

Newsletter, July/August 2009

EU Law News

A bi-monthly review of EU legal developments affecting business in Europe

Pharmaceutical sector under scrutiny

Report on sector finalized and antitrust investigations launched

On 8 July 2009 the European Commission published the results of a report on competition in the pharmaceutical sector. According to the report's findings, company practices are among the main causes of the delay imposed on market entry of generic drugs. This delay has resulted in a decrease in the number of novel medicines reaching the market. However, additional factors such as shortcomings in the regulatory framework have also played a role in this delay.

In order to address this situation the European Commission intends to intensify the scrutiny of the pharmaceutical sector under EC antitrust law, including continued monitoring of settlements between originator and generic drug companies. In some cases anti-trust investigations are already ongoing. Defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts will also remain under scrutiny.

Based on the report's findings, Member States are requested to introduce legislation that would facilitate the market entry of generic drugs. To assist Member States in delivering speedy generic uptake and improved price competition, the report contains an overview of national measures and their effects on generic market uptake (volume, prices, number of entrants).

Furthermore, stakeholders have supported the introduction of a Community Patent and a specialised patent litigation system in Europe to reduce administrative burdens and uncertainty for companies.

The regulatory framework can cause delays through its lengthy marketing authorisation and its pricing and reimbursement

procedures. Company behaviour such as the use of certain patent application and enforcement strategies, certain patent settlements aiming at the restriction of generic market entry as well as interventions in marketing authorisation procedures concerning generic medicines can also contribute to delays.

Restriction of parallel trade

Next round in the GSK case

GlaxoSmithKline ('GSK') had agreed with wholesalers in Spain that they were charged lower prices when they sold GSK medicines in their domestic market and that they were charged higher prices in case of exports in any other EU member state. GSK obviously aimed at restricting parallel trade in order to maintain higher price levels in some countries. The European Commission found these agreements anticompetitive. The Court of First Instance upheld the Commission's decision in part. In the pending appeal before the European Court of Justice Advocate General ('AG') Trstenjak has now (30 June 2009) rendered her opinion that the Commission correctly found that the agreements had as their object a restriction of competition.

However, in the view of the AG, the Commission did not properly examine whether the agreement could benefit from an exemption of the cartel prohibition. GSK had asserted that its agreements promoted technical progress and had backed up its arguments with detailed economic arguments, and economic and econometric data. The AG finds that where an undertaking submits detailed arguments and data the Commission must deal with those arguments in a similar detailed manner. In her view the Commission failed to do so. A judgment of the ECJ can be expected in a few months.



Strengthening energy consumers' protection

Council decision on internal energy market

On 25 June 2009 the Council adopted new rules on the internal energy market. The main objective of the legislative package is to put in place the regulatory framework needed to make market opening fully effective. The rules adopted aim at:

- providing for more effective regulatory oversight by truly independent and competent National Energy Regulators. Certain cross-border issues will be addressed by an EU Agency for the Cooperation of Energy Regulators.
- increasing cross-border collaboration and investment with a new European Network for Transmission System Operators (ENTSO). Grid operators in the EU will have to develop common commercial and technical codes and security standards, as well as coordinate the investments needed at EU level.
- increasing solidarity between Member States to assist one another in case of energy supply threats.
- creating a level playing field by separating effectively the production and sale of energy from the transmission of energy. This is to avoid companies involved with both the generation and transmission of energy to use their privileged position on transmission to block access to transmission grids to other suppliers. Unbundling supply from transmission activities of integrated companies aims at promoting network investments and prevent any discriminatory behaviour.

EU rules on the size and shape of fruit and vegetables

Changes in the existing rules of specific marketing standards

As of 1 July 2009 the EU rules governing the size and shape of many fruit and vegetables ceased to exist when specific marketing standards for 26 types of fruit and vegetables were repealed. For 10 of these Member States could for the first time allow shops to sell products that don't respect the standards, as long as they are labelled to distinguish them from 'extra', 'class I' and 'class II' fruit. In other words, the new rules will allow national authorities to permit the sale of all fruit and vegetables, regardless of their size and shape.

Specific marketing standards will remain for 10 products which account for 75 percent of the value of EU trade: apples, citrus fruit, kiwi fruit, lettuces, peaches and nectarines, pears, strawberries, sweet peppers, table grapes and tomatoes. However, Member States may also exempt these from the standards if they are sold in the shops with an appropriate label. In practical terms, this means that an apple which does not meet the standard may still be sold in the shop, as long as it is labelled 'product intended for processing' or equivalent wording.

Analysis of state aid based on State Aid Action Plan

Commission's guidance on in-depth assessment of regional aid to large investment projects

On 24 June 2009 the European Commission adopted a guidance paper setting out criteria for the in-depth assessment of regional aid to large investment projects. The guidance outlines the kind of information required by the Commission for its detailed compatibility assessment and the assessment methodology, which is based on the balancing of the positive and negative effects of the aid.

The Regional Aid Guidelines 2007-13 foresee that large investment projects above certain thresholds need to be individually notified to the Commission because they may carry a greater risk of distorting competition. The Commission opens a formal investigation procedure for projects where the aid beneficiary has a market share of more than 25% or the production capacity created by the project exceeds 5% of the market (while the growth rate of the product market concerned is below the EEA GDP growth rate). Regional aid to such large investments entails a higher risk of distorting competition.

This publication has been carefully prepared but is intended for general guidance only. On any specific matter, reference should be made to the appropriate adviser.

Luther, EU Law Center

Avenue Louise 240, B-1050 Brussels

Telephone +32 (2) 6277 760, Telefax +32 (2) 6277 761

Helmut.Janssen@luther-lawfirm.com

www.luther-lawfirm.com

Luther Rechtsanwaltsgesellschaft mbH employs approximately 280 lawyers and tax advisers in Germany and consults in all areas of commercial law. Among our clients are medium-sized and large companies as well as the public sector. Luther has offices at 13 German locations as well as in Brussels, Budapest, Istanbul, Shanghai and Singapore and is a member of the international law firm associations PMLG (Pinsent Masons Luther Group) and Taxand, a worldwide network of independent tax firms.

Berlin, Cologne, Dresden, Dusseldorf, Essen, Eschborn/Frankfurt a. M., Hamburg, Hanover, Leipzig, Mannheim, Munich, Nuremberg, Stuttgart | Brussels, Budapest, Istanbul, Shanghai, Singapore

