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The Dutch Cross-Border Still Going Strong: Novartis v Mylan

Rik Lambers (Brinkhof) · Wednesday, November 18th, 2020

In his (or her) younger years at school, a once to be Dutch patent litigator was learned that the Netherlands share a borders with Germany and Belgium. On the geography maps, they seemed to be set in stone. History class already provided a different perspective: now friendly neighbours would once surprise each other with unannounced visits. Grown up, and practising the intricacies of patent litigation, he (or she) learns a different lesson: borders are fluid and can be crossed with injunctions. The decision of the PI Judge of the District Court of The Hague in the Novartis v. Mylan case teaches this once again.

This is not the time and place to delve into the history of the Dutch cross-border. The road from the EU Court of Justice's GAT/LUK to Solvay/Honeywell will be sufficiently familiar to most of the readers. If not, let's just say the Dutch courts have assumed jurisdiction to grant an injunction covering the Netherlands *and* other European states where a European Patent (or SPC) is held to be valid and infringed. Specifically in preliminary relief proceedings (cf. Solvay/Honeywell), though the cross-border is available in merits proceedings (but the claim is dismissed or decision stayed cf. Art. 24 (4) Brussels 1 Regulation if a defendant alleges the foreign patent rights are invalid). Interestingly, and as always depending on the circumstances of the case, a Dutch entity may serve as an anchor defendant for the Dutch court to assume jurisdiction against foreign entities. This is exemplified by the Novartis/Mylan case (29 September 2020, PI proceedings).

This case concerns Novartis's Exjade product (INN: deferasorix), once protected by its patent EP 0 914 118. The patent expired in 2017, but Novartis received an SPC (until 30 August 2021) and a paediatric extension (until 28 February 2022). Mylan SAS (France) was granted a Marketing Authorization ('MA') for Mylan's generic version of deferasorix on 26 September 2019. Other Mylan entities involved were Mylan BV and Mylan NV, the latter being the parent company of Mylan SAS and Mylan B.V.

Novartis' counsel – as one does – informed Mylan if its IP rights, including the SPC and paediatric extension. Mylan's counsel i.a. responded:

> As you are aware, the applciation for a marketing authorization and the mere fact of being granted a marketing authorization does not constitute patent infringement.
>
> In addition, we wish you to note that Mylan is under no obligation to provide any commercial information, assurances or notices regarding the Dutch market entry of any product having deferasorix as its active ingredient. Such information is

> considered to be confidential and part of Mylan's business secrets. Nonetheless, we confirm that we do not currently have plans to launch a deferasorix product in the Netherlands prior to 30 August 2021. We do not believe that the paediatric extension to SPC No. 300248 is valid.

This response did not fare well with the PI Judge in his assessment of Novartis' urgent interest in preliminary relief. While Mylan disputed such interest, the PI Judge considered the response to speak volumes. By only mentioning that there were no plans to launch before 30 August 2021 (expiration of the SPC), and expressing the believe that the paediatric extension was invalid, it was clear to the Judge that Mylan would not respect the extended SPC and would indeed use its MA after the SPC's expiration.

Following the flow of the judgment, this urgent interest decision came after the PI Judge considered to have cross-border jurisdiction against all Mylan entities and before he decided to also grant cross-border relief against all entities. The middle part of his decision considered the question – in short – whether the paediatric extension was rightly granted to Novartis. The answer was: yes, and not fully unexpected in view of earlier case law (the PI Judge referred to the 2016 Teva/Glivec case, Dutch language version available here).

As a background, orphan medicines are excluded from the 6 month SPC extension (cf. Art. 36 (1) jo. (4) Paediatric Regulation), but may enjoy a two year extension of market exclusivity (cf. Art. 37 Paediatric Regulation). The indication of Exjade as an orphan medicine was withdrawn by the Commission, while Novartis had not enjoyed the two year market exclusivity extension. Also, Novartis had fulfilled all material conditions to be eligible for a reward for its paediatric research.

Mylan argued that the exemption that no SPC extension is granted for orphan medicines should also apply if a medicine was indicated as such in the past (but no longer is). Novartis should have relied on the reward of the market exclusivity extension (even if the Novartis could not have received such extension because the exclusivity was expired when it could have been granted an extension).

The PI Judge did not agree. After a review of the structure and aim of the Paediatric Regulation, he concludes that there is no reason to interpret the exemption of article 36 (4) Paediatric Regulation such that also former orphan medicines are excluded from an SPC extension.

Back to crossing borders…

The PI Judge found cross-border jurisdiction for both Dutch entities (Mylan BV and Mylan NV) based on Art. 4 Brussels I. Little surprise here. As to Mylan NV, Novartis alleged Mylan NV acted unlawful – i.e. a general tort, rather than patent infringement – in the Netherlands and other European states by inciting and facilitating infringement of the extended SPCs in those countries by its subsidiaries. This brings us to the French entity Mylan SAS. Mylan NV proofed to be the bridge to finding jurisdiction for Mylan SAS based on Article 8 Brussels I.

Article 8 Brussels I stipulates that in case of a number of defendants, a person may be sued in the courts for (1) the place where any one of them is domiciled, (2) provided the claims are so closely connected that it is expedient to hear and determine them together to avoid the risk of irreconcilable judgments resulting from separate proceedings.

The first condition was easily fulfilled, given the domicile of Mylan BV and Mylan NV in the Netherlands. The second condition was – according to the PI Judge – also met. To be brief: Novartis alleged that both Mylan NV and Mylan SAS acted unlawful by facilitating, inciting, or provoking local Mylan entities to infringe the extended SPC, based on the same European Patent, with the same product (deferasorix Mylan). The NV's acts being 'operational', in short giving orders to and facilitating the SAS to – on its turn – unlawfully facilitate local Mylan entities. The SAS's acts being 'regulatory', in short facilitating infringement by allowing local entities to use its MA for deferasorix Mylan.

According to the PI Judge, the alleged acts of the NV and SAS were so intertwined that also decisions on these acts were intertwined. If another court would have to decide on the alleged unlawful acts of the SAS, this would bring the risk of irreconcilable judgments. Moreover, the SAS could have foreseen that it would be sued for a Dutch court (as the SAS was asked to perform acts by the Dutch NV, while the SAS made its MA available to Mylan BV).

Jurisdiction accepted, but not yet case closed: Novartis was also granted cross-border relief against both Mylan NV and Mylan SAS (against Mylan BV only relief for the Netherlands was requested, and granted).

As to Mylan SAS, the PI Judge referred to earlier case law (the 2012 Teva/Boehringer case, Dutch language version available here). The SAS, as the MA holder, would act unlawfully if it would allow/facilitate the market launch of deferasorix Mylan by making the MA available. Not just in the Netherlands, but also in other states where the extended SPC is in force. Noteworthy is that Novartis had submitted declarations to evidence that the SAS's acts would also be considered unlawful according to the laws of the foreign countries. Such evidence may be expected from a plaintiff according to DC The Hague case law, and apparently convinced the Judge in this case.

As to Mylan NV, Novartis alleged that the NV is directly involved in managing, organizing and making infringement possible in the relevant states. According to Novartis, the NV had control over its subsidiaries, including the BV and the SAS. Mylan insufficiently disputed this, according to the Judge. At least there was a threat of involvement of the NV in the unlawful acts of its subsidiaries. A cross-border injunction was granted against the NV and the SAS.

This case is a showcase for the Dutch cross-border. In particular, it is interesting to see how cross-border jurisdiction is found and an injunction granted against a foreign MA holder, and that a controlling parent company is held to act unlawful in and outside the Netherlands. This is also a major win for Novartis. As Novartis knows – and to slightly adjust the expectations of the reader – cross-border claims are not always granted. The same PI Judge denied Novartis cross-border relief against Teva and Ratiopharm in a different case decided on of different facts (Dutch language decision available here). To almost finish a long post with a long sentence, one fact from that case: in view of the earlier cross-border case law that a Dutch MA holder also acts unlawful if a foreign entity, holding a pharmaceutical authorization, infringes with a generic product, Teva decided that the MA and pharmaceutical authorization should be held by the same entity within the group. The reasoning behind this being that possible infringement claims should be brought before the court of that foreign entity…. The reader can speculate if this creative solution will hold in the future.

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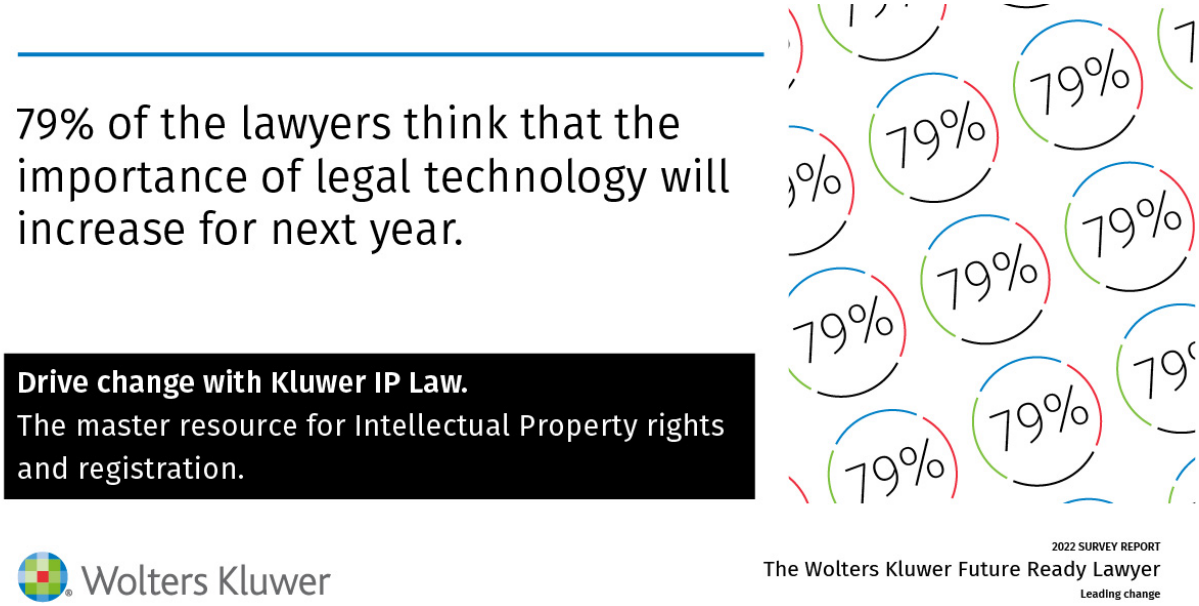

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