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When is it the right time for a pharmaceutical company to apply for a trademark for its medicinal products?

The pharmaceutical market presents unique challenges to pharmaceutical companies seeking to launch new medicinal products. Before they can introduce a new medicinal product on the market, they must go through a lengthy process of executing clinical trials as a prerequisite for obtaining a market authorisation. A crucial question in this context is whether they could already register their trademark during the clinical trials phase, without risking revocation of their trademarks (i.e. due to non-use when the marketing approval process outlasts the five-year grace period).

In its decision dated 3 July 2019, the CJEU stated that when choosing to register a trademark for their medicinal product early on, pharmaceutical companies will either have to make sure that they are certain to obtain a marketing authorisation within the five-year timeframe or to make sure that they invest sufficient financial resources to reasonably expect obtaining a marketing authorisation within the five-year timeframe.

The case brought before the CJEU

On 3 July 2019, the Court of Justice of the European Union (CJEU) rendered an important decision for pharmaceutical companies. The case revolved around a trademark dispute, in relation to medicinal products, that raised two far-reaching issues concerning the scope and definition of the requirement of genuine use within the provisions of Article 58 of Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trademark ("EUTMR"). You can read the judgement here (in Dutch, currently not available in English).

The decision was given in the context of an appeal brought by Viridis Pharmaceutical Ltd. ("Viridis") against the judgment of the General Court in Case T-276/16, *Viridis v European Union Intellectual Property Office* ("EUIPO"). The primary proceedings concerned the revocation by the EUIPO of the EU trademark "Boswelan", registered by Viridis for class 5 of the Nice classification (pharmaceutical and sanitary preparations), following the application filed by Hecht-Pharma GmbH to have the trademark revoked due to lack of genuine use for a period of more than five years by Viridis.

In short, the main points of discussion were whether the use of the trademark during clinical trials may constitute genuine use and, if not, whether conducting clinical trials, as a prerequisite for receiving a market authorisation[1], may constitute a proper reason for non-use.

1 For the requirement in Belgium, see art. 6, § 1, section 3 Law of 25 March 1964 on medicinal products *juncto* art. 5 § 2, 10) Royal Decree of 14 December 2006 on medicinal products for human and veterinary use.

Genuine use

According to settled case law, genuine use is made of a trademark within the meaning of Article 51(1)(a) of Regulation No 207/2009 (now article 58.1(a) EUTMR), when it is used, in accordance with its essential function of ensuring the identity of the origin of the goods or services in respect of which it is registered, to find or preserve an outlet for those goods or services, to the exclusion of any symbolic use intended solely to enforce the rights conferred by the trademark (judgements of 11 March 2003, Case C-40/01 Ansul, EU:C:2003:145, paragraph 43, and 8 June 2017, *W.F. Gözze Frottierweberei and Gözze*, Case C-689/15, EU:C:2017:434, paragraph 37 and the case law cited there).

Thus, the normal use of the trademark presupposes that it is used on the market for the goods or services protected by the trademark and not only within the undertaking concerned. The use of the trademark must relate to goods or services which have already been placed on the market or which can be placed on the market at any time, and the company is preparing to do so with a view to winning customers, in particular in the context of advertising campaigns (see, to that effect, Case C-40/01 *Ansul v Commission* [2003] ECR I-145, paragraph 37).

On the other hand, the affixing of a trademark to goods which are not supplied to the customer with a view to their penetration into the market for the goods covered by the trademark registration cannot be regarded as genuine use of that mark, since such affixing does not help to find a market for those goods or to distinguish them, in the interests of consumers, from goods originating from other undertakings (see, to that effect, Case C-495/07 *Silberquelle v Commission* [2009] ECR I-10, paragraph 21).

After recalling the settled case law and general principles on genuine use, the CJEU went on to address the first plea.

The CJEU affirmed the observations of the General Court:

- That Viridis had adopted preparatory acts which consisted in the conduct of a clinical trial carried out in view to apply for marketing authorisation and which included certain acts in the form of advertising for that trial;
- However, the use of the trademark during the clinical trials could not be equated with marketing or even with a direct preparatory act, but had to be regarded as an internal use, since that use had taken place outside competition, within a limited circle of participants, and without its purpose being to obtain or maintain market shares. Also, the use (400.000 capsules) had not been shown to be significant in the pharmaceutical sector;
- In addition, Viridis did not demonstrate that the marketing of the medicinal product designated by the trademark was imminent since it had not produced any evidence to show that the clinical trial was almost complete; and
- In any event, only the acquisition of a marketing authorisation by the competent authorities could have allowed a public and outward-looking use of the trademark, since the legislation on medicinal products prohibits the advertising of medicinal products which have not yet been the subject of marketing authorisation and, consequently, any communication intended to gain or maintain a market share. It was therefore impossible to use the trademark designating a medicinal product on the relevant market as required by the settled case law.

The CJEU dismissed the following two arguments of Viridis as irrelevant:

- The fact that the acts of use relied on were in conformity with the applicable legal provisions; and
- The argument that the five-year period to make genuine use is inadequate for the pharmaceutical sector and does not take into account the specific circumstances of the pharmaceutical market.

The CJEU thus followed the reasoning of the General Court and declared the first plea in law partly unfounded and partly irrelevant.

Proper reasons for non-use

Again, the CJEU started with recalling the settled case law and general principles on proper reasons for non-use. According to the case law of the Court, only obstacles which are sufficiently directly related to a trademark and render its use impossible or unreasonable and which are beyond the control of the proprietor of that mark can be regarded as 'valid reasons' for non-use of that mark. It must be determined on a case-by-case basis whether a change in the business strategy in order to overcome the obstacle in question would render the use of that mark unreasonable (judgments of 14 June 2007 in Case C-246/05 Häupl, EU:C:2007:340, paragraph 54, and of 17 March 2016 in Case C-252/15 *P Naazneen Investments v OHIM*, not published, EU:C:2016:178, paragraph 96).

Regarding the second plea, the CJEU affirmed that conducting a clinical trial may constitute a proper reason for non-use, but observed that the acts and events in the present case, were within the sphere of influence and under the responsibility of Viridis and, therefore, could not be regarded as obstacles which arose outside its control.

The CJEU argued that Viridis had already, on the basis of its own choice and not on the basis of any legal obligation, applied for registration of the trademark even though there was considerable uncertainty as to both the date and the possibility of marketing the goods designated by that mark, since those goods were in the clinical trials phase. It noted that Viridis' application for a clinical trial had been submitted more than three years after the registration of the trademark. Also, the difficulties alleged during the clinical trial in question were, in view of the specific characteristics of the sector concerned, due to insufficient investments by Viridis.

With the above reasoning, the CJEU declared the second plea unfounded and dismissed the appeal in its entirety.

Key takeaways

It can be tricky to register a trademark in relation to a medicinal product for which no market authorisation has yet been obtained. Pharmaceutical companies will have to determine whether or not the benefit of registering the trademark early on outweighs the risk of losing the trademark due to non-use.

The judgement, read together with the opinion of AG SZPUNAR, makes it clear that the chances for a pharmaceutical company to make genuine use of their registered trademark during the clinical trial phase are, although not fully excluded, very low[1]. The use during clinical trials, no matter how quantitatively large, is aimed at testing the medicinal product (scientific objective) and is not aimed at maintaining or creating a share in the market for the goods or services protected by the mark (economic objective). The restrictions flowing from the legal framework relating to medicinal products (prohibition of sales and advertisement of non-authorised medicinal products) make it (nearly) impossible to make genuine use of the registered trademark during the clinical trial phase.

When choosing to register a trademark for their medicinal product early on, pharmaceutical companies will thus either have to make sure that they are certain to obtain a marketing authorisation within the five-year timeframe or to make sure that they invest sufficient financial resources in order to reasonably expect to obtain a marketing authorisation within the five-year timeframe.

1 In rare circumstances, a pharmaceutical company may place unauthorised products on the market and thus make genuine use of its registered trademark (see: "compassionate use" in art. 83 Regulation no. 726/2004).

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The CJEU confirmed that a clinical trial and the restrictions of use flowing from the legal framework relating to medicinal products that go with it may constitute a proper reason for non-use.

However, pharmaceutical companies' own behaviour in coping with the legal barriers to use its trademark is also taken into consideration when examining the proper reasons for non-use. Waiting three years after registering the trademark to start the clinical trials with insufficient funds will clearly not suffice for the CJEU. Conversely, the reasoning of the Court does seem to suggest that a pharmaceutical company that registers a trademark and starts the clinical trials early on with sufficient funds and reasonable expectations of finishing the clinical trials and obtaining a market authorisation to make use of the trademark before the expiry of the five-year period, may successfully invoke clinical trials and the unexpected delay during the clinical trials as a proper reason for non-use.

In sum, the decision teaches us that timing, careful assessment and awareness are essential when it comes to applying for and maintaining a trademark for medicinal products in the pharmaceutical context.

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You may always contact us should you have any questions.

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