Clinical trials may constitute use, but when they do not, then there is no justification for non-use, says the CJEU

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The concept of genuine use of a trademark should be the same for all sorts of products/services, but for pharmaceuticals this is not always the case.
Given the particular regulatory regime which applies to pharmaceuticals, often many years pass before the marketing authorization to any given new pharmaceutical specialty is granted. During that time, do clinical trials constitute genuine trademark use, and if not, do pharmaceutical companies have a justification for not using their trademarks while the corresponding product is awaiting marketing authorization? This is what the CJEU had to answer in case C-668/17 P, decided on July 3, 2019 ("Viridis").

Ehct-Pharma GmbH filed a non-use revocation action against the EUTM registration for BOSWELAN, to designate pharmaceutical for the cure of multiple sclerosis, not yet authorized for marketing, owned by Viridis Pharmaceutical Ltd.

The mark was revoked by EUIPO and the revocation was confirmed by both the Board of Appeals and the General Court. Viridis appealed to the CJEU pleading two grounds:

First, Viridis criticized the GC for finding that use of the mark in relation to third parties in a clinical trial could not be treated as "placing on the market" or even as a "direct preparatory act", since it was part of an internal use.

Second, Viridis argued that the GC was wrong denying proper reasons for non-use, where the mark was used in the context of a clinical trial and that trial was initiated long after the registration of the mark or the financial resources involved were not sufficient to conclude the clinical trial as soon as possible.

The CJEU, however, was unconvinced by Viridis' arguments.

With regard to the value of clinical trials, the Court recognized that use of the mark may relate not only to goods already marketed but also to those about to be marketed, so that genuine use of a trademark may be demonstrated by acts occurred before commercialization (for example, during clinical trials). However, it must be shown that the market launch is imminent so that the preparatory acts have external character, with effects for future consumers of the goods about to be marketed. In the case at hand, Viridis did not prove imminent commercialization, because it did not provide evidence that the clinical trials were about to be concluded.

As to whether Viridis had a justification for its non-use of BOSWELAN, the CJEU reiterated that proper reasons for non-use must be independent of the will of the proprietor of the mark, have a sufficiently direct relationship with the mark, and be of such a nature as to make the use of the mark impossible or unreasonable (see C-246/05, Häupl). The CJEU noted that the GC had not denied that clinical trials may be proper reasons for non-use. However, the GC had correctly observed that Viridis chose to file its trademark well in advance in respect of the estimated time of the starting of the commercialization, without considering the length of clinical trials and the lack of financial funding to speed up the procedure. Moreover, the clinical trials started only three years after the registration of BOSWELAN mark. Since all these factors, considered together, depended on Viridis, the CJEU found that the non-use could not be justified.

So what's the take home for pharma companies? As pharma companies need project certainty i.e. they need to start assigning names to new drugs when the process starts, the threshold set by the CJEU appears to be quite high, because waiting to secure a trademark registration until shortly before the marketing

authorization is requested AND make sure that this is then granted in the five years available, may sometimes be problematic and carry risks.

Perhaps, pharma companies might try to give some “external” resonance to clinical trials where the mark is used (although current legislation prohibits advertisements before the grant of the marketing authorization, thus there would be a fine line to be walked, and besides that whether such external resonance may be considered as genuine use is debatable). Or they might consider, for the most important projects which are near marketing authorization to refile a trademark when the five years period is nearing its end. Not a perfect solution, but given the costs necessary to clear a trademark, it might be more cost-effective than having one’s own mark revoked.