

# Patent / Know-How License Agreements

There is virtually no limit to the range of deal terms that can be found in patent/know-how license agreements. The negotiated terms are tailored to the specifics of the deal and depend on many factors, including the nature and stage of the technology and the leverage of the parties. Typical terms to consider include:

## The Parties

- Names and addresses of Licensor and Licensee

## Definitions

- Affiliate
- Confidential Information
- Effective Date
- Field of Use
- Improvements
- Licensed Know-How
- Licensed Patent Rights
- Net Sales (may include Combination Product calculation)
- Products and/or Services
- Sublicense Revenue
- Term
- Territory
- Valid Claim

## License Grant

- License granted under Licensed Patent Rights and/or Licensed Know-How to make, have made, use, sell and import Products and/or Services in the Field of Use and Territory
- May be exclusive, co-exclusive or non-exclusive
- May involve cross-license between both parties
- Is license granted to Affiliates?
- Does Licensee have right to sublicense? (see *Sublicense Issues* below)
- Is license subject to rights of United States Government?
- If Licensor is university, does university have retained rights?
- Will license include rights to Improvements made by Licensor?
- Will Licensee be obligated to grant-back Improvements to Licensor?
- May grant option or right of first refusal to related IP and/or use in other fields
- Transfer of Know-How and materials or other technology

## Sublicense Issues

- With or without consent of Licensor?
- Does sublicense survive termination of license?
- Have required consents been obtained?

## Consideration

- Up-front license fee
- Annual license fee/minimum royalty
- Royalties on Net Sales (see below)
- Profit share
- Payments on achievement of development and/or commercialization milestones
- Percentage of Sublicense Revenue
- Settlement of dispute or litigation
- Cross license
- Equity
- Reimbursement of patent prosecution expenses
- Currency of payments/exchange rate
- Taxes
- Interest on overdue amounts

## Royalties on Net Sales

- May be tiered based on Net Sales thresholds
- May be subject to reduction:
  - if royalties also due to third parties (anti-stacking)
  - if competing products
  - if no patent coverage
- May pass through to sublicensees
- Duration of payment obligation (may raise patent misuse issue in US)

## Duties of Licensee

- Use commercially reasonable efforts to exploit Licensed Patent Rights and/or meet specific time-based diligence milestones
- Provide periodic progress or status reports
- Provide periodic financial reports, including royalty calculation
- Make records of account available for audit

## Prosecution/Infringement

- Which party will prosecute Licensed Patent Rights? Which party will pay costs?
- Which party will pursue third-party infringers of Licensed Patent Rights?
- Which party will defend third-party claims of infringement?
- How will recoveries be allocated?

## Indemnification

- By Licensor
- By Licensee
- Licensee obligation to maintain insurance
- Limitation of Liability

## Confidential Information

- Restrictions on use and disclosure by recipient
- Exceptions
- Duration of obligation

## Term and Termination

- Expiration
- Termination for Material Breach
- Termination for Failure to Meet Diligence (or conversion to non-exclusive)
- Termination by Mutual Consent
- Termination by Licensee for Convenience
- Effect of Termination
- Effect of Bankruptcy
- Survival of Obligations

## Representations and Warranties

- Parties have right and authority to execute agreement
- No conflict with other obligations
- Licensor owns or controls licensed rights
- Qualified representations regarding validity, enforceability and non-infringement of third-party rights
- Disclaimer of warranties

## Assignment of Agreement

- With consent
- In event of sale of business or merger or other change of control

## Miscellaneous

- Publicity/Use of Name
- Arbitration or other dispute resolution
- Governing law
- Force Majeure
- Patent marking
- Notices
- Integration

# Life Sciences Collaboration Agreements

## Why Collaborate?

- Gain access to technology, expertise and specialized resources
- Gain license to patent rights that would otherwise be infringed
- Obtain research funding and/or capital
- Leverage the resources of each party to create new value
- Right to develop and commercialize the technology created in the collaboration
- Expand experience
- Generate publicity - serves as validation of technology and raises profile

## Parties' Possible Contributions to the Collaboration

- Funding and/or capital
- Intellectual property rights
- Confidential information, know-how, data or methodologies
- Specialized personnel
- Experience (e.g., manufacturing, regulatory and sales and marketing expertise)
- Unique resources
- Biological, chemical or other materials
- Platform or tool technology
- Equipment
- Software
- Global distribution network

## Ownership of Intellectual Property Created in Collaboration

- Allocation of ownership of IP created in collaboration depends on many factors
- New intellectual property may be owned by inventing party [if both parties invented, new intellectual property may be jointly owned (see below)]
- New intellectual property that is an improvement to existing intellectual property may be assigned to party that owns existing intellectual property, regardless of inventorship
- May allocate ownership based on inventorship for some IP and based on existing background rights for other IP
- What constitutes existing intellectual property and collaboration intellectual property needs to be clearly defined. Generally, each party retains ownership of its existing intellectual property

## Rights Granted

- Parties grant exclusive, co-exclusive or non-exclusive licenses to each other under existing IP and collaboration IP as necessary to further collaboration goals
- Rights to research tools may be non-exclusive
- May be field limited – how are rights outside field handled? May be territory-limited.
- Ability to sublicense?
- May have co-promotion or co-marketing rights in specified territory(ies)

## Joint Ownership Issues

- Collaboration may lead to joint inventorship under patent laws or joint ownership under agreement
- In U.S., each joint owner has an undivided interest in patent and may license and exploit the patent without consent and without accounting to other owner
- Not the case in some jurisdictions, such as the United Kingdom
- Each joint owner may sue infringers, other owner may be indispensable co-plaintiff
- Need to consider rights of joint owners upon termination

## Obligations of Parties

- Use commercially reasonable efforts to perform required activities
- Provide necessary cooperation and resources
- Make payments
- Refrain from selling competing products, subject to antitrust considerations
- Specify which party will perform research, conduct clinical trials, manufacture, obtain regulatory approvals and commercialize (may be territory by territory)
- Prompt disclosure of inventions
- Adhere to confidentiality obligations
- Establish governance structure, such as Steering Committee, and mechanism to resolve disputes
- Comply with restrictions on use of materials
- Ensure any required consents from third-party licensors of existing IP have been obtained
- Ensure any required terms of such third-party agreements have been passed through to the collaboration
- Effect of termination of third-party agreements
- Often multi-year relationship – parties' interests must be aligned

## Financial Terms

- May share profits and costs
- May be royalty based
- May be combination of profit share and royalties
- May include upfront and/or milestone payments
- May include research funding and/or capital
- Reimbursement of patent expenses
- Payments to third parties
- Taxes

## Patent Prosecution/Infringement

- Which party will prosecute collaboration patent rights?
- Which party will pursue infringers?
- Which party will defend against third-party claims of infringement, invalidity or unenforceability?

## Termination

- Expiration
- Termination for Material Breach
- Termination for Convenience
- Termination by Mutual Consent
- Bankruptcy
- Effect on intellectual property rights (e.g., if a party opts out of the collaboration or breaches, license granted to the other party may continue)
- Effect on financial terms
- Effect on regulatory approvals

## Miscellaneous

- Representations and Warranties
- Indemnification/Insurance
- Dispute Resolution
- Assignment/Change of Control
- Force Majeure
- Publicity/Use of Name
- Notices
- Governing Law

If you would like further information, contact an attorney with Edwards Angell Palmer & Dodge's Business Law Group at 617.239.0100 or visit our website at [eapdlaw.com](http://eapdlaw.com).

ATTORNEY ADVERTISING: The hiring of an attorney is an important decision that should not be based solely on advertisements. Before you decide, ask us to send you free written information about our qualifications and experience. Prior results do not guarantee a similar outcome.