

Michaël De Vroey & Arnaud Detry | January 2024

**In a judgment of 11 January 2024 in *Mylan v Gilead* (C-473/22), the Court of Justice of the European Union (CJEU) has accepted that a party enforcing a provisional measure can be held liable to compensate the defendant for any damages and costs caused by the enforcement, when the intellectual property right on the basis of which that measure was granted is subsequently found to be invalid, or if it ultimately transpires that there has been no infringement.**

This judgment adds an important clarification to the CJEU's previous judgment handed down in 2019 in the *Bayer* case (*Bayer Pharma*, C-688/17). In that case, the CJEU had upheld the validity of national legislation denying automatic compensation for damages caused by the enforcement of provisional measures on the basis of a patent that was later found to be invalid. The CJEU seemed to require a liability based on fault and specified that compensation could be due when the applicant had committed an abuse (of rights or process) when applying for the measures. Some inferred from this judgment that the CJEU had ruled out a system of strict (or no fault) liability resulting in automatic compensation, and even that compensation would only be possible if the applicant had committed an abuse, which sets a very high bar for defendants to obtain compensation for injury suffered from provisional measures that are subsequently reversed.

## THE FACTS

In September 2017, pharmaceutical company Gilead sought a preliminary injunction before the Finnish Market Court against generic manufacturer Mylan for infringement of a supplementary protection certificate (SPC) for an antiretroviral medicine for the treatment of people with HIV. Mylan filed a claim to invalidate the SPC.

In December 2017, the Market court upheld Gilead's claim and imposed a preliminary injunction prohibiting Mylan from importing, manufacturing, possessing, offering, placing on the market and using the generic medicine during the period of validity of the SPC, on pain of a fine of EUR 500,000.

These preliminary measures were subsequently revoked after the SPC was found to be invalid. Mylan claimed damages for the injury caused by Gilead enforcing provisional measures on the basis of an invalid SPC. Finnish law applies a system of strict liability according to which the enforcer of a provisional measure is liable to pay compensation if the underlying IP right is subsequently found to be invalid. The Market court turned to the CJEU to have its view on whether the system of strict liability under Finnish law is compatible with Article 9(7) of the IP Enforcement Directive (2004/48).

EUROPEAN COURT  
OF JUSTICE  
ALLOWS STRICT  
LIABILITY WHEN  
ENFORCING  
PROVISIONAL  
MEASURES FOR IP  
INFRINGEMENT

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## THE CJEU'S JUDGMENT

The CJEU first recalls that three conditions must be met in order to grant a defendant appropriate compensation for any injury caused by provisional measures on the basis of Article 9(7) of the IP Enforcement Directive:

1. the provisional measures have been revoked or have lapsed due to any act or omission by the applicant, or there has been no infringement or threat of infringement of that applicant's intellectual property right;
2. there must be an injury;
3. there must be a causal link between that injury and those measures.

The CJEU explains that Article 9(7) of the IP Enforcement Directive lays down a minimum standard, leaving the Member States leeway to opt, as the case may be, for a system of strict liability or a fault-based liability. The fact that the defendant does not have to demonstrate a fault committed by the applicant is a counterweight to the fact that the applicant was able to obtain such measures without having to adduce definitive evidence of any infringement.

The CJEU also clarifies that its previous judgment in Bayer dealt with a specific scenario and that it cannot be inferred from this judgment that Article 9(7) only allows a liability based on the applicant's fault. However, this does not mean that national courts should automatically and in any event order the applicant to provide compensation since they must still take into account all the circumstances of the case, including the conduct of the parties. They may also reduce the amount of compensation according to national law where the defendant enabled the injury to occur or failed to take reasonable measures to avoid or mitigate it.

With this judgment, the CJEU confirms the validity of a mechanism for compensation for injury caused by a provisional measure based on a system of strict liability of the applicant, thereby deviating from the Advocate-General's opinion who had found that a strict liability standard does not comply with Article 9 (7) of the IP Enforcement Directive.

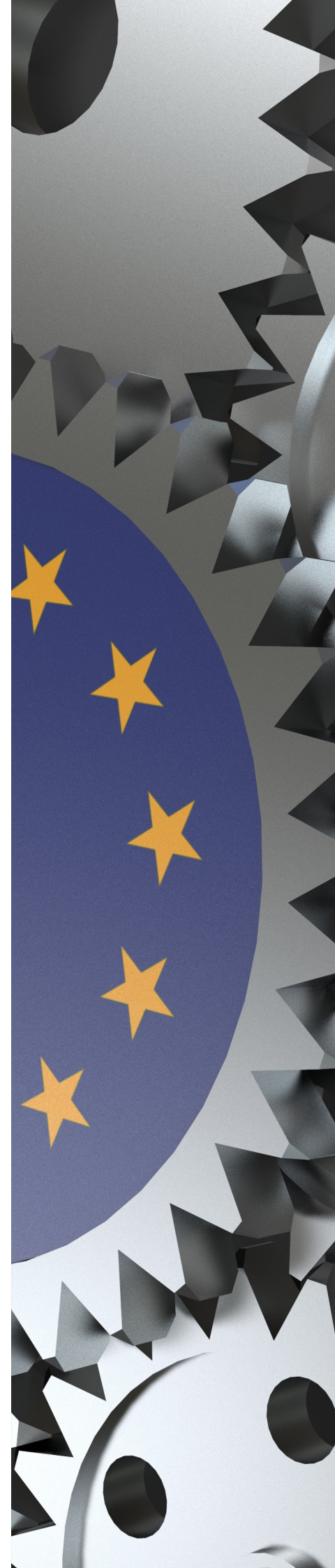
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## THE BELGIAN LIABILITY REGIME

Under Belgian law, the provisional enforcement of a judgment is carried out only at the risk of the enforcer (and without any bond or similar guarantee if the judge has not ordered it).

It is generally accepted that when a summary order (provisional in nature) is subsequently overturned on appeal (i.e. within the same lawsuit = scenario 1), the applicant who enforced the provisional measure must compensate the defendant for the damage suffered, even if the applicant has not committed a fault (strict liability).

In contrast, if the provisional measure is ended following a judgment on the merits that invalidates the underlying IP right or dismisses the infringement claim (i.e. in another lawsuit = scenario 2), the tendency is to consider that the applicant would only have to compensate the defendant if he had committed



a fault. In a judgment of 28 February 2018 in the *Snowfall case*, the Brussels Court of Appeal held that no liability arises from the mere execution of a provisional measure (such as an *ex parte* counterfeit seizure), even if it is later found that there was no infringement of the IP right invoked, thereby rejecting the idea of strict liability as this could otherwise discourage IP holders from applying for such measures, which would be contrary to the IP Enforcement Directive. In another judgment of 11 October 2022 in *Mylan v Novartis*, the Brussels Court of Appeal applied the CJEU's decision in *Bayer* and once again confirmed the principle of fault-based liability (appeal pending before the Belgian Supreme Court).

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## COMMENT

In the *Mylan v Gilead* judgment, the CJEU gives some discretion to the national courts to apply a strict or fault-based liability according to national law and to adjust the amount of damages by taking into account the circumstances of the case.

It will be interesting to see how Belgian courts will apply this judgment going forward in intellectual property disputes similar to scenario 2, and whether the Brussels Court of Appeal's current case-law of denying strict liability for being contrary to the IP Enforcement Directive can be maintained.

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If you want to know more about this case or about IP protection/enforcement in general, please contact our Intellectual Property team via [ip@simontbraun.eu](mailto:ip@simontbraun.eu).

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