

# Kluwer Patent Blog

## The CJEU judgment of 11 January 2024 in *Gilead v. Mylan*. Will it prompt an exodus of patent owners to the UPC?

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As readers will be well aware, one of the preferred hobbies of the Court of Justice of the European Union (“CJEU”) is to issue controversial judgments in intellectual property matters which, quite often, instead of providing guidance to national courts, raise more questions than they answer. After the Christmas break, the CJEU seems to have resumed this hobby with renewed vigour, as shown by the judgment issued last Thursday in case C-473/22 (*Mylan AB and Gilead Sciences Finland Oy et altri*).

The judgment stemmed from a request for a preliminary ruling under article 267 of the Treaty on the Functioning of the European Union (“TFEU”) from the Finnish Market Court (“FMC”). The FMC had ordered a preliminary injunction requested by Gilead against Mylan invoking a supplementary protection certificate (“SPC”) that was later found to be invalid. Mylan then filed a complaint against Gilead claiming the damages allegedly caused by the preliminary injunction. According to Finnish law, any damage claim arising from the lifting of a preliminary injunction must be decided according to a strict liability principle. However, the FMC had doubts as to whether this strict liability standard was in line with article 9(7) of Directive 2004/48/EC, as interpreted by the CJEU in its judgment of 12 September 2019 (case C-688/17 *Bayer Pharma and Richter Gedeon*). These doubts were no doubt justified as illustrated, for example, by the fact that the Advocate General, in paragraph 66 of his Opinion of 21 September 2023, had found the strict liability standard to be contrary to article 9(7) of Directive 2004/48/EC as interpreted by the CJEU in its judgment of 12 September 2019.

The CJEU, in its recent judgment of 11 January 2024, in which it has completely ignored the Advocate General’s Opinion – it is not even cited –, as mentioned at the beginning, has raised more questions than it has really answered. To put the debate in context, it is worth transcribing the questions referred by the FMC:

“(1) *Is a compensation regime based on strict liability, such as that ... in force in Finland, to be regarded as compatible with Article 9(7) of [Directive 2004/48]?*

(2) *If the first question is answered in the negative, what then is the nature of the liability for compensation on which the liability under Article 9(7) of [Directive 2004/48] is based? Is that liability to be regarded as a form of liability based on fault, an abuse of rights, or some other ground?*

(3) *In relation to the second question, what circumstances must be taken into account in assessing the existence of liability?*

(4) *In particular, as regards the third question, must the assessment be made solely on the basis of the circumstances known at the time when the provisional measure was obtained, or is it permissible to take into account, for example, the fact that the intellectual property right on whose alleged infringement the provisional measure was based was subsequently, after that measure was obtained, found to be invalid ab initio and, if so, what significance is to be attached to that circumstance?"*

In its judgment of 11 January 2024, rather astonishingly, the CJEU has found that Directive 2004/48 did not intend to harmonise the rules on compensation for defendants beyond what is required by the TRIPS Agreement and that therefore, it leaves the Member States leeway to opt for a strict liability regime or a fault-based liability regime:

*" 35. Thus, by reproducing, in Article 9(7) of Directive 2004/48, the very broad wording of Article 50(7) of the TRIPS Agreement, the EU legislature expressed its intention, first, not to harmonise the rules on compensation for defendants beyond what is required by that agreement and, second, to allow the Member States discretion as to the specific implementation of the rules governing the applicant's liability.*

*36. It follows that Article 9(7) of Directive 2004/48, read in the light of Article 50(7) of the TRIPS Agreement, must be interpreted as laying down a minimum standard concerning the enforcement of intellectual property rights while, in principle, leaving the Member States leeway to opt, as the case may be, for a strict liability regime or a fault-based liability regime."*

In a nutshell, the message is that each Member State is free to go its own way. Put another way, a colossal invitation to forum shopping (more on this later) that will raise the eyebrows of European Union ("EU") law aficionados who, until last Thursday, had always understood that the purpose of a Directive was to harmonise (not disharmonise) law across the EU. Certainly, reading last Thursday's judgment, the eyebrows of those who drafted the Recitals of Directive 2004/48 will be heading skyward. For Recital 9, for example, justified the need for a Directive on the fact that "the current disparities also lead to a weakening of the substantive law on intellectual property and to a fragmentation of the internal market in this field." Building from this problem (disparities), Recital 10 proclaimed that "The objective of this Directive is to approximate legislature systems so as to ensure a high, equivalent and homogeneous level of protection in the internal market."

Certainly, letting each Member State go its own way it does not seem aligned with the objective of ensuring a high, equivalent and homogeneous level of protection in the internal market.

Building from the crystal premise announced in paragraphs 35-36, and after trying to find a rather convoluted way to reconcile the new judgment with its previous judgment of 12 September 2019, last Thursday the CJEU reached the following conclusion:

*"Article 9(7) of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights must be interpreted as not precluding national legislation which provides for a mechanism for compensation for any injury caused by a provisional measure, within the meaning of that provision, based on a system of strict liability of the applicant for those measures, in the context of which the court is entitled to adjust the amount of damages by taking into account the circumstances of the case, including whether the defendant*

*played a part in the occurrence of the injury.”*

This conclusion, as announced at the beginning of this entry, raises more questions that it really answers:

First, from the legal grounds developed by the judgment, it is doubtful whether this conclusion applies to strict liability systems *per se*. In the course of the judgment, the CJEU makes it very clear that, as stated in its previous judgment of 12 September 2019, the national court must take into account “all the circumstances of the case”, a caveat that does not appear to be in line with a pure strict liability system, as generally understood in civil law. In fact, the new judgment reiterates in paragraph 39 that “Although the power of the competent national courts to grant such compensation is strictly subject to the conditions set out in Article 9(7) of Directive 2004/48, the fact that those conditions are satisfied in a specific case does not mean that those courts are automatically and in any event obliged to order the applicant to provide compensation for any injury suffered by the defendant as a result of those measures (see, to that effect, the judgment in Bayer Pharma, paragraph 52).” In paragraph 40, the CJEU also makes it very clear that, “irrespective of the liability regime adopted”, national courts must always take into account all the circumstances of the case before them, including the conduct of the parties. Throughout the judgment, the CJEU has been very careful to introduce the caveat that the conclusion applies to a strict liability mechanism “such as that at issue in the main proceedings”, where the national court can take into account all the circumstances of the case (paragraphs 46, 48, etc.).

Second, the CJEU seems to have taken the position that Directive 2004/48 does not clarify whether a fault or a strict liability standard should be followed. This view does not seem easy to reconcile with Recital 22 of Directive 2004/48, which foresees the right to compensation in the case of an “unjustified” preliminary injunction request. This sentence, interpreted *a contrario*, shows that compensation may not be in order when the request was “justified.” And, for obvious reasons, the relevant date to assess whether or not the request for a preliminary injunction was “unjustified” or “justified” is the date when the request was filed.

Third, the CJEU also seems to have adopted the stance that the TRIPS Agreement does not contain any guidance on this point either. With all due respect, this is yet another example of the lack of familiarity of the CJEU with the architecture of the TRIPS Agreement. As we see it, the judgment published last Thursday has not taken into account the context where article 50 (7), which article 9(7) of Directive 2004/48 sought to implement, is enshrined. This article, as is typical in the TRIPS Agreement, is subject to the general principles announced in the previous section. In this regard, Section 2 of Part III of the TRIPS Agreement, as its title illustrates, sets out the general principles applicable to “Civil and Administrative Procedures and Remedies.” Article 48, entitled “Indemnification of the Defendant”, sheds light on the reasons why the EU Legislator, when it drafted Directive 2004/48, in Recital 22 inserted the caveat that compensation would only be appropriate in the case of an “unjustified” request. In particular, article 48 of the TRIPS Agreement reads as follows:

*“Article 48 Indemnification of the Defendant*

1. *The judicial authorities shall have the authority to order a party at whose request measures were taken and who has abused enforcement procedures to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses,*

*which may include appropriate attorney's fees."*

Clearly, this article, which of course binds the EU and Member States, including the Finnish Court that sent the request for a preliminary ruling, is at odds with a strict liability standard. In this regard it is a bit of a paradox that the only way for the Finnish Court to prevent Finland from violating its international law obligations under article 48 of the TRIPS Agreement would be to disregard the answer received from the CJEU last Thursday. The Finnish Court would be perfectly entitled to do so, not only because the judgment has opened the path to doing just that (see paragraph 36 transcribed above) but also, and more importantly, because Recital 5 of Directive 2004/48 makes it very clear that "This Directive should not affect Member States' international obligations, including those under the TRIPS Agreement." So, Member States are free to follow the TRIPS Agreement instead of the Directive. In the case at hand, this would be particularly justified, taking into account that article 48 of the TRIPS Agreement does not have a counterpart in the text of the Directive.

Our final respectful remark takes us back to the title of this blog: will last Thursday's judgment prompt an exodus of patent owners to the UPC or to jurisdictions which do not follow a strict liability standard? As mentioned above, paragraphs 35 and 36 of the judgment are a colossal invitation to forum shopping. In this regard, the drafters of the UPCA and the UPC's Rules of Procedure, which seem to be more familiar with the TRIPS Agreement than the CJEU, were very careful with the language they used. In particular, in article 60(9) UPCA, which is the counterpart of article 9(7) of Directive 2004/48, they stated that the UPC "may order" compensation when a preliminary injunction or similar order is revoked (see the referral of article 62(5) to article 60(9) UPCA). The Rules of Procedure of course follow the same regime (Rules 213(2), 354(2) and 125). Needless to say, a system that states that the Court "may order" compensation for the defendant when a preliminary injunction is lifted does not seem to have in mind a strict liability standard.

All in all, for the reasons explained above, this year's entry promises CJEU's case law on intellectual property matters will continue to entertain intellectual property aficionados in the months to come.

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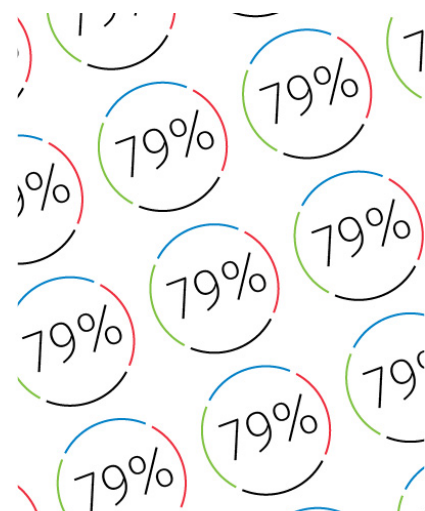
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