

DuaneMorris®

[www.duanemorris.com](http://www.duanemorris.com)

# GRx+Biosims

Engineering the Future of Generic + Biosimilar Medicines

September 6, 2018

©2018 Duane Morris LLP. All Rights Reserved. Duane Morris is a registered service mark of Duane Morris LLP.  
Duane Morris – Firm Offices | New York | London | Singapore | Philadelphia | Chicago | Washington, D.C. | San Francisco | Silicon Valley | San Diego | Los Angeles | Taiwan | Boston | Houston | Austin | Hanoi | Ho Chi Minh City | Shanghai | Atlanta | Baltimore  
Wilmington | Miami | Boca Raton | Pittsburgh | Newark | Las Vegas | Cherry Hill | Lake Tahoe | Myanmar | Oman | Duane Morris – Affiliate Offices | Mexico City | Sri Lanka | Duane Morris LLP – A Delaware limited liability partnership

DuaneMorris®

[www.duanemorris.com](http://www.duanemorris.com)

## Emerging Legal Issues in IP and Paragraph IV Litigation

DuaneMorris®

[www.duanemorris.com](http://www.duanemorris.com)

Frederick R. Ball, Duane Morris LLP  
Patrick Gallagher, Ph.D., Duane Morris LLP

## 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.

## 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. Iancu (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