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UPC Opines on Second Medical Use Claims

Sanofi Biotechnology SAS, Regeneron Pharmaceuticals Inc.,v Amgen Inc. and others UPC_CFI_505/2024

Decision of 13 May 2025 ORD_598583/2023

This decision from the Düsseldorf Local Division sets out for the first time the UPC's view on how second medical use claims should be interpreted, that is, what is required in order to infringe such a claim. This is an issue because second medical use claims are product claims but with a use (purpose) limitation. Only this claim format has such a mix of features.

Regeneron is the proprietor and Sanofi the exclusive licensee of EP 3536712 which was asserted against Amgen in relation to their PCSK9 inhibitor product Repatha. Claim 1 of the patent required use in:

reducing lipoprotein(a) (Lp(a)) levels in a patient who exhibits a serum Lp(a) level greater than 30 mg/dL and who is diagnosed with or identified as being at risk of developing a cardiovascular disease or disorder prior to or at the time of administration of the composition, or who is diagnosed with or identified as being at risk of developing a thrombotic occlusive disease or disorder prior to or at the time of administration of the composition...

The court dismissed all the validity challenges to the patent. On the key question of infringement, the Court first noted as follows:

There are no statutory provisions regarding infringement of second medical use claims and so far, there is no harmonised approach in the UPC. The legal framework for the assessment of (direct) infringement is primarily set out in Art. 25 UPCA and 69 EPC (and

the Protocol).

p2 The nature of the second medical use claim as a purpose-limited product claim includes, on the one hand, the characteristics of a product claim meaning it can be infringed like one (cf. Art. 25(a) UPCA and the infringing acts specified therein). On the other hand, the purpose limitation contrasts the claim from a "normal" product claim which affords "absolute" protection, regardless of its (intended) use. In order to find infringement of a purpose-limited product claim, the Claimants must therefore prove that the allegedly infringing product fulfils the "use" feature(s) of the claim.

In finding a balance between a fair protection for the patent proprietor and a reasonable degree of legal certainty for third parties, a limitation of the scope of protection to cases where the product is already or actually being used for the claimed therapeutic purposes would unduly limit the protection of the patent proprietor. It is the opinion of the Court that, for a finding of infringement of a second medical use claim, the alleged infringer must offer or place the medical product on the market in such way that it leads or may lead to the claimed therapeutic use of which the alleged infringer knows or reasonably should have known that it does. In other words, as an objective element, there must be either a prescription in order to lower Lp(a) levels, or there must be at least circumstances showing that such a use may be expected to occur. In addition, as a subjective element the infringer must know this or reasonably should have known.

The requirements of such behaviour cannot be defined in an abstract manner but require an analysis of all the relevant facts and circumstances of the case at hand. Starting from the construction of the patent claim in question, relevant facts may include

- the extent or significance of the allegedly infringing use,
- the relevant market including what is customary on that market,
- the market share of the claimed use compared to other uses,
- what actions the alleged infringer has taken to influence the respective market,
    - either "positively", de facto encouraging the patented use,
    - or "negatively" by taking measures to prevent the product from being used for patented use.

The manufacturing of the product and in particular the package insert and the SmPC [Summary of Product Characteristics] of a pharmaceutical product can be important. However, they are not always the only decisive factor to be taken into account in assessing whether the alleged infringer is in the end liable for patent infringement. Additionally, the extent to which the alleged infringer knows or should have known that the product will be used for the claimed purpose is of relevance.

p3

Applying these considerations to the facts, the Court noted that in Section 4.1. of the SmPC (therapeutic indications), there is no indication of Repatha for lowering Lp(a) levels, meaning the drug is not approved for this purpose. Rather, the purpose for which Repatha was approved is for lowering LDL-C [low-density lipoprotein cholesterol] and mixed hyperlipodemia.

While Section 5.1 SmPC (pharmacodynamics properties) mentions under pharmacodynamics effects that in clinical trials, Repatha reduced unbound PCSK9 (amongst other effects), the court noted that that, in contrast to Section 4.1, Section 5.1 SmPC does not report a clinical relevance (efficacy and safety) of this effect in terms of improving the CVD [cardiovascular disease] risk for patients.

Thus, the court considered that while a physician prescribing Repatha can note the information that it reduces Lp(a), and can derived from studies mentioned in the SmPC that it can lower the Lp(a) level value by around 25%, nevertheless the physician's decision to prescribe is based on the therapeutic indications for which the drug is approved, namely lowering LDL-C and mixed hyperlipodemia. If in reducing LDL-C, an elevated Lp(a) value was also reduced, the court viewed this as a "windfall effect". Put another way, the court noted that "if the physician prescribes the product for lowering Lp(a) and LDL-C, they are prescribing the drug 'off-label'." The court further observed that the Defendants do not emphasise in any way that Repatha reduces Lp(a) (e.g. by labelling it as recommended for that use). The information in Section 5.1 of SmPC is relevant for consideration of side effects, and cannot be taken to indicate the purpose for which the product is prescribed.

Additionally the court considered that the Claimants had failed to demonstrate that placing the product on the market would actually lead to the claimed use. The evidence provided did not prove a likelihood that physicians will prescribe the product for use in reducing Lp(a) levels.

Therefore, the infringement action, as well as the counterclaim for revocation, were dismissed.