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Association for Accessible Medicines

Biosimilars Council
A Division of the Association for Accessible Medicines

GRx+Biosims™

Generic + Biosimilar Medicines Conference

The Changing Landscape of Patents, Hatch-Waxman, and the BPCIA

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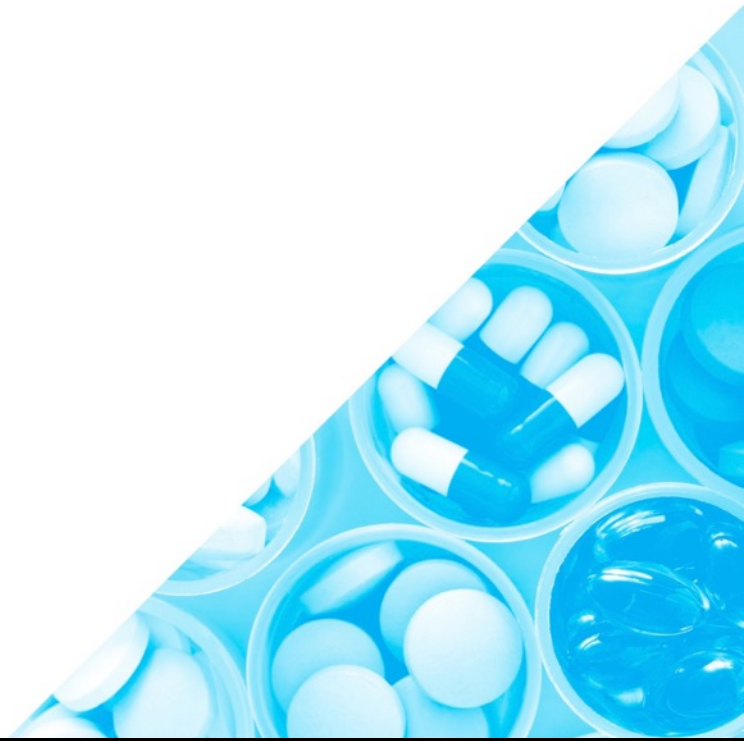
Agenda

- **Business Considerations for Biosimilar Development**
  - Indications and Extrapolation
  - Patent Dance
    - Section 2(A) Production
    - Cornyn-Blumenthal Legislation
  - Manufacturing At-Risk
  - Settlement of Patent Litigation
  - Imports and Exports
  - Utility of Purple Book
- **180-Day Exclusivity**
- **Section 101 of the Patent Act**



Business Considerations for

Biosimilar Development

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Cornyn-Blumenthal (S. 1416)

- Caps brands at **20 patents** if BSA complies with patent dance
  - 10 patents can be after-acquired or later-issuing patents
- Number of patents **outside the cap**:
  - Method of treatment patents
  - Device patents
  - Patents with actual filing dates before and up to 4 years after BLA approval
- Brand can seek **additional patents** if:
  - Section 2(a) manufacturing information not sufficiently provided
  - PTO delays
  - Material change in biosimilar product or process

Federal and California Patent Settlements Legislation

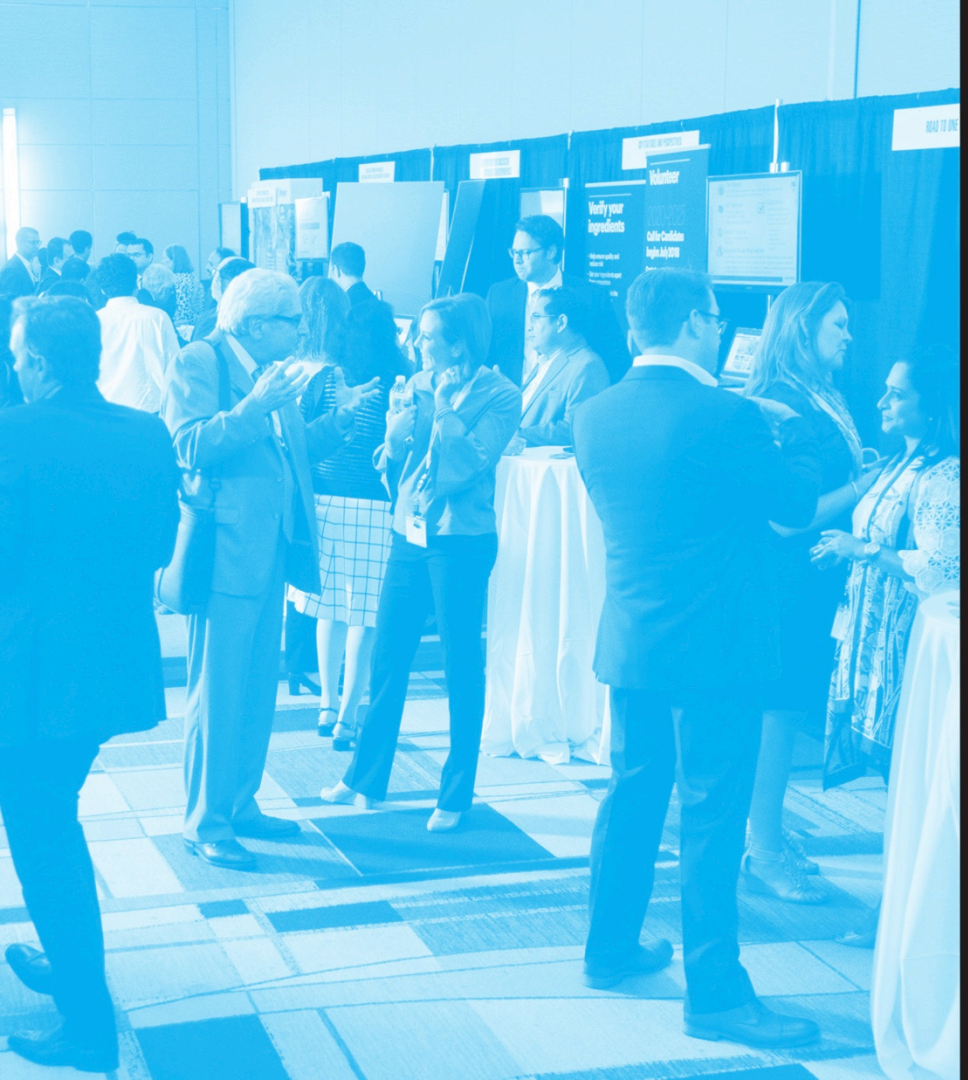
- Anticompetitive presumption if:
  - **"Anything of value"** is given to generic/biosimilar company;
    - Includes "exclusive licenses"
    - Federal bill includes any type of license
  - Delayed generic/biosimilar entry relative to the date of settlement

Federal and California Patent Settlements Legislation

- Rebuttable Presumption:
  - California: preponderance of the evidence
  - Federal: clear and convincing evidence
- Provisions Exempted from Liability:
  - Litigation Costs
    - California: Requires budget corroboration
    - Federal: Up to $7.5 million
  - Acceleration clauses
    - California: Product hop, others potentially possible
    - Federal: Standard acceleration clauses
- Penalties:
  - California: greater of $20 million or treble the value exchanged
    - Can be applied to individuals
  - Federal: treble the value exchanged
    - Limited to companies

Purple Book Bills

Issue	Purple Book Continuity Act (HR 1520)	Biologic Patent Transparency Act (S. 1895)
Patent Listings	Requires patent listing in Purple Book 30 days after patents are listed in a 3(A) patent dance list or supplement to that list	Within 60 days of approval, both brand and biosimilar companies must list all patents for which a claim of infringement could reasonably be asserted
Penalty	None	Public listing of companies that do not comply



180-Day **Exclusivity**

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180-Day Exclusivity: The BLOCKING Act (S. 1895)

- 180-day exclusivity period is triggered if:
  - No first applicant has final approval 33 months after submission;
  - A subsequent applicant would be able to get final approval but for the existence of 180-day exclusivity;
  - Subsequent applicant has not agreed to delay commercial launch through a settlement; and
  - The 30-month stay has run as to least one first applicant

The BLOCKING Act: Issues

- Reasons a **first applicant** may not have **final approval at month 33**
  - Paragraph III certification as to compound patent
  - Citizen petition
  - Delayed FDA inspection at a foreign facility
  - Change in the review or requirements for approval
- **No guarantee** that subsequent applicant actually launches
  - Month 33 is in the middle of patent litigation; patent certainty not likely achievable until month ~48

Section 101 of
The Patent Act

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Thank you