

GRx+Biosims

Engineering the Future of Generic + Biosimilar Medicines

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Emerging Legal Issues in IP and Paragraph IV Litigation



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Usual Disclaimers

- These are our views and opinions, not those of Duane Morris
- Nothing in this presentation is intended to be legal advice
- We likely represent some of your companies
- But for those we do not, we are their or your lawyers
- But we would like to be
- Please pepper us with questions. We will try to answer them.



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What are we going to talk about

I. Biggest Challenges

- i. The Federal Circuit's Lead Compound Analysis
- ii. Too Many Filers on NCE-1 cases

II. Biggest Opportunities

- i. Product Selection
- ii. The Carve In
- iii. IPR

III. Recent Case Law and Legislative Developments

- i. Venue—TC Heartland plays out in Delaware and New Jersey
- ii. IPR for pharmaceutical cases



Biggest Challenge—Federal Circuit's Lead Compound Analysis and New Chemical Entity Patents

- Federal Circuit is very hostile to challenges to NCEs
- Even if Trial Judge Finds Obvious—Federal Circuit likely to overturn
- Millennium Pharmaceuticals, Inc. v. Sandoz Inc.
 - a generic version of Velcade®, a chemotherapy drug with the active ingredient bortezomib
 - Patent claimed the mannitol ester of bortezomib
 - Judge Sleet found it obvious by "clear and convincing" evidence that lyophilizing bortezomib
 with mannitol was a known and obvious solution to the problem of instability
 - Federal Circuit Reversed
 - Jumped through hopes to discount the expert testimony of the ANDA filers, turned what is supposed to be a fact issue into one of law, and disregarded its own precedent and KSR



Biggest Challenges—Too Many NCE -1 Filers

- Tecfidera
 - Over 20 filers
 - Likely fully genericized as soon as someone comes on the market
 - ➤ Limited 180 day exclusivity value
 - > MFNs
 - > Even if some drop out
 - Results in JDG challenges
 - Little Incentive for brand to settle



Biggest Opportunities—Product Selection

- Smaller Products with complicated technology where you can predict fewer filers
 - Unique Non-Infringement Technology
 - Complicated to manufacture
 - Example
 - Billion Dollar product with 20 filers upon entry market is now a \$50,000,000 product of which you may get \$2,500,000 if lucky
 - > \$100,000,000 product with 3 filers market drops to \$20,000,000 but you get 20% \$4,000,000
- Portfolio Management Products -- leverage your market expertise



Biggest Opportunities—Reverse Section viii—The Carve in - Velcade® Citizen Petition

- Initial Approval "Velcade is indicated for the treatment of patients with mantle cell lymphoma who have received at least 1 prior therapy."
- Revised Labeling following an amendment for an ODE indication "VELCADE is indicated for the treatment of patients with mantle cell lymphoma"
- In order to avoid the ODE exclusivity, Fresenius wanted to go back to the original language -- the Carve-In
- Millennium files a citizens petition asking FDA to deny the "carve-in" -- FDA denied

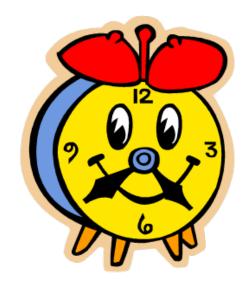


Biggest Opportunities—IPR

- Offensive Use of IPR
 - Clearing blocking patents before you file
 - Non-Infringement Strategy
 - Process patents
 - Follow-on Filers
 - Preparing but not filing petition for IPR



Inter Partes Review (IPR) strategies and opportunities



- Timing is Everything
 - Before filing ANDA or aBLA
 - After filing application but before receiving notice of acceptance from FDA
 - At the same time as sending Notice Letter
 - After litigation has been filed but no later than 1 year from the date the complaint was served



Venue—Impact of *TC Heartland* on Pharma cases

- In re ZTE
 - Federal Circuit law applies to venue question in patent cases
 - Burden of persuasion on Plaintiff to establish venue
- In re BigCommerce
 - Corporation "resides" in single judicial district, not every judicial district in state



Venue—Impact of TC Heartland on Pharma cases

- Satellite cases on parallel tracks
 - Competing schedules
 - Claim construction
 - Fact discovery across cases
- Majority of Hatch-Waxman cases remain in Delaware and New Jersey
 - Experienced judges/crowded dockets
 - New Judges in Delaware
 - Judge Maryellen Noreika
 - ➤ Judge Colm F. Connolly
- Protective cases



Venue—Impact of TC Heartland on Pharma cases

- Considerations and Opportunities
 - Lone Wolf or Part of the Pack?
 - Does your case have any distinguishing characteristics?
 - Are you incorporated or based in Delaware or New Jersey?







Inter Partes Review (IPR) cases

- Oil States v. Greene's Energy (S.Ct. 7-2)
 - IPR does not violate Article II or Seventh Amendment
 - IPR as agency action
 - > public rights doctrine—public interest in scope of patent grant, IPR as agency action
- SAS v. lancu (S.Ct. 5-4)
 - PTAB must institute on all challenged claims (all grounds)
 - IPR "mimics civil litigation"
- St. Regis Mohawk Tribe v. Mylan (Fed. Cir.)
 - Tribal sovereign immunity cannot be applied in IPR
 - IPR more like an agency enforcement action than civil lawsuit of private parties



Inter Partes Review (IPR) cases

- Click-To-Call Tech. v. Ingenio (Fed. Cir.)
 - Section 315(b)—One-year time-bar applies to case where complaint was served more than one year before IPR petition filed but case voluntarily dismissed without prejudice (en banc)



Inter Partes Review (IPR) proposed legislation

- Hatch-Waxman Integrity Act of 2018 (Senator Hatch)
 - Choose either IPR or abbreviated H/W pathway
 - Limitations on filing IPR petitions and short-selling shares of patent holder
 - Proposed amendment to CREATES ACT (prevent REMS abuses, ensure access to samples, prevent delay of generic and biosimilar competition)
 - Hatch amendment not included in bill reported out of judiciary committee
- STRONGER Patent Act (proposed March 2018) (in committee)
 - Claim construction standard equivalent to District Court standard
 - PTAB to consider prior District Court claim construction decisions
 - Presumption of validity—proof by clear and convincing evidence
 - Standing to file IPR—sued or "charged" with infringement