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CLIENT ALERT

European Commission Publishes Final Report in Pharmaceutical Sector Inquiry and Opens Formal Proceedings against Patent Settlements

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The European Commission today published the final report in its Pharmaceutical Sector Inquiry. The Commission's findings remain largely unchanged from those in the interim report published in November last year. However, the language of the final report is less overtly critical of originator companies and the Commission's focus appears to have shifted away from the pursuit of individual antitrust cases and towards changes to the regulatory framework governing pharmaceutical markets.

In the interim report, the Commission referred to what it called a "tool box" of strategies used by originators to delay generic entry, including:

- the creation of patent clusters;
- strategic use of litigation;
- interventions in national regulatory processes for authorizing generic medicines;
- lifecycle management ('evergreening'); and
- pay-for-delay patent settlements.

The final report identifies the same strategies, but scales back the critical rhetoric: the term 'tool box' has disappeared, and a new section emphasizing the importance of innovation by originators has been inserted.

In terms of pursuing individual infringements, Competition Commissioner Neelie Kroes, introducing the final report, said only "*We will not hesitate to apply the antitrust rules where such delays [in generic entry] result from anticompetitive practices*" and "*The first antitrust investigations are already underway*". The focus for future action appears to be changes to the regulatory framework rather than individual cases and the Commissioner's quote on the final report finishes "*regulatory changes are expected to follow dealing with a range of problems in the sector.*"

The formal opening of one set of infringement proceedings was also announced today, against the originator Servier and five generic companies. The proceedings concern both alleged abuse of dominance by Servier in respect of its patented cardiovascular medicine perindopril and settlement agreements entered into between Servier and the five generics. This will be an interesting case, particularly in relation to the line the Commission takes on settlement agreements. However, it may not herald widespread enforcement action. The Servier case was identified by commentators as a potential target for enforcement action some time ago (even before the publication of the interim report, see here) as the perindopril patent had been heavily criticized as a "try-on" and "the sort of patent which can give the patent system a bad name" by the UK Court of Appeal in 2008.

In terms of regulatory changes, the Commission highlighted an "urgent need" for the establishment of a unified specialized patent litigation system across the EU and an EU patent as well as the "relevance" of recent initiatives by the European Patent Office to improve its procedures. The Commission also called on Member States to take action to accelerate approval

procedures for generic medicines - by reducing delays caused by originator interventions and granting automatic pricing and reimbursement status - and against misleading information campaigns by originators questioning the quality of generic medicines.

Overall, it seems likely that both sides of the pharmaceutical industry will take some comfort from the final report. Originators will be relieved that the Commission has stepped back from the rhetoric of the interim report and that the prospect of widespread antitrust enforcement against originators seems to have receded somewhat. At the same time, generics manufacturers will be pleased that the Commission is now pushing for a number of regulatory changes that facilitate the early entry of generic medicines onto the market.

The Head of the Commission's Sector Inquiry Task Force, Dr Dominik Schnichels, will be giving his first public presentation on the findings of the sector inquiry at the Brussels Offices of Crowell & Moring next Tuesday, 14 July 2009. Click here for more information on the event.

Click here for the full text of the final report [PDF]

Click below for:

- The Commission's Press Release
- Frequently Asked Questions

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