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TRU-VA-DI TRU-VA-DA, Life goes on at Gilead

Matthieu Dhenne (Ipsilon) · Tuesday, December 22nd, 2020

Each time I hear "TRUVADA", the catchy chorus of the Beatles' Ob-La-Di Ob-La-Da sounds different to me… However, TV addicts or literature lovers also keen on pharmaceutical litigation should not have failed to notice a more disturbing coincidence: "Gilead" is moreover the sweet name given to the dictatorship where *The Handmaid's Tale* is set – a sort of reminiscence of *Oceania* in *1984*. Randomness. No doubt. In any case, the Paris Court of Appeal's decision of June 19, 2020 is by now the last episode in our TRUVADA® Pharma Saga, perhaps its final point.

As a reminder, TRUVADA® is an anti-HIV drug consisting of the combination of tenofovir disoproxil (TD) and emtricitabine (FT), which has been approved for pre-exposure prophylaxis (PreP) of HIV infection. It has been shown to reduce the risk of HIV infection by 86%. This combination was the object of a European patent (EP0915894) until July 25, 2017. Its protection was extended by Supplementary Protection Certificates (SPCs), including one for "*tenofovir disoproxil and its salts, hydrates, tautomers and solvates in combination with other therapeutic compounds such as emtricitabine*" and expiring on February 21, 2020 in the French territory (FR08C0020), based on European Union marketing authorization EU/1/04/305/001 and the patent claim 27, which reads as follows : "*A pharmaceutical composition comprising a compound complying with any of claims 1 to 25* [tenofovir disoproxil is claimed in claim 25]*, together with a pharmaceutically acceptable vehicle, and where appropriate, other therapeutic ingredients*." [emphasis added]. In the meantime, the description also disclosed this possibility of combining a claimed active ingredient with "other therapeutic ingredients", but also does not specifically mentioned emtricitabine [09-15]. Based on SPC FR08C0020, Gilead decided to take action for infringement against Mylan, which launched TENOFOVIR DISOPROXIL, a generic of TRUVADA®. Thus, the issue raised by this case was the following: could emtricitabine (FTC) constitute a product protected by the basic patent within the meaning of Article 3(a) of Regulation (EC) No 469/2009, even though the patent did not explicitly refer to it and only cited possible combinations with "other therapeutic ingredients"?

Three French decisions answered negatively, including the most recent one handed down by the Paris Court of Appeal on June 19, 2020. First, the Paris High Court, in an interim order dismissing a preliminary injunction, which held that the SPC was probably void, and then dismissing an infringement action, in a judgment on the merits on May 25, 2018, invalidated the SPC. Finally, the Paris Court of Appeals

confirmed the latter decision, after the decision rendered by the Court of Justice of the European Union following the preliminary question put in England by Mr Justice Arnold.

The position adopted by the French Courts was not surprising: not only is it settled law in France (especially since the "irbesartan" case), but, in addition, apart from two *ex parte* decisions (in Belgium and Spain), judges in other countries had adopted a similar point of view (in England, Sweden, the Netherlands, Greece, Germany, Austria and Denmark). That said, the TRUVADA® case will have given the French judges the opportunity to clarify their interpretation of article 3(a). Thus, the Paris High Court, in its judgment of May 25, 2018, confirmed by the Court of Appeal on June 19, 2020, indicated that the requirement for that product to be protected by a basic patent in force "*presupposes*":

- "*that the product is mentioned in the wording of one of the claims or at least, if not mentioned by name, that it is necessarily and specifically identifiable as such by a person skilled in the art";*
- [with a combination of active ingredients] *"each active ingredient be also mentioned in the claims or, failing that, necessarily and specifically identifiable individually";*
- *"if it may considered that* [to be considered protected by the basic patent] *an active ingredient is not mentioned in the claims of the basic patent by means of a structural definition but simply by means of a functional definition, it is also important to establish that these claims, interpreted inter alia in light of the invention's description, as provided by Article 69 of the Convention of 5 October 1973 on the Grant of European Patents (EPC) and its interpretative protocol, implicitly but necessarily aim in a specific manner at the active principle in question."* [emphasis added].

In the meantime the European Court of Justice specified that:

- *"the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and*
- *each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent*" [emphasis added].

Thus, logically, the Court of Appeal upheld the first instance judgment, stating in particular that:

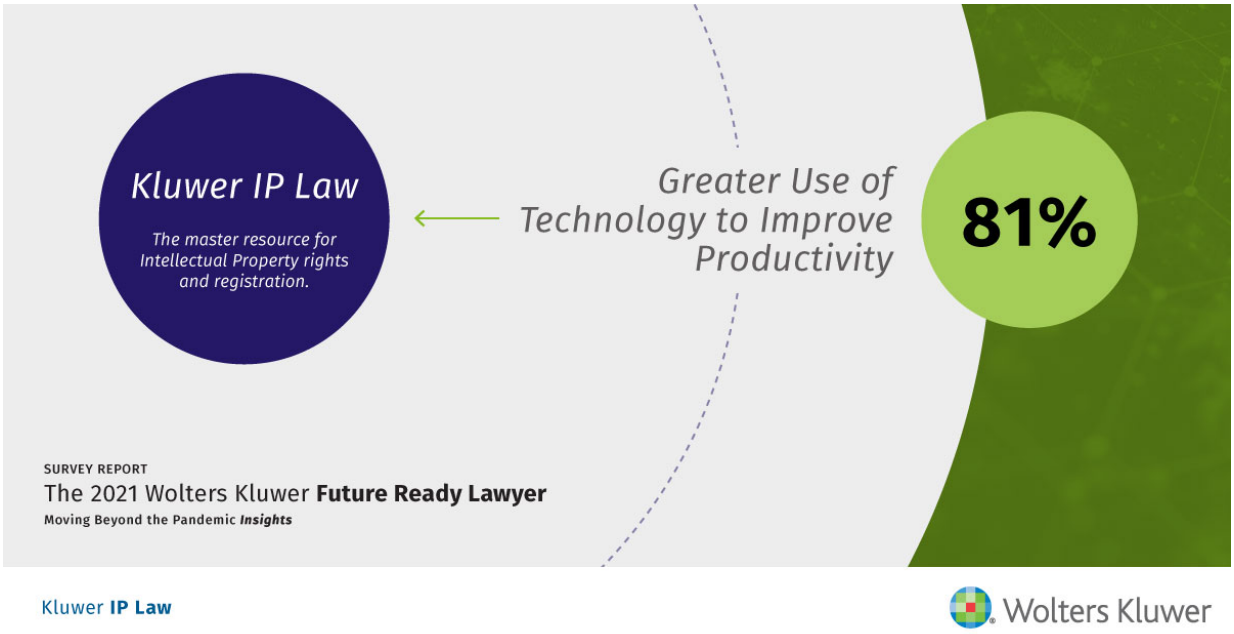
"The Court, which studied the consultations and scientific articles submitted by the parties, retains that if it is not contested that the person skilled in the art knew that for treating HIV a therapy combining several active principles was more effective than a mono-therapy, nothing establishes that in 1996 the person skilled in the art, given the general state of its knowledge, necessarily and specifically thought of emtricitabine to combine it to TD upon reading claim 27 which is drafted in very general terms.

The judgement will be therefore confirmed in that it retained that no functional formula necessarily and specifically related to emtricitabine and that consequently the

combination of the two products TD and emtricitabine could not be made the subject of an SPC on the basis of the EP 894 patent" [emphasis added].

In the end, not only did the earlier French first judgment foreshadow the CJEU judgment, but it already provides some guidance for its interpretation. However, let us be sincere, and not too patriotic: we should also note that the part of the judgment relating to article 69 appears contradictory in relation to other recent judgments of the Paris High Court. Indeed, in TRUVADA®, the Court ruled on the interpretation of Article 69 EPC and held that "*the interpretation pursuant to which, for the person skilled in the art, in the context of European Patent No 894, the sentence 'and, where appropriate other therapeutic ingredients' would target an active ingredient with therapeutic properties which may be capable of being combined with tenofovir disoproxil, such as emtricitabine, clearly exceeds what is permitted by Article 69 EPC and its interpretative protocol in this respect, therefore leading to the admission that "the protection also extends to what, in the opinion of a person skilled in the art having examined the description and the drawings, the patent owner intended to protect", and may therefore disregard the reasonable degree of legal certainty that third parties are entitled to expect.*" However, the same Court implicitly stated the opposite in the ROSUVASTATINE® and PEMETREXED® cases by searching into the description salts not mentioned in a claim (see my report here).

At any rate, although after this umpteenth episode, the suspense begins to wane, we can't help wondering: was this the last episode of the TRUVADA® Saga? While waiting, we can always take comfort with the Beatles and *The Handmaid's tale*.



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