Kluwer Competition Law Blog

Misleading Information and Competition Law: Case C-179/16 CJEU Judgment of 23 January 2018 (Avastin/Lucentis – Italy)

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This case relates to the interplay between EU competition law and the pharmaceutical regulatory regime. It arose in the context of an arrangement in which Genentech licensed Bevacizumab to one company in the field of Ophthalmology ('Lucentis') and to another company for the treatment of cancers ('Avastin'). There was a delay in obtaining an MA for Lucentis, during which time doctors in Italy prescribed Avastin off-label for ophthalmic conditions. The licensees under the Genentech licence drew the attention of regulators to various concerns about potential adverse consequences when Avastin was used off-label for ophthalmic indications.

The Italian Competition Authority ('ICA') found that:

- Avastin and Lucentis were in competition with each other;
- The licensees of those products agreed to undermine confidence in the off-label use of Avastin for ophthalmic conditions by disseminating information which the ICA held to be misleading;
- This was an infringement of Article 101 TFEU by object (meaning that there is no need to show any specific effects in the market).

The case was referred to the CJEU which made four principal findings. The first two are of most immediate relevance to pharma companies while points 3 and 4 are of more interest to specialist competition lawyers:

1. Products which are prescribed 'off-label' may be in the same relevant market as products with an MA for a particular indication as long as, on the facts, they are actually substitutable for that indication. In deciding whether they are in fact substitutable, the actual supply and demand of the products must be considered.

2. An arrangement between two companies to disseminate misleading information (including to regulatory authorities) about adverse reactions to the off-label use of one product for a particular indication with a view to reducing the competitive pressure on a product which has an MA for that indication is a restriction of competition 'by object'.

3. An arrangement between parties to a licence to restrict the conduct of third parties so as to reduce the competitive pressure on one medical product by another is not to be assessed as 'ancillary' to the main pro-competitive licence agreement and is contrary to Article 101 TFEU.

4. Such an arrangement cannot be exempted.

Comment

The fact that off-label products, may be regarded as competing with authorised products, even though they are on the market 'illegally' is interesting, but not wholly surprising.

A crucial question in future will be when information supplied to third parties may be misleading. The CJEU spent less time than the Advocate General (see here) in discussing the meaning of 'misleading information'. Key considerations were:

• Under the regulatory regime for pharmaceutical products the requirements for pharmacovigilance 'rest solely with the holder of the MA for that medicinal product and not with another undertaking marketing a competing medicinal product covered by a separate MA'. Therefore an arrangement between two companies marketing competing products to disseminate information about one of those products might be evidence that pharmacovigilance was not the true purpose of the arrangement.

• Information is to be regarded as misleading when:

- It does not comply with the requirements of completeness and accuracy in Article 1(1) of regulation 658/2007 (laying down financial penalties for the holders of MAs in certain circumstances);
- It was intended to confuse the regulatory authorities, and to have adverse reactions mentioned in the Summary of Product Characteristics, which would enable a communications campaign to exaggerate the perception of the likelihood of adverse consequences; and
- It was intended to emphasise the public perception of risk, in a context of scientific uncertainty.

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