of the class action mechanism.

Indeed, since the *Mediator* case, pending in France, an anti-diabetic drug, marketed since 1976 which was prescribed off-label as an appetite suppressant, and caused several cases of valvular disease, patients and authorities brought several actions, in particular in 2013.

Above the *Poly Implant Prosthesis (PIP)* case, and the abnormal level of PIP breast implant ruptures, or the recall of the Ceraver orthopedic prostheses, the French government and the ANSM contributed to a so-called 'contraceptive pills scandal' widely publicised through the media in early 2013. In January 2013, the ANSM suspended the marketing authorisation of Diane 35, and its generic treatments against acne, also prescribed off-label as an oral contraceptive, given the risk of venous or arterial thrombosis. However, the European Commission decided on 15 July 2013, that, contrary to the French Authority's decision, the risk-benefit balance remained favourable, but that the prescription should be restricted. Following the decision of the European Commission, the ANSM initiated a procedure to inform pharmaceutical laboratories that the marketing authorisation's suspension was withdrawn. A similar legal and regulatory imbroglio focused on the third and fouth generation of pills with the same result. However, these regulatory and legal actions have drawn litigations before the courts initiated by a lot of patients.

The ANSM, again, in June 2013, issued a general alert on a possible error of the diuretic drug Furosemide's packaging, which was suspected of containing sleeping pills, based on a single report. The Agency decided to recall every batch of the drug as a 'precautionary measure' and to stop the corresponding manufacturing lines. This case was given wide media coverage, despite the fact that, after several months, the investigation concluded that it was a possible error on the part of the patient concerned and of the pharmacist involved.

In October 2013, several complaints for manslaughter were filed against a new oral anticoagulant medicinal product, suspected to cause life-threatening bleedings, which is, however, an expected side effect of the drug concerned.

Finally, in December 2013, victims of the alleged adverse effects of Gardasil, a vaccine against cervical cancer, have filed complaints for unintentional impairment to physical integrity. The victims claimed that they had contracted severely debilitating diseases in the weeks and months following vaccination without having any medical history.

Beyond the increase of civil and criminal litigations in 2013, which can be considered as a key and central new factual and legal fact in particular within the health sector, the possibility to now embrace the class action mechanism in France will without a doubt multiply the potential risk of litigations in all the industrial sectors, which will lead companies to adopt renewed and protective behaviours or to reinforce them, in terms, for example, of internal compliance and audit, which will have to duly consider the whole regulation of the sector concerned (regulatory obligations, transparency rules, or conflict of interests, for example).

Appendix 1

ABOUT THE AUTHORS

CHRISTOPHE HENIN

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After having received a PhD in European and pharmaceutical law, Christophe Hénin, partner, founder of the firm in 2005, was previously a partner of the US law firm Proskauer Rose. Christophe has a comprehensive expertise and regularly assists eight out of the ten most important innovative pharmaceutical companies in every area of pharmaceutical law, in European and French law, and intervenes in product liability, regulatory, competition or distribution law cases, in civil, criminal, competition and arbitration litigations. Christophe has built close relationships with government institutions, public and administrative authorities, as well as with the pharmaceutical and health associations.

In 2013, Christophe was particularly active within product liability cases and issues, in particular within the health sector in France and at the European level. He had notably to manage many cases within the 'contraceptive pill scandal' for several pharmaceutical companies, as well as the Furosemide case, and was entrusted with advising the pharmaceutical manufacturer on the criminal complaints issued against the oral anticoagulant medicinal product.

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