

Developing Immunotherapy Combinations

Logistical Issues/Legal Matters

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Legal Barriers to Combination Research

- Intellectual Property
- Contracts
- Antitrust Law
- Product Liability

Thesis: There are very few true legal barriers. However, there are transactional dynamics that are sometimes expressed in legal terms.

Negative Dynamics in Combo Therapy Research Negotiations

- Failure to grasp the key interests and concerns of the other negotiating partner(s)
- The desire of one party to extract more value from the partnership than is warranted by its own contribution.

Objectives of the Key Players

- Government
 - Do research; get credit
 - Avoid criticism from Congress and media of cozy relationship with industry
- Academia
 - Do research; get credit
 - Extract maximum financial benefit for academic institution
 - Ability to publish
 - Freedom to operate

Objectives of the Key Players

- Large Pharma/Biotech
 - Get regulatory approval/sales
 - Ensure a maximum period of product exclusivity
 - Minimize royalties/third-party payments
 - Freedom to operate
- Small Pharma/Biotech
 - Continue compound development with sufficient resources
 - Extract maximum current and future financial value from big pharma/biotech partner
 - Structure transaction in a way that enables continued access to capital markets
 - Freedom to operate

Intellectual Property

Typical Scenarios:

- Company X holds patent claims covering the combination of Drug A (its own) and Drug B (owned by Company Y).
- Same scenario, but the combination patent also covers other innovative drugs in the same class as Drug B. These drugs belong to other companies.
- Same scenario, but the other innovative drugs in the class belong to Company X or Company Y.

Intellectual Property

Key Issues

- Freedom to Operate
- Royalty Flow
- Participation in other economic value created by IP:
 - Exclusivity vs. generic versions of the individual component drugs
 - Exclusivity vs. (or royalties from) innovative therapeutic competitors who are covered by broader patent claims

If the IP is not serving any of the above purposes, why fight about it?

- *Confusing IP ownership with “scientific credit”*
- *Legal restrictions or perceived political imperatives (government)*
- *Academic policies and Tech Transfer Office imperatives*
- *Fear of giving “concessions” in negotiations*
- *Fear of the not fully understood consequences*

Contracts

Sources of Contention

- Money: Expenses and Profits
 - Clinical Supplies (when these are high cost or in short supply)
 - Development Expenses
 - Compensation for a license to one party's patent
 - Who pays for royalties to third party licensors
- Exclusive Arrangements
- Possibility of Regulatory Delay for Single Agent
- Commercial Strategy
- Combo Product Pricing

The greatest barrier is the desire of one party to extract more value from the partnership than is warranted by its contribution.

Antitrust Law

Key element of concern: An exclusive arrangement that would prohibit one partner from developing combinations with the products of third companies

Otherwise, antitrust law is rarely a barrier to collaboration.

Product Liability Risk

- Rarely a factor in clinical trials involving serious diseases
- Proper patient Informed Consent is key
- Post marketing, the issue is “failure to warn”, and thus controllable

Conclusion

- Understanding the key interests and concerns of the other negotiating partner(s) can result in a speedier conclusion of a better deal for everyone.
- Having a realistic understanding the value of the contribution of each party contribution can help to avoid the breakdown of an otherwise fruitful collaboration.
- And never lose sight of the patients who may benefit from the combination therapy.