To: [redacted]

Subject: Flash: meeting with EFPIA's IP Expert Group, 12 December 2019

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Background: The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the research-based (originators) pharmaceutical industry operating in Europe.

Participants :

- Chairperson: Kristine PEERS (EFPIA's General Counsel).
- GROW F3 (Intellectual Property): [redacted]
- Representatives from EFPIA, national associations (DE, SE, DK) and company-members.

Discussion:

The Commission representatives debriefed on the following:

- Opening remark about the publication of The European Green Deal package.
- Work on an IP Strategy:
    - Upgrade of IP rules: designs, SPC, etc. The unitary-patent remains a priority.
    - IP literacy (14 November event). Need to stimulate local authorities to reach out SMEs. Horizon 2020, the Enterprise Europe Network and IPHelpdesks can help.
    - Enforcement: cyber theft aspects; EFPIA is in contact with DG TAXUD in relation to border enforcement of counterfeiting medicines. The issue of the MoUs, liability of platforms and the preparation of the Digital Services Act were also discussed during the meeting.
- Artificial Intelligence (AI): a Commission initiative is expected within 100 days.
    - IP angle, including trade secrets aspects. Many patent filings on AI. WIPO has brought together key IP governments/agencies, including the European Commission (GROW/F) aiming at coordinating approaches on IP and AI.
    - Data is key for the pharmaceutical industry and for the health sector at large. Important the aspects of data ownership, standardisation and sharing.
    - Policy makers need inputs from the industry, including the pharmaceutical one.
- On-going review of EU pharmaceutical incentives (2016 Health Council's request):
    - DG COMP published its report on competition aspects/work on the pharma sector.
    - DG SANTE published a roadmap on the evaluation of orphan and paediatric incentives/rewards. An evaluation report expected for 2020.
    - DG GROW working on a formal evaluation of the SPC system, based on the studies and consultations concluded during the last years.

- Aspects of transparency, unitary SPC and the new idea about an "SPC single grant mechanism".
- The "SPC single grant mechanism" can be a first step towards the unitary-SPC. It would be compatible with the unitary-SPC as some EU MS will remain out of the future unitary-patent system.
- Tentative workshop with SPC stakeholders for April 2020.

Feedback from EFPIA and industry representatives:

- The industry remains worried with the chilling effect on investment that the on-going incentives review can bring (especially the review of the orphan incentives). The industry is working on raising awareness about the issues that hinder access to medicines.
- Welcomed and showed major interest for the "SPC single grant mechanism". They are analysing it ,and would like to be consulted.
- On Data:
    - Some proposals on the need to explore the creation of a sui generis right as an incentive for the industry to generate and standardise clinical data for follow-on uses (clinical data is very expensive to generate).
    - The Public Private Partnership Innovative Medicines Initiative (INI) is already generating and sharing pharmaceutical data. IMI has generated a safe environment.
    - Need to share data with academia and other actors.
    - Important to consider what other leading countries, outside the EU, are doing.
    - GDPR aspects to be born in mind.
- Big companies can play a role on IP literacy. Important to reach out SMEs.

Next steps

- Potential workshops on the SPC with pharma stakeholders in April 2020

Best,

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