Ken Krisko
Partner, Life Sciences Transactions Group
Cooley LLP

- Practice exclusively focused on representing public and private life sciences companies in strategic corporate partnering and intellectual property commercial transactions
- Representative transactions include: Eagle/Teva; Newlink/Merck; Forma/Genentech; Molecular Partners/Allergan; immatics/ Roche; Micromet/Amgen; AMAG/Takeda; Serenex/Pfizer; and Bayer/Onyx
- Transaction experience includes a broad range of transactions: Pharma/Biotech, medical device and diagnostic product collaboration transactions, co-promotion and commercial-stage assets; discovery and research collaborations, asset-spin-out and sale transactions, technology in-license, manufacturing and supply, clinical trial and research agreements
• Cooley is a premier international law firm that excels in high-stakes, complex business and litigation matters

• We represent public and private companies of all sizes, across a broad industry spectrum with a special focus in the technology and life sciences industries. Our clients include both high growth and mature companies as well as entrepreneurs, venture capitalists and financial institutions

• We have a highly diverse client base and represent many of the leading and most sophisticated technology and life sciences companies in the world

• 850 attorneys with offices in Palo Alto, CA; New York, NY; San Diego, CA; San Francisco, CA; Reston, VA; Broomfield, CO; Washington, DC; Seattle, WA; Boston, MA; London and Shanghai, China

• Several key industry verticals with the firm, including Best in Class Life Sciences Practice

• Dedicated practice group focused on corporate partnering, licensing and strategic commercial transactions for life sciences companies
Our Session Today

• Broad overview of structuring and contract considerations for Biotech/Pharma collaboration agreements

• “Term Sheet” level treatment with deeper dives into specific areas
Areas of Focus

• Focus on the following key areas:
  – What rights are granted (scope of license/retained rights) and what is the “price”? 
  – Provisions you will re-read later
  – Other selected topics – diligence, exclusivity, governance, etc.
The Big Picture

• Why partner?
• Financing needs / leverage?
• Retaining rights to preserve future deals, trade sales and other options
• Board and investors interests
• What is “market”?
• What does your Partner want?
• Objectives always will shape deal structure – there is no single approach
• Is this deal a “stepping stone” to an acquisition?
Constructing the Deal and Retaining Value
What is the Overall Deal “Story”? 

- Every deal has a “story” and is driven by key underlying corporate objectives on both sides
- Breadth of collaboration
- Market opportunity and product positioning
- Risk and stage – risk reduction/value inflection points
- Strengths, weaknesses and competition
What is “in” the deal?

• The starting point of negotiations, but term sheets can be vague or incomplete
• What rights are granted?
• Key terms: Licensed Product and Licensed IP
• Beware of “deal creep”
• Overall objective – match rights granted with economics
• There are so many different possible deal “sizes” you want to be sure you and your partner are clear:
  • Single molecule/single form of administration (e.g., IV, topical, ophthalmic, pulmonary)?
  • Single molecule in all formulations?
Retaining Rights?

- Where can you (or need to) retain rights to achieve your company’s underlying objectives?
- Important to preserve value, ability to do other deals, sell the company, and provide “exit” for investors
- The usual suspects
  - Not licensing all rights (think rights as a bundle) – product, indication, territory?
  - Development, manufacturing, and/or commercialization?
- How do retained rights fit into the deal “story”?
- Need to match the scope of the deal with the value proposition
Retained Rights

• How NOT to ... “sell the company without selling the company”

• What works to keep value?
  – Product rights granted – current; future
  – Field – therapeutics and diagnostics?
  – Territory
  – Indication-splitting – its own topic

• Focus on the creation of and rights to future IP – both inside and outside of the collaboration
Licensed Product

• Product Scope:
  – Single compound? Backups?
  – All molecules covered by specified patent(s)?
  – All molecules active against a specified target?
    • Is that all molecules? Small molecules vs. biologics? Antibodies? Vaccines? Agonists vs. antagonists?
    • Can a specified level of activity (assay results) be used in the definition?
    • If it is all molecules “created” during a research program, does that mean “invented” (patent filing) or “made” or “recognized” (run through an assay)?

• Slippery slope from defining “Product” to hidden exclusivity/non-compete obligation
Licensed Product Definition

• 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

• Examples:
  – “Any product that incorporates a molecule that binds Target X”
  – “Any human pharmaceutical product”
  – “Any product that incorporates a molecule identified by Licensee in the course of practicing the Licensed Technology”
  – “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

• Will there be any limits?
• Therapeutic vs. diagnostic products?
• All delivery routes (oral, intravenous, systemic, etc.)?
• Particular diseases or medical conditions (beware of Amgen/Ortho issues for substitutable formulations)?
Territory

• Any limitations?
• Geographical limits
  – Watch for ambiguity in territory definition
• Implications for dividing on country or regional lines
Licensed Intellectual Property

- A key area to retain value
- How broad is the category of IP licensed to pharmaceuticals
- Existing IP
- Future IP
  - In and out of collaboration?
  - Licensed?
- Acquiror IP
- Generally, all IP owned or controlled by licensor that reads on licensed product
Intellectual Property

• Allocation of IP generated during the collaboration
  – Inventorship by your collaborator – how is ownership assigned and what about each party’s right to use this IP (during the term and post-termination)?
  – Do you need to be worried that a collaborator could develop new patents that might block your future development path?

• Third Party IP
  – If acquired during the term who controls and pays?
  – Don’t automatically sweep in acquiror IP; consider this issue with potential poison pill implications
Other Retained Rights

- Co-Development
- Co-Promotion
- Splitting Territories
- Splitting Indications
Co-Development

• Can be an attractive way to share risk/return
• Right vs. obligation?
• What do you really mean by co-development?
• Primary approaches (with plenty of variants)
  – Biotech performs pre-defined development activities and is reimbursed by Pharma
  – Biotech opts-into Pharma’s ongoing development activities to buy-up royalty
  – Broad sharing of development activities in a fully, risk-shared deal
Co-Development

• Why do it?
  – Biotech retains input into development decisions
  – Maybe some ability to increase economics by risk sharing
  – Biotech obtains access to Pharma’s clinical/regulatory expertise and resources
  – Allows Biotech to utilize & grow its own capabilities

• Issues you’ll encounter
  – Pharma will tolerate it, but doesn’t like it generally – doesn’t need the cash and would prefer not to complicate decision-making
  – What control rights?
  – Cash is expensive to Biotech
Co-Development

• Reimbursement is easiest – usually short term participation; key issues are budget, decision-making

• Option is more complicated –
  – When can you opt-in and for what activities?
  – What is the risk premium and what happens to economics – royalty step-up or conversion to profit share?
  – How does decision-making change?
  – Need to consider the opt-out

• Obligation to co-develop/truly risk shared deals
Co-Development

• How do I fund?
  – Own pocket?
  – Sale of equity or loans to Pharma?

• Well, on second thought....opt-out rights
  – Can Biotech opt-out of development rights once Biotech is obligated to conduct activities?
  – When is this right exercisable?
  – What are the economic implications?
Co-Development

• Implementation Issues
  – Global vs. regional development activities
  – Parallel development – safety reporting; regulatory responsibilities
  – Cost allocation for shared territories
  – Decision making issues
  – Rights of use and reference to data and filings
  – Product supply
Co-Promotion

• What do we mean here?
  – A single brand promoted by two different companies
  – One company typically takes lead in establishing strategy (Pharma) and Biotech compensated for its sales effort

• Option vs. obligation

• Distinctions between royalty vs. profit sharing deals
Co-Promotion

• What are Benefits of Co-Promotion?
  – Biotech can leverage the deal to build sales force
  – Biotech can utilize its expertise in “niche” detailing
  – Wall Street value

• What are Problems with Co-Promotion?
  – Pharma does not particularly like it
    • Selling drugs is what Pharma *does*
    • Would prefer not to train or coordinate with Biotech
  – A sales force is not always an asset for a Biotech
    • Once established, a sales force needs products
  – Potential for overlapping efforts & inconsistent messages
Co-Promotion

• Biotech option or obligation?
• In the option scenario
  – When is the right exercisable?
  – How do parties allocate sales efforts (by territory, physician group)?
  – How is compensation determined – by detail? FTE? Stepped-up royalty?
• What terms are negotiated now vs. agreed later?
• More complication in the “obligation” scenario
Splitting Territories

• Can be an attractive option for Biotech and for a locally-focused Pharma partner

• A few key considerations at the term sheet stage -
  – Impact on economics and control rights for aspects of the “global” plan
  – Cross-licensing of IP and how will data be shared
  – Operational issues – common or multiple sources of product supply? Ability to run trials in the other party’s territory?
Splitting Indications

• Indication splitting limits license to particular diseases or conditions
• It can be done, but complicated
  – Is the product substitutable between indications?
  – Separation of product in the market
  – Contractual/financial engineering
Splitting Indications

• Pros
  – Can increase probability that the product will be developed for multiple indications
  – Can find best suited partner for each indication
  – Can retain right to develop drug for niche indication while partnering indications that require more expensive clinical trials and extensive commercial operation

• Cons
  – Off-label sales
    • Once approved for one indication, MDs can prescribe for any indication
    • Need to make sure that not earning profits for sales in other party’s field
    • Simplest if unique formulation or mode of administration

• Potential disputes over field
• Safety and pricing issues are not indication-specific
Economic Terms
“What is the Price”?
Economic Considerations

• Royalties
  – Typically in earlier stage or less collaborative deals
  – Straightforward administration
  – Economics can be comparable to profit sharing

• Upfront and Milestone Payments
  – Development and/or commercialization

• Profit Share
  – Typically in “risk shared” deals co-funding
  – Detailed cost accounting
  – Allocation of losses

• Other Forms of Consideration
  – Equity (at a premium?)
  – Loans (convertible, repayable, forgivable, creditable?)
Initial Thoughts

• You won’t get what you don’t ask for, but credibility is important
• Who shows their hand first?
• Your first proposal is the ceiling – it’s all downhill from there
• Competition is the key – either apparent or actual
• Interplay with M&A proposals?
Upfront License Fees

• Up-Front Payment
  – The price of entry
  – *Watch*: revenue recognition and involve your finance team

• What can you ask for?
  – Willing buyer/seller
  – The role of comparables
  – Other proxies – R&D expenses
Milestone Payments

• Rationale:
  – Delayed “license fees” – risk mitigation for licensee
  – Reward for success that shows value of the licensed IP

• Typically tied to development and commercial events:
  – Research milestones (defined per deal)
  – Filing of an IND
  – Initiation of a clinical trial (e.g., Phase II)
  – Filing and approval of NDA or BLA
  – Commercial launch
  – Sales thresholds
Milestone Payments (cont’d.)

• Milestone triggering events must be carefully defined (it’s money after all)
  – Clinical milestones – what is “initiation” of trial (usually dosing)?; when is a trial “complete” (e.g., submission of final report)?
  – Approval – include pricing approval where applicable?

• Appreciate the various payment scenarios
  – One or more products?
  – Different formulations?
  – By indication?
Milestone Payments (cont’d.)

• Multiple products and indications
  – What is considered a new product?
• Back-up products
  – What if the lead fails – generally exclude prior milestones and continue on with future payments
  – Are milestones due for every back-up product, or only separate 2nd generation products (however defined)?
• Milestone “skipping” protection:
  – Payment of any “skipped” milestones (e.g., for a Phase IIb/III trial) due when next milestone is paid
Royalties

• Payments based on product sales or other commercial use of the licensed IP
• Each party shares risks and rewards of success
• Rate, duration and reductions are highly negotiated though there are some guidelines
Royalties

• Royalty Rate depends on a number of factors:
  – Type of IP licensed (patent claims or know-how)
  – Stage of development when licensed
  – “Value” of IP and Product (perceived vs. real)
  – Comparables can help guide the discussion
  – No substitution for competition
Royalties

• Pay on Product (or use of Product) based on nature of theLicensed IP used
• Capture all uses of Licensed IP?
  – License scope rarely broader than royalty-bearing product definition, at least not intentionally
• Is royalty based solely on patented subject matter?
  – Are products “derived from”, “identified through the use of” or “would not have been developed without use of” the Licensed IP?
  – Know-how can be highly valuable, but its use difficult to trace
Calculation of Royalties

- Usually a percentage of “Net Sales” of Licensed Products
  - Important to define Licensed Product clearly
  - “Net sales” – negotiated but some degree of standardization
  - CFO or Controller often involved
  - Licensor’s or Pharma’s internal standards will impact flexibility
“Typical” Royalty Rates

• What are “typical” royalty rate ranges?
• How do I bridge the gap?
• Market factors
  – Albeit imperfect, it is a market – market conditions may change
  – Deal-specific factors determine where your deal falls in the spectrum
  – Consult advisors (board members, transaction counsel, VCs)
Royalties – Tips

• Seeking “profit share” economics with a substantial royalty
  – Payments begin on launch not when profitability reached
  – No risk of high manufacturing costs or third party royalties

• Tiered Royalties
  – Calibrating royalties to success in marketplace

• Include other forms of exclusivity in the royalty term
  – Examples: Orphan drug exclusivity, data exclusivity, lack of generic competition
Royalties – Tips

• Tiered Royalties
  – Clarify if first tier rate applies to first sales in year, even if total sales qualify for higher tier
    • Example: $1-250 million 10%
    • $251-500 million 12%
    • For sales of $350 million, is the royalty $37 million \((250 \times 0.1 + 100 \times 0.12)\) or $47 million \((350 \times 0.12)\)?
  – If always starts at first tier, consider impact on quarterly financial reporting
  – If payments based on total year sales (same rate applies to all sales), need mechanism for estimating at outset and truing up at end of year
Calculation of Royalties

• Usually a percentage of “Net Sales” of Licensed Products
  – Important to define Licensed Product clearly
  – “Net sales” – negotiated but some degree of standardization
  – CFO or Controller often involved
  – Licensor’s or Pharma’s internal standards will impact flexibility
Areas of Potential Negotiation: Net Sales

- Amounts billed vs. received
- Sale to end user vs. third party purchaser
- Extent of deductible rebates, discounts and commissions
- Taxes and duties that are deductible
- Uncollectible amounts (if based on amounts billed)
- Transportation (outbound, caps)
- Extent of deductible returns and whether recall expenses are included
- Inclusion of combination or bundled Product reduction
- Exclusion of sales of clinical trial supplies or “compassionate use” products
- Non-cash consideration value
- Overall cap on total % deduction allowed or set % to cover all deductions
Other “Net Sales” Concerns

- Upstream “Net Sales” definition
- Upstream (or future) royalty obligations
- Combination products
Royalties -- Term

• Term – usually “greater of” patent life (regulatory exclusivity) or stated period (often 10 years) from first commercial sale in the country
  – Last to expire patent having a “Valid Claim” that covers the Licensed Product or its manufacture or use in country of sale (or manufacture?)
  – Does “Valid Claim” include patent applications? Time restrictions?
• Alternatively, royalty term can last for so long as products are being sold (with some step down)
Royalties -- Term

- Include regulatory and other forms of patent extensions in the royalty term
- Each prong should be country by country -
  - Launch clock should start when launched in the particular country
  - Patent clock should be based on claims in country of sale, with possible extension if patent in country of manufacture has not expired
Royalties – Reductions

• Three common reductions
  – patent expiry,
  – third party payments, and
  – generic entry

• Reduction may shorten the royalty term or reduce the royalty rate
Royalties – Patent Expiration Reductions

- Patent expiry implicates the “patent misuse” doctrine in the US, which is a complicated and detailed topic; also can consult patent and antitrust groups for specific questions
  - Mitigate risk by reducing royalty rate after patent expiration if there is Know-How involved in the license; royalty rate is “blended” across the royalty term to account for both patents and Know-How
  - Separate competition law issues arise ex-U.S., including duration and requirements for know-how licenses
Royalties – Third Party License Payments

• What is included?
  – How likely is third party IP?
  – Product-based or broader?

• If Licensor: try to limit cut back to those license payments made to 3rd parties for IP “necessary to practice” the IP licensed by Licensor

• The “50/50” Rule
  – Deduct 50% of royalties paid to 3rd party
  – Never pay less than 50% of base royalty rate

• Process and control over who obtains third party rights also is important

• Watch correlation of payments – milestones, royalties and “carry forward” of payments in excess of a cap
Royalties – Generic Entry Reductions

• Reduction or elimination of royalties for “generic entry”?  
• Generally defined in terms of some threshold of generic entry – is the standard pricing decreases, volume thresholds or a combination  
• Definition of generic product is key but may be tough in the case of biologics  
• Should not be a product that is enabled by licensee (no authorized generic)  
• What happens if a generic proceeds “at risk” and need to address Licensee’s obligation to stop the generic entry (restoration of higher royalty if generic is taken off the market)
Profit Sharing

• A topic worthy of its own presentation

• Several top line thoughts for deal structuring
When Do You Profit Share?

• Opportunity for a “risk-shared” asset
  – Biotech has a clinical stage compound
  – AND a significant cash position (or access to cash)
  – Business strategy of biotech = more fully integrate upstream capabilities

• Typical relationship:
  – Biotech retains co-development, co-promotion obligations/rights in home territory
  – Pharma gets exclusive rights in ROW
  – Operating profits split 50/50 in home territory
  – Royalty on Net Sales in ROW

• Corporate strategy and Wall Street may favor
• Don’t forget about costs and sharing of “losses”
Profit Sharing – Tips

• Establishing the profit share – fixed vs. adjustable
  – Most frequently fixed and tied to development funding
  – Consider adjustments if obligations change – e.g., Biotech opts in to perform development or commercialization activities

• Consider and balance decision-making control and operational responsibilities with profit/loss allocation
  – Who will carry out and finance activities – e.g., manufacturing?
  – Does decision-making control align with financial impact?
Profit Sharing – Tips

• Don’t forget about “shared” costs in deals with profit sharing and royalty split by territory
  – Will certain shared costs be allocated between the profit-sharing territory and royalty territory?
  – Many cost categories potentially could be shared – clinical development costs used for a core dossier; third-party IP acquisition/license costs; manufacturing costs?
Profit Sharing – Tips

• What flexibility might Biotech need given potential financing limitations?
  – Right to opt-out to a reduced profit share or royalty arrangement? By territory?
  – Is commercialization an obligation or an option?
  – Financing by Pharma – advancing launch costs with P&L “payback” royalty
Profit Sharing – Tips

• Address significant P&L items at the term sheet stage
  – Launch costs
  – Sales force expenditures when parties are co-promoting
  – Cost of goods where a party is supplying product or product components
Terms You Will Re-Read – Dos and Don'ts
License Grants

- If there is a dispute, you will re-read this language countless times;
- The definitions and grant should be as clear and precise as possible;
- Read the definitions in the context of how they are used;
- Pay particular attention to the term, any surviving research licenses particularly.
Third Party Rights – Sublicenses and Assignment

- Two related but distinct concepts
  - The further grant of license rights to a third party vs. assignment (or other transfer) of the license agreement itself
- The ability to transfer rights is critical as licensees generally will partner or further license IP; every biotech should expect (and perhaps hope) to be acquired some day
- It is important to be clear in the license agreement regarding sublicensing and assignment as the background legal rules (if the contract is silent) are not always clear
General Sublicensing Issues

• May all or a subset of rights be sublicensed?
  – Licensor’s prior consent (not to be unreasonably withheld)?

• Can a sublicensee grant further sublicenses?

• If sublicensing is permitted, what (if any) restrictions apply –
  – All or certain rights?
  – Time or territory-based limits?
  – Identity of the sublicensee – independent contractors, partners, competitors?
  – No “naked” sublicenses

• What about affiliates?
Impact of Sublicensing

- Economic terms
- Flow-through and application of license agreement terms to a sublicensee
- Disclosure of confidential information and IP generation
- Risk allocation and obligation of the licensor to remain responsible for payment and sublicensee activities
- Consequences of termination
- Pay careful attention to the “upstream” agreements ... what rights can you license and what economics are owed to your licensor
Sublicensing Economics

• How does licensor receive an economic benefit from licensee’s grant of a sublicense?

• Fundamental approaches
  – Same royalty rate applies to sales by licensee and sublicensees (licensee keeps any excess collected from sublicensees) and licensor receives a percentage of other amounts paid by sublicensees
  – Licensor receives a percentage of all amounts paid by sublicensees (i.e., “sublicensing revenue”)

• Definition of “Sublicensing Revenues” is highly negotiated
  – Should include all consideration for the sublicense granted – upfront, milestones, royalties, non-cash consideration, premium on equity purchase, and low or no interest loans
  – Should exclude payments for other goods or services - equity purchase at fair market value, loans at market rates, research funding payments, or reimbursement for patent expenses
Assignment

• A “deal breaker” issue is today’s environment
• Common scenarios –
  – Assignment in connection with a change of control transaction - sale of entire business, merger or asset sale (generally, always should be assignable)
  – Spin off transactions?
  – Affiliate transfers?
Assignment

• Need right to assign agreement in an M&A transaction:
  – “the entire company”... OR ... “that part of such Party’s business to which this Agreement relates”
  – Allow assigning to affiliates for acquiror restructuring
  – Still see significant restrictions – particularly in collaborative research work

• Right to disclose agreement to potential acquirers – what about targets, lead candidates, etc.?

• Carve out M&A from rights of first refusal and negotiation to avoid unintended M&A block

• Pay particular attention to the “Change of Control” definition
Change in Control Consequences

• A strong company with a hot product can insist on there being no effect.

• More commonly:
  – Adjust terms only in the event of a buy-out by a big company or competitor of the licensee
  – Then adjust control rights and information flow; do not change economics
  – Terminate co-promotion rights if the product has not yet launched?
Termination

• Frequently under-negotiated
• It’s at the back of the agreement and no one wants to think about it (or, left out of the term sheet completely)
• Negotiate this as a business point (not boilerplate)
• The scenarios –
  – Voluntary termination by Pharma licensee (Maybe)
  – Material breach
• Consequences are the key
Termination – Voluntary by Licensee

• Can the license terminate at its discretion?
  – My advice: Yes after a minimum period of time. You do not want a “partner” who holds a license under duress.
  – But be careful about country-by-country termination. Could this be a way to avoid royalties?

• Easy way out or the lesser of two evils

• Assess time periods in which the company or the program is particularly vulnerable

• Limit window for exercise
  – Repartnering without excessive loss of time to market or upheaval (e.g. pre-launch phase)

• Product-by-Product termination?
  – Caution: termination of lead program in favor of back-up program only for cause
  – Consequences-acceleration of payments; long notice period.
Termination – Voluntary by Licensee

- Licensors generally should start by proposing that the program be returned to the original licensor *in its then-current condition*
- Need to address issues of grant-back licenses, know-how and regulatory transfer, interim supply, etc.
- Is a royalty due under the grant-back license? This may depend on the stage of development. (Or perhaps just “no” because the program is now seen as damaged goods.)
Termination – Material Breach

• This is really a discussion about breach and remedies
• Can be very frustrating
• I believe that “the punishment should fit the crime”
• But many licensees work hard to make the consequences of material breach overwhelming and object to product revision
Termination – Material Breach

- If the licensor breaches, the idea that all licenses should become royalty-free is widely proposed, but absurd
- The damage caused by the breach may be a small fraction of the value of the royalty stream
- Just provide for money damages in this case, or a partial reduction in royalties (credited against actual damages)?
- Do sublicenses terminate as well? If not, then the licensor may not get the product back
Other Selected Topics

• Diligence
• Exclusivity
• Governance
• Option-based deals
Diligence

• Licensors are frequently unhappy when programs get “lost” inside Pharma – slowed down, sidetracked, or just the victim of bureaucracy
• When might incentives not match?
• But “diligence” provisions are perhaps the most difficult to negotiate
  • Future events are unpredictable. For all kinds of reasons, licensees have a very limited ability to commit their future resources
Diligence

• Text alone without any detail ("Commercially Reasonable Efforts") may not mean much. Consider:
  – The weakest CRE language could arguably mean no effort at all. What if it is "commercially reasonable" to do nothing?
  – Consider reference to an “industry” standard rather than a standard based on the normal practices of the particular licensee. Or even the “reasonable best practices” of the industry?
  – Require the application of CRE “within an active and ongoing program”?

• There is no substitute for choosing the right partner
Diligence

• Best to be as specific as possible:
  – For example, attach a Development Plan and obtain a commitment to carry it out
  – Or obtain a commitment to the first one or two clinical trials that can presently be defined
  – A minimum spending level? (A minimum might be very meaningful, even if it is well below expected spending levels)
  – Minimum launch effort (sales force size)?
Exclusivity

• The licensor is almost always exclusive to the licensee, just by reason of granting an exclusive license
• Does this work both ways?
• Is it OK for the licensee Pharma to have a directly competitive program underway while still practicing your license?
• This issue should almost always be discussed and negotiated, whether the answer is “yes” or “no”
Exclusivity

• If the relationship will be mutually exclusive, then the boundary of this exclusivity needs to be carefully defined
  – A class of molecules (e.g., a particular mechanism of action)?
  – What duration? (For example, only during a “research term”, or the life of the agreement?)
  – Is competitive research OK, but not clinical development?
Exclusivity

• Key argument for exclusivity:
  – Nothing will *undermine trust* in a working relationship faster than the suspicion that your “partner” is pursuing a separate agenda

• If the licensee *is* permitted to have a directly competitive program, now you really need to re-focus on economics, licenses, timelines & diligence provisions with this in mind

• Address change of control implications; this cannot become an acquisition poison pill
Governance

• Included as part of every collaboration agreement for input or decision making over operational issues (not all disputes under the agreement)

• Typical flow -
  – Unanimous decisions at committee level
  – Escalation process
  – Final decision by: one party (specific issues or overall), independent expert, mediation, etc.
  – Goal: Process for rapid and effective resolution of disagreements arising from collaboration
Governance (cont’d.)

• Final decision by one party
  – Expect to see unilateral decisions by the “funding” party (the “golden” rule)
• Veto rights for specific decisions
  – Delay of development program
  – Abandonment of product/indication/major market
  – Decisions that “adversely affect” the vetoing party’s interests in its retained territory
  – Regulatory compliance
• Independent expert
• Mediation/Arbitration
Other Topics

• Current trends/observations
• Option-based deals
• Asset specific transactions
Option-Based Deals

- Most every collaboration agreement is an “option” in that Pharma can terminate for convenience

- Other possible option structures

- “Shared” risks and rights / control prior to option exercise

- Purchase Options
Asset-Specific Transactions

• Increasing consideration of “asset-centric” transactions, involving collaboration components and partner right to acquire assets at specified time points

• Collaboration arrangement PLUS put/call rights to sell/acquire defined products structured as an asset or stock purchase of a product-specific Newco

• Facilitates effective liquidation and spin-out of desired asset, with retention of other rights

• Tax-intensive structuring and acquisition consideration

• Examples: Forma/Genentech; Constellation/Genentech; Nimbus
Concluding Remarks

• Understand the market and who is really a potential collaborator/buyer
• Do your homework – understand the partners and have a strategy and goals
• Control and be thoughtful about the process, particularly timing
• Be straightforward about the goals
• Be willing to walk away or choose a different path
• Stay focused on key objectives but watch impact on future deals
• Engineering is fun – but don’t let the “deal” get in the way of the deal
• Don’t overlook complexity or underestimate the costs of your commitments
Questions? Comments?

Contact Information
Ken Krisko

Cooley LLP
Tel: (703) 456-8581
Email: kkrisko@cooley.com