UPC DELIVERS FIRST RULING ON SECOND MEDICAL USE PATENTS

On 13 May 2025 the Local Division of the Unified Patent Court in Düsseldorf (UPC) published a closely watched judgment in case UPC_CFI_505/2024, pitting Sanofi and Regeneron against Amgen over European patent EP 3 536 712, which protects the use of PCSK9 inhibitors for lowering lipoprotein(a) (Lp(a)) concentrations in statin-free patients. The claimants had asked for a pan-European injunction that would have forced Amgen to withdraw its blockbuster monoclonal antibody Repatha® (evolocumab) from UPC territories. Amgen, in turn, sought revocation of the patent in every contracting state.

In delivering its decision, the Local Division acknowledged the lack of both any specific statutory provisions regarding infringement of second medical use claims and of any established case law of the UPC of that point. Thus, the Judges had to first set some guidelines to follow and apply to for the assessment of the infringement of such kind of patent claims.

The Local Division stated that a two-step evaluation process should be used to establish infringement of a patent claim for secondary medical use. First, it must be ascertained that the alleged infringer has offered or placed the medicinal product on the market in such a way as to lead or be likely to lead to the therapeutic use claimed by the patent: this is defined as the "objective" part of the test. Second, it must be shown that the alleged infringer knew or reasonably should have known of such use: this is the "subjective" part of the test.

Judges emphasized that these requirements cannot be defined abstractly, but require an analysis of all relevant facts and circumstances of the case, such as the relevant market and its customary uses, magnitude or importance of the alleged infringing use and the market share of the claimed use relative to other uses. The Court also stated that actions that the alleged infringer has taken to influence the respective market, should also be considered, taking into account that such actions can be either positive or negative.

The Court ultimately sided with neither party's main ambition. It dismissed the infringement action because it found no convincing evidence that Amgen was actively promoting or knowingly facilitating the claimed therapeutic use, whilst it upheld the patent in full, rejecting every validity challenge levelled by the defence. Each side therefore left the courtroom with a costly half-victory that the judges translated into a split-cost order capped at EUR 1.875 million.

In construing the second-medical-use claim the panel, chaired by Presiding Judge Dr Joachim Bender, reiterated that Article 54(5) of the European Patent Convention confers only a "notional" layer of novelty: the substance is already known, so the fresh therapeutic application must be what distinguishes the claim. For the

Düsseldorf judges that meant homing in on the patent's narrow patient indication for individuals presenting Lp(a) levels above 30 mg/dL and not receiving statins. In the absence of evidence that the allegedly infringing drug is administered under the above-mentioned conditions, the infringement cannot be held to exist.

Sanofi and Regeneron relied heavily on a brief paragraph in the Repatha® Summary of Product Characteristics (SmPC) mentioning possible Lp(a) reductions. The Court characterised that sentence as a mere piece of scientific information, devoid of promotional intent, and demanded harder proof of marketing conduct aimed at the patented indication. Four patient letters produced by the claimants were brushed aside as anecdotal. Without a pattern of targeted prescriptions or data demonstrating Amgen's knowledge, the infringement limb collapsed.

On validity the patent emerged unscathed. The judges accepted priority from two US provisional filings, noting that the specification expressly disclosed both the 30 mg/dL threshold and the "no-statin" subgroup. Added-matter and priority attacks therefore failed. Novelty and inventive-step challenges stumbled because the prior art focussed on LDL-C lowering; no prior document suggested that PCSK9 inhibition could reduce elevated Lp(a) levels in the specific cohort identified by the patent. Insufficiency arguments met the wall of placebo-controlled trial data and expert testimony confirming that the invention works as promised.

The judgment has broader resonance for life-science litigants. First, it underscores how demanding the evidential threshold is for second-medical-use infringement in the UPC: the content of the SmPC alone will rarely tip the scales, and patentees must map real-world prescribing behaviour back to the defendant's conscious actions. Second, Düsseldorf confirms that a well-documented niche indication can withstand aggressive validity attacks even when built around a drug that is otherwise old.

What happens next? Both parties have until 13 July 2025 to lodge an appeal in Luxembourg. Sanofi and Regeneron may hope to persuade the Court of Appeal that the first-instance judges set the bar for infringement evidence too high. Amgen, conversely, might prefer to bank its win and reinforce its programme rather than reopen the issue of validity. Outside the UPC, parallel German litigation over the opted-out parent patent EP 2 756 004 continues, and today's reasoning will inevitably colour those proceedings.

For practitioners the takeaway is straightforward: when drafting or enforcing purpose-limited claims, clinical specificity is a sword and a shield, but success in court will ultimately turn on meticulous evidence of the behaviour on the market of the alleged infringer and the preventive steps taken by the same to avoid it.

Marco Blei, Partner
Email: marco.blei@grplex.com