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INFRINGEMENT BY EQUIVALENCE BEFORE THE PRELIMINARY INJUNCTION JUDGE: WHERE HAS THE OBVIOUSSNESS GONE?

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Is it possible to obtain a preliminary injunction (PI) based only on infringement by equivalence?

While a 2017 PI order clearly answered no to this question, the tide is turning for defendants.

We recall the order handed down in 2021 in the pemetrexed case, upholding the likelihood of infringement "if not by reproduction, at least by equivalence", and which was upheld on appeal.

Three years after, the PI order in the rivaroxaban case opposing Bayer to Zentiva once again rules in favor of the possibility of arguing infringement by equivalence in PI proceedings. Even if this order was ultimately favorable to the defendant, it is likely that it will be used in the future by rights holders to argue that infringement by equivalence does indeed have standing in PI proceedings.

It is therefore worth recalling some of the background to this case.

The question of whether it is possible to obtain a PI based on infringement by equivalence has been the subject of several contradictory decisions in the last ten years:

- Decisions in 2013 and 2015 accepted the possibility of granting PI based on infringement by equivalence[1].
- However, in 2017, an order issued by the same judge who had handed down the above mentionned 2015 orders - expressly went against the previous case law, holding that *"infringement by equivalence presupposes an assessment which in itself escapes the obviousness required in summary proceedings"**[2]** . This position had the merit of clarity and was in line with the requirements of summary proceedings (the summary proceedings judge is also known as the "judge of urgency and obviousness").*
- A new twist happened in 2021, in the pemetrexed case between Eli Lilly and Zentiva, where the first instance PI judge and the Court of Appeal found that there was a likelihood of infringement "*if not by reproduction, at least by equivalence*"[3] because Zentiva's generic drug, a pemetrexed using a diarginine salt, was a likely infringement of the patent covering a pemetrexed using a disodium salt.

However, the impact of this order could be put into perspective by the circumstances of the case:

- On the day the PI judge ruled, a court ruling on the merits in the pemetrexed case opposing Eli Lilly to Fresenius Kabi - had already considered that "*the variant related to the use of a different salt (in this case a tromethamine diacid) is totally secondary*"[4] . It was therefore not surprising that the preliminary injunction judge considered that Zentiva's drug, which used a third form of salt, could be infringing.
- In addition, the amend in the claims from "pemetrexed" to "pemetrexed disodium" had been made during the examination to counter **a formal** observation by the EPO, made on the ground of article 123 (2) EPC. As the order recalled the amendment was therefore made for "overcoming an objection which was not related to patentability". One could therefore believe that, in case of an amendment made in response to a **substantive** objection relating to patentability, the solution might have been different.

With the 28 March 2024 PI order in the rivaroxaban case, the PI judge seems to have gone even further than in the pemetrexed case[5].

This order considers that "*it is irrelevant whether the alleged infringement refers to a literal reproduction of the claims or to a reproduction by equivalent of the same claims. All that matters is that the infringement of the patent owner's rights be shown to be probable, even if by equivalent*".

What is most striking, however, is that the judge merely states that the feature at stake in the infringing product consists of "*an embodiment variant*" of one of the claimed features "*or, at the very least, a reproduction by equivalent of that feature*", omitting to examine - or at least omitting to say that he has examined - the criteria for infringement by equivalence, i.e. whether the two means claimed to be equivalent fulfil the same function for an identical or similar result, and whether this function is new, which are nevertheless the fundamental basis of infringement by equivalence.

In this case, it was even more necessary to analyze the criteria for infringement by equivalence, as the feature at stake had been introduced during the examination to counter an objection on the merits, unlike in the pemetrexed case.

In the rivaroxaban case, one of the differences between the patent and the allegedly infringing product was that the claims were directed to a "*rapid-release tablet*", whereas Zentiva's product was a rapid-release "*capsule*". However, the "*rapid-release tablet"* feature, which appeared in the original patent application in a dependent claim 5, had been moved up into the main claim 1 by the patentee during the examination to avoid an objection raised by the examiner relating to patentability. Indeed, in his reply to the examiner dated January 24, 2011, in which he presented his amended claims, the patentee concluded: *" The dose form and the use mentioned in the present application are not mentioned in detail in the prior art, (…). Furthermore, looking at the half-life of rivaroxaban it is surprising that administration of rivaroxaban* ***as rapid-release tablet*** *once daily is sufficient for the therapy. Therefore, the present application shows novelty and an inventive step".*

The patent was therefore granted in part by the limitation to the specific tablet form. The case is therefore quite different from that of the pemetrexed jurisprudence and, unless Zentiva has not contested the equivalence, it is highly regrettable that the order so quickly passes over it, merely pointing out that Zentiva's summary of product characteristics (SmPC) indicates that the studies on tablets apply *mutatis mutandis* to capsules. Indeed, it was on this basis alone that the PI judge upheld the infringement of features 1 to 4: *"It is clear from the documents submitted to the court,* ***in particular Zentiva's summary of product characteristics****, that features 1 to 4 of the aforementioned claim are reproduced (Bayer exhibit no. 202). This is particularly the case for Zentiva's capsule products, which consist of a variant of a rapid-release tablet, or at least an equivalent reproduction of this feature".*

Although the PI judge ultimately did not grant the requested PI on the grounds that there was no likely infringement of feature 5 of claim 1, it is regrettable that he was so quick to conclude that feature 1 was infringed by equivalence.

By its very nature, infringement by equivalence should be handled with care by the “judge of obviousness”. In this respect, the order does not fail to point out, in the analysis of validity, that obviousness is required in summary proceedings (§30 and 31)[6]. Shouldn't this obviousness requirement, which is required to assess the likelihood of invalidity, also be required to assess that the likelihood of infringement? All the more so for an analysis of infringement by equivalence? Or is there a double standard here?

In conclusion, and perhaps to relativize the scope of this order, it should be remembered that the conditions under which it was issued are - once again - peculiar. The defendant was offering both tablets and capsules. The situation might have been different if the defendant had only offered capsules.

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[1] TGI Paris, 8 Dec. 2015, Orion c. EG Labo, RG 15/59244 ; TGI Paris, 8 Dec. 2015, Orion c/ Biogaran, RG 15/59861 ; TGI Paris, 20 June 2013, Vorwerk c/ Demarle, RG 12/11488

[2] TGI Paris, 20 Jan. 2017, St Gobain v Knauf, RG 16/60052

[3] TJ Paris, ord. JME, 7 Jan. 2021, Zentiva v. Eli Lilly, RG 19/06927; CA Paris, 9 Nov. 2021, Zentiva v. Eli Lilly, RG 21/01880

[4] TJ Paris, 3. 3., 11 Sept. 2020 Eli Lilly v. Fresenius Kabi, RG17/10421

[5] TJ Paris, ord. ref, 28 March 2024, RG24/51632

[6] Even though the judge on the merits in the rivaroxaban case against Sandoz, ruling on the same day, held that the patent was invalid (TJ Paris, 28 March 2024, Sandoz v. Bayer RG22/08612).