

KEY TAKE-AWAYS

Pharmaceutical Patents put at Risk by Changes to Double Patenting Law

Rob Sahr, Counsel in Choate's Intellectual Property Group, moderated the panel "Are Your Pharmaceutical Patents at Risk?" at the 2018 BIO International Convention. The panel addressed protective measures that patentees may take for existing patents as well as risk mitigating strategies for patent families in prosecution.

Here are some key take-aways from the panel discussion.

Double patenting law continues to evolve

- In 2014, the Federal Circuit held that an earlier expiring patent can be used as a reference patent for double patenting regardless of issue date (*Gilead v. Natco*, 2014)
- The Federal Circuit has held that a Terminal Disclaimer (TD) over an expired reference patent is ineffective (*Boehringer v. Barr*, 2010)
- Reference patent availability for double patent challenges may expand
 - Cases pending before the Federal Circuit to decide:
 - Whether a post-GATT continuation can be used as reference patent against a pre-GATT parent patent with Patent Term Extension (PTE) (*Novartis v. Breckenridge*, argued June 4, 2018)
 - Whether a patent having a later-expiring 35 USC § 154 statutory term can be used as reference patent against a patent having an earlier-expiring 35 USC § 154 term, but a later date of expiration due to PTE under 35 USC § 156 (*Novartis v. Ezra*, argued June 5, 2018)

Pharmaceutical patents with PTE are particularly vulnerable under current law

- Common scenarios include:
 - Reference patent and PTE patent in different families
 - Reference patent and PTE patent in the same family but have different 35 USC § 154 expiration dates (e.g., due to Patent Term Adjustment)
- Additional vulnerability may arise from pending cases before Federal Circuit
 - PTE patent with earlier 35 USC § 154 expiration date than reference (or same day expiration)
- Patents challenged in PTE period after reference patent expiration cannot be saved by TD
- Nonstatutory double patenting is a ground for *ex parte* reexamination

Measures to mitigate risk

- Strategically prosecute patent portfolios to reduce likelihood of double patenting (e.g., judiciously file continuations, avail of 35 USC § 121 Safe Harbor for divisionals)
- Be mindful of timing and content of later filed patents (e.g., method of treatment claim reciting composition can anticipate claim to composition)
- Consider filing TDs over potential reference patents when appropriate:
 - Before reference patent expires
 - Before filing request for PTE
- If PTE request already filed, can file TD and amend PTE request if certificate of extension has not yet issued

FOR MORE INFORMATION

To learn more about pharmaceutical patent risk, please contact:

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