4 KEY TAKEAWAYS

Pharmaceutical Patents: Evolving Standards for Written Description and Enablement

Kilpatrick's Allison Dobson and Tamara Allen recently analyzed and provided strategic suggestions in light of six recent cases* where the Federal Circuit generally applies more stringent requirements for sufficiency of written description and enablement of pharmaceutical patent claims. Speaking at the firm's "IP Innovations" webinar, Allison and Tamara distilled practical lessons for drafting robust specifications and for attacking or defending validity in litigation.

Key takeaways from their presentation include:

1

Genus claims can be highly susceptible to attack under § 112, 1st para. **Generally:**

- A bounded genus (e.g., 14 possible polymorphs) may avoid the concerns raised by genus claims with "potentially vast numbers of species."
- Break up any large genus into smaller genus groupings with sufficient additional disclosure to support claims directed to each smaller genus and decide later, when more data is available, which genus claims to prioritize in prosecution.
- At the inventor's direction, use AI or other tools to generate all possible options so the full genus intended by the inventor is expressly disclosed.

2

For ***Written Description***, disclose a "representative number of species" (such as the complete AI listing suggested above) and describe structural commonalities with "blaze marks" to the genus:

- Each application in the priority chain must satisfy § 112: "the written description of the provisional must adequately support the claims of the non-provisional application."
- File new applications as soon as additional subject matter becomes available.
- Know before you assert the patent what the inventors and other key business personnel think, would say, and have already said about the invention timeline for each claim.
- With surprising frequency the testimony from patent owner company personnel regarding these timeline details leads to invalidation of key claims.

3

For ***Enablement***, carefully consider timing of patent filings where testing is ongoing:

- Prosecute claims having solid enablement support in the specification.
- While dose-range method of treatment claims are not *per se* invalid, claiming broad dose ranges for human treatment without supporting *in vivo* data may be fatal.
- Disclosure of the detailed processes used to make the invention may be helpful.
- When claiming a genus with functional terms, describe extensively the identification and/or selection of species within the genus that meet the functional requirement.
- "The more one claims the more one must enable."

4

Use caution when arguing something is "well-known" in an IPR, where invalidity is based on prior art, if/when quoting these statements from the IPR in a parallel litigation might later help the patent owner demonstrate sufficiency of written description for related claims.

Based on the following cases:

- *Duke University v. Sandoz Inc., 160 F.4th 1305 (Fed. Cir. Nov. 18, 2025)*
- *Seagen Inc. v. Daiichi Sankyo Company, Ltd., No. 23-2424, 24-1176 (Fed. Cir. Dec. 2, 2025)*
- *Teva Pharmaceuticals International GmbH v. Eli Lilly & Co., 172 F.4th 1367 (Fed. Cir. Apr. 16, 2026)*
- *Wyeth LLC v. AstraZeneca Pharmaceuticals LP, No. 2024-2325 (Fed. Cir. July 9, 2026)*
- *Enanta Pharmaceuticals, Inc. v. Pfizer Inc., Appeal No. 2025-1427 (Fed. Cir. June 23, 2026)*
- *Exelixis, Inc. v. MSN Labs. Private Ltd., No. 2025-1236, 2026 WL 2560739 (Fed. Cir. Aug. 31, 2026)*

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