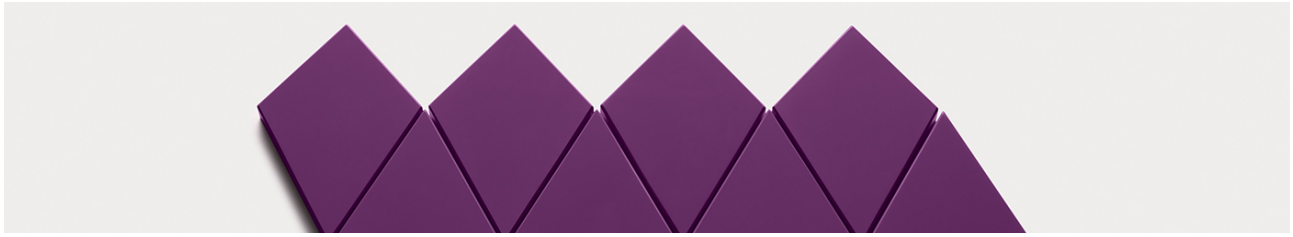

When is a Medical Device a Medicinal Product?

The Court of Justice of the European Union (CJEU) has recently handed down a decision on a reference from the Finnish Courts in Case C-109/12 Laboratoires Lyocentre v Lääkealan turvallisuus- ja kehittämiskeskus (the Centre for Safety and Development in the pharmaceutical sectors), Sosiaali- ja terveysalan lupa- ja valvontavirasto (Social and Health Authorisation and Supervision Authority).

On 3 October 2013, the CJEU held that a product which is classified by the competent authorities in one member state of the European Union (EU) as a medicinal product, could be classified by the competent authorities in another member state as a medical device and that similar products could be classified, one as a medicinal product and the other as a medical device, in the same member state. Where medicinal products fall in Class 5 and medical devices fall in Class 10, pharmaceutical brand owners will need to consider "borderline" goods, which could be classified in both classes, when clearing new brands for registration and use and when considering the scope of protection which is appropriate for their mark.

Background

The French pharmaceutical company, Laboratoires Lyocentre, marketed a pessary, in the form of a capsule, under the brand name GYNOCAPS. This capsule contained live bacteria intended to restore balance to the protective bacterial flora in the vagina. The GYNOCAPS product had been on the market in Finland since 1984 and was intended for use by women of all ages. Until 2008, GYNOCAPS was marketed in Finland as a medical device bearing a mandatory CE marking. (A CE marking is the manufacturer's declaration that a product meets the requirements of the applicable EC directives). The product continues to be marketed as a medical device in a number of other member states of the EU, including Spain, France, Italy and Austria.

The European Medicines Agency (EMA), which is responsible for licensing medicinal products within the EU, had not adopted a firm position on the categorisation of vaginal products containing live bacteria, such as GYNOCAPS, but took the general view that they satisfied the conditions necessary for classification as a "medicinal product".

The Finnish Lääkelaitos (National Agency for Medicines) was informed that a third party was marketing a vaginal preparation similar to GYNOCAPS, which also contained live bacteria. However, unlike Laboratoires Lyocentre, this third party was marketing their product as a medicinal product rather than a medical device. In the light of this information and taking into

account the principal effect of the product, which was to correct or restore certain physiological functions through metabolic and pharmacological action, the Lääkelaitos took the view that GYNOCAPS was not a medical device, but a medicinal product. The product would therefore need to be licensed for sale in the EU by the EMA.

Laboratoires Lyocentre challenged this decision before the Finnish Korkein hallinto-oikeus (Supreme Administrative Court), claiming that the action performed by GYNOCAPS was limited to inducing the effects created by the introduction of live bacteria into the human body. Where that mode of action did not proceed from an immediate pharmacological or other effect on the human body, GYNOCAPS should not be classified as a medicinal product. In response to this appeal, the Finnish Supreme Administrative Court stayed proceedings and referred three questions to the CJEU.

CJEU Reference

The questions referred to the CJEU and the answers provided by the Court can be summarised as follows:

1. Question: Where a product is categorised as a medical device in one member state of the EU, does that finding preclude the same product from being categorised as a medicinal product in another member state?

Answer: No. Although in most cases it should be clear whether a product is a medicinal product or a medical device, products should be assessed by the national authorities on a case by case basis, taking into account all of their characteristics. It is therefore open to different member states to categorise the same product differently. However, in cases of doubt, Article 2(2) of the Medicinal Products Directive (2001/83/EEC) provides that the provisions of that Directive will apply where, taking into account all its characteristics, a product can fall within the definition of a "medicinal product", irrespective of whether it may also fall within the definition of a product covered by other EU legislation.

2. Question: If the answer to question 1 is "no", where a product has been categorised as a medical device in one member state and the competent authorities in another member state wish to categorised that same product as a medicinal product, should they first follow the procedures set out in Articles 8 and 18 of the Devices Directive (93/42/EEC) before applying the classification procedures of Directive 2001/83/EEC?

Answer: Yes. The procedures set out in Articles 8 and 18 of the Devices Directive (93/42/EEC) must be applied before the product can be re-categorised as a medicinal product. Articles 8 and 18 provide for the withdrawal of medical devices from the market where the CE mark has been inappropriately applied. To the extent that the product is deemed to be a medicinal product, it should not carry the CE device. The manufacturer would then need to apply for a marketing authorisation in order to market the product, so

as to comply with the classification procedures of Directive 001/83/EEC.

3. Question: Do either of the Medicinal Products Directive (2001/83/EEC) or the Devices Directive (93/42/EEC) or any other European legislation preclude similar products containing the same substance and having the same mode of action from being marketed in the same member state, one as a medicinal product and the other as a medical device?

Answer: No. Similar products could be classified, one as a medicinal product and the other as a medical device, in the same member state. This would be a question for the national competent authorities to decide.

Comment

This judgment highlights the potential that goods in Classes 5 and 10 could be found to be identical or highly similar from a trade mark opposition/infringement perspective. This is a factor to which brand owners may need to pay greater attention when clearing new pharmaceutical brands for registration and use. The CJEU's judgment certainly has the potential to increase the risk of successful objection to the adoption of brands in Class 5 on the basis of earlier Class 10 registrations, especially those which are broad in scope and not yet vulnerable to non-use revocation, and vice versa. Clients in the pharmaceutical industry may also wish to consider whether they should seek to register their brands in Class 10, given the potential overlap with goods in Class 5.

From a regulatory perspective, the manufacturers of medical devices may need to prepare to comply with the more onerous provisions of Medicinal Products Directive (2001/83/EEC) if the competent authorities in any member state decide to categorise the device as a medicinal product. The European Parliament is currently considering draft legislation to regulate medical devices more tightly in any event, which could result in similar regulatory regime for both medical devices and medicinal products.

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