London 2019

Pharma 3:
Hot and hostile: recent developments in SPCs and patent term extensions

Recent court decisions and new regulations are having a significant impact on the value and viability of Supplementary Protection Certificates (SPCs) for pharmaceutical products in Europe, and corresponding Patent Term Extension (PTE) provisions in other countries. How will these changes affect new innovations, and how do they compare and contrast across jurisdictions?

SPCs and PTEs provide an additional period of protection to a basic patent – up to five years – to compensate for patent term lost in regulatory review. The regulations generally require that only one SPC or PTE can be granted to a product for the first marketing authorization.

Recent decisions from and referrals to the Court of Justice of the European Union (CJEU) will impact the validity of SPCs for combination products, and for holders of a patent that covers a marketing authorization held by a third party. In addition, new EU regulations will allow manufacturing and stockpiling of medicinal products during the term of an SPC.

Key issues include:

- *How are provisions for patent term restoration similar and different across jurisdictions?*
- *When is a new product not a new product?*
- *What are the pros and cons of allowing an SPC to a patent holder who is not the marketing authorization holder?*
- *How will the SPC manufacturing waiver work in practice?*
- *What are the implications for the future of patent term extensions and SPCs?*