



Business Development Basics Course

Contract Basics



Business Development Basics Course

AGENDA

- 8:30 – 10:00 Introduction
Deal Formation and Contracting
Deal Terms
- 10:00 – 10:30 Break
- 10:30 – 12:00 Deal Terms (cont.)
Traps for the Unwary
Mystifying Provisions (if time allows)
Questions and Discussion



Business Development Basics Course

Introduction



Business Development Basics Course

Instructors

- Christopher Lynch
 - Director, Licensing and Acquisitions at AbbVie; Ten years at AbbVie in a variety of roles in licensing and R&D
 - Prior to joining AbbVie, a Research Fellow at Merck & Company in the Department of Medicinal Chemistry in the field of GPCR receptor modulators
 - Education
 - B.S. in Biochemistry from the University of Wisconsin
 - M.B.A. from the Cardinal Stritch University
 - Ph.D. in Organic Chemistry from the University of Wisconsin



Instructors (cont.)

- Steven Barrett
 - Partner, WilmerHale
 - Co-Chair, WilmerHale Technology Transactions and Licensing Practice Group
 - Education
 - S.B. in Mechanical Engineering from MIT
 - M.B.A. from University of Michigan School of Business Administration
 - J.D. from University of Michigan Law School



Course Objectives

- Outline preparation activities leading up to a business transaction
- Summarize selected key elements of a contract
- Equip participants with background to enroll in advanced level courses
 - Focus on fundamentals; not possible to be comprehensive
- Provide foundation for improving business development skills
- Allow opportunity to address questions of particular interest to participants



Business Development Basics Course

Class Poll

- Who is our audience?
 - Allows a better understanding of each other
- Healthcare sector?
 - Pharma, Biotech, Life Sciences, Academics, Non-profits
- Line of business?
 - Product focused (buy-side or sell-side), platforms
- Number of years of experience in business development?
- Reason for taking course?
 - New job
 - Review of basics



What is a contract?

- **Contract:** An agreement with specific terms between two or more persons or entities in which there is a promise to do something in return for a valuable benefit (consideration); a contract includes the following elements:
 - An offer
 - An acceptance (“meeting of the minds”)
 - A promise to perform
 - Valuable consideration (which can be a promise or payment in some form)
 - A time or event when performance must be made (meet commitments)
 - Terms and conditions for performance, including fulfilling promises

(source: www.freedictionary.com)



Preparation And Initial Steps



Preparing For Initial Business Discussions

- Gain an understanding of both parties' interests, expectations and partnering process
- Know who is sitting across the table
- Clear communication and transparency is critical early in the business discussions
- What value does each party bring to the relationship?
- What will it take to get the other side interested in a deal?



Licensors' Goals

- Return on investment and maximize value of licensed technology
- Incentivize investment in development and commercialization
- Access complementary capabilities to build a company
- Validation of technology platform
- Risk mitigation and shift cost to licensee going forward
- Generate non-dilutive financing for other programs
- Exit strategy
- Related time horizons
- Must understand licensee's value proposition in order to structure deal to maximize benefits



Licensee's Goals

- Identification of opportunities that align with internal strategy and complement licensee's portfolio
- Access complementary capabilities
- Stage of assets; timing to market
- Products to build or enable a pipeline
- What is the preferred structure of the transaction?
 - Technology license, collaboration (co-development and co-commercialization), asset purchase, M&A



Licensee's Goals (cont.)

- Provide risk-sharing between parties by structuring financial terms to align with program de-risking
- Preserve licensor's incentives to contribute to program success where needed
- Preserve licensee's flexibility to make portfolio investment decisions going forward based on overall business merits
- Must understand licensor's value proposition in order to structure deal to maximize benefits



Identification And Assessment Of Opportunities



Initial Steps For Identifying Potential Partners/Opportunities

- Sourcing through databases, press releases, partnering meetings, etc.
- Filter and align with internal strategy or objectives
- Depending on nature of the opportunity, assemble the appropriate team (technical, commercial and legal)
- Identify an internal champion for the opportunity
- Identifying likely partnering fits through public information and through personal outreach
- Opportunities often driven by licensor R&D and by evolving licensee commercial and portfolio priorities



Assessment Of Opportunity By Licensee

- Staged process with non-confidential and confidential info under confidential disclosure agreement
- Identify key criteria: MoA, level of validation, stage, launch timing, regulatory pathway and IP
- Findings through due diligence will impact value and sharing of risk
- Assess the asset under a material transfer agreement
- Valuation & Financial modeling (e.g. benchmarks, DCF)



Initial Term Discussions



Platform or Product-Specific Technology?

- Platform technology
 - How does platform facilitate licensees' development and commercialization goals?
 - Potential for licensees to generate improvement IP that could interfere with licensor/other licensees?
 - Potential for licensees to compete with platform?
 - Gatekeeping and level of exclusivity?
- Product-specific technology
 - Single product or multiple products?
 - Back-ups?
 - Product-specific concerns?



Nonbinding Term Sheet (NBTS)

- Depending on partnering process, discussion of terms is often in parallel with due diligence
- NBTS will serve as basis for overall structure of contract
 - Achieve alignment between the parties
 - Clearly define/discuss non-starting positions
 - Understand what previous transaction structures your company has executed
- Findings from the assessment/diligence will inform a party regarding input for the NBTS



Nonbinding Term Sheet (NBTS) (cont.)

- Components may include:
 - Scope of transaction, including grants, field, territories, IP, level of exclusivity
 - Roles & responsibilities (research, development, regulatory and manufacturing)
 - Financials
 - Miscellaneous (e.g. governance, publicity)
- Binding term sheets are generally not a preferred approach



QUESTIONS



License Grants



Nature of Rights

- Patent Rights
- Technology/Know-How/Trade Secrets
- Products
- Other?
- Note: The essence of a license is permitting the licensee to do that which the licensor has the right or ability to exclude the licensee from doing, whether by statutory monopoly (e.g., patent rights) or by withholding something proprietary (e.g., trade secrets)
- Are licensed rights capable of conferring exclusivity as what will be developed and commercialized?
- Will resulting product be eligible for regulatory exclusivity?



Exclusive or Non-Exclusive

- Interaction of licensor's licensing model with licensee's value proposition
- Exclusivity variations (e.g., field-limited exclusive)
- Exclusivity/non-exclusivity will affect various agreement provisions
 - Sublicensing rights
 - Diligence obligations
 - Non-compete/exclusivity restrictions
 - Deal price
 - Rights and obligations as to patent prosecution and enforcement
 - Information sharing if parties will be competitors as to licensed technology applications going forward



Licensed Product Definitions

- May be defined in terms of:
 - Attributes of the product or process
 - Relationship of product or process to licensee
 - Relationship of product or process to licensed technology
- Licensor may want a broad definition to ensure licensee's royalty and other payment obligations cannot be avoided
- But an overly broad Licensed Product definition may result in an overly broad license grant and/or function as a one-way non-compete obligation of the licensor



Licensed Product Definitions (cont.)

- Examples:
 - “Any product that incorporates a molecule that binds Target X”
 - “Any product that incorporates a [specified base molecule or related molecule with specified chemical relationship to base molecule]”
 - “Any product developed and sold by licensee for use in the Field”
 - “Any product (a) the manufacture, use or sale of which would, but for the license granted herein, infringe a claim of a licensed patent or misappropriate licensed know-how or (b) that incorporates, uses, is based upon or otherwise is conceived, developed or reduced to practice using any of the licensed technology”



Field Definition

- Broad definition:
 - All fields of use, including therapeutic and diagnostic (prophylactic, palliative?)
 - All species (human and veterinary health fields)
 - Agriculture?
- Specific fields or exceptions:
 - Split indications
 - Technology class
 - Biologic target
 - Route of administration
 - Disease state
 - Product specific



Licensed Product, Field and Territory Concerns

- Licensor's typical concerns: maximizing licensing revenues and ensuring technology is fully exploited
- Licensee's typical concerns: protecting licensed products from off-label competition, competition from grey market goods and competition from me-too products, and maximizing flexibility
 - How broad of a license and level of exclusivity is desired by licensee?
 - And in what territories?



Performance Obligations and Diligence



Commercially Reasonable Efforts

- Objective vs. subjective (efforts and resources that a party of similar size and resources would devote vs. efforts and resources that such party would devote)
- Nature of opportunity (product at similar stage of development with similar potential)
- Caveats for relevant factors (safety, efficacy, competitive landscape, IP landscape, regulatory hurdles)
- Exclusions from caveats (licensee's competitive programs, licensee's opportunity costs, licensee's ability to obtain financing, amounts payable to licensor)?
- Treat my baby as you would treat your own baby



Typical Scope of General Diligence Obligations

- Develop and seek regulatory approval in specified major territories (e.g., U.S., E.U. and Japan)
- Diligence in E.U. satisfied by diligence in specified major E.U. countries (e.g., three of U.K., Germany, France, Italy and Spain)
- Commercialize in each territory in which regulatory approval is obtained
- Note: general diligence obligations may be viewed by courts differently in licensing context than in M&A context



Specific Performance Obligations

- Conduct specified activities (e.g., supply product, provide services, technology transfer, sales force activities, specified tasks)
- Conduct a specified development program pursuant to a specified development plan, timeline and budget
- Invest specified resources in commercial launch and promotional activities during initial commercialization period
- Note that negotiated CRE definition may not be tailored for all kinds of obligations, particularly those where the performing party's motivations are not driven by profit motive, and therefore some obligations should not be qualified by the CRE construct
- Consider “efficient breach” problems for fundamental obligations



Interplay Between General and Specific Obligations

- Often obligations are difficult to specify in a granular way, as what activities will be needed will depend on factors that cannot be predicted or controlled
- General obligations establish principle that licensee is required to pursue overall goal with a level of efforts and resources that is appropriate to the opportunity
- Governance structure can be used to monitor and amend activities to meet agreed to obligations



Pre-Specified Remedies for Certain Breaches

- May be appropriate in special circumstances
- Can sometimes provide disincentive for “efficient breach”
- Beware of boomerang effect during negotiations (the other party may have special concerns too, and proposing special remedies for your special concerns may open the door for the other party to seek special remedies for its special concerns)
- Background law on “liquidated damages” may make financial penalty clauses unenforceable in some circumstances



Financial Provisions



Typical Forms of Consideration

- Upfront Payments
- Milestone Payments
- Maintenance Fees
- Royalties
- Transfer Pricing Payments
- Profit (Loss) Sharing Arrangements
- Sublicensing Revenue Sharing
- Other Forms of Consideration



Purpose Of Consideration

- Understanding structure and motives of proposed transaction
- Level of exclusivity, benchmarks
- Purpose for consideration
 - Compensation for past value created
 - Compensation for going forward investment and risk-sharing
 - Reimbursement of costs
- Co-development/co-commercialization
- Anticipated timing of consideration and risk allocation



Upfront Payments

- The price of entry – typically a non-creditable, one-time payment (though sometimes deferred in time or subject to contingencies)
- Variety of considerations:
 - Partly for license grant itself
 - Opportunity cost of granting a license to one entity
 - Reimbursement for historic costs to develop the IP
 - Funding for future development costs to be incurred by licensor
 - Patent expenses
 - Accounting ramifications depending on characterization so involve the finance team
- Potential interplay with upstream license sublicense revenue sharing



Milestone Payments

- Rationale:
 - Delayed license fees – risk mitigation for licensee
 - Reward for success
- Typically tied to development and commercial events:
 - Research and development milestones
 - Patent issuances
 - Filing or approval of NDA or BLA
 - Commercial launch
 - Sales thresholds



Milestone Payments

- Definitions of milestone triggers often critical
 - Examples: “Phase 1 Clinical Trial”; “Pivotal Clinical Trial”; “Clinical Proof of Concept”; “Second Indication”; “Regulatory Approval”
- Consider potential for avoidance on technical grounds
 - Examples: Potential for skipping milestones; avoiding EMEA filing by filing with individual EU country regulatory authorities
- Credit for milestones already paid if lead is dropped and back-up developed in its place
- Permutations for multiple products or indications
 - Example #1: Initially, a particular product or indication is “first,” but later a different product or indication has reached a subsequent milestone first
 - Example #2: Milestones only payable for “first” product, but first product is abandoned at early stage



Maintenance Fees

- May be a “payment plan” for the upfront fee or proxy for “diligence”
- Periodicity varies
- Amounts variable
- Licensor may want large amounts to ensure diligence and to cover opportunity cost; licensee typically objects as large maintenance fees may undermine licensee’s risk sharing goals and create an incentive for licensee to terminate by compounding licensee’s risk
- More common in university licenses or non-exclusive licensing arrangements (where amounts are usually modest)
- Are the payments creditable (e.g., minimum royalty variant)?



Royalties

- Net Sales definition
- Royalty rates (tiering; marginal tax rate model the norm)
- Royalty reductions and offsets
- Term (period ending on latest of period of years (from first commercial sale), patent expiration or expiration of regulatory exclusivity)
- Reporting and auditing concerns
- Particularly in early stage deals, royalties are often highly discounted in licensor's financial model due to their contingent nature and the time that will elapse before they are paid; licensee may be more sensitive due to licensee's focus on long-term success scenarios



Transfer Pricing Payments

- Sometimes an alternative or partial alternative to royalties
- Licensor also supplies products and makes margin on supply
- May facilitate beneficial tax structuring (more common in larger late stage deals where focus on tax structuring is a greater)



Profit (Loss) Sharing Arrangements

- Most common in co-promotion context
- Makes most sense where both parties will be incurring substantial capital expenditure or ongoing commercial costs and performance incentives will be best served by ensuring that costs of performance are recognized in economic split
- How will licensor's share of upfront costs/losses be financed?
- Presents difficult governance, budgeting and accounting issues
- Difficult to establish objective ground rules for overhead allocations
- Consider opt-out structures allowing licensor to fall back to a "fat" royalty (e.g., if decisions regarding expense budgets become problematic)



Sublicensing Revenue Sharing

- Most common in academic licenses and deals in which an early stage technology is licensed for modest economics and licensor is concerned about licensee “flipping” license rights for a profit
- All sublicensing revenue or non-royalty sublicensing revenue (conform Net Sales definition accordingly)?
- Potential double-dipping vis-à-vis milestone payments
- Can be problematic for licensee/sublicensor where multiple technologies may be used for a product (analogous to royalty stacking)
- Can create an incentive for licensee/sublicensor to seek an M&A exit rather than a sublicensing deal



Sublicensing Revenue Sharing (cont.)

- Start with broad inclusionary criteria, then allow for specific exclusions
- Typical exclusions:
 - reasonable cost-based R&D payments for post-licensing R&D activities (e.g., reasonable FTE-based R&D payments)
 - purchase price of debt or equity securities at fair [market] value (i.e., premiums not excluded)
 - other cost-based reimbursements?
- Can be problematic in profit-share deals (often profit-share deals are structured as separate revenue sharing and cost-sharing; upstream licensor should not get a share of licensee/sublicensor's revenue share without first netting out cost-share)



Other Forms of Consideration

- Research and Development Funding
 - Governance and budgeting
 - FTE rates and accounting; out-of-pocket costs
- Equity
 - Price (at a premium?)
 - Preferred stock terms; class voting issues
 - Corporate governance issues
- Loans
 - How repaid?
 - Repayment required if program fails?



Indemnification



Scope of Indemnities

- Third party claims vs. all claims
- Typically different in license agreements than in acquisition agreements
- Breaches
- Negligence, gross negligence, willful misconduct
- Intellectual property infringement
- Product liability (manufacturing defects vs. other)
- Exclusions for losses resulting from indemnitee's fault



Scope of Indemnities

- Allocations between licensor and licensee differ depending on circumstances
- Sometimes indemnity clauses allocate certain losses (e.g., 50%/50%) between parties in accordance with their respective economic interests or otherwise
- Typically not capped as to third party claims
- Allocations of losses can be varied to reflect overall allocation of benefits and burdens under the agreement



Indemnitees

- Party to the agreement
- Affiliates
- Officers, directors, employees
- Agents
- Upstream licensors and sublicensees?



Indemnification Procedures

- Indemnifying party typically has right to control
- Indemnified party typically has right to be separately represented (but not control) at own cost, but if separate representation needed due to conflict of interests, then at indemnifying party's cost
- Selection of counsel
- Prompt notice, cooperation
- Expenses of cooperating
- Consent right over settlements that impose obligations other than payments that the indemnitor will pay or that do not include a full release of indemnitee



Termination



Termination Events

- Expiration of agreement term
- Termination for breach
- Termination for shelving
- Termination for licensee's convenience
- Termination for bankruptcy/insolvency
- Termination for patent challenge



Termination Variations

- Expiration vs. termination
- Entire agreement
- Product-by-product or program-by-program
- Territory-by-territory
- Consequences in lieu of termination



Termination Consequences

- Termination of licenses
- Grant-back licenses; reverse royalties
- Reversion/assignment of program assets (regulatory filings, data, ongoing clinical trials, service contracts)
- Tech transfer; transitional services; related costs
- Transitional supply



Termination Consequences

- Disposition of existing inventory
- Wind-up of ongoing activities and commitments; related costs
- Survival of exclusivity restrictions
- Survival clauses; post-termination rights
- Termination consequences generally in addition to, not in lieu of, right to seek damages for breaches



Traps for the Unwary



Definitions

- Important terms often addressed through definitional language
- Understanding of building block definitional terms can be critical
- Be sensitive to unconventional definitional language, which is often a signal that the drafter is trying to address a specific concern without saying so with an overt declarative statement in an operational clause
- Definitional language does not always track plain vanilla meaning of defined term
- Be careful to use defined terms properly; failing to do so can lead to ambiguity or unintended implications



“Affiliates”

- Typically defined to look upwards to parent entities (and their Affiliates!) and sometimes defined to include major investors (and their Affiliates!)
- Parent entities can be future acquirers (watch out for potential “poison pill” effect)
- Major investors can be VC firms and their portfolio companies
- Sometimes agreement terms refer to Affiliates in ways that make sense based on the current corporate structure, but would not make sense if corporate structure changes
- Examples: intellectual property category definitions and exclusivity/non-compete clauses



Change of Control and Assignment Clauses

- If the deal terms change in important ways upon an acquisition, that can be a “poison pill” or affect valuation in acquisition scenarios
- Generally best to be explicit in assignment clauses that assignment of the agreement in acquisition scenarios is permitted; otherwise, the form of transaction and sometimes unpredictable background law will govern and may constrain future deals in unintended ways
- If you are on the side of the transaction being asked to make concessions based on a change of control, be skeptical and require that the requested concessions be justified in all foreseeable circumstances



Sublicensing Restrictions

- Similar to assignment clause issues, insofar as sublicensing may be necessary in order to achieve the licensee's business goals
- As licensee, beware of clauses that give your licensor approval rights over sublicenses that you will need to grant
- Hold-up risk; try to align contract rights so that you get all the rights you will need up front, without having to go back to the other party for consents
- Sometimes compromise is to permit sublicensing to a pre-specified class of sublicensees (e.g., affiliates, large pharmaceutical companies, bona fide collaborators, CROs and CMOs) and to require the licensor's consent (not to be unreasonably withheld, delayed or conditioned) for other sublicensees



Royalty Stacking and Sublicense Income

- If you are the licensee, think ahead and consider how the economics of your deal will affect your economic model and your prospects for obtaining new equity financing or attracting potential acquirers
- Will you have to obtain multiple licenses for your product that will require you to pay royalties to multiple licensors? Potentially include royalty offsets for IP necessary to commercialize the product.



Royalty Stacking and Sublicense Income

- Consider your development strategy in negotiating differential percentages in sublicense income clauses (e.g., if percentage goes down substantially at phase 2 POC, can you realistically carry the ball that far before sublicensing?)
- Will the royalty stack or sublicense income clauses make it difficult for you to obtain new equity financing or to attract potential acquirers?



Foreign Withholding Taxes

- Can be a big surprise to the licensor if not considered in advance
- Some deals are structured to avoid or minimize
- Some deals have nuanced allocations between the parties
- Requires sophisticated tax advice; how foreign withholding taxes work is not very intuitive to the uninitiated



“Flow-Down” Provisions from Upstream Licenses

- Need to understand what obligations are being imposed
- Licensing chains with multiple levels can be complicated and can result in additional risks
- As sublicensee, consider requiring “stand-by” license agreements from upstream licensors



Bankruptcy

- Complicated area
- Difficult to contract around risks
- Section 365(n) in the U.S. helps licensees, but U.S. bankruptcy code has ambiguity
- Meaningful risk mitigation strategies often require extensive deal structuring that may be expensive and objectionable to the licensor:
 - “Bankruptcy-remote” IP holding company
 - Assignment of IP to licensor, with reversion clauses if license agreement terminates



Mystifying Provisions



Menu of Mystifying Provisions

- Deduction from Net Sales for inventory management fees and other wholesaler services fees
- Deduction from Net Sales for bad debt/uncollectible amounts
- Combination Product allocations in Net Sales definitions
- Valid Claim definition issues
- Royalty step-downs upon patent expiration (avoidance of patent misuse)
- Royalty anti-stacking clauses



Menu of Mystifying Provisions (cont.)

- Generic competition triggers for royalty reductions
- Patent enforcement rights upon “Paragraph IV” certifications
- Obligation of licensor to join patent enforcement actions as a party if requested by licensee
- Allocations of recoveries from patent enforcement actions
- Governance committees/collaborative decision-making



Menu of Mystifying Provisions (cont.)

- Licenses to future IP/improvements
- “Grant-back” licenses
- Rights of First Offer/First Negotiation/First Refusal
- License option structures
- Opt-in/opt-out structures for co-development/co-commercialization
- Co-promotion considerations
- Supply interruption remedies in supply agreements
- Companion diagnostics



Menu of Mystifying Provisions (cont.)

- Publications
- Publicity
- Limitations of liability/exclusions of consequential damages
- Force majeure
- Bayh-Dole U.S. manufacturing preference
- 271(e)(1) safe harbor from infringement liability
- Hart-Scott-Rodino (HSR)



QUESTIONS AND DISCUSSION