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PTAB & FDA

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Patent Trial and Appeal Board

Key takeaways and recommendations

- The risk of some or all patent claims challenged in IPRs being invalidated remains significant. The USPTO should continue to study and release data to improve patent quality and decrease PTAB invalidations, and identify key areas for future study based on this data. Particular areas of focus may include search capabilities, potential for hindsight bias, and the use of expert testimony during IPR proceedings consistent with statutes.
- The PPAC encourages the USPTO to consider whether the doctrine of inequitable conduct, as currently applied, is encouraging well-intentioned behavior that ultimately decreases the quality of examination and any resulting patents.
- The PPAC encourages the USPTO to consider whether more robust use of section 325(d), with applicable rules that would encourage patent applicants to highlight a limited number of references during examination, would improve patent quality.

FDA

- The USPTO is an important source of empirical data in support of patent policy- PPAC applauds the June 2024 release of the USPTO/FDA drug patent & exclusivity study
  - Key takeaway: The USPTO should continue to generate robust, accurate, and unbiased evidence and be an important source of the evidence that informs intellectual property policy discussions.


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