

Breakout 4

Intellectual Property Barriers
to the Development of Combinations

“New, Useful & Non-Obvious” Combinations

biologic-device

biologic-drug

biologic-device-drug

(biologic-biologic)

physical combination

chemically combination

combined in package or kit

cross-labeled stand-alone products

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

Micro Issues

- Fostering productive industry-academia collaboration
- Fostering productive industry-government collaboration
- Stimulating cross-industry collaboration
- Getting industry compounds “off the shelf”

Macro Issues

- Is the patent bar too high or too low?
- Do industry and academia give the correct valuation to IP ?
- Should there be additional IP and regulatory incentives for the development of combination therapies?

IP Barriers to Research & Development

- Multiple patents to a combination may be held by different parties – raising the cost of research and development
 - Transactional costs associated with negotiating rights
 - Stacking of royalties when in-licensing (ultimately raising product prices)
 - Requirement for “payment” via reach-through rights
- Chilling of materials exchanges for research, and strategic alliances between companies for commercial development – blocking innovation (access to materials is a related to, but different from, access to IP)
- Keeping in mind the ability to conduct research directed toward regulatory approval (i.e. barrier becomes more concrete at the point of commercialization; Merck KGaA v. Integra Lifesciences and 35 USC § 271(e)(1))

Issues for the Patent Holder

- Patents are a necessary Incentive for commercial development (Article 1, Section 8: “To promote the Progress of Science and useful Arts...”)
- Making material available for research can result in a second party’s developing rights or data that will restrict the first party’s ability to enter future markets
- Mechanism of action studies can lead to broad claims
- Providing material for further research, that results in data re such things as toxicity, can negatively affect owner’s IP
- Market “size” and patient cost for personalized medicine (a future of “orphans”?)
- Relationship of reimbursement to commercial success
- Development time and cost can erode value of IP
- Is there an incentive to raise the price of a marketed material that will be used in combination by others?

Solutions for Research and Development

Patents/Licensing

- Dedicate to the public domain
- Raise the bar for patentability (obviousness)
 - Legal conclusion based on factual inquiry
 - Supreme Court docket (KSR Teleflex)
- Create statutory exceptions to patent infringement
- Use voluntary and compulsory licensing (especially in post 2005 IP world) - patent pools, clearinghouses, consortia, cross-licensing
- Look to develop combinations of off-patent materials

Solutions for Research and Development

Collaborations

- Develop consensus IP, data, materials template among Gov, Univ, and Co
- Develop multi-party funding mechanisms – Gov & Univ & Co (a la NSF I/UCRC and NCI AP4); involving foundations (NIH?)
- Use funding to structure IP rights - Federal authorities/role?
 - 28 USC 1498 (damages limited to reasonable royalties)
 - Authorization and consent (in grants as well as contracts?)
- Provide IP incentives (patent term extension) and liability protection to contributors of materials
- “Off the shelf” IP consortium/pool ?
- Tissue donors could determine use of their materials, including for the generation and subsequent use of IP

Access to Data Issues

Right to use the data for research and regulatory purposes

- For stand-alone use
- Ability to label for combination use without inducing infringement

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?
- Post-2005 IP world: fewer countries making generics
- When generics/follow-ons are part of a combination product, damages for combination products are limited to the patented component