

# POST-GRANT PROCEDURES AT THE EPO

## LATEST DEVELOPMENTS IN VIEW OF THE EPC 2000

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- 1. Opposition**
- 2. Central Limitation & Revocation**
- 3. EPC 2000 and Medical Use Claims**



# Opposition Procedure

- Legal and Factual Framework of Opposition
- Third party observations
- Figures / Statistics
- Overview of Procedure
- Amendments
- Oral Proceedings
- Decisions
- Strategies for success in Opposition Proceedings



# Nature of Opposition Procedure

- **Post-grant** revocation procedure
- **Effect "ex tunc"** in all designated contracting states
- Independent, separate from examination procedure
- **Contentious procedure** initiated by opposite party
- One procedural language (DE/EN/FR)
- **Centralised** procedure

# Who, When and How?

- **Any person** can file opposition but **not patentee**
- "Straw man" (if not abuse)
- **Joint oppositions** possible with common representative
- Within **9 months** after mention of grant
- Assumed infringer also later
- **In writing** with EPO
- Preferably with EPO-form "**Notice of Opposition**"

# Grounds for Opposition

- **100 (a)** Patentability
  - 52 } unpatentable sub. matter (morality, methods of treatment)
  - 53 }
  - 54 Novelty
  - 56 Inventive Step
  - 57 Industrial Applicability
  
- **100 (b)** Lack of Disclosure (Art. 83)
  
- **100 (c)** Added subject-matter (Art. 123(2))

**Note:** Lack of clarity and support, lack of unity are not grounds for opposition

# Admissibility of Opposition

- Formal requirements
  - Identification of the opponent(s)
  - Extend of the opposition
  - Facts, evidence and reasoned statements (i.e. arguments)
- For oral disclosure / prior use:
  - **when, what, under which circumstances**
  - **substantiation**: Patentee and Division must be enabled to examine alleged ground of opposition without recourse to independent enquiries
- Opposition filed
  - **before** the 9 months period is considered **as third party observations**
  - **after** the 9 months period is a priori **late filed** and need not to be considered

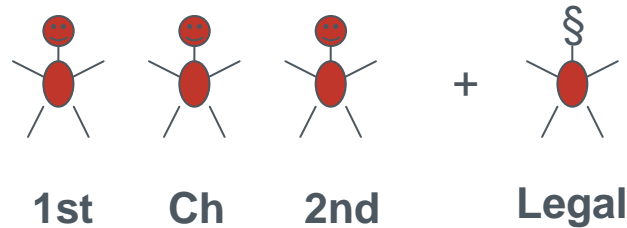
If Opposition inadmissible: Appealable intermediate decision by Opposition Division

# Framework of Examination

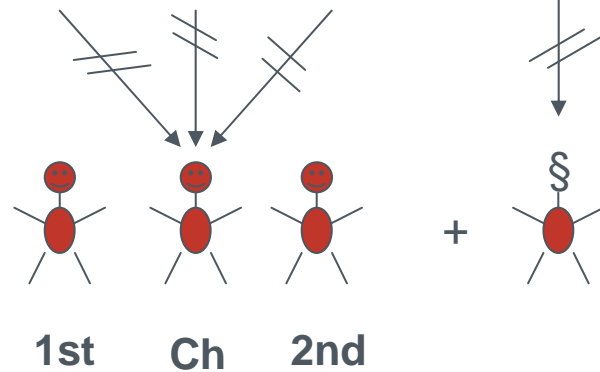
- If no admissible opposition: no examination possible
  - Principle of party disposition:
    - initial request determines **extent** of proceedings ("**in its entirety**")
    - OD cannot examine un-opposed independent claims
  - Ex officio:
    - grounds of opposition not raised and substantiated initially can be introduced if prejudice "prima facie" maintenance of patent
- Examples:
- evidence from inadmissibility or withdrawn opposition
  - third party observations
  - examiners personal knowledge
  - documents from examination file

# Opposition Division

Examining Division



Opposition Division



Enlargement of Divisions: Decision by the 3 members  
Decisions: Vote; if enlarged: Chairman vote decisive

# Third party observations - Art. 115 EPC

Cheap possibility for any person to present observations concerning patentability of patent application and/or patent.

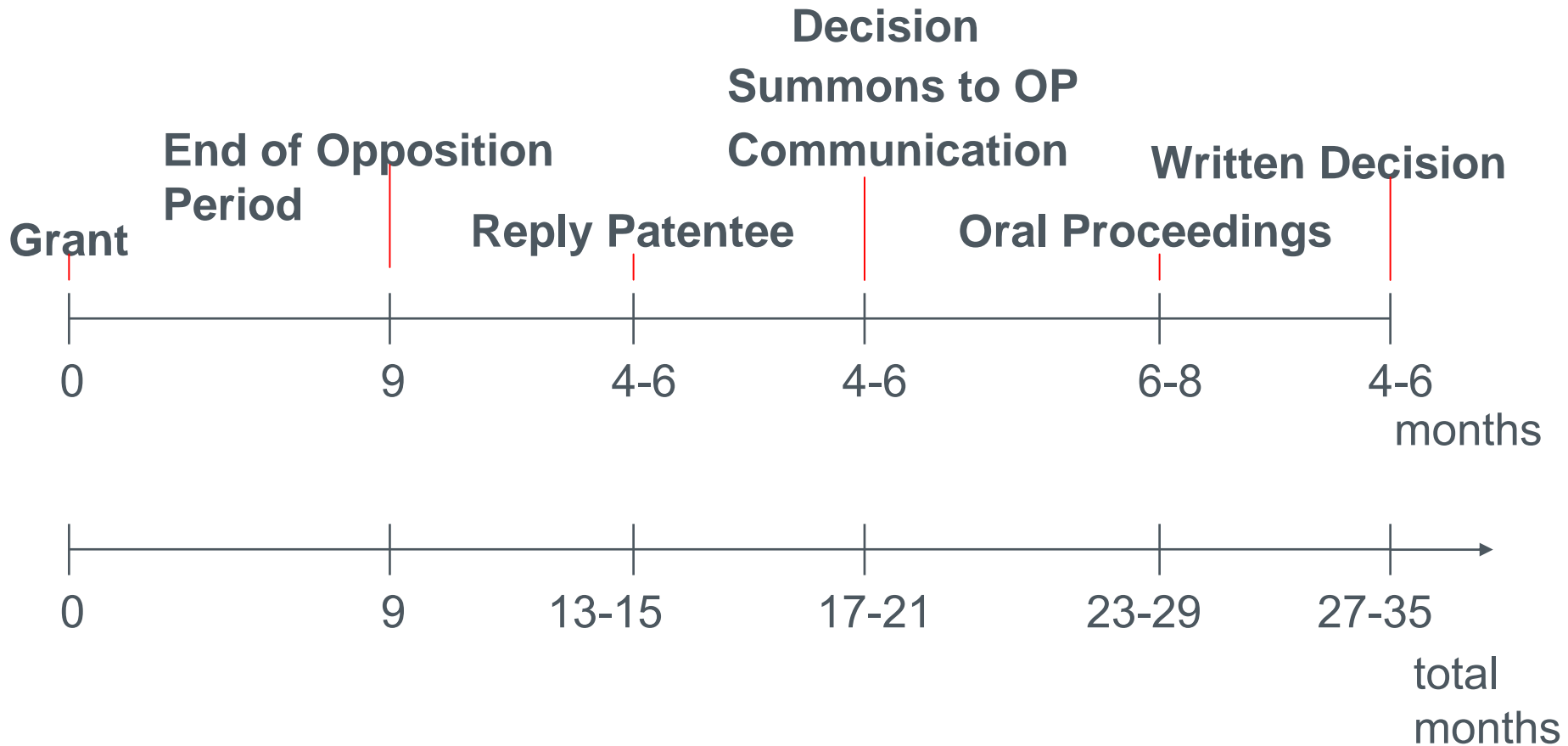
Grant of invalid patents can be avoided and competitor's claims influenced early.

- from publication to grant
- during opposition procedure
- in written form incl. statement of grounds
- no need to reveal identity
- observations communicated to applicant/patentee and in public part of file
- third party not party to proceedings

# Figures - Oppositions filed

|                  |                      | <u>2003</u> | <u>2004</u> | <u>2005</u> | <u>2006</u> |
|------------------|----------------------|-------------|-------------|-------------|-------------|
| <b>A61K</b>      | % of opposed patents | 10,07       | 10,22       | 11,80       | 10,90       |
|                  | no. of opponents     | 1,49        | 1,42        | 1,48        | 1,53        |
| <b>C07</b>       | % of opposed patents | 3,47        | 3,78        | 4,50        | 4,00        |
|                  | no. of opponents     | 1,19        | 1,36        | 1,31        | 1,23        |
| <b>EPO Total</b> | % of opposed patents | 5,24        | 5,32        | 5,50        | 5,40        |
|                  | no. of opponents     | 1,23        | 1,24        | 1,25        | 1,25        |

# Procedure - Overview



# Amendments - Admissibility

- Amendment must be **occasioned by a ground for opposition (Rule 80 - former Rule 57a)**
- Amendment must be filed in time (**Rule 116 (1) - former R.71a**): late amendments can be refused
- Ground need not to be invoked by opposition
- **Auxiliary requests** (claims) should be reasonable in number
- Correction of obvious errors possible

# Amendments - Substantive Examination

- Amendment must meet the requirements of EPC "as a whole"  
(**Clarity!**)
- Unclear features present in granted claims are not amended
- Added subject-matter:
  - **Art. 123 (2)**: amendment may not extend beyond the content of application as filed
  - **Art. 123(3)**: claims of patent as amended may not extend the protection conferred
- **Conflict Art. 123(2) - Art. 123(2)**

inescapable trap: feature added contrary to Art. 123(2) in examination cannot be removed in opposition → revocation

examples: unallowable disclaimers, non patentable method of treatment features, change of category of claims

# Oral Proceedings - Summons

Oral Proceedings must be held if requested by a party or if Opposition Division considers expedient.

Purpose is to settle all outstanding questions relevant to the decision.

## Summons

- Date, time, location (MU, BE, TH)
- List of points to be discussed
- Non-binding **preliminary opinion** of Opposition Division
- **Limit date** (Rule 116) for written submissions (non-extendable)
- Is signed by all 3 (or 4) members after discussion

# Oral Proceedings - Conduct

- Each party has opportunity to make one comprehensive statement
- Each point discussed is followed by decision/opinion of Division
- **Art. 123 (2)** - very strict approach
- **Novelty** - narrow approach
- **Prior use** - standard proof not balance of probabilities but "beyond reasonable doubt"
- **Inventive step** - use of problem-solution approach, definition of closest prior art and good argument decisive, benefit of doubt for patentee
- **Lack of disclosure**: burden of proof on behalf of opponent, provide data not simply arguments

# Oral Proceedings - Conduct

- **Absent party:**
  - no decision can be taken against, based on new facts and evidence
  - new arguments always possible
- **Late filed facts and evidence:** reasons for and relevance of to be assessed before refusal / admittance
- **Experts:** only if announced beforehand, under control of representative
- Apportionment of costs possible for OP  
(non-appearance, late filed evidence, abuse of proceedings)
- **Auxiliary requests:**
  - reasonable number ( $\approx 3$ )
  - if features from description: unlikely to be allowed

# Decisions



## 3 possibilities:

- Art. 101 (2),(3b) **Revocation of Patent**
- Art. 101 (2) **Rejection of the Opposition**
- Art. 101 (3a) **Maintenance of the Patent in amended form**

# Decisions - Figures

| Decision %                                 | <u>2003</u> |      | <u>2004</u> |      | <u>2005</u> |     | <u>2006</u> |     |
|--|-------------|------|-------------|------|-------------|-----|-------------|-----|
|  | A61K        | C07  | A61K        | C07  | A61K        | C07 | A61K        | C07 |
| <b>Revocation</b>                          | 42,9        | 33,9 | 29,8        | 29,3 | 63          | 35  | 29          | 24  |
| <b>Rejection<br/>Opposition</b>            | 23,6        | 27,1 | 24,5        | 32,6 | 15          | 19  | 28          | 26  |
| <b>Maintenance<br/>in amended<br/>form</b> | 33,6        | 39   | 45,7        | 38   | 22          | 46  | 42          | 50  |

Appeals allowed in ca. 40 - 50% in chemistry.

# Strategies for success in Opposition Proceedings

## Patentee

- Defending your patent begins with **drafting of application**
  - Provide **enough fallback positions**
  - **Support inventive step** over whole scope with sufficient data
- Be careful with **amendments** during examination, even if proposed by examiner
- File **full reply** to notice(s) of opposition
- File amendments and evidence as early as possible
- Be prepared to file **comparative data** for inventive step
- If comparative data stick strictly to experimental conditions
- **Request oral proceedings** as a safeguard

# Strategies for success in Opposition Proceedings

## Opponent

- Monitor carefully **examination procedure** (EPOLINE)
- Consider early influence on patent by third party observations
- Do a thorough **prior art search**
- Attack all claims and possible fallback positions in description
- Select carefully **strong grounds for opposition**
- File all facts and evidence with notice of opposition
- Extend in "**its entirety**" as a safeguard
- Consider **common strategy** if several opponents
- Stick strictly to problem solution approach for inventive step
- **Provide data** not only arguments for lack of sufficiency of disclosure
- **Request oral proceedings** as a safeguard

# Central Limitation / Revocation Procedure

## Art. 105a, 105b, 105c

- Legal and Factual Framework
- Figures / Statistics



# Limitation procedure

- For requesting **limitation** of an European Patent (**as granted** or **as amended** in opposition or in previous limitation proceedings before the EPO (Rule 90), subject to payment of a fee
- At the request of the **patent proprietor**
- **Ex parte** procedure  $\Leftrightarrow$  examining division
- At **any time**, even after expiry of the patent
- **Reasons are not needed**
- Possible to file **successive requests**
- The final decision applies to all designated states ***ab initio effect***
- The decision is **appealable** (Art. 106, Art. 21)

# Limitation procedure

## Framework of Examination

- Limitation does not mean rewording of the claims or change of category
- Only examination of **Art. 123(2), 123(3) and 84 EPC**
- The EPO does not examine
  - the aim of the limitation
  - the patentability of the subject-matter under Art. 52 to 57 EPC

# Revocation procedure

- For requesting **revocation** of an European Patent (**as granted** or **as amended** in opposition or in previous limitation proceedings before the EPO (Rule 90), subject to payment of a fee
- At the request of the **patent proprietor**
- At **any time**, even after expiry of the patent
- **Reasons** are **not needed**
- The final decision applies to all designated states ***ab initio effect***
- The decision is **appealable** (Art. 106, Art. 21)

# Limitation/Revocation versus Opposition

- **Pending oppositions** have **precedence** over limitation / revocation proceedings Art. 105a(2) and Rule 93(1)
- Opposition has precedence over **pending limitation** procedure (Rule 93(2))
- Opposition has no precedence over **pending revocation** procedure (Rule 93(2) does refer only to limitation);  
Opposition would continue only if revocation request is deemed not to have been filed (revocation fees not paid, rejected as inadmissible or withdrawn)
- **National proceedings** DO NOT have precedence over central limitation proceedings

# Limitation versus Opposition - Case 1

9 months opposition period



- 1) publication of the patent
- 2) request for limitation
- 3) oppo filed
- 4) end oppo period

=> limitation is terminated, fees refunded (Rule 93(2) EPC)

# Revocation versus Opposition - Case 1

9 months opposition period



=> Revocation continues if revocation fees paid, revocation admissible and not withdrawn. Otherwise request is deemed not to have been filed and opposition continues

# Limitation / Revocation vs. Opposition - Case 2

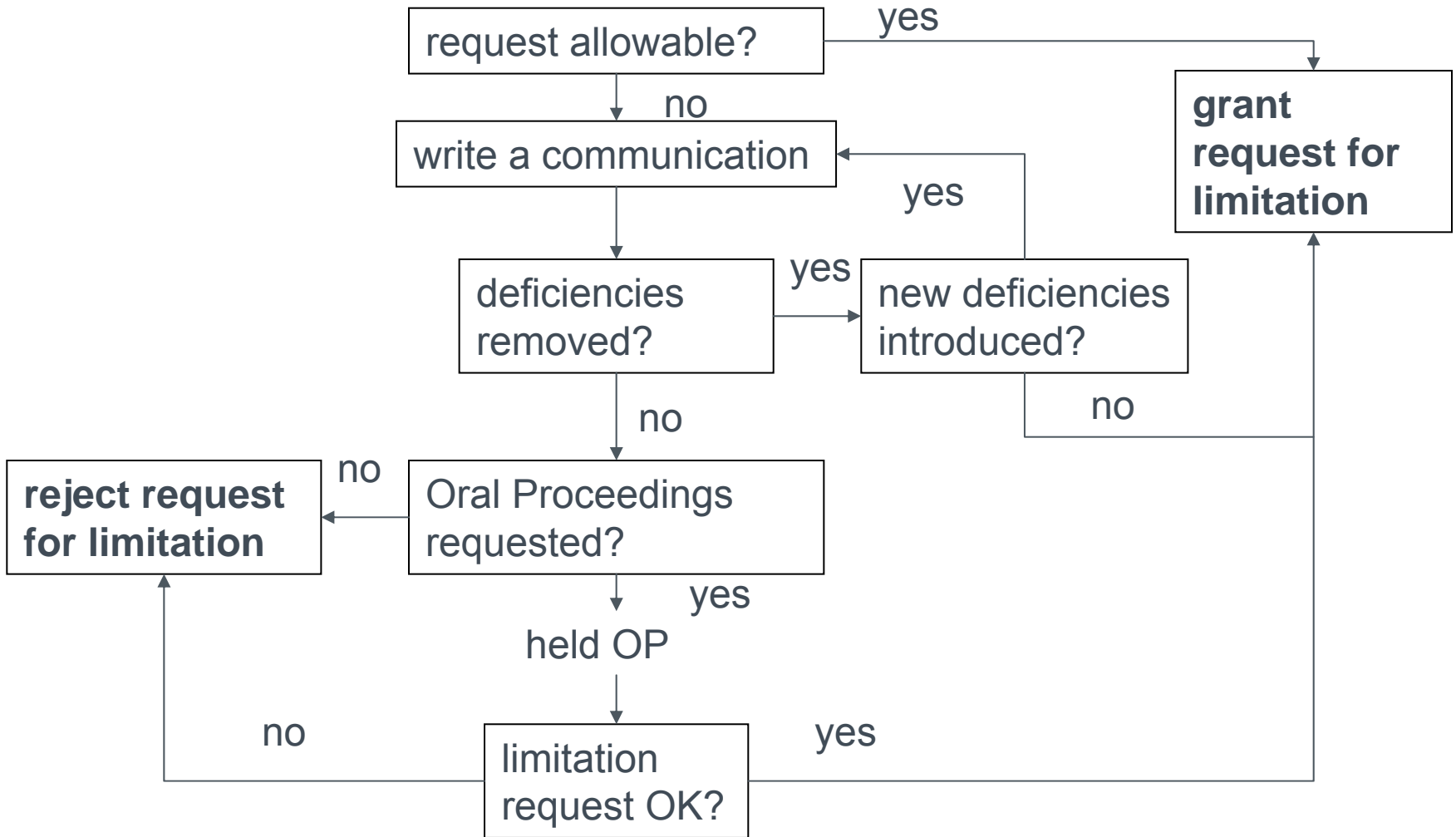
9 months opposition period



- 1) publication of the patent
- 2) oppo filed
- 3) request for limitation/revocation
- 4) end oppo period

=> request is considered not to have been filed, fees refunded  
(Rule 93(1) EPC)

# Central Limitation - Procedure

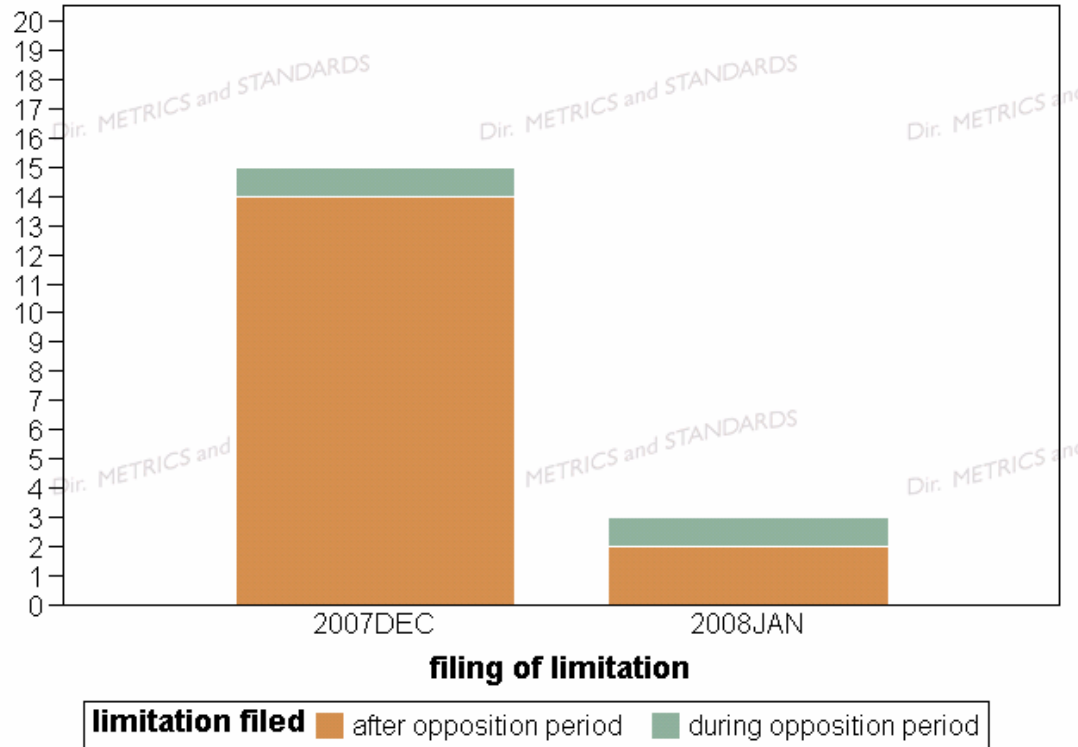


# Limitation/Revocation Decision

- Decision **to reject the request**
- Decision **to revoke the patent**
- Decision **to limit the patent**
  - . The request is not found inadmissible under R. 94 for failure to comply with R.92 and
  - . The claims constitute a limitation and comply with Art. 123(2)(3), 84 EPC.
  - . Within 3 months, the requester is invited to pay the publishing fee and file a translation of the claims into the other two EPO languages other than the procedural language

# Figures - Central limitation

number of requests



- **Note:** 24 central limitations requests, 19 coded as admissible 2008/WK7
  - 3 filed during opposition period; 21 after opposition period
  - 1 of the requests is for a patent which was opposed in 1999
- **Note:** 2 requests for central revocation as of 2008/WK7, not processed yet

# Medical use claims under EPC 2000

- Art. 54(4)(5) EPC
- Assessment of novelty
- Examples



# First medical use

## Art. 54(4) EPC 2000 = Art. 54(5) EPC 1973

- EPC 1973 - Art. 54 (5)
  - "Compound X (for use) as a medicament"
- EPC 2000 - Art. 54 (4)
  - "Compound X (for use) as a medicament"

Same wording, different Article

# Second and further medical uses Art. 54(5) vs. Swiss-Type claims

- EPC 1973 - "Swiss-type claims"
  - "Use of compound X for the manufacture of a medicament for the treatment of disease Y"
  
- EPC 2000
  - "Compound X for the use in the treatment of a disease Y"

# Examples

| Claim   | Patentable?                             | EPC 2000   |
|---|---|------------|
| Use of X for the treatment of melanoma<br><i>[X known as herbicide]</i>     | <b>NO</b><br>exception to patentability | Art. 53(c) |
| X for use as a medicament<br><i>[X known as herbicide]</i>                  | <b>YES</b><br>first medical use         | Art. 54(4) |
| X for the treatment of cancer<br><i>[X known as medicament]</i>             | <b>YES</b><br>second medical use        | Art. 54(5) |
| X for the treatment of Alzheimer<br><i>[X known as treatment of cancer]</i> | <b>YES</b><br>further medical uses      | Art. 54(5) |

# Art. 54(5) vs. Swiss-type claims

- Swiss-Type claims can still be granted after 13.12.2007
- Swiss-Type claims are accepted even if the application also contains Art. 54(5) claims
- Art. 54(5) claims and Swiss-Type claims are interchangeable
- Swiss-Type claims can be reformulated into an Art. 54(5) claim and vice-versa: no Art. 123(2) objection if the application as filed discloses in some way a "disease Y" being treated by "compound X"

# Assessment of novelty

## – First medical use

- A claim falls under the provisions of Art. 54(4) when the compound is used for the first time as a medicament irrespective of its scope

## – Second and further medical uses

- When assessing novelty of a 2nd and further medical use (Art. 54(5)), the approach applied to generic vs. specific disclosures applies

# Assessment of novelty

| Claim   | Patentable?                                    | EPC 2000   |
|---|--|------------|
| Use of X for the treatment of cancer<br><i>[X known as herbicide]</i>     | <b>NO</b><br>exception to patentability        | Art. 53(c) |
| X for the treatment of cancer<br><i>[X known as herbicide]</i>            | <b>YES</b><br>first medical use                | Art. 54(4) |
| X for use of a medicament<br><i>[X known for the treatment of cancer]</i> | <b>NO</b><br>not novel / not first medical use | Art. 54(5) |
| X for the treatment of asthma<br><i>[X known as treatment of cancer]</i>  | <b>YES</b><br>second medical use               | Art. 54(5) |