To:

[redacted]

Subject: Flash: Webinar IP & Competition, Anatomy of a failure to launch: A review of barriers to generic and biosimilar entry and the use of competition law, 5 November

Attachments: Medicines for Europe Whitepaper - Anatomy of a Failure to Launch - Nov 2020 FINAL.pdf

Webinar IP & Competition, Anatomy of a failure to launch: A review of barriers to generic and biosimilar entry and the use of competition law, 5 November

Background

Medicines for Europe (MfE), the European industry association representing developers of generic and biosimilar medicines, **presented the attached White paper "Anatomy of a Failure to Launch: a review of barriers to generic and biosimilar market entry and the use of competition law as a remedy"**. With the launch of the Whitepaper, MfE aims at informing the debate on the upcoming pharmaceutical and IP strategy with a description of the main topics of relevance for the generic, biosimilar, and value added medicines industries in relation to IP.

MfE sought a discussion focus on how to make sure that current barriers to generic and biosimilar medicines market entry can be tackled in order to avoid any unnecessary delays to patient access.

Participants

- Presentation of the Whitepaper [redacted]
- Panel discussion moderated [redacted]
  - ✓ Paul Csiszar (Director for Basic Industries, Manufacturing and Agriculture, DG Competition, European Commission)
  - ✓ [redacted] (DG GROW/F5 – IP Unit)
  - ✓ [redacted] at the Ministry of Economy, Permanent Representation of Poland to the EU)

- ✓ [redacted] IP Management, [redacted] Medicines for Europe)
- ✓ [redacted]
- An audience of around 200 participants.

Discussions on IP

- I provided a general overview of the work of SANTE and GROW during the last years: preparation of the Pharma strategy and IP action plan, as well as the evaluations of the orphan incentives and the supplementary protection certificate (SPC) legislation. I briefly mentioned the next steps from a procedural point of view (I avoided details on potential content/actions as the strategies are still not published).
- [redacted]
- The main concerns for generics and biosimilars: legal uncertainty provoked by fragmentation of the IP system, the tactic filing of multiple "patent divisionals" (see the attachment), and filing of multiple SPCs for the same medicine (situation improved by recent rulings of the CJEU).

Best,

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