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New class action regime in France affecting healthcare and pharmaceutical companies

Introduction

Class action litigation has long been a hallmark of American jurisprudence, but it is a newer and growing litigation device in many other countries. While the Supreme Court of the United States is arguably making class actions more difficult to pursue (as reflected in its recent Spokeo, Inc. v. Robins ruling, explaining, in a putative class action, that a showing of concrete and particularized injury is required to establish standing), France has enacted the Loi de santé, which goes into effect on July 1, 2016, and will permit class action litigation in France within the healthcare and cosmetic product industries.

The Loi de santé is not France's first foray into class actions. Antitrust and consumer class action litigation has been available in France since the Consumer Act (the Loi Hamon) went into effect on October 1, 2014. To date, only seven consumer class actions have been filed under the Loi Hamon. While healthcare class actions may follow a similar path, it is equally possible that this will be a much more active area of class action litigation.

Key Points

- **What is the class action mechanism provided for in the Loi de santé – and what claims does it permit?**

The class action mechanism provided for in the Loi de santé, which was motivated by a series of high-profile French healthcare scandals, goes into effect in France on July 1, 2016. Amongst other features, the Loi de santé introduces a healthcare industry class action mechanism that allows identically or similarly situated "healthcare system users" to group their claims for bodily harm against healthcare and cosmetic product manufacturers, suppliers and service providers.

For health-product-related claims, bodily harm must have been caused by specific health products controlled by the French National Drug and Health Products Safety Agency and set out in the French Public Health Code. The Code's non-exhaustive list of health products includes pharmaceutical drugs, contraceptives, biomaterials, medical devices, organs and other human- or animal-based products, as well as software used by biomedical laboratories in biomedical testing.

Class actions may be brought for bodily harm suffered prior to the law's effective date (including for products that are no longer on the market), provided that the applicable ten-year statute of limitations period for the action has not expired.

- **Who can pursue a class action under the Loi de santé?**

The Loi de santé only permits organizations known as "authorized health system user associations" (of which there are over 450 in France) to bring an action on behalf of healthcare system users. To initiate a class action, the authorized association must identify at least two plaintiffs ("test" users) who have suffered the harm that the authorized association seeks to redress. Nothing in the law requires the test users to be from France. Other eligible class members have the opportunity to "opt in" after liability has been determined.

There is no limit to the number of authorized associations that can simultaneously pursue a class action claim concerning the same product or service. Moreover, because class action proceedings need not be publicized unless and until a determination of liability has been made, there is no way to be entirely sure whether another authorized association is already pursuing the same or similar claims.

- **How is liability determined?**

The French court assigned to the authorized association's case will rule on (i) whether the proposed class action can proceed; (ii) the existence and scope of any liability; (iii) the criteria to be used in identifying potential class members; (iv) how to determine damages (e.g., based upon financial loss or pain and suffering); and (v) how to provide notice of a final liability judgment to potential class members. While the assigned court establishes criteria for determining damages, it does not make plaintiff-specific damages determinations at the liability phase.

A liability determination is subject to appeal, and the French appeals process typically lasts between twelve and eighteen months. Once any appeals have been exhausted, and if liability is ultimately found against the defendant, the ruling is publicized and other healthcare system users are given a chance to opt into the class. They will be given at least six months, and potentially as long as five years, to make this decision.

- **How are damages determined?**

Because bodily harm suffered in medical injury cases can vary greatly from one person to another, the Loi de santé provides for damages calculations to be made on a case-by-case basis for each individual who opts into the class. After opting into the class, a healthcare system user must file a request for individual compensation. The defendant can choose to award or reject the compensation requested by the healthcare system user. If no agreement can be reached, the healthcare system user can seek court intervention to determine a damages award.

- **Will this process completely preclude other litigation on the same claims or issues?**

No. As noted above, any number of authorized health system user associations can commence a class action relating to the same facts, conduct and injury – and can do so at any time until a judgment on the defendant's liability has been rendered in one class action. Moreover, while a judgment on liability in one class action will preclude the initiation of any additional class action, it will not stop any previously filed class actions from continuing. In practice, it is very possible that multiple class actions relating to the same alleged facts, conduct and injury will be consolidated before one court, although there is no guarantee that this will occur.

In addition, healthcare system users can pursue individual actions, either concurrently with or following litigation of a class action, provided that they do so within the statute of limitations period and do not opt into a class. In addition, class members may initiate individual proceedings based upon issues or claims that were not part of the underlying class action litigation, or seek damages not available through the class action system. No double recovery is allowed.

A judgment in an individual healthcare action has no preclusive effect on healthcare class actions, nor will a judgment in a class action prohibit healthcare system users from either commencing or continuing an individual action. Thus, if a class action results in a pro-defendant finding of "no liability," individuals can simply choose not to opt into the class and instead commence an individual action in which the issue of liability will be decided

anew.

The preclusive effect of a French healthcare class action judgment on parties' claims and defenses in US courts is unclear. What is clear, however, is that a negative outcome in a French healthcare class action lawsuit will be published and publicized, and may then impact, or generate interest in, litigation in the United States – particularly as more US class action firms establish offices in Europe and focus on potential litigation that can cross borders.

- **Is there the possibility of inconsistent judgments?**

Yes. Even after a judgment has been rendered in one class action, it is possible that another court hearing the same claims in a different, already-initiated class action may reach a different (opposite) determination on liability. Moreover, individual claims can be brought at any time within the limitations period, and judgments in individual healthcare actions need not be consistent with judgments in healthcare class actions, and vice versa. In these scenarios, however, a French court would likely at least consider a prior judgment or finding of fact.

Moreover, there is the possibility of inconsistent judgments between courts in France and in the United States that rule on the same conduct and claims. There is also the possibility of competing litigations outside of France, especially because litigants in the United States and elsewhere may not be aware of any pending French class action.

- **Does the Loi de santé have extraterritorial reach?**

Unlike the Loi Hamon, which specifically provides that the Paris Tribunal de grande instance has exclusive jurisdiction where a defendant is domiciled abroad, the Loi de santé is silent as to jurisdictional reach. That said, nothing in the Loi de santé expressly prevents (1) healthcare system users located outside of France from opting into a class or (2) pursuit of an action against a defendant domiciled outside of France (subject to France's general rules regarding jurisdiction). More generally, pursuant to French rules of private international law, French courts may assert jurisdiction over a defendant domiciled outside of the European Union where:

- a company delivers goods to, or provides services in, France;
- the underlying conduct occurred in France, or the alleged bodily harm was suffered in France;
- a company is one of multiple co-defendants, one of which is domiciled in France, provided that the claims against the co-defendants are closely connected; or
- a company has consented to the jurisdiction of the French courts.

- **Is US-style discovery available in French healthcare actions?**

While broad discovery obligations do not exist in France, foreign litigants frequently seek broad discovery in the United States pursuant to 28 U.S.C. § 1782. With class actions now permitted in France in the healthcare industry, healthcare companies with US headquarters or significant US operations may find themselves subject to broad discovery requests in aid of these French healthcare class actions.

Only seven class actions have been brought under the Loi Hamon since October 2014, and it remains to be seen whether the new healthcare class action mechanism created by the Loi de santé will generate more class activity. US healthcare clients should nevertheless be mindful of the potential interplay between US and French healthcare litigation, and of the various risks identified above – including the risks of protracted litigations and inconsistent judgments – in defending against potential class actions in France.

If you would like to discuss this development, please contact Dimitri Lecat, Alexandra Szekely, Linda H. Martin or Timothy Harkness.

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