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FIRST UNIFIED PATENT COURT RULING ON SECOND MEDICAL USE CLAIMS

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On 13 May 2025, the Düsseldorf Local Division of the Unified Patent Court issued a landmark decision on the merits relating to a second medical use claim (*Sanofi Biotechnology SAS and Regeneron Pharmaceuticals Inc. v. Amgen Inc. et al.*, 13 May 2025, UPC_CFI_505/2024).

The decision follows an infringement action brought by Regeneron and Sanofi, respectively the proprietor and exclusive licensee of European Patent No 3 536 712 ("EP'712"), against various entities of the Amgen group, which subsequently filed a counterclaim for revocation. The claimants argued that the defendants' product, evolocumab, marketed as Repatha® infringed EP'712.

EP'712 covers a therapeutic treatment for diseases and disorders related to high levels of lipoproteins. More precisely, the construction of the claim 1 adopted by the Court is the following:

> ***1.*** *A pharmaceutical composition comprising a PCSK9 inhibitor,*
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> ***2.*** *the PCSK9 inhibitor is an antibody or antigen-binding fragment thereof that specifically binds PCSK9,*
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> ***3.*** ***for use in reducing lipoprotein(a) (Lp(a)) levels***
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> ***4.*** *in a patient who*
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> ***4.1.*** *is diagnosed with or identified as being at risk of developing a cardiovascular disease or disorder or a thrombotic occlusive disease or disorder prior to or at the time of administration of the composition,*
>
> ***4.2.*** *is not on a therapeutic statin regimen at the time of administration of the composition, and*
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> ***4.3.*** *exhibits a serum Lp(a) level above 30 mg/dL.*

It should be highlighted that the use of the PCSK9 inhibitor was already known in prior art for lowering LDL-C lipoprotein levels in the blood. EP'712 specifically covers the use of the PCSK9 inhibitor to reduce the Lp(a) lipoprotein level in the blood.

Although challenged on various grounds, EP'712 was ultimately upheld while the Court found that it has not been infringed by the defendants.

More specifically on infringement, the Court started by laying out the general principles and useful guidelines to be applied when qualifying acts of infringement of a second medical use patent.

It highlighted that infringement of a second medical use claim, a purpose-limited product claim, involves (1) the reproduction of the product concerned (2) for the "use" feature(s) of the claim (§181).

In the Court's view, to establish infringement in relation to a second medical use claim, claimants must demonstrate that the alleged infringer offers or places an infringing product on the market in a way that leads or may lead to the use of the therapeutic use covered by the patent, *i.e.*, the objective element. Claimants must also demonstrate that the alleged infringer knew or reasonably should have known that its product could be the subject of the protected therapeutic use, *i.e.*, the subjective element (*i.e.*, indirect infringement within the meaning of Art. 26 UPCA).

On the latter, the Court added that establishing such behaviour requires an analysis of the relevant facts and circumstances of the case. It provides a non-limitative list of pointers of relevant facts and circumstances to be taken into account when assessing such behaviour (§183):

- 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.

In the case at hand, the Court found that the claimants have not demonstrated that the marketing of Repatha® led or could have led to the therapeutic use covered by EP'712. It pointed out that section 4.1 of the allegedly infringing product's SmPC, which sets out the therapeutic indications, does not at all refer to the reduction of Lp(a) levels. In addition, the Court noted that section 5.1 of the SmPC does not report a clinical relevance of the reduction of Lp(a) in the blood in terms of improving the cardiovascular deceases risks for patients (§190), which does not incentivise physicians to prescribe Repatha® to limit such a risk. Of note, section 4.1 of the SmPC of Sanofi's product alirocumab, marketed under Praluent®, also does not refer to the reduction of Lp(a) levels.

What is more, it appears that expert opinions played a decisive role in the Court's decision. In fact, according to two opinions produced by the defendants' experts, physicians are not encouraged, in light of the information available (particularly within the SmPC), to prescribe Repatha® to lower the levels of Lp(a) for certain patients. According to the experts, PCSK9 inhibitors are simply not used by physicians to treat elevated Lp(a) levels. The evidence set forth in this case convinced the Court that the claimants did not show a likelihood that physicians would prescribe the contested embodiment for use in reducing Lp(a) levels.

All of the foregoing led the Court to dismiss the claimants' infringement claims.

This landmark decision from the UPC indeed sets some interesting guidelines on the assessment of infringement of second medical use claims. It will be interesting to see how the UPC will assess skinny labelling cases, and notably whether the UPC will consider whether it will be sufficient for alleged infringers to carve-out the protected indications from the SmPC and the patient leaflet or whether the UPC will consider that such carve-out is indeed necessary, but not sufficient.

For instance, in France, a mere skinny label would not be deemed to be sufficient to rule out infringement. Indeed, in the French *Pregabalin* cases[1] which are the seminal French cases on second medical use, the generic manufacturers carved-out the therapeutic indication covered by the patent-in-suit and launched massive communication campaigns to inform healthcare professionals that the generic products were intended for use for the therapeutic indications which were in the public domain. This shows the importance French courts carefully examine the defendants' behaviour in these kinds of matters.

According to the general principles set forth by the 13 May 2025 decision, it also – naturally – seems to be the case before the UPC.

The decision can be found here.

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[1] TGI Paris, 26 October 2015, RG n°15/58725; and TGI Paris, 2 December 2016, RG n°16/57469 – in these cases, the generic manufacturers had carved out from their SmPCs the protected indication and issues multiple letters to HCPs.