Proportionality of Injunctive Relief

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Proportionality of Injunctive Relief

Automatically granted or only if proportionate?
General principles or case-by-case decisions?
Differences between UK, BE, HU and DE?
Where are or should we be heading?
Possible difficulties

Life-saving medicines

- Patent to a life-saving medicine to treat a rare condition
- P’s product has method of administration that is not suitable for treating children
  - Regulatory approval will take at least 1 year
- I’s product on the market with a particular method of administration, and safe to administer to children
  - Injection against I’s product?
Possible difficulties

Complex products

• Patent covering a functionality of LTE
• I is a car manufacturer and offers "connected cars“, including a chip which makes use of the patented technology in LTE
  • Responsible for entertainment functionalities but also vehicle management and safety
  • Injunction which affects entire car?
Possible difficulties

NPEs or “patent trolls“

• P has a patent but does not commercialize the invention
• I has a product applying the invention
• Injunction notwithstanding lack of commercialization?
Possible difficulties

What if PI and patent is later held invalid?

• P obtained a preliminary injunction for patent infringement against I
• P’s patent is held invalid in a final decision on the merits
• Is I automatically entitled to compensation?
Proportionality of Injunctive Relief

I. Enforcement Directive
II. Preliminary Injunctions
III. Final Injunctions
IV. Damages in case of later revocation
V. Change on the horizon?
VI. Conclusion & Questions
I. Proportionality in the Enforcement Directive

General obligation

Article 3

1. Member States shall provide for the measures, procedures and remedies necessary to ensure the enforcement of the intellectual property rights covered by this Directive. Those measures, procedures and remedies shall be fair and equitable and shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

2. Those measures, procedures and remedies shall also be effective, proportionate and dissuasive and shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.
17) The measures, procedures and remedies provided for in this Directive should be determined in each case in such a manner as to take due account of the specific characteristics of that case, including the specific features of each intellectual property right and, where appropriate, the intentional or unintentional character of the infringement.
1. (...) in response to a justified and proportionate request of the claimant, the competent judicial authorities may order that information on the origin and distribution networks of the goods or services which infringe an intellectual property right be provided by the infringer.
I. Proportionality in the Enforcement Directive

Provisional and precautionary measures

Article 9

1. (…) the judicial authorities may, at the request of the applicant:
(a) issue an interlocutory injunction
(b) Order the seizure or delivery up of the goods

Preamble

22) It is also essential to provide for provisional measures for the immediate termination of infringements, without awaiting a decision on the substance of the case, while observing the rights of the defence, ensuring the proportionality of the provisional measures as appropriate to the characteristics of the case in question and providing the guarantees needed to cover the costs and the injury caused to the defendant by an unjustified request. Such measures are particularly justified where any delay would cause irreparable harm to the holder of an intellectual property right.
I. Proportionality in the Enforcement Directive

Measures on the merits

Article 10 (3) on corrective measures
In considering a request for corrective measures, the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties shall be taken into account.

Article 11 on injunctions
… where a judicial decision is taken finding an infringement of an intellectual property right, the judicial authorities may issue against the infringer an injunction aimed at prohibiting the continuation of the infringement.
Measures on the merits

Article 12 on alternative measures
Member States may provide that, in appropriate cases and at the request of the person liable to be subject to [corrective or injunctive measures on the merits], the competent judicial authorities may order pecuniary compensation to be paid to the injured party instead of applying the [corrective or injunctive measures on the merits] if that person acted unintentionally and without negligence, if execution of the measures in question would cause him/her disproportionate harm and if pecuniary compensation to the injured party appears reasonably satisfactory.
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Preliminary injunctions in Hungary
National régime: Easily granted PIs

- HU system complies with ED
- Patent Act – specific rules [Art. 104 (2)-(8)]
- Bifurcation
- Patentee-friendly system

- If the preconditions are fulfilled (and the probability of infringement stands), an injunction will most likely be granted...
What are these preconditions?

- basic condition: **establishment of the probability of infringement**

- **necessity**: Art. 103 (1) d) CCP and Art. 104 (2) Patent Act – **special presumption**

  + **1 out of 4 alternative conditions** contained in Art 103 (1) CCP
    
    a) preserve status quo
    b) ensure the applicant’s subsequent exercise of right
    c) **eliminate any harm the applicant may directly be exposed to**
    d) in other cases of exceptional circumstances

- **proportionality**
What does this mean in practice?

1) Probability of infringement / Infringing activity?

2) Validity?

3) Necessity?

4) Proportionality?
The role of proportionality

• former Code of Civil Procedure: *cumulative condition* for obtaining a PI

• **CCP 104 (2)** “When deliberating the application for provisional measures the court has to consider whether ordering the measure - *including the provision of security, if any* - is likely to cause greater harm to the applicant’s adversary by comparison to the degree of harm the applicant is likely to suffer if the measure is not ordered.”

• 2 possibilities
  → rejection
  → granting + security bond

• public interest, interest of third parties
Remedies

• **cease and desist order**
  + other remedies according to Art. 35 Patent Act
  + HU speciality: return of profit

• **Specific injunction** (e.g. prohibiting the distribution of X medicinal product on Y market)
  
  e.g. what happens if the name of the product changes?

• **no infringing activity - no injunction** → it follows from the wording of Art. 35 (2) because it is aimed at prohibiting the *continuation of the infringement*
General considerations

- Bifurcated system: separate infringement and nullity proceedings

- nullity actions may be filed by everyone
- infringement proceedings (main actions) may be stayed
General considerations

- German Patent Law does *not* recognize a general principle of proportionality when granting injunctions, Sec. 139, para 1 GPA:
  - automatically granted, if patent is infringed
  - validity to be assessed by infringement court

- some procedural "tools" nevertheless allow to take the individual interests into account

- ongoing discussions on potential change of Patent Law...
Preliminary Injunction Proceedings

- summary proceedings, securing of rights
- available remedies:
  - cease and desist
  - information (over origin and distribution channels of infringing goods)
  - no recall, no destruction of goods
  - no damages or rendering of account in preparation therefor
Preliminary Injunction Proceedings

- **conditions:**
  - **prima facie** evidence of infringement
  - sufficient certainty re validity of the injunction patent
    - In principle, only if the injunction patent has already survived opposition or nullity proceedings at first instance (several exceptions exist)
    - attacks on validity only relevant if proceeding is actually pending
  - weighing of interests in general
  - urgency: limited time to apply for PI
Preliminary Injunction Proceedings

- How are infringer's rights secured?
  - enforcement usually dependent on security
  - decision must be enforced within a month otherwise injunction loses its effect and will immediately be overturned
  - infringer can demand that main action is initiated, otherwise PI can be overturned
Preliminary Injunction Proceedings

- ex parte PI awarded and enforced: appeal against PI, motion to discontinue enforcement
- inter partes proceeding: argue that security has to be particularly high before PI is awarded
  - appeal: request to discontinue enforcement
    - can be granted with or without security
    - e.g. show that enforcement would create irreparable harm/disadvantage
  - request to raise security of plaintiff
Preliminary injunctions in the UK
Preliminary Injunctions

• The Courts apply the following principles [American Cyanamid]:
  1. Is there a serious issue to be tried?
  2. Would damages be an adequate remedy for either side?
  3. Where does the balance of convenience lie?

• Preliminary injunction can be agreed by consent and the court will usually honour the agreement

• Preliminary injunctions are only really used in pharmaceutical brand v generic cases (but maybe not for life saving medicines)

• May be difficulties in obtaining a preliminary injunction for second medical use cases

• It is possible to obtain a preliminary injunction whilst an appeal of the first instance decision invalidating the patent is ongoing [Novartis v Hospira]
Cross-undertaking for Damages

• When a preliminary injunction is granted the claimant will be ordered to give a cross-undertaking for damages

• Used to reduce the risk of injustice as preliminary injunctions are normally granted “at a stage when the evidence is incomplete”

• Serious obligation - failure to meet obligation under cross-undertakings is contempt of Court

• Can be extended to cover the position of third parties that suffer damage
  - National Health Service – Yes in principle [Abbott v Ranbaxy] [Warner Lambert v Actavis]
  - all customers/potential customers - No [Actavis v BI]
Preliminary injunctions in Belgium
CLASSICAL REQUIREMENTS

• **Urgency** (= an immediate decision is necessary to avoid immediate damage or serious discomfort)

• **Prima facie** infringement

• **Prima facie** validity

• **Balance of interests?**

• **Absolute necessity** (in case of ex parte PI)
IN PRACTICE

• PIs are generally granted unless
  ➤ patentee did not take diligent and timely steps
  ➤ smoking gun re *prima facie* invalidity
  ➤ infringement requires thorough examination

• Balance of interests? Three positions:
  ➤ No room for balance of interests if other conditions OK
    ➤ OR in line with decision regarding (*prima facie*) validity of patent
  ➤ Balance of interests can weigh in, but only to mitigate the measures requested
  ➤ Almost never to refuse PI where other conditions met
IN PRACTICE

• PIs can be imposed pending appeal against a first instance revocation decision on the merits
  ➢ Opposition division [Cass. 2012, Novartis v Mylan]
  ➢ National decision [Cass. 2013, Lundbeck v Eurogenerics]
    ➢ BUT reversal burden of proof
      [Cass. 2014, Sandoz v Astrazeneca]
• PI has been refused for **lack of urgency** where:
  ➢ patentee had applied for, but not yet been granted a MA
    ➢ No immediate damage or serious discomfort
    ➢ Immediate decision is **not** necessary
      [Pres. Brussels Ent. 2019, Fresenius v Amgen]
  ➢ commercialisation had already started three months prior to PI proceedings, hearing on the merits takes place half a year later and market position of patentee is solid enough
      [Pres. Antwerp Ent. 2012, Unilever v Nestec]
IN PRACTICE

• Pls mainly, but not exclusively used for pharmaceuticals

• Order for cross-undertaking for damages or security is rare
IN PRACTICE

• *Ex parte* PI requires immediate follow-up by contradictory PI proceedings (*case law*)
  [Pres. Brussels Ent., 5 October 2018, Merck v Mylan]

• *Inter partes* PI requires follow-up by proceedings on the merits within one month (*law*)
Proportionality of injunctive relief

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Final Injunctions in Germany
Main Actions – Injunctions

- Available remedies:
  - cease and desist
  - information (over origin and distribution channels of infringing goods)
  - recall
  - surrender for purposes of destruction of goods
  - acknowledgement of right to claim damages and rendering of account in preparation therefor
  - rarely: publication of judgment
Main Actions – Injunctions

- How to deal with insecurities re validity?
  - stay of infringement proceedings
    - within the court's discretion
    - allows to take into account also potential harm/damages in case of invalidation
  - argue that security has to be high
  - on appeal: request to raise security/discontinue enforcement
"Special" Remedies
"Grace period"

- **liquidation of stocks** (Aufbrauchsfrist)
  - BGH, GRUR 2016, 1031 - Wärmetauscher
  - "only if the preliminary enforcement of the injunction against the infringer, also taking into account his interests due to special circumstances of the individual case, would constitute a disproportionate hardship, not justified by the exclusive right and the regular consequences of its enforcement, and would therefore be unfair"
  - weighing of interests (extraordinary harm, degree of fault)
  - discussed a for the first (and so far the only) time a potential limitation of the claim for cease and desist based on the principle of proportionality as part of the principle of good faith
Compulsory License

- Sec. 24, para. 1 German Patent Act

(1) The non-exclusive authorisation to commercially use an invention shall be granted by the Federal Patent Court in an individual case in accordance with the following provisions (compulsory licence) where

1. a licence seeker has, within a reasonable period of time, *unsuccessfully attempted to obtain permission* from the proprietor of the patent to use the invention on reasonable commercial terms and conditions, and

2. the *public interest* calls for the grant of a compulsory licence.
Compulsory License

- BGH, GRUR 1996, 190 – Polyferon

"public interest exists if certain circumstances - above all technical, economic, socio-political and medical aspects - are added which cause the unrestricted recognition of the exclusive right and the interests of the patentee to rescind, because the interests of the general public require the use of the patent by the licence seeker"
Compulsory License

- BGH, GRUR 2017, 1017 – Raltegravir
  - "Isentress": treatment of HIV, avoids undesirable side effects which appear with other drugs on the market
  - first compulsory license granted in preliminary injunction proceedings acc. to Sec. 85 German Patent Act
  - granted in first instance by BPatG and upheld on appeal

- BPatG, BeckRS 2018, 34096 – Praluent
  - license denied due to lack of sufficient efforts of license seeker and doubts re public interest
Final Injunctions in the UK
Remedies When a Patent is Held Valid and Infringed

- Declaration of infringement
- Damages or an account of profits (and basic disclosure to enable a choice to be made [Island Records v Tring])
- Dissemination/publication of the decision
- Reimbursement of legal costs
- Certificate of contested validity
- An injunction
Injunctions for Patent Infringement

• Discretionary Remedy historically in the form: “... not to infringe EP (UK)…” and must be exercised proportionally

• But virtually always granted

• Virgin Atlantic v Premium - only to be withheld if it is grossly disproportionate

• So can be refused in rare cases for example where it is in the public interest or would have an oppressive effect on the infringer [Navitare v Easyjet]

• Guidelines from Shelfer v City of London Electric Lighting Co [1895] that damages can be awarded instead of an injunction if 4 conditions are met:
  i. Injury to C’s legal rights is small
  ii. Is capable of being estimated in money
  iii. Can be adequately compensated by a small money payment
  iv. It would be oppressive to D to grant an injunction
Proportionality considered by the UK Court

• Court refused to order damages in lieu even where superior medical product – [Biogen v Medeva]

• Stay awarded to final injunction [Regenron v Kymab, Boston v Edwards] – on the balance of convenience or to allow retraining of medical professionals on non-infringing devices

• Carve-out to injunction for patients with no alternatives [Boston v Edwards] – no injunction covering those patients who have no other options

• Second medical use infringement by skinny label products [Warner Lambert v Actavis] – form of final injunction would need to be considered as standard form is not appropriate.
Proportionality considered by the UK Court

- Injunction in non-SEP telecoms case [Nokia v HTC] (but stayed pending appeal for key product)

- Valid and infringed standard essential patent – FRAND injunction [Unwired Planet v Huawei]

- No stay of injunction for company holding-out - [TQ Delta v ZyXEL]
Final injunctions in Hungary
Final injunctions

• typical defence strategy: initiation of a revocation procedure → no judgment on the merits

• valid and infringed → automatic (based on the established court practice)

• objective consequences [Art. 35 (2) Patent Act]

• no proportionality requirement
Final injunctions in Belgium
REMEDIES

- Declaration of infringement
- Injunction
- Recall of the products if appropriate
- Account of sales
- Damages: patentee’s loss of profits
- Dissemination/publication of the decision
- Reimbursement of legal costs
Patent infringement = injunction

>< abuse of right?
Proportionality of injunctive relief

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Enforcement Directive

**Article 9(7)**

7. Where the 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.
Compensation in Hungary
What happens if the patent is later revoked?

- PI granted (easily) – main action pending – patent revoked

- Art 9 (7) ED → no explicit legal provision

- Hungarian civil law speciality: indemnification - damages

- first step: the unjustly injunctioned party may seek satisfaction from the security bond

- second step: if the security bond does not cover the damage suffered, the party may bring an action for damages

- only 1 recent case C-688/17.
Facts of the case C-688/17.

- innovative company vs. generic companies
- generics launched at risk (no decision on the validity of the patent)
- PI granted
- patent revoked
- PI lifted
- damage claims
• interpretation of Art. 9 (7) ED

1) Must Article 9(7) of the Directive EC 2004/48 of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (Directive), in particular the concept of “appropriate compensation”, be interpreted as meaning that it is for the member states to determine the substantive rules relating to the liability of the parties and to the extent of compensation, based on which the courts of the member states will order the plaintiff to compensate the defendant for the damages caused by such injunctions which were later reversed by the court or which later ceased to have effect through the plaintiff’s act or failure to act, or the court subsequently established that no intellectual property right was infringed or there was no risk of such infringement?

2) If the answer to the first question is in the affirmative, does Article 9(7) of the above Directive preclude such legislation of a member state, under which for the compensation corresponding to this provision of the Directive the general rules of the member state relating to civil liability and compensation are applicable, and on the basis of which rules of the member state the court does not oblige the plaintiff to compensate for damages caused by the preliminary injunction subsequently turned to be unfounded because of the revocation of the patent, or for the occurrence of which the defendant is responsible by failing to act as it is generally expected in the given situation, provided that the plaintiff, by requesting preliminary injunction, acted as it is generally expected in the given situation?
• Member States have the freedom to lay down substantive rules and mechanisms of providing appropriate compensation

• It is in line with the Directive that courts take into account the acts of injuncted defendant when deciding on a case-by-case basis on the compensation to be awarded

• It is not acceptable to exclude compensation for the period before the first instance revocation decision when the defendant came to the market without earlier disputing the validity of the patent

• DECISION EXPECTED IN THE SUMMER OF 2019
Compensation in Belgium
In cases where the preliminary measures are revoked or cease to apply due to any action or omission of the claimant, or in cases where it is subsequently established that there was no infringement nor any threat of infringement of the intellectual property rights concerned, the court may order the claimant, at the defendant’s request, to pay the latter an appropriate compensation for the damage caused by these measures.
IN PRACTICE

- Art. 9(7) ED and Art. 1369 ter §3 JC: not applicable in case of confirmation of PI in appeal, but later revocation on the merits considering that:
  - PI was not revoked (↔ appeal decision in PI proceedings overturning PI decision)
  - PI did not cease to apply due to an act or omission of the claimant
  - No later establishment of lack of (threat of) infringement
    - Infringement ↔ validity discussion

[Brussels Ent. Court 2013, Novartis v Mylan]
IN PRACTICE

• PI based on later revoked patent => discussion
  • Strict (or objective) liability OR
  • Fault liability = majority
    • Fault
    • Damage
    • Causal link


• Case pending with Brussels court of appeal which is expected to set the benchmark rule
Compensation in Germany
**Damages**

- **Preliminary injunction:**
  - subsequent change of circumstances, e.g. patent is later limited or revoked → injunction will be lifted acc. to Sec. 927 Civil Procedure Code → damages acc. to Sec. 945 Civil Procedure Code

- Injunction granted in proceedings on the merits, preliminary enforcement, subsequently overturned on appeal
  - Damages, Sec. 717 para 2 Civil Procedure Code
  - use security to cover damages

- Final injunction can be overturned in separate proceeding after invalidation of patent (*Restitutionsklage, Sec. 580 Civil Procedure Code*)
Compensation in the UK
Compensation for PI when the patent is later invalidated/found not to be infringed

• Covered by the cross-undertaking given when the PI is granted

• The patentee has to cover damage suffered by the infringer being kept off the market during the term of the PI. May also cover damage to third parties included in the cross undertaking

• A damages enquiry is a long and costly process so many parties settle the sums due out of court

• The level of damages can be high – AstraZeneca was ordered to pay £27 million

• May be substantially increased if NHS also covered by cross-undertaking
Proportionality of injunctive relief

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Change on the horizon?

UPC

- UPCA
  - Art. 63(1) first sentence on permanent injunctions ~ Art 11 ED (“may”)
  - Art. 64(1) first sentence on preliminary injunctions ~ Art 9 ED (“may”)
- Rules of procedure:
  - Rule 211 on preliminary injunctions:
    3. In taking its decision the Court shall in the exercise of its discretion *weigh up the interests of the parties* and, in particular, take into account the potential harm for either of the parties resulting from the granting or the refusal of the injunction.
    4. The Court shall have regard to any *unreasonable delay in seeking provisional measures*.
    5. The Court may order the applicant to provide *adequate security* for appropriate compensation for any injury likely to be caused to the defendant which the applicant may be liable to bear in the event that the Court revokes the order for provisional measures.
Change on the horizon?

UPC

• Rule 118 on permanent injunctions
  – Until draft 10: no reference to discretion / proportionality
  – 2012 question to Committee: “consider whether the grant of an injunction following final decision(s) on infringement and validity should be automatic, or whether there are circumstances in which an injunction might not be granted: and if the latter should there be guidelines as to the factors which the Court should take into account?”
  – Rule 118 in draft 10: “In appropriate cases and at the request of the [the defendant] the Court may order damages and/or compensation to be paid to the injured party instead of [ordering an injunction] if [the defendant] acted unintentionally and without negligence, if execution of the orders and measures in question would cause such party disproportionate harm and if damages and/or compensation to [the patentee] appears to the Court to be reasonably satisfactory.”
  – Eventually: deleted again => no reference to discretion/proportionality
Change on the horizon?

In the meantime: European Commission on ED

- Communication of 29 November 2017 on SEPs (Com (2017) 712 final)
  
  “3.2 Proportionality Considerations”

  - When assessing the availability of *injunctive relief*, courts are bound by Article 3(2) of the IPR Enforcement Directive, and notably the requirement to ensure that injunctive relief is *effective, proportionate and dissuasive*.

  - Given the broad impact an injunction may have on businesses, consumers and on the public interest, particularly in the context of the digitalized economy, the *proportionality assessment needs to be done carefully on a case-by-case basis*. The Commission feels that considerations need to be given to the relative relevance of the disputed technology for the application in question and the potential spill-over effects of an injunction on third parties.
Change on the horizon?

In the meantime: European Commission on ED

• Communication of 29 November 2017 on the ED (Com (2017) 712 final)
  
  – The competent judicial authority … determines what measures will have to be taken (in any) by the defendant. That judicial authority should assess the application by taking due account of the specific characteristics of the case (see Recital 17 of IPRED) and any injunction issued must be in accordance with the principle of proportionality and the other general requirements laid down in Article 3 as well as the applicable fundamental rights

  – At the same time, the addressee of the injunction should not be required to make unbearable sacrifices
Change on the horizon?

CJEU?

• Decisions in non-patent cases, among which:
  – L’Oreal vs eBay (C-324/09) – **trade marks**:
    » injunctions must be “proportionate” or “strike a fair balance between the various rights and interests”
  – Scarlet vs Sabam (C-70/10) – **copyright**:
    » in the context of measures adopted to protect copyright holders, national authorities and courts must strike a fair balance between the protection of copyright and the protection of the fundamental rights of individuals who are affected by such measures
Change on the horizon?

CJEU?

• Also waiting for CJEU in patent cases?
  – Inspiration in US Supreme Court’s *eBay v MerckExchange*?
  – To obtain a permanent injunction, a patentee must demonstrate *that*
    
    (1) *it has suffered irreparable injury*,
    
    (2) *monetary damages are inadequate*
    
    • E.g. NPEs or “patent trolls”
    
    (3) *considering the balance of hardships, an injunction is warranted*,
    
    and
    
    • E.g. infringing part of commercialized complex product

(4) *the public interest would not be disserved by a permanent injunction*
    
    • E.g. life-saving medicines not exploited by patentee itself
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Questions?
Thank you!