Wait Three Years and Then Two Come at Once: European Commission Moves Against Pharma Patent Settlements

Matthew Hall
McGuireWoods, Brussels

In July 2012, three years after it published its final report into competition in the pharmaceutical sector in the EU, the European Commission (EC) took a significant step in two pharmaceutical patent settlement cases. Statements of Objections (SO) were sent to a number of companies concerning potentially anticompetitive activities, including principally the use of reverse payment patent settlements, relating to two products: citalopram (an antidepressant) and perindopril (a cardiovascular medicine). SOs, which are not public documents, are preliminary statements of the EC's case, but the fact that they have been sent indicates that the EC has substantial prima facie concerns.

The cases are without doubt high profile since, in particular, they are the first EC cases to address the use of reverse payment patent settlements in the pharmaceutical sector. However, on the facts available, they do not appear to be surprising, given the stance taken by the EC in this area, and in particular on the issue of such settlements.

Background – the EC's 2009 Pharmaceutical Sector Inquiry

In July 2009, the EC published the results of its very important study into competition in the pharmaceutical sector in the EU. The EC's main conclusions were that market entry of generic drugs was being unnecessarily delayed and that the number of novel medicines reaching the market was in decline. Specifically in relation to generics, on the basis of a sample of medicines that faced loss of exclusivity in the period 2000-2007 in 17 EU member states, the inquiry found that in general it took seven months after patent expiry for generic medicines to arrive. The inquiry showed that "originator companies used a variety of instruments to extend the commercial life of their products without generic entry for as long as possible." The principal strategies identified were as follows:

- patenting strategies such as patent clusters;
- disputes and litigation against potential generic competitors;
- patent settlements with generic companies; and
- various interventions before regulators and launch of follow-on products.

So far as concerns the decline of novel medicines reaching the market, the inquiry also "pointed to certain company practices that might have contributed to this phenomenon." In particular, the inquiry identified the following problems:

- patents aimed exclusively against the development of a competing product;
- litigation against other originator companies; and
- opposition against (mainly) secondary patents.

Sector inquiries such as this are a tool under EU competition law and therefore the main focus was on company behaviour. However, the inquiry also considered the regulatory framework in the EU and highlighted three main areas of concern: patents; marketing authorizations; and pricing and reimbursement. With respect to patents, the EC reaffirmed at the time the urgent need for the estab-lishment of an EU patent and for a unified and specialised patent litigation system in the EU.

There have been general policy follow ups to the sector inquiry and in addition the EC has started a number of competition law investigations. The competition law world, however, had been waiting for a patent settlement case to reach a significant stage, and now it has two.

The EC's Concerns in its Two July 2012 Cases

In the citalopram case, the EC's concern is that Lundbeck and several generic competitors entered into agreements that may have hindered the entry of generic citalopram into markets in the EU, causing "substantial consumer harm" in the form of high prices. According to the EC, the companies concluded these agreements when generic entry became possible in principle, because certain of Lundbeck's citalopram patents had expired. The agreements foresaw substantial value transfers from Lundbeck to the four generic competitors. In turn, the generic companies abstained from entering the market with generic citalopram. Lundbeck's value transfers to the generic competitors included direct payments as well as other forms such as purchase of generic citalopram stock for destruction or guaranteed profits in a distribution agreement.

The EC's concerns in the perindopril case are similar. The EC alleged that in exchange for payments by Les Laboratoires Servier, several generic companies agreed not to enter the market with their cheaper generic products

and/or not to further challenge the validity of the patents that protected Servier's more expensive medicine. The case differs from that concerning citalopram, however, in that the EC's concerns also relate to unilateral behavior by Servier, since it "appears to be" dominant in the market for perindopril. Servier may have implemented a "comprehensive strategy" to prevent market entry of cheaper generic versions of perindopril, when perindopril was about to reach the end of its patent protection. Among the practices allegedly used by Servier were patent acquisitions that could potentially shut out competitors from the market and "inducing" its generic challengers to conclude the patent settlements.

The Cases Are in Line with Previous EC Thinking

It has taken the EC a long time after the 2009 sector inquiry report to reach this advanced stage in a patent settlement case, but from the facts available in the public domain, it is not surprising that the EC has chosen to proceed in these two. Both concern so-called reverse payment patent settlements of a particular type; the EC has long and consistently expressed the view, including in the report, that if an originator company eliminates or delays cheaper generic competition through significant payments or other benefits to a generic company for discontinuing or delaying the launch of generic medicine challenging the originator's patent, this can lead to substantial anticompetitive consumer harm. The EC considers this to be a form of collusion or cartel since the companies involved in effect share the originator's "monopoly rents."

On the issue of Servier's behavior, again the EC has long held the view that unilateral practices of dominant companies, such as those aimed at shutting out generic competitors from the market, can cause serious competition problems. It is supported in this regard by case law, including the seminal AstraZeneca case. The EC found there that the company had misused the regulatory framework to prevent or, at the very least, delay the market entry of competing generic products. The EU General Court has confirmed the EC's findings that such behavior was illegal, although this is now on appeal to the EU's highest court, the Court of Justice. However, in the Servier case, the EC appears to be proceeding primarily against the settlement agreements, with these unilateral practices as an ancillary or supporting activity.

Conclusion

The EC's citalopram and perindopril cases are reminders to the pharmaceutical industry that the EC is still watching it very carefully. Companies should consider whether their compliance procedures need updating. Competitors potentially affected by the behavior of originator companies have an ally in the EC. It is still looking for cases.