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Collaborative Agreements in Life Sciences: Key Considerations

Structuring Terms to Expand Product Lines, Reduce Costs and Risks, and Leverage and Protect Assets

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1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

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Life Sciences Collaboration Agreements

Judith Hasko, Latham & Watkins LLP

January 26, 2012

Agenda

- Overview
- Scope of Collaboration: License Grants, IP Definitions, Product Definitions, Fields of Use, Territories
- Economics: Upfront payments, Milestones, Royalties, Profit Sharing, R&D Payments, Promotion Payments
- Governance and Decision Making: Committee Structures, Role of Executives, Final Dispute Resolution (court, mediation, arbitration)

Overview

- Capital and Time
  - A biotech product takes
    - $800 million to $1.2 billion to develop
    - 8 to 12 years from R&D to commercialization
- Statistics
  - Only between 10% and 20% of products entering clinical trials will be approved and commercialized
- Regulatory Environment
  - New administration, periodic safety concerns, etc. drive fluctuation and uncertainty
- Innovation and Serendipity
  - It's hard to have "on-demand" solutions to problems vexing medicine for centuries

Overview

- Timing:
  - Weeks (at the very short end) to 6 months or more from agreed term sheet to signed agreement
  - Business people initiate contacts and pursue discussions for months, and work with attorneys to structure transaction once they get traction
- Unique deals
  - No such thing as a "form" collaborative transaction
  - Precise drafting to allocate rights, craft tight payment provisions
  - Tailored to the product, disease area, partner and client in many ways
- Dynamics
  - Given long development cycles and need to collaborate to solve problems, agreements must be win/win in nature
  - Not a zero sum game negotiation

Overview

- Types of Collaborative Agreements

- License
- Collaboration
- Distribution
- Co-Development
- Co-Promotion
- Formal Joint Venture
- Combinations of the foregoing
  - Uniquely tailored arrangements

Overview

- Common Themes

- Collaboration between parties, to varying degrees, in the research, development, manufacture and commercialization of new products
  - Simple grant of rights
  - Collaboration in all material respects

Overview

- Allocation of risks and rewards depending on each party's contributions
- Competitors collaborating
- Regulatory approval pathway drives the structure of the collaborative activities
- Clear definitions of collaborative activities and areas reserved for each party outside the collaboration

Defining Scope: License Grants

- What rights must be conveyed to achieve the desired business purpose?
  - Research
  - Manufacture
  - Sales
- Is there a need or desire to grant or obtain a right to sublicense or work with third parties?
- What restrictions are contemplated?
  - Field of Use
  - Product type
  - Geography
  - Market

License Grant Anatomy

[Subject to the terms and conditions of this Agreement,] [Licensor hereby grants] to Licensee [and its Affiliates that agree in writing to be bound by the terms of this Agreement], a [royalty-bearing/fully paid], [perpetual and irrevocable], [non-transferable/transferable subject to section X], [non-/co-/exclusive] license[, including/without the right to grant sublicenses through multiple tiers of sublicensees] under the Licensed Technology, [to make, have made, use, sell, offer for sale and import Licensed Products][for use in the Field] in the Territory.

License Grant – Exclusivity

- Some licenses may be appropriate to obtain or grant on a nonexclusive basis
  - Research tool patents, not covering end product
  - Rights to perform research
- Co-exclusive or semi-exclusive: Define what you mean
- Patents covering a drug, biologic, or medical device itself (as a composition of matter, article of manufacture) will be key to keeping competitors out of the relevant market, if asserted
  - Typically, licenses granted to develop and commercialize such products are exclusive, even as to the licensor
  - Licensee will want rights to enforce such patents against infringers

License Grant – Exclusivity

- Patents covering a drug, biologic, or medical device itself (as a composition of matter, article of manufacture) will be key to keeping competitors out of the relevant market, if asserted
  - Typically, licenses granted to develop and commercialize such products are exclusive, even as to the licensor
  - Licensee will want rights to enforce such patents against infringers

- Use patents may also be useful to keep competitors from selling a product for treating a given condition
  - Less common to rely on use patents alone for exclusivity but it does happen

License Grant – Right to Sublicense

- " . . . including/without the right to grant sublicenses through multiple tiers of sublicensees . . ."
  - Are the rights sublicensable?
  - Through how many tiers?
  - Best practice is for license agreement to address sublicensing expressly
  - If not well tailored, can cripple life science company
  - Nonexclusive licenses: Generally not sublicensable

License Grant – Right to Sublicense

- Possible restrictions on sublicense rights:
  - Restrict to Affiliates
  - Subject to approval of Licensor
  - Only a subset of rights (e.g. manufacturing)
  - Prohibit "naked" sublicense: Licensee can only sublicense in conjunction with license to IP it owns (and it developed in the course of practicing its license)
  - Limit to certain types of entities (e.g. subcontractors and collaborators)

License Grant – To What?

- “ . . . under the Licensed Technology . . .”
  - Under what IP is the license granted?
    - Typically, patent rights (including patent applications), and “know-how”; sometimes, trademarks
    - Highly tailored definitions depending on the nature of the license
  - Static (owned today) or dynamic (and developed in future)

License Grant – To Do What?

- "... to make, have made, use, sell, offer for sale and import ..."
  - 35 U.S.C. § 271(a): Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell or sells any patented invention in the United States or imports into the United States any patented invention during the term of the patent thereof, infringes on the patent.
  - Other types of uses may be specified although not in the patent code, e.g. to research, develop, promote
  - "Have made" right gives licensee right to engage third party manufacturer

License Grant – For What Purpose, and Where?

- "... for use in the Field and in the Territory."
  - Field Definition:
    - Will there be any limitations or uses or applications of products? If so, where do limits apply?
    - Field limitations
      - Research area restrictions
      - Therapeutics v. diagnostics
      - Product indications (beware: Amgen/Ortho issues for substitutable formulations)
    - The field may be included in the Licensed Product definition
  - Territory Definition:
    - Geographical limitations?
      - Watch for potential ambiguity in territory definition – North America, E.U.
      - Distinguish between development and commercialization activities

Definitions

- Generally
  - Building blocks of any legal contract
  - Must clearly capture complex concepts
  - Some are routine and others are highly customized; pay attention to both
- Practice Pointers
  - Understand key definitions early in the process
  - Avoid circularity
  - Use defined terms consistently
  - Use intuitive names
  - Keep it as simple as you can

Definition - Licensed IP

- Specify scope of patents to be licensed
- Understand the relevance of Know-How
- Defining the set of IP to be licensed
  - Existing as of a particular date
  - Created during performance of an agreement
  - Improvements
  - Sublicensing of third party IP: upstream constraints
- Define “Controlled”

Definition - Patents

"**Patents**" means (a) United States patents, re-examinations, reissues, renewals, extensions and term restorations, inventors' certificates and foreign counterparts thereof, and (b) pending applications for United States patents, including without limitation provisional, nonprovisional, continuation, continuation-in-part, continued prosecution, divisional and substitute applications and foreign counterparts thereof.

Definition – Know-How

"**Know-How**" means all tangible and intangible (a) techniques, technology, practices, trade secrets, inventions (whether or not patentable), methods, knowledge, know-how, skill, experience, test data and results (including without limitation pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms and (b) compounds, compositions of matter, complexes, cells, cell lines, assays, animal models and physical, biological or chemical material, but shall not include Patents.

Definition – Controlled

"**Controlled**" means, with respect to any intellectual property right, that the party owns or has a license to such intellectual property right and has the ability to grant to the other party a license or sublicense to such intellectual property right as provided for herein without violating the terms of any agreement or any other arrangement with any third party existing at the time such party would first be required hereunder to grant such license or sublicense to the other party.

Definitions – Party-Specific

"**Biotech Patents**" means all Patents Controlled by Biotech during the term of this Agreement that claim inventions necessary or useful for the research, development, manufacture, use or commercialization of the Licensed Product. (Licensed Product is a product containing Compound X.)

"**Biotech Know-How**" means all Know-How Controlled by Biotech during the term of this Agreement that is necessary or useful for the research, development, manufacture, use or commercialization of the Licensed Product.

"**Licensed Technology**" means the Biotech Patents and the Biotech Know-How.

Definitions – Party-Specific (Alternate Approach)

"**Biotech Patents**" means:

(a) all U.S. patents and patent applications Controlled by Biotech as of the Effective Date claiming inventions necessary or useful for the research, development, use or commercialization of the Licensed Product;

(b) all continuations, continuations-in-part [(but only to the extent claiming subject matter disclosed in patent applications described in (a))], divisionals and non-provisionals of the applications described in (a);

(c) all patents issuing from the applications described in (a) or (b);

(d) all reissues, re-examinations, renewals or extensions of the patents described in (a); and

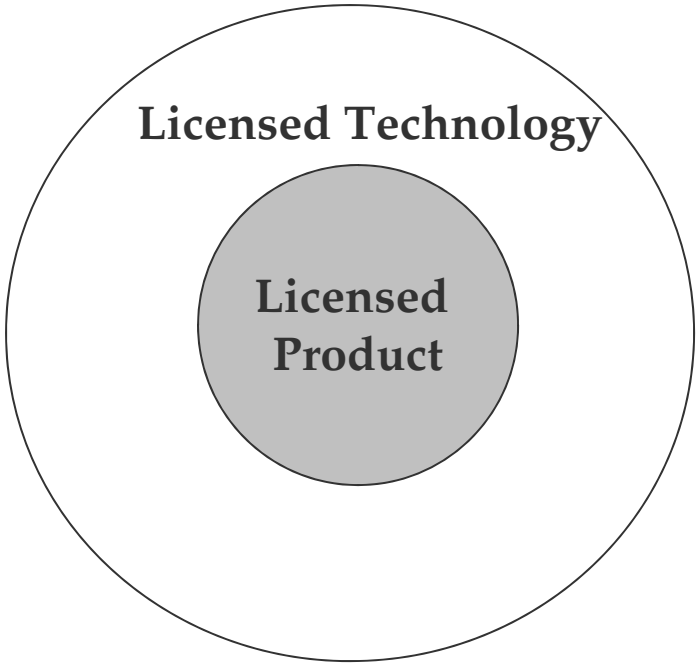
(e) all foreign equivalents of the foregoing.

Definition - Licensed Product

- May be defined in terms of:
  - Attributes of the product or process
  - Relationship of the product or process to the Licensee
- Examples:
  - "Any product, the manufacture, use or sale of which would, but for the license granted herein, infringe on any claim of a Licensed Patent" (Licensed Patents are listed patents)*
  - "Any product that incorporates a molecule that binds to Target X"
  - "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 treating condition X"
  - "Any human pharmaceutical product"
  - "Any molecule that contains Compound X."*

Interplay of Key Definitions

- A narrow Licensed Product definition can compensate for a broad Licensed Technology definition.



- Be careful to avoid circularity between Licensed Product and Licensed Patents definitions.

"**Licensed Product**" means a product claimed by the Licensed Patents.

"**Licensed Patents**" means the patents of Licensor that claim the Licensed Products.

Defining the Field: Beware of Indication-Splitting

- Same active ingredient, commercially interchangeable formulation
  - 60 mg pill, two 30 mg pills
  - i.v. formulations at different concentrations and dosing regimens
- The "Amgen-Ortho" issue:
  - Physicians can prescribe approved drugs for uses not included in the NDA
  - Hard to track and recoup revenues from products marketed by different companies and approved for different indications
  - If you have two different licensees, licensed for treating different conditions, you have significant potential for disputes as to which should derive revenue from sale of a given product
- Generally avoided; used in very specific situations

Payment Provisions

- Business experts are usually (extremely) focused on this topic

- From a legal perspective, make sure you cover the exact timing for each type of payment, and clear guidelines for their calculation:

Payment Provisions

- Upfront Payments
  - Cash
  - Equity purchase?

- Milestone payments
  - Achievement of research, development, approval, sales milestones results in specified payments.
  - These payments must anticipate changes in approval strategy and law to work well

Payment Provisions

- Royalties
  - Most often paid on net sales of specified products
  - Standard deductions for amounts invoiced to purchasers but paid to third parties
  - Consider combination products, product bundling treatments
  - For medical devices, consider portion of value attributable to licensed product
- Offsets for third party payments, reductions for lack of patent coverage and compulsory licenses granted

Payment Provisions

- Profit Sharing
  - More complex than royalty structure
  - Requires defining how profits are calculated, including as applicable COGS, selling costs, costs of product-related litigation, etc.
  - More common when parties have an extensive collaboration and/or are co-promoting products

Payment Provisions

- R&D Payments
  - Payments made by one party to the other to support R&D efforts for products
  - Often FTE-based
  - Fully Burdened Costs
  - Pass-through costs for contractors

- Manufacturing Payments
  - Where product is supplied by one party
  - Fully Burdened Costs
  - Pass-through costs
  - Markup?

Payment Provisions

- Co-Promotion Payments
  - Payment on a per detail basis
  - Payment on an FTE basis
  - Increased royalties or profit share

Governance (Complex licenses/partnering)

- Provide for governing committees and project teams to conduct specific activities
- Often a senior committee with subcommittees tasked with specific roles
- Regular meetings, meeting minutes and updates to product development plans
- Can be critical to product success
- Hard to legislate a good relationship

Governance (Complex licenses/partnering)

- Nature of committees may need to reflect pharma partners' standard practices
- Specified number of representatives per committee
- Frequency, nature and location of meetings
- Meeting agendas
- Minute-taking obligations
- Chairperson(s)

Governance (Complex licenses/partnering)

- Often decision-making by consensus or unanimity, particularly at junior committee level
- At senior committee level, one party may have final decision making rights on all, or certain specified, types of matters
- Senior committee may be required to submit open issues to designated officers of each party
- Open issues may be submitted for final dispute resolution

Governance (Complex licenses/partnering)

- Mediation?
- Expert resolution of technical matters?
- Arbitration (particularly for international disputes)
- Court

Contact Information

Questions?

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Collaborative Agreements in Life Sciences Transactions

Amy Toro, Partner, Covington & Burling LLP

January 26, 2012

Part I: Allocating Responsibility for Regulatory, Commercialization and Manufacturing and Supply Obligations

Regulatory Matters

- Type of product (small molecule, biologic, devices, diagnostics, etc.)
- Regulatory filings and communications
  - Attending regulatory meetings
  - Review and comment or approval rights
  - Product labels
- Post-marketing
  - Safety data exchange
  - Recall matters
  - Commercial regulatory matters
- Pricing and reimbursement

Commercialization Activities

- General considerations
  - Which party should commercialize the product?
  - Diligence obligations
  - Co-detailing
  - Dividing territories
- Product trademarks
- Sales and marketing materials
- Generic product and related issues
- “Commercializing” in the developing world

Manufacturing and Supply

- Key terms v. supply agreement terms
- Cost of supplies
  - Methods for determining cost
  - Common issues related to cost
- Other supply terms
  - Specifications and changes to specifications
  - Shortage allocation and failure to supply
  - Duration of supply and backup supply

Part II: Allocating IP Ownership and Related Rights

IP Ownership

- Determining allocation of Collaboration IP
- Joint ownership issues
  - Use and licensing
  - Accounting obligations
- Control during bankruptcy
- Effect upon termination

IP Related Rights

- Prosecution of patents
  - Allocating prosecution rights
  - Orange Book issues
- Enforcement of patents
  - Defense of patents
  - Trademark enforcement

Hatch-Waxman Act

- Primary patent enforcement activity is against generics that exercise their rights under this Act to file ANDAs (Abbreviated New Drug Applications)
- Act requires FDA to approve generic drugs that are shown to be “bioequivalent” to a previously approved drug without requiring further clinical studies by filing an ANDA. Generics that are first-to-file an ANDA have 180-day exclusivity.
- Patent enforcement provisions need to take account of the special procedures and timing
- Damages typically not available - generic manufacturers can mount a validity challenge without incurring the cost of entry or risking damage flowing from possible infringement
- Need to be careful regarding settlements with generic companies that may be viewed as anticompetitive

BPCIA (Biologics Price Competition and Innovation Act of 2009)

- Purpose: to create a framework for FDA approval of follow-on biologics
- Although analogous to the ANDA process, the procedures are quite different:
  - Step 1: Biosimilar applicant shares information about biosimilar product
  - Step 2: Biosimilar applicant and reference product sponsor (RPS) identify potentially relevant patents
  - Step 3: Parties agree to subset of patents for expedited litigation
  - Step 4: 180 days before commercial marketing of biosimilar, RPS has opportunity to bring suit on remaining patents
- Information exchange/confidentiality issues

Part III: Term, Termination and Consequences of Termination

Term

- General considerations
- Common triggers for expiration
- Automatic renewals

Grounds for Termination

- Material Breach
- Convenience
- Bankruptcy
- Other Grounds:
  - Patent Challenge
  - Change of Control
  - Safety Issues; Certain Regulatory Actions
  - Antitrust Issues

Mechanics of Termination

- Cure periods
- Country-by-country and/or product-by-product
- Different types of breaches

Consequences of Termination and Related Considerations

- Be specific
- Self-executing v. transition agreements
- Who walks away with what?
- Allocating post-termination risks and responsibilities.

Consequences of Termination

- License grants and other IP implications
- Exclusivity or other covenants
- Payment considerations
- Assistance/cooperation requirements
- Manufacturing considerations
- Cross-defaults

Other Termination-Related Issues

- Effect of termination on sublicenses
- Return or destruction of confidential information and proprietary materials
- Inventory sell-off period
- Survival of agreement terms

Part IV: Indemnification and Liability Limitations

Indemnification

- General approach
  - How to determine allocation of risk
  - Control
  - Upside (which party is profiting more?)
  - Different from M&A context
- Indemnification for past conduct
- Indemnification for post-termination conduct
- Survival of indemnities

Liability Limitations

- Limits on consequential damages
- Liability caps and carve-outs

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