if measures less restrictive of trade would be likely to achieve its broader and more general health objectives) subtly moderates free movement and other common-market principles in favour of national autonomy. This was neatly exemplified in the decision of the Inner House of Court of Session. Furthermore, the principles provided by the Court of Justice to guide the review undertaken by the national court in the application of the principle of proportionality have begun to create a clearer framework for the appraisal of the weighing of competing EU and national interests.

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## REVERSE PATENT SETTLEMENTS AND EU COMPETITION LAW

THE judgment of the General Court in Case T-472/13, *Lundbeck v Commission* EU:T:2016:449 is the first decision of the CJEU on the application of EU competition law to reverse patent settlements. It confirms that Article 101 TFEU applies to agreements that restrict potential competition, and discusses the circumstances in which reverse patent settlements will amount to a restriction by object. However, the judgment provides little by way of practical guidance for those involved in negotiating patent settlements and leaves many questions unanswered.

"Reverse patent settlements" between originator drug companies and their generic counterparts are so called because they involve the originator making a payment to the generic. They are not necessarily problematic under EU competition law, where they seek to settle a genuine patent dispute and do not prevent generic entry. But they may infringe Article 101 TFEU where the originator pays the generic to stay out of the market (referred to as "pay-for-delay"). The concern is that the originator is able to continue earning monopoly profits even after its patent has expired, frustrating the normal effect of generic entry (which causes prices to fall). The European Commission has had reverse settlements between originators and generics firmly within its sights since their widespread usage became apparent during the course of its pharmaceutical sector inquiry in 2008–09, and it continues to monitor them, publishing annual update reports.

However, the Commission's interest in the reverse settlement agreements entered into by the Danish originator, Lundbeck, with four generic firms, pre-dates the sector inquiry and goes back to 2003, following a tip-off from the Danish competition authority. The Commission investigated, carrying out dawn raids between 2003 and 2006, though only opening formal proceedings in 2010. In 2013, the Commission issued an infringement decision, imposing fines totalling nearly €150 million on Lundbeck and the

generics (AT.39226, *Lundbeck* O.J. [2015] C 80/13). This was followed by infringement decisions in two other similar cases (AT.39685, *Fentanyl* O.J. [2015] C 142/21, and AT.39612, *Perindopril (Servier)* O.J. [2016] C 393/7).

The General Court has now delivered its judgment on the appeal by Lundbeck and on the separate appeals by the generics, comprehensively dismissing the applicants' arguments. The case arose from a series of agreements entered into by Lundbeck just as the patent on the active ingredient for its citalopram antidepressant was expiring, but at a time when it still retained various patents relating to the manufacturing process. The Court agreed with the Commission that the generics were potential competitors of Lundbeck and that the agreements under which they received substantial payments, in return for agreeing to stay out of the market, amounted to a restriction by object, in breach of Article 101 TFEU. However, this "restriction by object" characterisation is likely to prove controversial, representing a stricter standard than the "rule of reason" approach favoured by the majority of the US Supreme Court in *Federal Trade Commission v Actavis* (133 S.Ct. 2223 (2013)). The Court also rejected the "scope of patent" argument, holding that Article 101 TFEU can be infringed even where the restrictions contained in an agreement fall within the scope of the patent (an approach that is consistent with the majority view in *Actavis*, 133 S.Ct. at 2231).

The proposition that Article 101 TFEU protects both actual and potential competition finds implicit support in nearly two decades of case law (see e.g. Cases T-374/94, T-375/94, T-384/94 and T-388/94, *European Night Services v Commission* EU:T:1998:98, at [137]) and is stated explicitly by the Court in *Lundbeck* (at [471]). Intuitively, it seems hard to argue that a market-exclusion agreement with a potential entrant should not engage Article 101 TFEU. But determining when a firm is a potential entrant is not always straightforward. For the Court in *Lundbeck*, the test (citing *European Night Services*) was whether, if the agreements had not been entered into, there would have been "real concrete possibilities" for entry (at [99]). Evidence of intent to enter in the near future was considered unnecessary (at [102]), as the mere existence of a potential competitor may act as a constraint (i.e. the incumbent may see the potential competitor as a credible threat, irrespective of its actual plans for entry). But what if, as here, the originator held patents that might be infringed by entry? If entry was potentially unlawful, and likely to provoke litigation, in what sense did this create "real concrete possibilities" for entry? The Court sought to square the circle in a Delphic pronouncement, noting (at [121]) that, while patents are presumed valid until revoked or invalidated by a competent authority or court, "that presumption of validity cannot be equated with a presumption of illegality of generic products validly placed on the market which the patent holder deems to be infringing the patent".

That logic is hard to follow. While "at risk" entry is not presumed to be unlawful (in the sense that the patent holder still needs to prove that the generic product infringes its patent), it would be unlawful if successfully challenged by the patent holder. The Court swept aside such objections, noting that "at risk" entry, with the possibility of having to face infringement proceedings, "represents the expression of potential competition" in circumstances where generics are able to use production processes that have not previously been found to infringe the originator's patents (at [129]). On the other hand, the Court was probably on stronger ground in noting that the generics in this case had made significant investments with a view to entry, including obtaining or applying for marketing authorisations (at [131]). More difficult still for Lundbeck was the fact that it had agreed to make substantial payments to the generics to keep them out of the market (at [144]): if they were not credible potential entrants, why would a rational firm have done this?

The essence of a restriction by object is that anti-competitive effects are presumed, so there is no need to consider the counterfactual (i.e. how competition would have developed in the absence of the agreement) and prove actual effects on the market. Classic examples include price fixing and market sharing. This is not the same as the per se standard under US antitrust law, since a restriction by object may still escape prohibition under Article 101(1) TFEU, either because it meets the criteria for exemption under Article 101(3) TFEU, or because it is objectively necessary for the implementation of a benign agreement, and thus "ancillary". By contrast, when assessing whether a restriction by effect appreciably restricts competition, contrary to Article 101(1) TFEU, the analysis turns on the counterfactual, and anti-competitive effects must be demonstrated. However, the Court blurred this distinction when assessing whether the generics were potential competitors of Lundbeck, since the question of whether they had "real concrete possibilities" for entry necessarily implies some consideration of the counterfactual – a point that the Court fails to recognise (at [437], [472]–[476]).

For the Court in *Lundbeck*, the decisive factor leading to the conclusion that the agreements entailed a restriction by object seems to have been the size of the payments, which the Commission had labelled as "disproportionate" (at [354], [366]; cf. *Actavis*, 133 S.Ct. at 2237, referring to "large and unjustified" payments bringing the risk of significant anti-competitive effects). But the Court was also swayed by the fact that the payments were based on the profits that the generics could have expected to make if they had entered the market (at [362], [414]). Further, there was evidence that Lundbeck had doubts about the validity of its patents; the agreements with the generics therefore meant that Lundbeck was able to exchange that uncertainty for the certainty that the generics would not enter the market (at [363], [369], [401]). Arguments

by Lundbeck that the agreements enabled the parties to avoid significant litigation costs were rejected, partly it seems because the agreements made no reference to those costs (at [388]). Although the agreements did not contain an explicit no-challenge clause, the Court was satisfied that, in practice, the level of the payments removed any practical incentive to contest the validity of Lundbeck's patents (at [398], [399]). But this approach is problematic in practice. How large do payments have to be before they amount to a restriction by object? Should the fact that the payments reflected the expected profits of the generics have assumed such importance in the Court's judgment? If payments are calculated by reference to avoided litigation costs, will they be compatible with Article 101 TFEU (an approach that would appear consistent with the majority view in *Actavis* (133 S.Ct. at 2236))? The Court in *Lundbeck* did not provide clear answers to these questions.

The Court of Justice has previously rejected arguments for an expansive interpretation of the restriction by object concept (Case C-67/13 P, *Groupement des cartes bancaires v Commission* EU:C:2014:2204 at [58]). Yet, on one view, that is precisely what the Court has done in *Lundbeck*. An effects-based approach would have required proof of an appreciable restriction of competition, taking account (inter alia) of Lundbeck's market share and the level of competition in the market. The judgment is now under appeal, offering an opportunity for the Court of Justice to provide clarity on some of the difficult questions left unanswered by the General Court.

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## HYPERLINKS AND COPYRIGHT INFRINGEMENT

DOES the posting of a hyperlink to somebody else's work that has been uploaded onto the Internet infringe their copyright? Although dissenters did exist, most copyright lawyers long assumed that the answer to that question was an obvious "no". In 2014, this nonchalant approach was rejected by the CJEU in *Svensson* (Case C-466/12, EU:C:2014:76) in favour of a more complex analysis. More recently, the CJEU's approach to hyperlinks has been further developed in *GS Media* (Case C-160/15, EU:C:2016:644).

As both judgments make clear, the answer depends on the interpretation of the notion of "communication to the public". This is established as an exclusive right of copyright-holders by Article 3(1) of the Information Society Directive ([2001] OJ L 167/10). As no definition of that right is given in that provision, the CJEU has outlined it in its case law.