

# *Helsinn v. Teva:* That Wasn't Supposed to Be For Sale! (and Other Practical Implications)

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## Avoiding the On-Sale Bar

- *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 139 S.Ct. 628, 586 U.S. \_\_\_\_ (2019).
- File patent applications early
  - Before any disclosure!
  - Definitely before a year goes by. . . .
- Coordinate patent prosecution and commercialization strategies to ensure a patent application is filed before any agreement with purchase provisions is entered
  - Resist publicizing such agreements, if you can



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## On-Sale Bar

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- *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998)
  - Invention was the subject of a commercial offer for sale
  - Invention was “ready for patenting”:
    - reduction to practice before the critical date, or
    - *inventor had prepared drawings or other descriptions of the invention that were to sufficiently enable the invention*

SALE

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## Sale or Offer For Sale

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- The *Helsinn* Supply and Purchase Agreement was announced in a joint press release and MGI’s Form 8-K Filing with the SEC, including a partially redacted copy of the Supply and Purchase Agreement
- Federal Circuit: “[A]fter the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of the sale”
  - Being “on sale” does not require publication of sale details

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# Keep Sales Transactions Confidential

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- Keep transaction and commercial agreements secret until AFTER a patent application is filed
- Enter into a Non-Disclosure Agreement
- Add Non-Publication provision

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# Advanced Tip: Avoid Transfer of Title

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- Federal Circuit: “MGI agreed to purchase exclusively from Helsinn, and Helsinn agreed to supply MGI’s requirements of the 0.25 mg and 0.75 mg palonosetron products...”
- *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016): The absence of the passage of title, the confidential nature of the transaction, and the absence of commercial marketing of the invention all counsel against applying the on-sale bar

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"On Sale Bar / Impact of Helsinn - 102 Nuts and Bolts"