European General Court dismisses Lundbeck’s appeal against the Commission’s fine for delaying market entry of generic medicines

Contributor Feature Article – October 2016

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Elena Martini
Partner
UK and European patent attorney

Via Meravigli No. 16,
20123 Milan, Italy
elena.martini@martinimanna.com
By decision of 8 September 2016 in T-472/13, the European General Court (GC) dismissed Lundbeck’s appeal against the European Commission (EC)’s decision to fine it – and a number of generic companies – for delaying market entry of generic versions of Lundbeck’s anti-depressant citalopram product.

We talked about that EC decision and its background here on this blog. Basically, after the expiry of the basic patents covering citalopram, Lundbeck had entered into agreements with generic companies which provided for substantial payments in exchange for them abstaining from entering the market with generic citalopram. According to the EC, this infringed Article 101 TFEU that prohibits restrictive business practices, and caused substantial consumer harm, because it unlawfully delayed the entry of generic medicine for up to two years and the prices for citalopram remained high as a result. Hence why the EC had imposed a fine of €93.8 million on Lundbeck, further than fines totaling €52.2 million on several producers of generic medicines.

Lundbeck’s appeal before the GC was mainly grounded on the allegation that, at the time when the agreements with the generic companies were entered into, citalopram was actually still covered by a process patent, which would have been infringed by the generic companies had they launched their generic medicines on the market before its expiry. Thus, the agreements were not anticompetitive but they legitimately settled disputes grounded on Lundbeck’s valid patent.

In confirming the EC’s decision and relevant fines, the GC issued a very long and detailed decision of which we summarise hereunder just a few points.

First, the GC stated that the EC was right in considering that a competition relationship existed between Lundbeck and the generic companies at the times the agreements were stipulated, even if Lundbeck’s product was covered by a process patent which could have prevented generic companies from entering the market: in fact, “an ‘at risk’ entry is not unlawful in itself” and the generic companies “could have contested the validity of the patent on which Lundbeck relied”, or they could have produced citalopram through a different process not covered by that patent. Hence “the generic undertakings had several routes — constituting real concrete possibilities — to enter the market at the time the agreements at issue were concluded”, which possibilities were actually acknowledged by the same Lundbeck base on the evidence acquired, and “represent the expression of potential competition”. “In addition, the steps taken and investments made by the generic undertakings in order to enter the citalopram market before concluding the agreements
at issue (...) — the existence of which has not been contested by the applicants — show that they were ready to enter the market and to accept the risks involved in such an entry” (para 121-129). Moreover, it would be surprising if an undertaking as experienced as Lundbeck would have decided to pay several million euros to the generic undertakings in exchange for their commitment not to enter the market during a certain period if the possibility that those generic undertakings could enter the market was purely theoretical” (para 161).

The GC then stated that the Commission was right in finding that the agreements in issue fall within the scope of Article 101(1) TFEU amounting to restrictions of competition ‘by object’, as they contain significant reverse payments, which reduce or eliminate any incentive for the generic undertakings to enter the market for a certain period, without, however, resolving the underlying patent dispute. A significant factor in this assessment was the fact that Lundbeck “do not dispute that the amounts which they paid to the generic undertakings may have been calculated by taking into consideration the profit or turnover which those undertakings expected to make during the term of the agreements at issue if they had entered the market” (para 362). “What matters is that there was uncertainty, at the time the agreements at issue were concluded, as to the possibility, for the generic undertakings, of entering the market without being subject to injunctions or infringement actions, or of successfully challenging the validity of the applicants’ patents, and that those agreements had replaced that uncertainty, by means of significant reverse payments, with the certainty that the generic undertakings would not enter the market during the term of the agreements at issue” (para 369).

Finally, the GC concluded that the EC had correctly excluded the applicability of the exception under Art. 101(3) TFEU to the case in issue, rightly observing that this could be applied only where it was demonstrated that the agreements met the following four conditions:

(1) Contribute to improving production or distribution or to promoting technical or economic progress;

(2) Don’t impose restrictions which are not indispensable to the attainment of those objectives;

(3) Give consumers a fair share of the benefits obtained;

(4) Don’t allow undertakings to eliminate all competition or a substantial part of that competition in respect of the products in question.

On the contrary, the GC said, “it is clear in the present case that the agreements at issue, which sought to delay the entry of generics on the market by means of reverse payments, were not essential in order to preserve the applicants’ incentive to innovate. Furthermore, it is difficult to discern the benefits that consumers would derive from such agreements. Finally, the condition that all competition should not be eliminated is also not satisfied in the present case” (para 714).

In conclusion, for the first time, by this decision, the GC confirmed the EC’s findings that pay-for-delay agreements infringe the EU competition law.