Chambers AND PARTNERS

CHAMBERS GLOBAL PRACTICE GUIDES

Life Sciences 2026

Definitive global law guides offering comparative analysis from top-ranked lawyers

France: Trends and Developments

Liliana Eskenazi and Pauline Lecrenais
Fréget Glaser & Associés

FRANCE

Trends and Developments

Contributed by:
Liliana Eskenazi and Pauline Lecrenais
Fréget Glaser & Associés

Fréget Glaser & Associés was founded in 2014 as a spin-off from a leading international antitrust practice and has become a firmly established high-end boutique in competition and economic regulation, with a distinctive focus on the pharmaceuticals and broader life sciences sectors. Bringing together 20 lawyers, including six partners, based in Paris and active before both French and EU courts and authorities, the firm designs sophisticated, multi-forum litigation and regulatory strategies that align closely with clients' commercial objectives. Its team combines sharp expertise in competition, EU, public, commercial and civil law with a granular understanding of highly regulated industries, enabling it to address complex dominance, pricing, distribution and state intervention issues in markets where compliance is critical to business performance. Acting for innovative pharmaceutical and biotech companies, industry associations and other health sector stakeholders, the firm handles complex investigations, high-value litigation and advisory mandates in which it actively fuses legal and economic analysis from the outset to secure sustainable outcomes for its clients in fast-moving markets.

Authors

Liliana Eskenazi is a partner at Fréget Glaser et Associés and an accomplished EU and competition/antitrust lawyer with extensive experience in both advisory work and litigation. She handles complex cases before the EU and the French courts, as well as before the administrative authorities (European Commission, French Competition Authority). Well-versed in all antitrust and distribution law matters, Liliana also handles multi-jurisdictional merger control cases within the context of corporate transactions. She has developed strong expertise in regulated sectors (pharma, energy, telecoms), and in high-stakes matters where intellectual property and competition law intersect.

Pauline Lecrenais is an associate and at Fréget Glaser & Associés specialising in competition law and regulated sectors, with a strong focus on the healthcare and digital industries. She represents French and international companies, including major pharmaceutical players, in high-stakes competition and private enforcement cases before the French and European courts and the French Competition Authority.

Fréget Glaser & Associés

7 rue Royale
75008
Paris
France

Tel: +33 1 47 23 78 80
Email: contact@freget-glaser.fr
Web: www.freget-glaser.fr

Contributed by: Liliana Eskenazi and Pauline Lecrenais, **Fréget Glaser & Associés**

When originator pharmaceutical companies develop a new medicinal product and successfully navigate all the scientific and regulatory steps required for its approval, they benefit from a period of patent protection during which they enjoy market exclusivity, designed to reward their research and development (R&D) efforts. Once this period expires, generic or biosimilar companies are free to enter the market with competing products.

As patent expiry approaches, originator companies typically seek to anticipate the loss of exclusivity and the entry of generic or biosimilar competitors, and to plan their commercial strategy accordingly. In doing so, they must bear in mind that, as a result of the exclusivity they have enjoyed, they will frequently hold a "dominant position" within the meaning of competition law. All the more so since the emergence of generic/biosimilar competition may lead to the definition of a narrow, molecule-level relevant market limited to medicines containing the same active ingredient.

Such a position comes with a "special responsibility" not to abuse it: originator companies can legitimately prepare for the arrival of competitors, provided that they refrain from conduct that does not constitute competition "on the merits" and that could impede or delay the entry of generic or biosimilar products, thereby amounting to an abuse under antitrust law and potentially resulting in the imposition of a substantial financial penalty.

When they design an action plan to prepare for generic or biosimilar entry, originator companies must therefore factor the "umbrella effect" of competition law into every aspect of their strategy.

Drawing on recent French decisions that have, in some instances, inspired European cases, this article aims to highlight key competition concerns that originator companies need to be aware of and to set out practical safeguards applicable both to strategies implemented before patent expiry and to conduct adopted after expiry.

Before Patent Expiry: Originator Companies' Options Constrained by Competition Law

A few months before a patent expires, an originator company may consider several courses of action. While some – such as initiating a new R&D programme to develop a medicine addressing a different therapeutic need – may not raise particular concerns, most must be implemented with caution so as not to hinder competitors' entry into the market.

Competition concerns may, for example, relate to the originator company's conduct in relation to intellectual property rights and in its interactions with the health authorities.

Limited exercise of intellectual property rights

Divisional patents – innovation, yes; artificial extension of exclusivity, no

Originator companies are entitled to file divisional patent applications to protect their inventions.

However, there is a risk that divisional patents, although lawful under patent rules, may be perceived as serving primarily to artificially extend the exclusivity period for an originator product rather than to protect an innovation.

Such conduct may amount to an abuse of a dominant position under Article 102 of the Treaty on the Functioning of the European Union (TFEU) where strategic patenting hinders or delays generic entry – for example, by increasing litigation costs, securing injunctions or prolonging legal uncertainty for competitors. This concern was central to the recent *Teva Copaxone* case, in which the European Commission imposed a fine of EUR462.6 million on Teva for abuse of a dominant position in relation to its multiple sclerosis medicine Copaxone by misusing divisional patents and other practices to delay competition (EU Commission, 31 October 2024, *Teva Copaxone*, AT.40588).

Key competition law takeaways – before filing divisional patent applications, originator companies should ensure that:

- the filing reflects real innovation, supported by robust documentation, and that the relevant parts

of the parent filings (and the differences) are disclosed and clearly explained;
- its overall IP strategy cannot reasonably be regarded as being aimed at artificially prolonging legal uncertainty and delaying generic/biosimilar entry – for example, by filing cascades of divisional patent applications at different times, defending those patents before the European Patent Office, enforcing them before national courts, and then strategically withdrawing them shortly before revocation to avoid a formal invalidity decision.

Settlement to resolve a patent validity dispute, yes; settlement to delay competitors' market entry, no

A generic company may challenge the validity of an originator's parent patent or its secondary patent(s) before they expire, and the two companies may ultimately reach an agreement to settle the dispute. Such agreements can produce pro-competitive effects by bringing legal disputes to an end, thereby helping to eliminate invalid intellectual property rights or, conversely, to preserve valid ones.

However, they may also raise competition law concerns where they result in so-called pay for delay agreements. Settlement agreements between originator and generic companies may indeed be anti-competitive where the generic agrees to delay or restrict its market entry in return for a value transfer from the originator – whether through direct payments or other advantages – and this leads to consumers paying higher prices than they would have in the absence of the agreement. Such "pay for delay" agreements have given rise to well-established case law based on Article 101 TFEU, including very recent decisions of the Court of Justice (CJEU, 27 June 2024, *Servier*, 9 decisions; CJEU, 23 October 2025, *Teva/Cephalon*, C-2/24 P).

Key competition law takeaways – before entering into any settlement that involves a value transfer between an originator and a generic/biosimilar company, the parties should:

- verify that the transfer is objectively justifiable – for example, compensation for litigation costs or payment for goods or services provided by the generic/biosimilar – and that the settlement does not risk going beyond "normal" competition on the merits by acting as an incentive for the generic/biosimilar to stay out of the market or to delay its entry (eg, a payment that offers the generic a risk-free profit without having to launch its product, etc); and
- keep all evidence that explains the economic/commercial rationale for their settlement and demonstrates that it facilitates, rather than restricts, competition.

Limited contact with health authorities regarding competing products

Pharmaceutical companies may communicate with health authorities in the context of their statutory and regulatory obligations, provided they comply with the applicable rules.

However, the situation is different for an originator company that approaches a health authority before the expiry of its patent to draw attention to a competing generic product.

Under EU and French law, a generic product is defined as one whose key characteristics – safety, efficacy, and bioequivalence with the reference (originator) medicine – have been recognised by the competent health authorities.

This assessment by the health authorities cannot, in principle, be challenged by originator companies, and competition authorities have treated any "unjustified" interference with it as abusive conduct.

For example, the European Commission reiterated in the recent *Teva Copaxone* decision that there is "no room for scientific debate" on generic products properties (case AT.40588, pt 1531). An originator company would therefore not be entitled to challenge a generic product, and any scientific debate concerning a generic product could emerge (i) only if "new relevant evidence" were available and (ii) on condition that this evidence is brought to the authorities that are competent to modify the generic product's marketing authorisation through the "appropriate procedures" (pt 1531) (the Commission also specifies that if Teva had genuine doubts about the generic products, it should have used the appropriate procedures "for pharmacovigilance", see pt 1620).

The French competition authority (FCA) *Durogesic* decision also addressed this issue, but from a different angle, as the originator company had actually raised its concerns with the health authority. In this decision, the FCA sanctioned Janssen-Cilag and Johnson & Johnson for abusing their dominant position, first by intervening in a "legally unfounded" manner with the health authority, and subsequently by disparaging generic products to healthcare professionals. As regards the first objection, the originator company allegedly presented to the health authority arguments that could prompt it to take a decision inconsistent with the legal framework to which it is subject – ie, to persuade it to refuse to grant generic status to products competing with Durogesic, despite lacking the competence to do so (FCA, decision 17-D-25 of 20 December 2017).

A closer look at the details of this case shows that it was Janssen-Cilag's "head pharmacist" (*pharmacien responsable*) who contacted the health authority to raise public health concerns relating to fentanyl (the active substance in Durogesic, which is 100 times stronger than morphine), in particular in light of differences in the pharmaceutical forms of the originator and generic products that could affect how the fentanyl is dispensed, and thus pose a risk to patients. The FCA did not dispute this scientific evidence and did not reproach the company for having presented to the health authority false or misleading information regarding competing products, but rather for putting forward arguments which it considered to be "without legal basis". It thus concluded that the company "unduly interfered in the health authority's decision making process" and had put forward "arguments likely to induce it to adopt a decision contrary to the legal framework binding upon it" (pt 435). The case is pending before the European Court of Human Rights, which is called upon to assess whether aspects of the sanction for this conduct are compatible with the freedom of expression protected by the Convention.

Key competition law takeaways – in light of recent case law, originator companies should not criticise the safety, efficacy or bioequivalence of competing generic or biosimilar products that have complied with the regulatory process and obtained the necessary approvals.

If a company nevertheless considers that there is a genuine public health issue with one of these products, it may raise this only with the competent health authorities, taking great care to:

- use the appropriate procedures;
- ensure that its intervention rests on a clear legal basis;
- submit relevant, objective and scientifically robust evidence, preferably from independent sources; and
- ensure that it never presents information in a biased or misleading manner, whether by selectively quoting certain passages, disclosing only some information, or otherwise giving a distorted overall picture.

After Patent Expiry: Competition Law Continues to Constrain the Conduct of Originator Companies

After patent expiry, an originator company may retain a dominant position for a significant period and must therefore ensure that all aspects of its conduct remain within the boundaries of competition on the merits.

Competition concerns frequently arise in relation to the design of commercial strategy towards hospitals and the messages conveyed to healthcare professionals.

Pricing strategy at patent expiry must not hinder market entry

Pharmaceutical companies are, in principle, free to determine the prices at which they supply hospitals. During the period of market exclusivity, they may set prices at their discretion, and once patent protection has ended and generic or biosimilar competitors enter, they are entitled to adjust their commercial strategy, including by lowering prices.

However, where an originator company holds a dominant position, EU and French competition law impose specific constraints on how such price adjustments may be implemented.

Key competition law takeaways – dominant pharmaceutical companies cannot simply mirror competitors' prices at patent expiry without further analysis. They must in particular avoid:

- setting prices below cost (predatory pricing), typically identified where prices are below average variable cost or between average variable cost and long-run average incremental cost as part of a plan to eliminate a competitor;
- offering products at abnormally low prices (Article L. 420 5 of the French Commercial Code);
- granting loyalty or exclusivity rebates that incentivise hospitals to obtain all or most of their products from the dominant company;
- conditioning the purchase of one product on the purchase of another separate product (tying); and
- co-ordinating prices, including minimum sales prices, or other commercially sensitive conditions with competitors.

When determining their commercial strategy, originator companies must ensure that any price reductions accompanying the loss of exclusivity do not impede the entry of generics or biosimilars and that the underlying pricing methodology is clearly documented in their internal documentation, objective and defensible from an economic and legal standpoint.

No disparaging communication with healthcare professionals

Pharmaceutical companies are free to share information and promote their products to healthcare professionals (doctors, pharmacists etc), provided they comply with the applicable regulatory framework, in particular the rules on advertising.

However, they must ensure that the information communicated to healthcare professionals cannot be regarded as a disparaging practice intended to hinder the entry of generic or biosimilar products into the market.

Competition authorities indeed adopt a relatively strict stance when an originator company criticises a generic product in its communications with healthcare professionals, given the "influence" it has over them. They have made clear that, even where it has legitimate health concerns about the safety or efficacy of competing generic or biosimilar products, it is not for the originator to "alert" healthcare professionals. The responsibility for reporting such risks lies solely with the holder of the marketing authorisation.

The FCA was the first to take up concerns about disparagement by originator companies and to treat such practices as a form of abuse within the meaning of Article 102 TFEU (see decisions 13-D-21, 13-D-11, 17-D-25). This enforcement trend has now been echoed by the European Commission, which has recently examined similar denigration-type conduct in the *Teva Copaxone* (AT.40588) and *Vifor* (AT.40577) cases. Across these cases, competition authorities typically criticise the following features of disparagement practices by dominant originator companies:

- targeting healthcare professionals with communications that question the safety, efficacy, quality or regulatory status of authorised generic or biosimilar products, in contradiction with the assessments of competent health authorities;
- disseminating incomplete, selective or out-of-context information, or alarmist wording, to "cast a doubt" in the minds of healthcare professionals and thereby discouraging prescription, substitution or uptake of competing products; and
- integrating such messaging into a broader exclusionary strategy (for example, alongside patent tactics or pricing conduct) with the objective of hindering entry of competitors.

Some originator companies have argued that their conduct is justified by the exercise of their freedom of expression protected by Article 10 of the European Convention on Human Rights (ECHR). While this argument is, in principle, admissible, recent case law indicates that a specific methodology must be applied to balance competition law and fundamental rights

The French Supreme Court (*Cour de cassation*) has very recently provided further clarification in this respect in the *Lucentis Avastin* case.

In short, Novartis, Roche and Genentech were fined more than EUR444 million by the FCA for collectively abusing their dominant position. The FCA considered that they had, first, disseminated disparaging messages that "overstated" the risks associated with the off-label use of Avastin to treat age-related macular degeneration (AMD), compared with Lucentis, which holds a marketing authorisation for that indication, and, second, conveyed alarmist/misleading informa-

tion to the health authorities about Avastin's off-label use to block or delay public initiatives aimed at facilitating and securing that off-label use (decision 20-D-11 of 9 September 2020).

The Paris Court of Appeal fully annulled this decision in February 2023. Relying on the case law of the *Cour de cassation*, it held that the companies' conduct fell within the scope of their freedom of expression protected by Article 10 ECHR, since the companies' communications related to a debate of general interest, relied on a sufficient factual basis and were measured in their tone. It therefore found that there could be no abuse within the meaning of Article 102 TFEU (Paris Court of Appeal, 16 February 2023, No 20/14632).

However, the *Cour de cassation* quashed that judgement because of the methodology applied by the Court of Appeal. According to the *Cour de cassation*, where competition rules and the fundamental freedom of expression are both at stake, the first step is to assess whether there is a potential abuse within the meaning of Article 102 TFEU by examining whether the conduct falls within competition on the merits, whether it has exclusionary effects and whether there are any objective justifications. It is only in the light of such an assessment that, where a breach of Article 10 ECHR is alleged, the proportionality of the restriction on freedom of expression resulting from that sanction can subsequently be assessed (Cass. Com., 25 June 2025, No 23-13.391). The case is pending before the Court of Appeal on remittal.

Key competition law takeaways – when communicating with healthcare professionals, originator companies must ensure that:

- their conduct remains strictly within the bounds of competition on the merits;
- they provide only objective information, presented in a measured manner and supported by robust evidence;
- their conduct does not risk preventing or slowing the market entry of competing generic or biosimilar products; and
- they refrain from providing information that is inaccurate, incomplete or ambiguous, and from sharing any "doubts" they may have about the safety, efficacy or bioequivalence of competing generic or biosimilar products.

CHAMBERS GLOBAL PRACTICE GUIDES

Chambers Global Practice Guides bring you up-to-date, expert legal commentary on the main practice areas from around the globe. Focusing on the practical legal issues affecting businesses, the guides enable readers to compare legislation and procedure and read trend forecasts from legal experts from across key jurisdictions.

To find out more information about how we select contributors, email Rob.Thomson@chambers.com