

11th IP Forefront Pharma Forum

An Analysis of Preliminary Injunctions in Patent Litigation in Europe

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An Analysis of Preliminary Injunctions in Europe

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1. Why preliminary injunctions in Europe matter

No patent linkage in Europe

MARKETING AUTHORISATION (MA) GRANTED INDEPENDENT OF PATENT STATUS

- No stay of MA grant pending resolution of patent disputes - unlike the US (Hatch-Waxman) or China.
- Infringer can launch at risk – erodes patentee's market and can force irreversible price reduction.
- Preliminary injunction can be used before trial to stop the infringer launching – but rules for grant differ
- Understanding when and if a preliminary injunction will be granted is an important part of a patent strategy:
 - Patentee –when and where to apply for a PI to protect its market and chance of success.
 - Infringer – launch in a jurisdiction where PI unlikely to be granted.

2. What are the triggers?



Triggers in national courts - overview

WHEN IS THE EARLIEST TIME A PATENTEE CAN SEEK A PI?

- **Historically, earliest PI trigger was available in the UK – even before grant of marketing authorization (MA)**
- **Other jurisdictions - additional steps in pricing and reimbursement needed for a trigger**
- **But has this changed in Germany? Aflibercept decision? Halozyme?**

What is a trigger?

- 1. the event that allows patentee to file for a PI;*
- 2. when there is imminent infringement; and*
- 3. Starts the urgency clock*

Earlier PI trigger in Germany? (I)

OFFICIAL HEADNOTES IN SCHÖN'S CROSS-BORDER EYLEA PI DECISION (VS. FORMYCON):

*“It would **suffice to argue that a marketing authorization has at least been applied for and that a distribution structure exists** that would make it possible to market the product. In the pharmaceutical sector in particular, the substantial investments in new products can only be recouped if the product is widely available. This applies especially to biosimilars, which are costly to develop. If such a demonstration has been made, it would be incumbent upon the party against whom the claim is made to demonstrate—and, if necessary, prove—that, despite the possibility, either distribution is not planned or the legal requirements in a given country would not justify a claim for injunctive relief.”*

■ Marketing authorisation application and distribution network is enough of a trigger to seek a PI?

■ BUT not considered by Court of Appeal – will it hold?

Earlier PI trigger in Germany? (II)

HALOZYME PI APPLICATION FILED BEFORE MA GRANTED

- **PI filed** before MA grant but **after positive CHMP opinion**
- But heard and decided after MA grant
- Trigger point was not a substantive issue by the time of the PI hearing

So unclear if Germany does have an earlier PI trigger.

3. What factors are taken into account?

Factors taken into account – varies between jurisdictions

Urgency/speed of the PI application once infringement risk is known

Imminence of infringement – how close is the infringer to carrying out an infringing act?

Validity of the patent

Infringement of the patent

Necessity of PI – is there a risk of irreparable harm?

Whether the product is already on the market – desire to maintain the status quo

Example - Divergent urgency requirements

BY WHEN SHOULD THE PATENTEE APPLY FOR A PI

- **UK** – typically **2-4 weeks**
- **Germany 1 month**, fairly strict
- **France – less strict**/no urgency requirement to file a PI
- **Netherlands – no clear cut deadline but** urgency is a requirement to be eligible for a PI (file swiftly)
- **Italy** – no strict urgency requirement, assessed as overall balancing of interest, **can be many months.**
- **Spain – no fixed time period** but must act quickly
- **UPC – 3 months can be too long** if no explanation why it took this long

UPC – PIs – urgency

URGENCY: “UNREASONABLE DELAY” MAY RULE OUT THE GRANT OF PI

■ *Guardant Health v Sophia Genetics* – Court of Appeal, 2 July 2026

- Held that Guardant had not acted with sufficient urgency
 - G’s **27 May 2025 UK warning letter cited** a User Manual that disclosed the Patent’s features – G must have had relevant details then
 - G could have established infringement within two weeks – all information relied on for PI application was public, no substantial investigative measures required
- **Guardant delayed more than 3 months – did not provide adequate explanation in evidence why it delayed**
- It is **applicant’s burden to show it acted without unreasonable delay**

UPC – PIs – urgency

URGENCY: “UNREASONABLE DELAY” MAY RULE OUT THE GRANT OF PI

■ *Guardant Health v Sophia Genetics* – Court of Appeal, 2 July 2026

key takeaways:

- Justifications for delay (e.g. need to consult technical experts) need to be fully evidenced and explained
- A UK warning letter can start the urgency clock for UPC actions
- UPC may not have tolerance for delay caused by waiting to build a combined case (patentee can bring separate PI applications)
- What matters is when information about a specific potential infringement was publicly available to the patentee, not when the patentee decided to consider it.

Summary of factors

- National courts – not UK and IE
 - Validity and infringement = key
 - Similar tests between countries for imminence requirements (except Germany?) – needs to be ready to go.
 - Speed of application once risk known (urgency)
- UK and IE
 - Adequacy of damages, balance of convenience, speed
- UPC
 - Biggest deciding factor (against grant) = assessment that patent not valid
 - Lack of imminence of infringement (has “the stage been set” for infringement?)
 - (lack of) necessity for an injunction – includes some consideration of risk of irreparable harm to patentee

4. Can a preliminary injunction be cross-border?

Overview on cross border PIs

UPC

- In-built long-arm jurisdiction for the **UPC states in which patent is in force**
- **More recently long-arm jurisdiction for non UPC and/or non-EU states**

National courts

- Pre-*Electrolux* – only NL really granted cross border PIs. UK granted cross border declarations of non-infringement.
- Post *Electrolux* – **Green light for European national courts** -they maintain competence to determine **cross border PIs and final injunctions**, even where revocation actions started in foreign jurisdictions (subject to defendant domicile). **Court has competence to consider validity defence of a third state patent (but only inter partes and not so as to change the patent register).**

National court – pan-EU PI post Electrolux

Formycon v Regeneron / Bayer – Eylea

Formycon, DE domiciled biosimilar maker

- F claimed DNIs for Germany, Spain, Portugal, Austria, Switzerland, Netherlands.
- Regeneron / Bayer counterclaims for threatened infringement re Germany and 19 other EP states and claims for a PI for Germany and 30 other EP states
- German patent found valid by Federal Patents Court, then likely infringed by equivalence at PI hearing
- Munich court grants cross border PI in 20+ jurisdictions

Parties settled so not considered on Appeal

Will we see more national attempts at national cross border PIs?

5. What happens if they are wrongly granted?

UPC – wrongly granted PIs (I)

IF PI SUBSEQUENTLY REVOKED FOLLOWING MERITS DECISION – WHAT HAPPENS?

■ UK & IE

- patentee required to **give a cross-undertaking** in damages to cover losses sustained by the alleged infringer in the event that the PI is later found to have been wrongly granted
- **Cross-undertaking can also extend to losses suffered by other parties – e.g. the NHS**

■ UPC

- Court can order applicant upon request of defendant to pay appropriate compensation for any injury caused by those measures
- UPC can order provision of security by patentee to ensure compensation for any damage suffered if PI subsequently revoked
- No requirement for patentee to give cross-undertaking in damages in order to have PI granted

■ FR, DE, IT, NL – no cross undertakings. Strict liability.

6. Takeaways

Takeaways

Do your due diligence:

Patentee

- Know where a PI is likely to be granted
- Surveillance for a trigger
- Don't delay application for a PI
- Understand the risks if it's wrongly granted

Alleged infringer

- Freedom to operate opinions - consider entire thicket
- Where is a PI least likely to be granted?
- Should you revoke the patent to clear the way?



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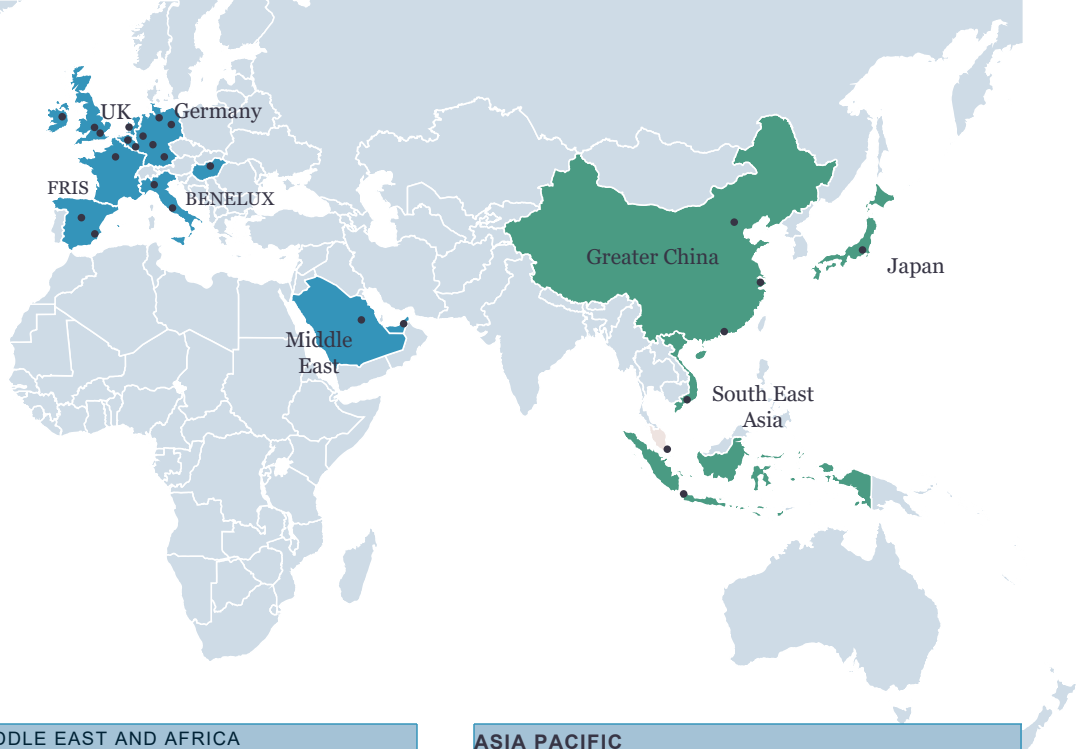
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