Legal Perspectives on Combination Therapy

Andrew D. Barofsky
VP & General Counsel
Oregon Biomedical Engineering Institute, Inc.

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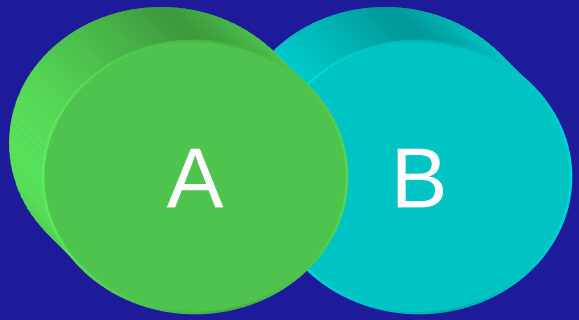
Combination Therapy



Biologic-device
Biologic-drug
Biologic-device-drug

Physical combination
Chemical combination
Combined in package or kit
Cross-labeled stand-alone products

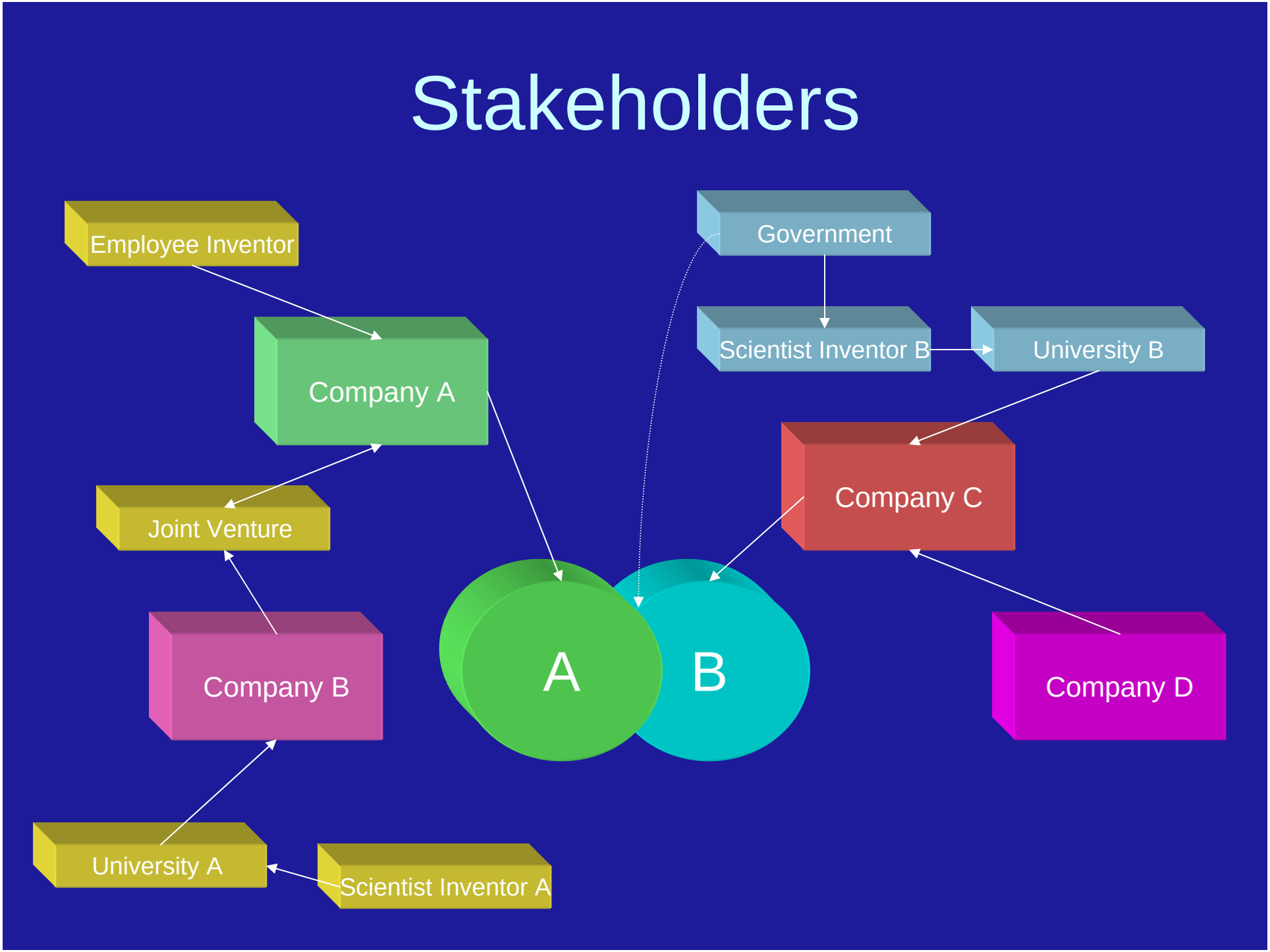
Citing in part: Mark Kramer, Dir. OCP, FDA

Collaborations

- Commercializing a combination therapy is a collaborative endeavor
- A key challenge is fostering productive collaborations
  - Industry-academia
  - Industry-government
  - Industry-industry

- Collaborative ventures create and/or bring together multiple IP stakeholders

Stakeholders



Complex IP Agreements

- Plain vanilla license is a thing of the past
- Hybrid agreements, option/license agreements, joint venture, corporate partnering, co-promotion/co-marketing arrangements, strategic alliances, consortium licensing.

Citing: Prof. Karl F.Forda, Franklin Pierce Law Center

Patent Paradox

- Patent rights provide incentive for commercial development
- Management/protection of patent rights may hinder inter-party collaborations
  - Inhibits material, data technology exchanges
  - Keeps compounds “on the shelf”
  - Raises cost of research
    - Increase transactional costs
    - Royalty stacking
    - Payments via reach-through rights

Material and IP Transfer Risks

- Recipient may develop IP that restricts patent holder’s ability to enter future markets
- Mechanism of action studies may lead to broad claims
- Negative results may devalue IP

Fostering Collaborations

- Develop consensus IP, data, contract templates
- Develop multi-party funding mechanisms - gov/univ/co./foundations (NSF I/UCRC, NCI AP4)
- Use funding to structure IP rights
  - 28 USC 1498
  - Authorization and consent (in grants as well as contracts)
- Off the shelf IP consortium/pool (risk sharing)
- Provide incentives (patent term extension, tax breaks, etc.) and liability protection to contributors of materials

Incentives vs. Risk

- Is the market big enough (e.g., for personalized medicine)?
- How important are reimbursements to commercial success
- Development time/costs erodes value of IP
- Indemnity / liability
- Valuation of IP (industry vs. academia)
  - Stage of development
  - Strength of patent
  - Degree exclusivity
  - Geographic scope

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Patent Law Considerations

- Is the patent bar to high or low?
  - Obviousness (KSR Teleflex)
- Patent Reform Act of 2007
  - first to file, post grant review
- USPTO Rule Changes (GSK injunction)
  - continuation limits, claim limits
- Globalization
  - Strengthening IP systems
  - Harmonization

Increasing Access to Technology

- Dedicate to public domain
- Create statutory exceptions to patent infringement
- Use voluntary and compulsory licensing
  - TRIPS
  - Patent pools, clearinghouses, consortia, cross-licensing
- Develop combinations of off-patent materials
- Challenge patent validity
- Design around

Generics Issues

- Extension of monopoly through combination claims delaying entry of generics/follow-ons (cross-labeled stand-alones)
- What is a biologic generic/follow-on?
- Fewer countries making generics
- When generics/follow-ons are part of a combination product, damages for combination products are limited to the patented components

Questions?

Thank you