EU Competition Law in the Pharmaceutical Sector: What Has Happened Since 2009?

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The European Commission's final report on competition in the pharmaceutical sector in the EU/EEA was published nearly two years ago (July 2009)[1]. At the time, the EC claimed that the inquiry leading to the report had already "contributed significantly to the debate on European policy for pharmaceuticals, in particular for generic medicines". It also said that it would "apply increased scrutiny under EC Treaty antitrust law to the sector and bring specific cases where appropriate"[2].

The report certainly generated a lot of debate, but in practice what has the EC done in this field since then?

The conclusions of the 2009 inquiry report

The EC's main conclusions in 2009 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.

With respect to 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/EEA and highlighted three main areas of concern: patents; marketing authorizations; and pricing and reimbursement. With respect to patents, the Commission reaffirmed at the time the urgent need for the establishment of a Community patent and for a unified and specialised patent litigation system in Europe.

A range of competition law investigations are under way

The knowledge acquired by the EC during the sector inquiry has "allowed [it] to draw conclusions on the areas where Commission action based on competition law could be appropriate and effective".

It did not delay in launching such actions. On the same day that the EC published its report, it opened a case against Les Laboratoires Servier and a number of generic pharmaceutical companies[3]. This followed dawn raids carried out by the EC on these companies in November 2008 in several member states. The case concerns alleged unilateral behaviour by Servier and also

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1 Pharmaceutical Sector Inquiry Report, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html. Press release IP/09/1098, 8 July 2009.

2 The EC is of course not the only body currently showing a particular interest in this area. For example, in October 2010 the OECD published a paper setting out the proceedings of a policy roundtable considering generic pharmaceuticals. OECD, Generic Pharmaceuticals – Competition Policy Roundtable (Oct. 2010), http://www.oecd.org/dataoecd/24/48/46138891.pdf.

3 Press release MEMO/09/322, 8 July 2009.

agreements between Servier and the generic companies[4] which, according to the EC, may have the object or effect of hindering entry on to the market of generic perindopril, a cardio-vascular medicine originally developed by Servier, on the EEA markets[5].

In January 2010, a case was opened against Lundbeck[6]. The allegations are very similar to those raised in the Servier case. In particular, the Commission is investigating unilateral behaviour and agreements by Lundbeck which may hinder the entry of generic citalopram into markets in the EEA. Citalopram, originally developed by Lundbeck, is a type of anti-depressant drug known as a selective serotonin reuptake inhibitor (SSRI).

The most recent activity directed against specific companies came in the form of dawn raids carried out by the EC in November 2010 reportedly concerning a heartburn drug called Nexium[7]. It remains to be seen whether these raids will develop into full-blown investigations as with the Servier and Lundbeck cases.

Monitoring of patent settlements

In addition to investigating particular settlement agreements in the Servier and Lundbeck cases, the EC instigated a high-level, industry-wide review of the issue. In January 2010, it sent requests for information to a number of pharmaceutical companies asking them to submit copies of their patent settlement agreements to the EC[8]. The requests covered patent settlement agreements concluded between originator and generic pharmaceutical companies in the period from 1 July 2008 to 31 December 2009 and relating to the EU/EEA. The Commission was in particular looking at patent settlements in which an originator company had paid off a generic competitor in return for delayed market entry of a generic drug.

The EC reported on the results of its investigation in July 2010[9]. The report on this investigation of settlement agreements provides a useful, if brief, analysis of the various types of agreements that the EC has identified. The settlements that may prove problematic are described as those that limit generic entry and foresee a value transfer from an originator to a generic company. The value transfer can take different forms, such as direct payments, but can also consist of other commercial advantages. The EC indicated that it would also have concerns about agreements that contain restrictions beyond the exclusionary zone of the patent, i.e., which grant protection against generic entry outside the time, product, or geographic scope of the patent.

The EC found that 93 patent settlement agreements were concluded between originator and generic companies during the 18 months covered by the survey. This compares with 207 agreements concluded during the 7.5 years covered by the sector inquiry (January 2000 to June 2008). However, the number of settlements that may be problematic from an EU/EEA competition law perspective decreased in importance and number. In the period covered by the sector inquiry, such settlements accounted for 45 out of 207 or 22% of the settlements reported. By contrast, in the period covered by the report, only 10% or 9 out of 93 of the settlements fell into this category and the direct value transfers involved in the settlements also decreased.

The EC stated at the time that the reduction in potentially problematic settlements indicated an increased awareness in the industry of the types settlement agreements might attract competition law scrutiny but that, at the same time, the overall number of patent settlements showed that the EC's heightened scrutiny of the sector had not hindered out-of-court settlement of litigation.

The EC also indicated that it would continue monitoring the sector, and, true to its word, on 17 January 2011, it launched its second monitoring exercise, covering the period 1 January 2010 to 31 December 2010[10]. Again, it asked a number of originator and generic companies to submit a copy of all patent settlement agreements relevant for the EU/EEA markets concluded in this period. The Commission indicated that it will again

4 It has also been reported that the investigation concerns alleged collusion via France's national generics industry association (GEMME).

5 It is also notable that that in July 2010 the EC sent formal objections to Servier alleging that it had provided misleading and inaccurate information during the pharmaceutical sector inquiry. This is a separate issue but is an example of an apparent current focus of the EC on punishing procedural violations (such as obstruction of dawn raids, as well as this type of alleged activity by Servier).

6 Press release IP/10/8, 7 January 2010.

7 Press release MEMO/10/647, 3 December 2010.

8 Press release IP/10/12, 12 January 2010.

9 Press release IP/10/887, 5 July 2010.

10 Press release IP/11/40, 17 January 2011.

publish a report providing a statistical overview (in the first half of 2011).

It is clear that the EC was pleased with the results of its first monitoring exercise and considers its monitoring to be a worthwhile exercise. Indeed, it seems likely that the monitoring itself (like other forms of competition law enforcement) has a deterrent effect; due to the monitoring, companies will think twice about entering into the types of reverse-payment agreements that the EC is worried about.

Conclusion

In the field of EU/EEA competition law, enforcement within the pharmaceutical industry has traditionally focused on prohibiting agreements that restrict parallel trade, particularly through the use of quotas and dual pricing. Although it certainly hasn't abandoned these areas, the EC is now focusing more on attempts by companies to delay or hamper the introduction of generic medicines or of new, innovative drugs that may compete with their products already on the market. The 2009 sector inquiry was aimed at investigating these issues.

The EC has followed up the inquiry with several competition law cases against specific companies and also with its monitoring exercises. It is certain that this sector will continue to be the subject of close interest from the EC, not least since, at a higher policy level, the pharmaceutical industry is seen as a key driver of future economic growth in the EU[11].

[11] The sector inquiry was part of Commission policies and initiatives relevant to the pharmaceutical sector, including the Lisbon Strategy, the Commission's Industrial Property Rights Strategy, the Communication on a Renewed Vision of the Pharmaceutical Sector, and the Innovative Medicines Initiative.