



The Intersection Between Hatch Waxman, PTAB, ITC & ED Texas. *Using All The Tools in the Tool Box.*

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Hatch Waxman Overview

› Initiation of Hatch Waxman Litigation

- Orange Book
- Generic drug company files ANDA with FDA
- Brand drug company receives notice and may bring litigation within 45 days

› Unique Statutory Provisions Distinguish Hatch Waxman Litigation from other Patent Litigation

- ANDA filing is an artificial act of infringement
- 30-month stay of FDA approval
- 180-day generic drug exclusivity



ED Texas Local Hatch Waxman Rule

- › Brief history of Local Patent Rule 3-8
- › Provisions of Local Patent Rule 3-8
 - Production of ANDA
 - Invalidity contentions followed by infringement contentions
 - Notification requirements regarding FDA correspondence
 - Final pretrial hearing set 24 months from date of filing
- › ED Texas local rule reflects experience adjudicating Hatch Waxman litigation and importance of timing



Unique Hatch Waxman Litigation Issues

- › Bench trial
- › No willful infringement
- › Joinder permitted for multiple ANDA filers
 - Exception to AIA
- › New patents issued during litigation
- › New evidence by ANDA filer in response to FDA comments
- › Potential “at-risk launch” of generic product



PTAB Proceedings and Hatch Waxman Litigation

- › IPR proceedings are increasingly popular tool for challenging pharmaceutical patents
- › Interests of first ANDA filer vs. subsequent ANDA filers
- › Effect of PTAB decision
- › Stay of litigation due to IPR proceeding
 - *Alcon Laboratories v. Akorn*, 2016 WL 99201 (D.N.J. Jan. 8, 2016)
 - *Eli Lilly & Co. v. Accord*, 2015 WL 8675158 (S.D. Ind. Dec. 11, 2015)



ITC Proceedings and Hatch Waxman

- › ITC proceedings not as common
 - ITC action not likely a basis for:
 - › 30-month stay; or
 - › Injunction barring FDA from approving ANDA
- › ITC actions are a possibility with:
 - Manufacturing process patents not listed in Orange Book
 - Importation of drug into U.S. for manufacture of final product sold overseas
 - Patents for which no 30-month stay would be available in district court action
- › Potential advantages of ITC action:
 - Exclusion orders applicable to multiple suppliers



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Questions?