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## Mastering Complex IP Licensing

Licensing in the Life Sciences: Developing Successful Strategic Alliances

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## Successful Strategic Alliances: **Topics**

- **Why a Strategic Alliance?**
- **Business Issues**
- **What Is It?**
- **Deal Terms**
- **Kinds of Partnerships**
- **The Contract**
- **Partnership Statistics**
- **Royalty Rates**
- **Steps for a Successful Partnership**
- **Critical Success Factors**

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## Why a Strategic Alliance?

- Leverage Scarce Resources
- Commercialize a Technology
- Expand Market Presence
- Gain Access to Technology
- Create Alternatives to Financing
- Improve Credibility
- Build Marketing Clout
- Strengthen Your Competitive Edge
- Diversify Your Business

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## What Is It?

*“A strategic alliance is a corporate relationship – not just a contract! – which helps each partner leverage resources to achieve business goals.”*

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## What Is It?

- No Typical Combination of Companies
- Wide Range of Functions to Leverage
- An Alternative to ...
  - Debt or Equity Financing - without dilution!
  - Make or Buy Decisions – with faster deployment
  - Hiring or Outsourcing – without the overhead

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## Why should the “small tech” want to enter into an Alliance?

- How to **Leverage** yours scarce **Resources**
- How to **Leverage** your **valuable IP & Know-How**
- How to **Leverage** their **Sales Force & Channels**
- How to **Leverage** their **Distribution** Network
- How to **Leverage** their installed **Customer** Base
- **How to create Scale for your Enterprise**

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## Kinds of Partnerships

### Typical:

- Joint Marketing
- Market Development
- Distribution
- Joint Support
- Joint Development
- R&D Partnership
- Manufacturing

### Other:

- Licensing
- Joint Venture
- Consortium
- Equity Investment
- Merger & Acquisition

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## Steps for a Successful Partnership **The Pre-Nuptials ...**

- Establish Clear Objectives
- Assess Your Company's Value to a Potential Partner
- Develop a Partnering Strategy
- Cultivate Prospective Partners
- Do Your Due Diligence !!

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## “It is a “Business Marriage”

- Trust, Honesty, Integrity, Faith, Compatibility & Commitment are all vitally important
- Why? ... *Because the odds are against you:* Two-Thirds of Strategic Alliances fail, usually within the first or second year
- *People*, not legal documents, make the difference

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## Steps for a Successful Marriage

### *The Wedding . . .*

- Business Issues
- Deal Terms
- The Contract
- Royalty Rates

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## Business Issues: Crucial Deal Terms

- License Grant: Field of Use, Product Application
- Exclusivity vs. Non-Exclusivity?
- Milestones, Deliverables & Progress Payments
- Most Favored Nations Pricing Provisions
- Rights of First Refusal: Improvements, New Applications, New Fields, New Technologies
- Joint Ownership of Patents, Technology
- Consequences of a Exit: Trade Sale or Merger

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## The Grant Clause

- Exclusive or Non-exclusive?
- World-wide or limited geographically?
- To make, use and/or sell?
- Limited to a particular Field of Use?
- Right to sublicense

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## Exclusivity: Bane or Gain?

Exclusivity without Commitment = NOTHING

Exclusivity → “Exclusive, Worldwide, Perpetual, Irrevocable, Transferable License” == Selling your company for NO VALUE !

Exclusivity → must be linked to financial, operational, measurable and cancelable commitment and performance

“The Pain of Disengagement”: for failure or breach → Render Non-Exclusive ... Terminate the License?

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## The **Exclusivity** Dilemma

### *In Return for Exclusivity:*

- Up-Front Fees
- Progress Payments
- Development Milestones
- Minimum Sales Volumes, Quantities
- Non-Refundable Payment Obligations

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“**Exclusivity**” = treacherous word: Mortgaging your Corporate Destiny

- SUBDIVIDE Your Markets!!!
- By Field of Use, Territory, Channel, Application, End-User, Platform, Sector, Industry, Horizontal, Vertical -- Any Way You Can Conceptualize Sources of Revenue
- NRE's, Up-Front Funding, Revenue Thresholds, Spending Commitments \$\$\$

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Exclusive **or** Non-exclusive?

- Industry standard?
- Is Licensee able to satisfy the market?
- What will bring the most money with the least risk?
- If you are licensing non-exclusively, consider offering alternative upfront, earned royalty arrangements.

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## What about **Semi-Exclusive**?

- Is Licensee only able to produce & distribute in a limited **geographic** area?
- Is Licensee's interest & experience limited to a certain **Field of Use**?
- Should Licensee have the right/obligation to **sublicense** other areas or should this remain with the Licensor?

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## Field Of Use Restrictions

- The Captive Subsidiary Syndrome: Giving it all Away and becoming an "R&D House"
- Limit Field of Use to specific application: diagnosis v. therapy, indication, territory (NA vs. EU, Asia), compound
- Earn the right for other uses – don't give it away
- Parse the Patent Rights Carefully: Make, Use, Sell, Import **vs.** Have Made, Have Used, Have Sold, Imported

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### Grant Clause: Running Definitions

- Licenser hereby grants to Licensee an exclusive, world-wide license, with the right to sublicense, to U.S. Pat. No. 6,000,000 to make and sell widgets for diagnostic use.

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### Grant Clause: Separate Definitions

- Licenser hereby grants to Licensee a license to the Licensed Patents to make and sell Licensed Products throughout the Territory within the Field.

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## Most Favored Nations (MFN) Clauses

- Opportunity for Licensee to always rebid the deal
- Licensor must match non-exclusive license deal with future deals and terms → trouble for Licensor
- Protective Language: Afford MFN provision only where “similar financial commitment, over similar periods of time, for similar volume of products, and involving substantially similar financial and operating terms & conditions”

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## Rights of First Refusal

- Licensee enjoys a constant review right on new Products, new Fields of Uses, new Territories
- ROFR: Licensor must always provide Licensee opportunity to have first and final right of bidding
- Switch to Right of First Offer (ROFO): Licensor can fashion a deal, bring it to Licensee, if rejected by Licensee → Licensor can go to market on that deal structure as long as Licensor does not reduce the material terms of the ROFO
- Allows Licensor freedom of negotiating new deals in a free market environment, without constant poaching

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### Joint Ownership of IP

- Joint Ownership of IP is a misnomer, an illusion
- If we collaborate, we share fruits of our labors: but what sounds fair & reasonable is often NOT
- One party (Licensor usually) is always undertaking more labor than the other party
- Party who does not undertake the labor usually gets a Free Ride on Your IP Coat Tails

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### Joint Ownership of IP

- Joint ownership has significant legal implications on exploitation, licensing, prosecution & enforcement of patented inventions
- Contribution to the “conception” of claimed invention
- Contribution to the subject matter of one or more claims
- Some level of collaboration between inventors

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## Joint Ownership of IP

- Company/institutional rights arise from a written assignment of invention from employee/inventor
- Ownership follows Inventorship:
  - Party A solely owns inventions made by the employees of Party A
  - Party B solely owns inventions made by the employees of Party B
  - Party A and Party B jointly own inventions made jointly by employees of Party A and Party B

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## Joint Ownership of IP

- Make, use, sell offer for sale and import the patented invention **without duty of accounting** to other joint owners (unless covered)
  - Contrast with copyright: duty of accounting
- **Right to non-exclusively license the patented invention**, even to competitors of other joint owners
- Joint owners rights **vary in foreign countries**

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## Joint Ownership of IP

- Right to participate, or not, in legal proceedings
  - Contrast with copyright
- Each joint owner is at the “mercy” of other joint owners → one can refuse to join or can license a defendant being sued by another

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## Joint Ownership – Practical Advice

- Joint Ownership is one (of many) critical legal (and business) issues that arises in joint development context
- Explore alternative relationships
- Joint Ownership issues can be minimized if joint owners **allocate their respective rights and obligations before a joint development effort**
- Work through **all** the issue areas with the client
- A prior written agreement is a must!

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## Don't Forget the Exit

- What is your long-term **Goal re Liquidity**: trade sale, public offering?
- No matter what ... ***NEVER let them control your Destiny***
- **Read the Boilerplate in the back, and focus on the "Assignment" provisions**
- You must have the freedom to assign the contract in the event of a merger, sale of assets, sale of capital stock or other business combination, "whether by operation of law or otherwise"

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## Business Issues

- Lower Up-Front / Royalty Rates
- Exclusivity Linked to Commitment
- Commitment Linked to Product Delivery Milestones, Patent Issuances, FDA Approvals
- Exclusivity for Defined Territories or Market Niches, Fields of Use, Applications
- Roles of Each Partner Carefully Defined
- Covenants: Non-Competition, Nonsolicitation  
Non-Development, Non-Marketing

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## Deal Terms

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- Royalty Rate “Bell Curves”
- Rights to Product Improvements
- Yardsticks for Loss of Exclusivity
- Milestones on Performance
  - Patent Issuances, country by country
  - FDA filings & approvals: NDA, Phase I – Phase II
  - Manufacturing and scale-up of operations

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## Consideration

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- Upfront Licensing Fees?
- Annual Maintenance Fees?
- Minimum Royalties?
- Milestones?
- Earned Royalties?

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## “Consideration” Considerations

- What are your needs?
- What are Licensee’s needs?
- Big Licensees prefer large upfronts and lower royalties
- Small Licensees may want the opposite

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## Earned Royalties

- No hard and fast rules about amounts (Oops! That’s not what you want to hear!)
- Modeling: GOOD LUCK!
- Always consider looking at similar licenses on Edgar

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## Royalty Rates

- All over the Place: Industry & Deal Dynamics
- Variables
  - Strength of Intellectual Property Position
  - Stage of Company Development
  - Size & Growth Rate of Market
  - Industry Dynamics & Trends, Customary & Recent
  - Impact on Margins, Gross & Operating Margins
  - “75-25” Rule: 25% of Operating Margin belongs to owner of technology = Proxy for % of Revenue

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## Royalty Base

- For royalties, must determine what the **royalty base** is: traditionally it is net sales (defined as invoiced sales minus shipping, taxes and industry-wide discounts)
- But could also be a set amount per unit sold or number of times process used

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## Unconventional Royalties

- Amount of pain saved by using patented process
- Value added by increased activity of patented drug
- Beware of issues in royalty base not related to patented product

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## *Forms of Royalty Structures*

- Running Royalty, Percent of Sales or Per SKU
- Minimum Royalty Payments (Exclusivity)
- Ascending/Descending Royalty (Staircase, Bell Curve)
- Variable Royalty Rates: Volume, Units, Time, Staircase, Overlapping Sine Curves
- Up Front Advances; Recoupment on Back-end Sales
- Pre-Set Annual Fees; Lump-Sum Payments
- Cross-Licensing of Technology
- ASP Model: Monthly Subscription ???

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Factors Affecting **Royalty Structures**

- Utility/Advantage
- Exclusivity
- Commercial Success
- License Duration
- Improvements/Refinements
- Time to Market
- IP Protection, Indemnity
- Maintenance/Support/Training
- Competition Risk
- Build Vs. License
- Territorial Restrictions
- Strength of IP

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Quantifying the **Profit Potential**

- Size of Relevant Market
- Industry Margins (Gross and Operating)
- Market Dynamics
- Characteristics of Technology
- Bargaining Power
- Quality of Partner Contribution
- Value of IP Contribution
- Licensee's Margins
- Scope and Duration
- Reselling Risks

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## Competitive Advantages

- Quality of IP, Breadth of Coverage?
- Head Start ... or ... Market Domination?
- Competitive Activity: ahead or behind, and length of lead ... or lagging?
- Scope of Legal Protection: Difficulty of Design Around or Reverse Engineering?
- Technology = Minor Improvement or Breakthrough Invention?

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## Competitive Advantage

- Stage of Development? research, development, application testing, prototype, commercialization
- Size of Potential Market & Market Dynamics re Pricing, Cost Structures, Operating Expenses
- Cost of Capital: Manufacturing, Marketing & Distribution Infrastructure Costs

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## Market-Based Analysis

- Ultimate Cash Flow from the Technology
- Quantify Assumptions relating to Value
- Competitive Advantage: availability of alternative technologies, quality of IP portfolio, useful life of IP
- Spectrum of Development: applied research vs. prototype, costs to commercialization
- Market Dynamics: strength and size of market, competitive environment, lower operating costs, freedom of pricing

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## Valuation Methodologies

- Cost Basis: Direct Cost & Opportunity Cost
- Market/Auction Approach: What the market will bear
- Industry Norms: Transaction Comparables
- Systematic Economic Analysis: Discounted Cash Flow, Quality of IP, Competitive Advantage, Risk Assessment, Market Size, Net Present Value of Future Earnings

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## Other Business Issues

- Assess Technology Specifications/Definitions
- Assess Distribution Channels of Technology
- Progress Reports, Meetings, Reviews, Audits, Forecasts
- Product Development Obligations of Each Side
- Manufacturing + Support Obligations

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## Contract Issues

- Reps + Warranties on Validity, Ownership & Infringement
- Confidentiality, Protection of Know-How
- Intellectual Property, Infringement Issues
- Termination Issues
  - Defined Voluntary Exit Strategies
  - Insolvency, Bankruptcy events
  - Failure of Support
  - Material Breaches, Milestone Defaults
  - Payment Defaults
- Maintenance & Support Obligations of Each Side

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## Term of the License

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- Generally, corresponds to the last of the patents to expire
- Should make the royalty payments terminate country by country as the patents expire
- If Know-How is also being licensed the term you may extend after patent termination, but reduce the royalties  
→ otherwise an unenforceable license “Patent Misuse Doctrine”

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## Termination for Cause

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- Failure of either party to perform their duties
- Consider whether damages are limited to loss of license ... or consequential damages as well
- Consider what provisions survive termination: confidentiality, IP indemnity, depletion of inventory

## Termination Without Cause

- Bilateral? Put yourself in the shoes of the other party:  
What have they spent to gear up for production?  
What about stock on hand? If they terminate, have you decreased the value of your IP for licensing to others?
- And again, consider what provisions survive.

## Other Provisions

- Record Keeping and Audits
- Confidentiality
- Improvement and grant-backs
- Implied and express warranties
- Indemnification and insurance

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## Steps for a Successful Partnership

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### *After the Honeymoon . . .*

- Continually “Manage” the Relationship
- Foster New Relationships
- Frequently Assess Progress and Benefits

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## Critical Success Factors

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- Clarity of Purpose
- Mutuality of Treatment
- Minimum Dependencies
- Strong Working Relationships



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## IP Value Harvesting

Our Intellectual Property and Corporate lawyers team up with inventors and management to maximize revenues and profits from the inventory of intangible assets.

- **Research** opportunities to extol value from existing IP (e.g., patents, trade secrets, know-how, data)
- **Identify** and **analyze** existing/potential opportunities
- **Establish strategies to maximize IP value** through
  - Out licensing
  - Strategic alliances
  - In licensing

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## Life sciences: Developing and Exploiting Inventions – Research

- **Seek Out** opportunities to extol value from existing IP (e.g., patents, trade secrets, know-how, data)
  - Valuate existing IP in relation to existing technology platforms
  - Identify suitable partners to co-develop existing technology platforms
  - Identify third parties necessary to develop existing technology platforms
  - Identify suitable partners to leverage existing assets: from well-established pharmaceutical and medical device companies to new start-up ventures

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## Life sciences: Developing and Exploiting BioMedical Inventions – Identify and Analyze Opportunities

- **Analyze** existing/potential opportunities
  - Evaluate IP rights related to relevant technology platforms of potential partners
  - Identify interplay and synergy
  - Integrate information related to the position of potential partners (e.g., financial factors, existing collaborations, on going research and development efforts, clinical trials etc...)

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Life sciences: Developing and Exploiting BioMedical Inventions –  
Strategize

- **Develop and Evaluate strategies to maximize IP value** through
  - Strategic alliances/Collaborations
  - Out licensing
  - In licensing
  - Start-Up ventures
  - Monetization Tools (e.g., royalty and revenue interest transactions as a financing alternative)

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Life sciences: Develop Successful Structures and Legal Tools to  
Implement Strategies

- **Devise Incentive-based Systems to drive developmental and commercialization efforts**
  - Milestones (ties to performance)
  - Standard royalties
  - Flow-through royalties
  - Reach-through royalties
- **Ensure Compliance and Enforcement of license portfolio**
  - Portfolio can include in-licensing, out-licensing and sublicenses
  - Diligence requirements
  - Reporting requirements
  - Royalty payments
  - Milestone payments
  - Disclosure requirements
  - Termination
  - Renewals
  - Options

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