



# Act in Haste, Repent at Leisure?

***Lessons from *Mylan v Gilead* for those seeking to “launch at risk” (and those seeking to stop them)!***

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# For Discussion:

- 01 “Launch at Risk” – Commercial Landscape
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# “Launch at Risk”

- Common issue in pharmaceutical industry
- Generics introduced to the market prior to Patent (or SPC) expiry
- Can bestow *significant* competitive advantage – an opportunity to gain market share prior to other generics manufacturers
- Risks:
  - **Interim measures** e.g. interim injunction obtained by rights holder
    - Resulting financial loss / failure to make ROI
    - But what if the right(s) in question is/are vulnerable?
      - Potential **Remedy: seek compensation** from rights holder for ‘unjustified’ block to market access



## Legal Regime - Compensation for “Unjustified” Interim Measures

*“Where... **provisional measures are revoked or where they lapse** due to any act or omission by the applicant, **or where it is subsequently found that there has been no infringement or threat of infringement** of an intellectual property right, the **judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation** for any injury caused by those measures.”*

(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 (“**Enforcement Directive**”), which implements Article 50(7) of TRIPS)



## ***Bayer Pharma (12 September 2019 - C-688/17, EU:C:2019:722) - Background***

- Bayer – patent holder for contraceptive medicine
- Bayer **granted interim injunctions** in the Hungarian courts against Richter Gedeon and Exeltis to restrain their distribution of generic equivalents
- Both **injunctions lifted**, and **patent invalidated** in main proceedings
- Richter Gedeon and Exeltis each sued Bayer to recover “**appropriate damages**” for the wrongly awarded injunctions
- Metropolitan Court of Budapest referred the matter of interpreting “appropriate damages” to the CJEU.





## ***Bayer Pharma* (12 September 2019 - C-688/17, EU:C:2019:722) – Questions referred to CJEU**

1

Is “**appropriate compensation**” to be interpreted autonomously or do Member States decide on the content, amount and methods of appropriate compensation?

2

Does the “**appropriate compensation**” concept preclude national law which provides that alleged infringers will not be compensated for losses arising due to interim measures, if:

- the alleged infringer didn't act reasonably; and
- even though the patent the interim measures are based on is later found to be invalid?



## ***Bayer Pharma* (12 September 2019 - C-688/17, EU:C:2019:722) - Decision**

Whether **compensation** is **appropriate** depends on the **specific circumstances** of a case.

1. To obtain compensation, it is necessary that an interim measure is lifted (e.g. due to non-infringement or invalidity); **however**
2. This doesn't **automatically** guarantee compensation: all circumstances of case are to be taken into account e.g. behaviour of parties.





## ***Bayer Pharma* (12 September 2019 - C-688/17, EU:C:2019:722) - Decision (2)**

- “Appropriate compensation” is a “*guarantee needed to cover the costs and the injury caused to the defendant by an unjustified [interim measure]*”.
- Interim measures “*unjustified*” if granted where there is no risk of irreparable harm to the rights holder.
- Marketing of a medicine infringing a patent constitutes *prima facie* risk of irreparable harm.
- Therefore – interim measures may be **justified** (i.e. no compensation available to defendant) **even if** patents found invalid/non infringed.
- Whether interim measures are justified is assessed at the time the interim measure is granted.
- Effect – potentially excludes “appropriate compensation” in many launch at risk cases.





## *Mylan AB v Gilead Sciences Finland Oy and others (Case C-473/22) - Background*

- Gilead had SPC for antiretroviral medication & Mylan “**launched at risk**” before SPC expiry
- Gilead obtained **interim injunction** but SPC later found to be **invalid**
- Mylan sought “**appropriate compensation**”
- Finnish Court doubted that Finland’s **strict liability** regime was consistent with *Bayer Pharma* and sought clarification on compatibility with EU law





# *Mylan AB v Gilead Sciences Finland Oy and others* (Case C-473/22) – Questions referred to CJEU

1

Is a strict liability compensation system, like the one in Finland, compatible with the “appropriate compensation” provision in the Enforcement Directive?

2

If the answer to (1) is “no”, what is liability for compensation based on? Is it based on fault, abuse of rights, or some other ground?

3

What circumstances need to be taken into account when assessing liability?

4

Regarding question 3, should the assessment focus only on the circumstances known when the provisional measure was obtained, or is it permissible to consider factors such as the IP right being later invalidated? If so, what importance should be given to this discovery?



# *Mylan v Gilead* (Case C-473/22) – Opinion (1)

21 September 2023 – AG Szpunar Opinion:

1

Strict liability / automatic compensation **not** consistent with *Bayer Pharma* or Article 9 (7) Enforcement Directive.

2

Circumstances of each case relevant to assessing whether appropriate to award compensation **at all**: not just the amount.

3

Confirms *Bayer*:

- interim measures may be **justified** even if right later found invalid/non infringed. Invalidation of right does not mean there is no risk of irreparable harm.
- whether provisional measures are **justified** is assessed at the **date of application** for those measures (with regard to the circumstances surrounding the application). A finding of no infringement/invalidity does **not** mean measures are unjustified, **but** can factor into an assessment of whether, *as at the application date*, they were justified.



## *Mylan v Gilead* (Case C-473/22) – Opinion (2)

Guidance for factors to be considered in assessing whether interim measures ‘justified’ and compensation ‘appropriate’ include:

1. The right holder’s **conduct** regarding **maintenance, extension, or renewal** of interim measures
2. Circumstances such as how the **dispute** “unfolds” between the parties
3. **Proportionality** of seeking interim measures
4. Whether the interim measures create **barriers** to **legitimate trade**
5. Whether the interim measures are **abusive** (which should automatically be considered ‘unjustified’ and give rise to compensation).





## *Mylan v Gilead* (Case C-473/22) – CJEU Decision

- CJEU decision awaited – will the CJEU follow the AG's opinion?
- CJEU did not follow AG opinion in *Bayer* (but AG opinion influential in majority of CJEU cases)





## Key Points (1) – EU and UK Considerations



*Bayer and Mylan v Gilead* indicate that the interpretation of “appropriate damages” and, in particular, a requirement that courts consider the circumstances of each case when considering if damages are appropriate is a matter of uniform EU law.

- Various EU member states including Spain, Sweden, and Finland traditionally had strict liability regimes: topic likely to be revisited by national courts following *Mylan*
- How will UK courts interpret the decisions? IP Enforcement Directive implemented in UK law (but Courts able to diverge on interpretation of “appropriate damages”) - typical UK approach is to grant interim injunctions subject to patent holders undertaking they will compensate for loss caused if injunction wrongly granted due to invalidity (mitigates abuse)
- Potential lower level of protection for rights holders / greater chance of successfully obtaining compensation for ‘wrongly’ granted interim measures in “launch at risk” context in UK



## Key Points (2) – Other Lessons Learned

Going forward, rights holders may **have greater protection** in EU member state courts against having to provide compensation for wrongly granted interim measures, especially in the context of “launch at risk” scenarios, by which interim measures may be considered *prima facie* justified

This means “launching at risk” may **be higher risk** than before and it may be harder to recover losses associated with interim measures

Rights holders must ensure that when seeking interim remedies, those remedies are *prima facie* **‘justifiable’, proportionate**, do not create **barriers to legitimate trade**, and are not **abused**. Abuse will, in most cases, mean that an application for interim measures is unjustified and that compensation is payable.



# Thank you – Questions?

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