Kluwer Patent Blog

Status Quo Vadis?

Rik Lambers (Brinkhof) · Wednesday, October 18th, 2023

The Status Quo injunction is not a variation on *Wayne's World* classic "No Stairway, Denied" joke. While some may yearn for a ban on their generic tunes, Status Quo is still not denied. That is not the faith of all generics, as Teva found out in Dutch litigation over its generic version of Grünenthal's Nebido: launch denied!

Nebido is used to treat long-term testosterone deficiency in men. Something which even listening to Status Quo on repeat would not fix. Grünenthal markets Nebido and holds a related patent (EP 1 457 208 – expiration March 2024). Teva was issued a Dutch marketing authorisation for a generic version of Nebido with the brand name Testosterone Teva in December 2022. Grünenthal informed Teva that a launch of its generic would infringe its patent in February and April 2023. The usual tune towards a generics launch….

All was quiet on the Dutch front the following months, but not in Germany and the UK. In February 2023, the German Federal Patent Court held Grünenthal's patent invalid due to lack of inventive step (German judgment here). In July 2023, the English High Court concluded "*all the claims of the Patent […] are insufficient for lack of plausibility across their scope and therefore invalid*" (English judgment here).

Two down, time to launch in the Netherlands….at least, that's how Teva's approach is reflected in the 13 September 2023 decision of the Preliminary Relief Judge ('PRJ', Ms Kokke) of the Hague District Court (par. 5.6): "*In its own words, Teva c.s. waited so long* [i.e. responding to Grünenthal's warning letters – RL] *because it wanted to wait for the aforementioned German and English judgments*." Following those judgments, Teva informed Grünenthal it intended to include its generic Teva Testosterone in the Dutch Taxe (*G-Standaard*) for October 2023 (deadline to submit: 13 September).

The German and English judgments did not stop the Dutch PRJ from first granting a status quo injunction on 13 September and then a preliminary injunction on 3 October 2023 (rough English machine translations here and here, not checked).

Status Quo

The status quo injunction is preliminary relief in preliminary relief proceedings. It freezes the 'status quo', in this case Teva not yet being on the market, pending a final decision in the preliminary relief proceedings. On 13 September the PRJ decided to grant a status quo injunction after balancing the interests of the parties. Grünenthal's arguments are the usual, i.e. that it would

suffer irreparable damages if Teva's product would be included in the Taxe, resulting in price erosion and loss of sales. Teva, at least that's what the 13 September judgment reflects, asserted to have an interest in a launch asap, i.e. not waiting another month until the 'final' decision in these preliminary relief proceedings.

The PRJ's decision boils down to that Grünenthal has – according to established case law – a very substantial interest in maintaining the status quo, while Teva did not convince the PRJ that a a delay of their launch for a month should outweigh this interest. Also, because there were no indications that third parties were in the process of obtaining a generic MA, while Teva could recover damages for the one-month delay.

No word on the German and English nullity decisions in this status quo injunction decision. That is to say, not beyond mentioning their existence and – possibly a sign of things to come – the suggestion that the claims of the Dutch part of the patent before the PRJ were different (because: amended in the Dutch proceedings).

Status quo maintained: Teva was injuncted from including its testosterone in the Taxe until the final preliminary decision.

More Status Quo

On 3 October the PRJ decided to prolong the status quo: Grünenthal was granted a preliminary injunction. This raises the obvious question: what about the German and English *merits* decisions?

As a background, there is the 'alignment rule': according to this rule of Dutch procedural law a PRJ is *in principle* obliged to align his/her judgement with a Dutch merits decision or even a decision of the EPO's Opposition Division or Technical Board of Appeal, but….this rule does not automatically apply to a foreign judgment.[1] This notwithstanding, a decision of an authoritative foreign court may play a role in a PRJ's decision whether there is a reasonable chance that the claim will be allowed or denied in the proceedings on the merits (the applied standard in preliminary relief proceedings).

So, why did the German and English merits decisions did not play a decisive role? Why did the PRJ not already conclude in view of those decisions, as Teva argued, that there was a reasonable chance the Dutch merits court would deny the injunction claim (i.e. find the patent invalid)?

In the words of the PRJ:

> *"4.13. In this case, the interim relief judge reached a different outcome from foreign courts with regard to parallel patents. Firstly, what is important in this respect is that in the present proceedings – following the partial surrender by Grünenthal – a narrower patent is before us than in the German and English proceedings, with claim 1 being further limited, as explained below. Also, the present contentions and defences are not identical to those in the foreign proceedings; for instance, both parties have relied on different experts (statements), so that the debate also differs in substance. Furthermore, the test to be applied in the Netherlands does not seem entirely the same. In particular, the English judgment with regard to plausibility […], is not the same as, according to this preliminary opinion, the test for inventive step to be used in the Netherlands in this case, following the ruling of the Enlarged Board of Appeal (EBoA) of the European Patent Office (EPO) of 23 March 2023 (G2/21)."*

The narrower 'Dutch' claims, these were limited to one particular testosterone ester (rather than a group), and the carrier to a specific co-solvent in a certain volume range. As to the inventive step test following G2/21, the discussion boiled down to whether a certain technical effect could be included in the inventive step assessment, specifically in formulating the objective technical problem, in view of the recent interpretation of G2/21 in Dutch case law.[2]

The PRJ considered the test amounted to the following (par. 4.36):

> *"Would the average person skilled in the art, using his common general knowledge on the priority date, understand from the original application, or at least would derive therefrom, that the alleged technical effect is encompassed by its technical teaching and embodies the same invention disclosed therein."*

The PRJ considered that it does not follow from G2/21 that the application must include evidence that the alleged technical effect actually occurs or that this is made plausible in the application. The question is if, in view of the specific circumstances of the case, the skilled person would be able to derive from the application that the alleged technical effect was encompassed by its technical teaching.

The PRJ considered that Grünenthal's application fulfilled above test. In particular, the PRJ considered that it is not necessary for the patentee to provide proof, or make it plausible in summary proceedings, that the technical effect works with at least the majority of the claimed compositions. The burden for the contrary (it does not work over the whole scope of the claim) is on Teva as the claimant, while Grünenthal filed post-published evidence supporting its position. To cut a longer decision short: the PRJ subsequently found that the skilled person would not arrive at the claimed invention starting from the closest prior art. Injunction granted.

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Different national courts (seem to) have now applied the G2/21 decision in different ways (see reports on the English and French status quo here and here). The PRJ follows the approach of Dutch CoA's earlier Apixaban decision (15 August 2023; rough, non-checked English machine translation here). In that decision the CoA – granting an injunction – found the reasoning of i.a. the French and Norwegian merits courts convincing, while it considered the test applied by the English court:

> *"[…] a different test from that of paragraph II of the Order in G2/21. The English test was developed by the English Supreme Court in a case that concerned sufficiency rather than inventive step [*the Warner-Lambert case – RL[3]*]. For sufficiency of second medical indication claims, the Enlarged Board in para 77 of G2/21 formulated a different test than the one formulated in paragraph II of the order. As already considered above in paragraph 6.9, the court of appeal does not consider it compatible with this consideration to apply the same test when assessing the inventive step of a claim that does not include the technical effect to be achieved, as is the case with the present compound claim."*

While the G2/21 status quo may start to crystallize in Dutch case law, this raises a question – in view of e.g. the pending *Fibrogen v Akabia* UK SC appeal – for the English court: *Quo vadis*? The plausibility elephant has clearly not yet left the room.

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[1] As to foreign judgments, this was considered e.g. in PI proceedings in DC Amsterdam 6 January 2023, DIVX/Netflix, and confirmed in this decision.

[2] In particular in view of CoA The Hague 15 August 2023, BMS/Sandoz (Apixaban).

[3] Warner-Lambert Company LLC (Respondent) v Generics (UK) Ltd v, Mylan and another (Appellants) [2018] UKSC 56.

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