Generic Drugs

By

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In October 2011, the European Commission reported that on its own initiative it launched an investigation into the contractual arrangement between Johnson & Johnson (J&J) and Sandoz (the generic drugs unit of Novartis to determine whether there was collusion to block the sale of cheaper generic medicines in the European Union (EU). The enquiry will establish whether the arrangement is hindering the entry onto the market of generic versions of Fentanyl patches in the Netherlands, in breach of the EU antitrust rules, specifically Article 101 of the Treaty on the Functioning of the EU (TFEU). Fentanyl is used to manage chronic pain. Article 101 of the TFEU prohibits practices that restrict competition within the EU.

Mr Joaquín Almunia, Vice President of the Commission in charge of competition policy commented that '*pharmaceutical companies are already rewarded for their innovation efforts by the patents they are granted. Paying a competitor to stay out of the market is a restriction of competition that the Commission will not tolerate.*'

Reason for the inquiry

The current J&J-Novartis inquiry came about as a result of the Commission's own monitoring of the sector, but more specifically, as a result of the AstraZeneca case (*AstraZeneca AB and another* v *European Commission (European Federation of Pharmaceutical Industries and Associations (EFPIA) intervening)* [2010]). See below.

The 2008 Pharmaceutical Sector Inquiry

In 2008-2009, the Commission conducted an inquiry into practices to delay the market entry of generic medicines, including agreements between pharmaceutical and generic companies. The trigger behind the inquiry was due to fewer new pharmaceutical drugs entering the market, and the apparent delay of the entry of generic pharmaceuticals into the market. With respect to novel medicines, the number of such medicines reaching the market declined. In 1995-1999, an average of 40 novel molecular entities was launched per year. By 2000-2004, there were only 28.

The inquiry considered whether:-

- Agreements between pharmaceutical companies, such as settlements in patent disputes, infringed Article 81 (the EC Treaty's prohibition on restrictive business practices);
- Companies had created artificial barriers to entry, whether through the misuse of patent rights, vexatious litigation or other means; and
- Such practices infringed Article 82 (the EC Treaty's ban on abuses of dominant market positions).

The Commission reported in 2009, that there were delays in generic medicines reaching the market, costing European consumers billions of euros. It found that:-

- Companies used certain methods to extend the commercial life of their medicines, which in turn contributed to generic delay. For instance, by patent filing - "*filing [of] numerous patent applications for the same medicine, forming so called "patent clusters" or "patent thickets"*." Furthermore "*documents gathered in the course of the inquiry confirm that an important objective of this approach is to delay or block the market entry of generic medicines*."
- Originator companies completed settlement agreements with other originator companies in the EU to resolve claims in patent disputes, oppositions or litigation. Approximately fifty percent generic entry was restricted and in nearly half of these arrangements, there was a

value transfer from the originator to the generic company. More than ten percent of the settlements were so-called "reverse payment settlements" which provided for direct payments. These payments amounted to more than €200 million.

- Originator companies concluded other types of agreements with each other, the majority of such agreements concerned the commercialisation phase.
- A large number of these agreements contained provisions for exclusivity between the companies. For example: exclusive supply, sourcing, licensing or any other kind of exclusivity agreements and/or non-compete obligations. The average duration of such agreements was eight years.
- There were around 700 cases of reported patent litigation cases with generic companies, which lasted on average three years.
- Originator companies also concluded more than 200 settlement agreements with generic companies in the EU, in which they agreed to end any ongoing litigation or disputes.
- Originator companies intervened in national procedures for the approval of generic medicines in a significant number of cases, which on average led to four months of delay for the launch of generic medicine.

Continual Monitoring

Following the pharmaceutical sector inquiry in 2008-2009, the Commission opened antitrust investigations into the practices of a number of companies, regularly monitoring potentially problematic patent settlements for possible violations of EU competition rules, including practices involving generic companies:

- AstraZeneca (AZ) was raided in December by antitrust regulators seeking evidence about steps it took to protect the $5 billion-a-year heartburn and stomach ulcer drug Nexium from generic competition.
- Commission also opened antitrust investigations against Servier (MEMO/09/322 and IP/10/1009), Lundbeck (IP/10/8), and Cephalon (IP/11/511).

AstraZeneca

AZ was fined by the commission in 2005, for delaying the market entry of competing generic drugs by misusing the patent system. It was held that from 1993 to 2000 AZ infringed EC and EEA competition rules by blocking or delaying market access for generic versions of Losec and preventing parallel imports of Losec by:-

- Giving misleading information to several national patent offices in the EEA resulting in AZ gaining extended patent protection for Losec through supplementary protection certificates (SPCs), amounting to an abuse in Belgium, Denmark, Germany, the Netherlands, Norway and the United Kingdom.
- Misusing rules and procedures applied by the national medicines agencies which issue market authorisations for medicines by selectively deregistering the market authorisations for Losec capsules in Denmark, Norway and Sweden with the intent of blocking or delaying entry by generic firms and parallel traders.

Subsequently, AstraZeneca plc and AstraZeneca AB then brought an action before the General Court for the annulment of the Commission's decision. The General Court annulled parts of the decision but found that AstraZeneca AB and AstraZeneca plc infringed Article 82 EC and Article 54 of the EEA Agreement by requesting the deregistration of the Losec capsule marketing authorisations in Denmark and Norway in combination with the withdrawal from the market of Losec capsules and the launch of Losec MUPS tablets in those two countries. Their actions were capable of restricting parallel imports of Losec capsules in those countries. They were fined a reduced amount of €52.5 million

Where does the decision leave pharmaceutical sector now?

- The opening of proceedings simply means that the Commission will be carrying out the J&J-Novartis investigation as a matter of priority.
- There is no strict deadline for the Commission to complete such inquiries into anti-competitive conduct.
- The duration of the inquiry would depend on the complexity of the case, the cooperation from J&J and Novartis and their defence.
- If they are found to be carrying out anti-competitive activities, this could lead to fines similar to those imposed on AZ.

With regard to the supply of generic medicines, the EU maintains that it remains vigilant in ensuring that companies' behaviour respect EU antitrust law and do not delay the entry of cheaper generic drugs onto the market.

Dr Rosanna Coopers specialises in pharmaceutical and regulatory law as well as being a specialist in intellectual property law.