



Insights: Events

Examining Pharmaceutical Patent Extensions: Patent Term Adjustment and Patent Term Restoration

ACIs Hatch-Waxman and BPCIA Passport to Proficiency Series

Thursday, October 21, 2021 -

April Abele Isaacson's presentation will include the following topics:

- Extension of patent term under 35 U.S.C. § 156 and 37 CFR 1.710 – 1.791
- Exploring the viability of extension applications to:
 - » Basic and combination compounds; secondary patents
- Important benchmarks in the drugs development and patent timelines
- Eligibility for patent term extension
- Regulatory review period determinations • How to calculate the patent term restored
 - » Respective roles of the FDA and PTO in granting patent extensions
 - » Third-party challenges – “diligence”
- Patent term extensions outside the U.S.
- Examining patent term adjustment due to delays in prosecution before the USPTO
 - » Strategies for:
 - f* Diligence in prosecution by the patent applicant
 - f* Calculating the adjustment period
- Understanding the link between patent extensions and exclusivity
 - » Extensions obtained through FDA Pediatric Exclusivity and Orphan Drug Exclusivity
- Obtaining patent coverage for pharmaceuticals through the use of second-generation patents, e.g.,
 - » Approaches taken by pharmaceutical companies in obtaining second-generation patents
 - » Enforcement of second-generation patents

Event Details

Thursday, October 21, 2021

2:30 p.m. - 4:00 p.m

Virtual

CLE Credit

Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education

requirements. This course is identified as nontransitional for the purposes of CLE accreditation.

Related People



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