Future of IP in Europe: Challenges and Perspectives
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Modernisation of the SPC system: achievements and next steps

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1. Political context
2. Studies and public consultations
3. Single Market Strategy: SPC waiver and unitary-SPC
4. Next steps

Political context related to EU pharmaceutical IP incentives

1. Commission's Single Market Strategy (SMS) (October 2015) → Competitiveness angle (!)
   - ✓ SPCs and unitary patents
   - ✓ Unitary-SPC
   - ✓ SPC-waiver
   - ✓ Bolar
2. Health Council conclusions of June 2016: call for a broad evaluation of pharma IP → impact on innovation, availability of medicines and pricing
3. European Parliament's support (resolutions on the SMS and access to medicines)

DG GROW / DG SANTE's consultations and studies on pharmaceutical IP incentives

- Public consultations (2017-2018) on:
  - ✓ SPC and patent exemptions by DG GROW
  - ✓ Legal aspects of the SPC by Max Planck Institute
  - ✓ Regulatory protection/incentives by DG SANTE
- DG GROW's studies on SPCs (2015-2018): CRA (exemptions), Kyle, MPI (legal framework)
- DG SANTE's study on paediatric rewards (2016)
- Joint study on the economics of pharmaceutical IP incentives: Copenhagen Economics (2018)
- DG SANTE's on-going study on orphan diseases

Some findings from the studies and consultations

- The EU offers the strongest world pharma IP and regulatory incentives
- IP just one of several factors for investment in R&D
- For 61% of analysed molecules, patent/SPC protection is the last to expire
- Average SPC duration: 3,5 years. SPC applicants are expanding the geographical coverage
- National practice and procedures of SPC registration can differ significantly. Support for harmonisation but not for ‘re-opening’ the the SPC regulations
- Strong support of the unitary-SPC
- Paediatric rewards often not enough to address some rear conditions in children

Commission's Single Market Strategy

- Commission's ‘inception impact assessment’ on SPCs and Bolar (16 February 2017)
- Impact assessment on the ‘SPC waiver’ (March 2018):
  - Two problems: EU-based generics face a competitiveness disadvantage in both export markets and EU day-one entry
  - Driver: global asymmetry of the SPC protection
  - Urgent need to act (!)
- Commission legislative proposal on a SPC waiver for export purposes (28 May 2018)

State of play of the SPC waiver

- Inter-institutional agreement on an SPC waiver (14 February):
  - ✓ For both export and stockpiling purposes (Parliament's strong access to health angle)
  - ✓ Stockpiling only the 6 months before expiry of the SPC
  - ✓ Safeguards (notification, due diligence and logo for export)
  - ✓ Entry into applicability (exclusion of SPCs already in effect)
- Agreement endorsed by Council (COREPER, 20 February) and Parliament (JURI, 26 February)
- Vote in Plenary of the Parliament (April 2019; 1st reading) and subsequent Council's validation
- Estimated entry into force: mid-2019

Options for a ‘unitary-SPC’

- Public consultation on SPCs (October 2017): large support
- Options for the granting authority: ‘virtual office’, EPO, EUIPO, ...
- Should it be based on unitary patents only? Based on national patents/European patents?
- Only for medicines authorised through the centralised procedure?
- Geographical coverage (might not extend to all MS?)
- A unitary patent Regulation could also clarify certain features of the current regime

..... So far, waiting for the unitary-patent

Next steps

- Complete the formal evaluation of the SPC
- Complete the broad pharma incentives evaluation (stake holders conference and final Commission report in within 2019)
- New studies:
  - ✓ Possible topics: follow-on patents, divisional patents, incentives for unmet medical conditions
- Possible work:
  - ✓ Guidelines on SPCs and Bolar
  - ✓ SPCs and the unitary patent
  - ✓ Unitary-SPC

Thank you for your attention!

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