European Union: CLINICAL TRIALS AS GENUINE TRADEMARK USE – TIMING IS EVERYTHING

By Robin L. Warren

***Viridis Pharmaceutical v. EUIPO*, Case No. C-668/17 (July 3, 2019)**

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In November 2013, Hecht-Pharma GmbH initiated the successful non-use cancellation action against Viridis' 2007 EUTM registration which was filed in 2003 by Viridis' legal predecessor. Following the EUIPO Annulment Division's decision to cancel its mark, Viridis unsuccessfully appealed to the EUIPO Court of Appeal, the EUIPO General Court of the EU and, most recently, the EU Court of Justice ("ECJ").

At the heart of the issue, and something many pharmaceutical companies struggle with, is the timing of the trademark filings by Viridis' legal predecessor. As evidence of use, Viridis asserted that BOSWELAN was used in connection with 400,000 capsules delivered to a university clinic participating

in the clinical trials, invoices to the third party organizing the clinical trials, volunteer recruitment, leaflets, and scientific publications. However, the ECJ considered the clinical trial use to be internal use only as use of the mark was directed at a limited pool of users and arose outside market competition. While evidence of use in connection with preparations for imminent entry into the market could serve as genuine use, here, Viridis had not applied for conducting a clinical trial until November 2010 (three years after its registration), nor did it submit any information indicating that clinical trials would even succeed. Also, notably, Viridis had not even applied for marketing authorization, so any market plans were very remote.

Given that marketing authorization is partly contingent on successful clinical trials, Viridis argued that the five year non-use period should not apply as five years is not sufficient for pharmaceutical companies to introduce a drug to market in view of the regulatory challenges they face in producing new drugs. Viridis also explained that problems recruiting candidates for clinical trials caused delays. However, the ECJ declined to accord special treatment to pharmaceutical companies, reasoning that they should already be familiar with such challenges and should anticipate delays. The Court further found that the non-use was unjustified as organizing and carrying out clinical trials was within Viridis' control.

It is important to note that the use analysis conducted in non-use cancellation actions is highly fact specific and varies from case to case. Therefore, with different facts, clinical trial use could conceivably constitute use. Also, it is worth noting that there may be more latitude for an owner to argue that clinical trial use should be sufficient if it could show diligent accounts of attempts to speed up any regulatory issues it encountered. However, in an effort to avoid running out the clock on the five-year non-use grace period for EUTM registrations, we advise our pharmaceutical clients to take into account potential regulatory challenges they may face when considering when to file their EU trademark applications.