

IP Law Update

December 2010

EPO topic:

Divisional applications:

extending the 24M filing deadline - details of significance

National Case Law News:

Medical devices & SPC in Germany & The Netherlands

(DE FPC decision 14W (pat) 12/07; NL No. AWB 02/1915OCT)

UK cases: High Court referral to CJEU (C-195/09) (C-427/09)

Biosimilars/EMA:

European Medicines Agency (EMA) – draft guideline on similar biological medicinal products/mAbs released

Miscellaneous:

Republic of ***Serbia*** joined the ***EPC*** as 38th member state (use updated forms 1010/request of grant and 1200/entry EP)

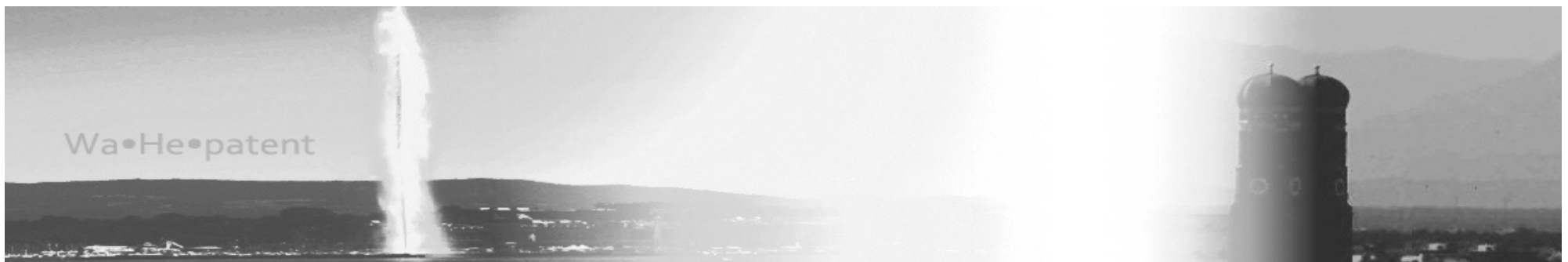
Hungary accedes London Protocol (applicable January 01, 2011)

Attention: ***EPC Rule changes*** effective January 1, 2011

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*EPO issue - Divisional application filings:
extending the 24-month deadline - details of significance*

Legal facts:

- 1st office action pursuant to A 94 (3) EPC triggers 24M deadline to file divisional applications in family (R 36 (1)a) EPC);
- Unity objection triggers 24M deadline independently (R 36 (1)b) EPC);
- New unity objection in A 94 (3) EPC office action triggers yet another 24M deadline;
- Unity objection in ISR, ESR, ESSR is of no relevance and does not trigger a 24M deadline;
- Only pending claims form the basis of the unity assessment – either those of PCT phase or new claims filed when entering EP regional phase, or claims filed in reply to R 161/162 EPC communication.



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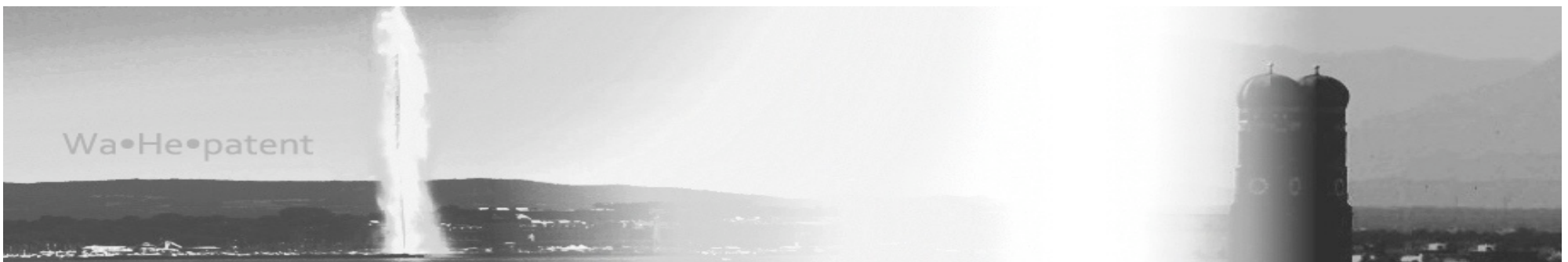
Scenarios:

I. No unity issues in application

The application does not contain subject matter that lacks unity

II. Unity issues in application

The specification contains subject matter that will potentially lead to a lack of unity objection



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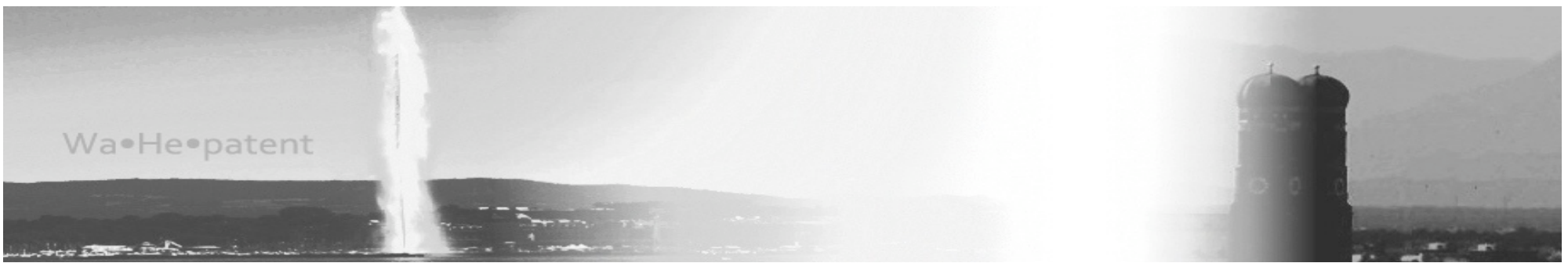
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***EPO issue - Divisional application filings:
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Options:

Re I. No unity issues in application

1. Filing a divisional application within 24M deadline (R 36 (1)a) EPC) possible
 2. Probably not possible to include subject matter in the claims of the divisional application to provoke lack of unity objection (R 36 (1)b) EPC) due to lack of such subject matter in the specification
- => 2nd 24M deadline to extend divisional filing deadline cannot be achieved



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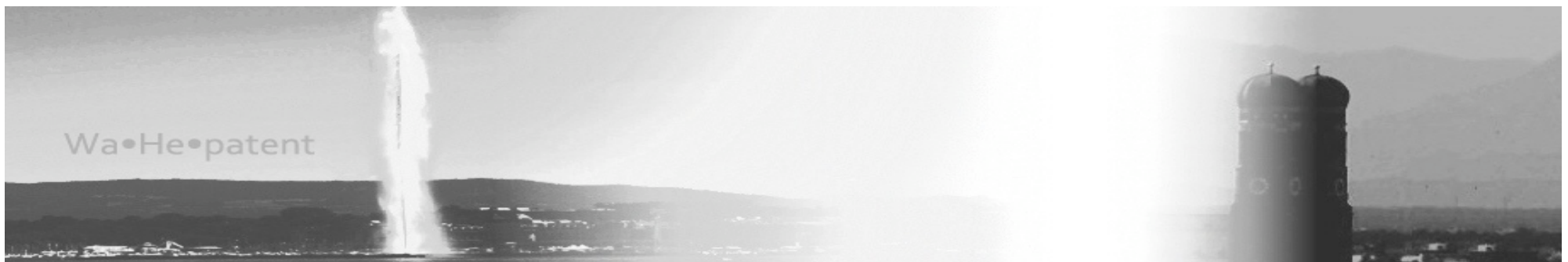
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***EPO issue - Divisional application filings:
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Options:

Re II. Unity issues in application

1. Filing a divisional application within 24M deadline (R 36 (1)a) EPC) possible;
 2. Filing new claims during prosecution proceedings that lack unity in order to provoke unity objection to trigger an additional 24M deadline – questionable: Examiner may issue a “non-searched subject matter” – objection (Rule 137 (4) EPC) instead
- ⇒ no new 24M deadline triggered



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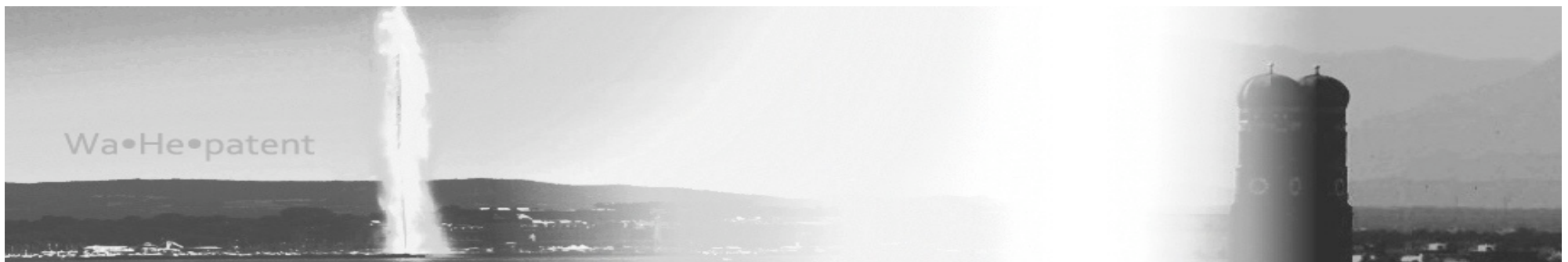
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Options:

Re II. Unity issues in application

3. Filing a divisional application within 24M deadline (R 36 (1)a) EPC) including claims which lack unity
 - ⇒ non-unity objection issued in search phase: primarily not relevant
 - ⇒ payment of additional search fee(s) may be required to trigger yet another 24M deadline (R 36 (1)b) EPC) after issuance of Art. 94 (3) EPC communication
 - ⇒ additional 24M deadline can be achieved (R 36 (1)b) EPC)
 - ⇒ staggering of 24M deadlines may be possible depending on case



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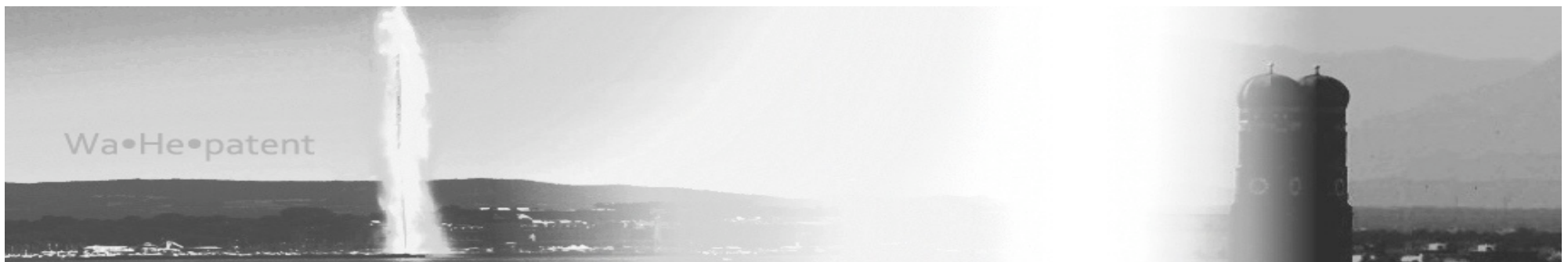
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Options:

Re II. Unity issues in application

4. EP regional phase: entering EP with fully searched PCT having received multiple non-unity objections in PCT phase
 - ⇒ unity objections of PCT-phase do not represent a bar to receive multiple 24M deadlines pursuant to R 36 (1)b) EPC
 - ⇒ enter EP with claims complying with unity requirements
 - ⇒ file divisional application with claims lacking unity (within 24M deadline (R 36 (1)a) EPC)) -> trigger new 24M deadline (R 36 (1)b) EPC
 - ⇒ option to repeat same in 2nd and additional divisional application(s) and thus staggering 24M deadlines



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***EPO issue - Divisional application filings:
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! Aspects to remember:

- ✓ Provoking unity objection of non-searched subject matter may not lead to an additional 24M deadline (R 36 (1)b) EPC)
- ✓ Including aspects in specification drafting that lack unity may be considered and useful to trigger a non-unity objection in prosecution proceedings (R 36 (1)b) EPC)
- ✓ Non-unity in PCT: Enter EP regional phase with claims that comply with the unity requirements to add at least one 24M deadline pursuant to R 36 (1)b) EPC
- ✓ Open question: Pursuing subject matter in 2nd divisional which formed already part of a unity objection of the parent case admissible? – Future case law will have to tell.



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Medical devices and patent term extension via Supplementary Protection Certificates (SPCs) in Europe

SPC for medical devices:

- in Germany (DE FPC decision 14W (pat) 12/07)
- in The Netherlands (NL No. AWB 02/1915OCT)
- other European jurisdictions: no uniform point of view
- UK: High Court referral to CJEU (C-195/09) (C-427/09)



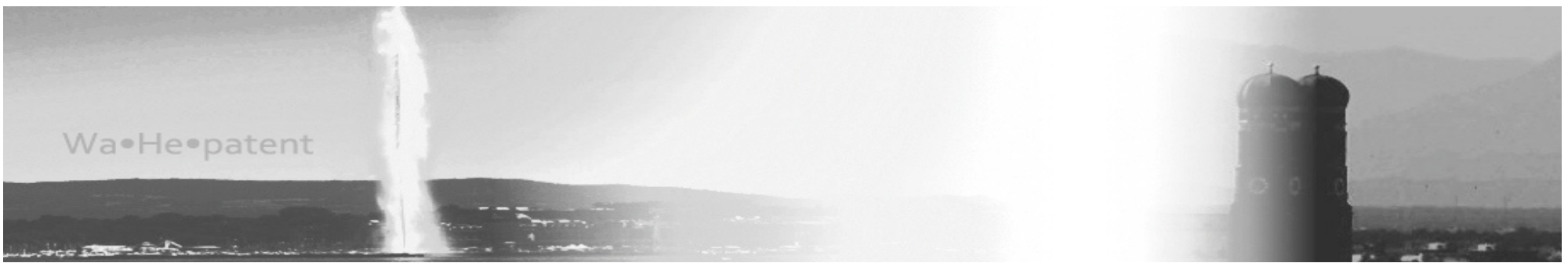
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Medical devices and patent term extension via Supplementary Protection Certificates (SPCs) in Europe

SPC for medical devices – ! Aspects to remember:

- ✓ SPC for medical devices available in DE & NL
- ✓ No uniform point of view in European jurisdictions
- ✓ Referral to CJEU pending



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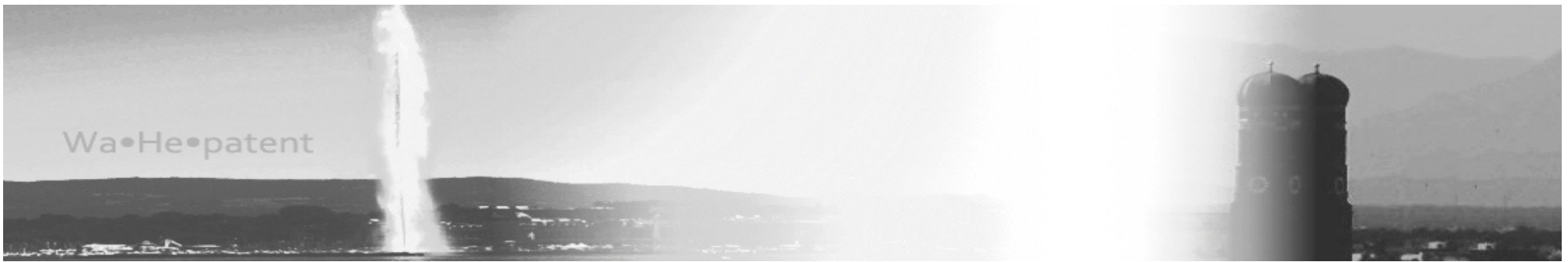
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Biosimilars/EMA:

- European Medicines Agency (EMA) has released its draft guideline on similar biological medicinal products containing monoclonal antibodies
- Deadline to submit comments on the draft guideline is May 31, 2011

Details:

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/11/WC500099361.pdf



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Republic of Serbia joined the EPO as 38th member state:

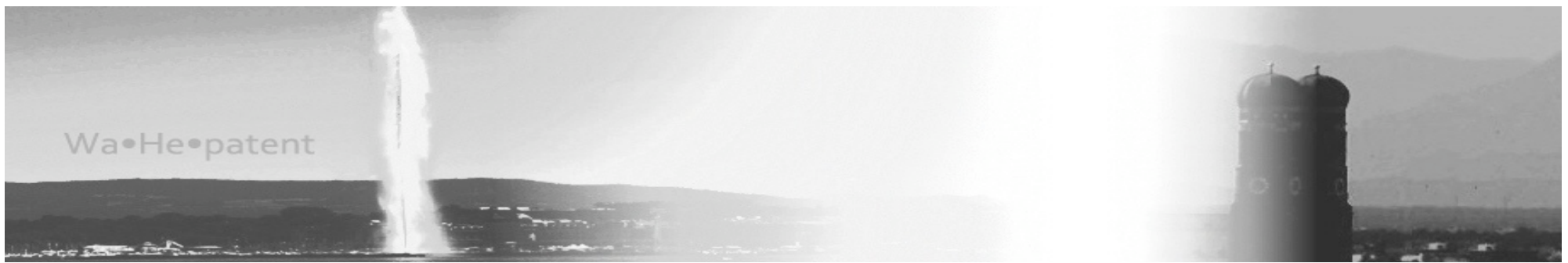
- use updated forms 1010/request of grant and 1200/entry EP

Hungary accedes to London Protocol

- applicable to patents granted as of January 01, 2011

Prepare internal company/firm procedures for EPC Rule change effective January 1, 2011:

- amended Rule 141 EPC / new Rule 70b EPC regarding information on prior art and foreign search results (for EP & PCT applications filed on or after January 1, 2011)



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