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THE LIFE SCIENCES GROWTH SERIES

Understanding University Licensing

Ben Pensak, Stephen Altieri and Oren Livne | November 13, 2018

Biography

Benjamin H. Pensak
San Francisco, CA
T +1.415.442.1368
F +1.415.442.1001

Benjamin H. Pensak counsels clients on technology transactions and related corporate matters, primarily in the life sciences industry. Ben represents international and US-based public and private companies and institutions, and his clients include biotechnology, pharmaceuticals, medical device, diagnostics, and medical informatics companies. Ben advises clients regarding negotiating and structuring acquisitions, divestitures, joint ventures, corporate partnering, licensing, and other complex collaborations. He also drafts and negotiates day-to-day technical contractual arrangements. He is the deputy leader of the firm's life sciences transactions practice.

In his transactional work, Ben handles arrangements related to discovery, development, manufacture and supply, marketing, and outsourcing for life sciences companies and other innovative and developed technology companies. He also works with research organizations and institutions. Recognized by Chambers USA, Ben is hailed as having "an extremely high legal and life sciences IQ . . . . He is quick on his feet and is an excellent technical drafter."

Biography

Stephen L. Altieri, Ph.D.
Boston, MA
T +1.617.951.8525
F +1.617.951.8736

Stephen Altieri, Ph.D., focuses his practice on patent counseling, procurement, and licensing in the life sciences sector. Throughout his career, Steve has represented clients of all sizes, including emerging companies as well as public companies and universities. He creates and develops US and international intellectual property rights that are aligned with client business objectives. Steve also handles post-grant proceedings, including inter partes reviews and reexaminations, as well as patent litigations.

Previously, Stephen was an associate at another international law firm, where his subject area focus was on life sciences, including biologics, diagnostics, oncology, immunotherapies and small molecule drugs.

Stephen, a Fulbright Fellow, received his Ph.D. from Yale University from the Department of Molecular Biophysics and Biochemistry. His doctoral research examined mechanisms of ion channel activation, particularly the structural and molecular basis of gating in cyclic nucleotide-gated ion channels. After finishing at Yale, Stephen received his J.D. from Boston College Law School, *magna cum laude* and Order of the Coif.

Stephen also serves as co-chair of the Massachusetts Biotechnology Council's Entrepreneur University.

Biography

Oren Livne
Princeton, NJ
T +1.609.919.6614
F +1.609.919.6701

Oren Livne counsels clients from startups to multinationals on variety of corporate and transactional matters globally, including license and collaboration agreements, commercial contracts, venture capital financings, mergers and acquisitions, and general corporate matters. His clients include life sciences, technology, and emerging growth companies. Oren is a guest lecturer at New York University entrepreneurship classes and has authored several intellectual property articles.

Oren brings first-hand, client-side licensing experience to his legal practice. Before becoming a lawyer, he co-founded a university technology transfer office and managed its licensing operations. He handled the licensing of an international patent portfolio in the light emitting diode and energy areas.

SECTION 01

DIFFERENT WORLDS

Motivations Behind Licensing

University Out-License

- Knowledge transfer
- Provide public with benefit of university research
- Support faculty
- Generate revenue
- Partner with company that has skill set to commercialize

Company In-License

- Access new technology to enhance development efforts
- Expand product pipeline
- Generate profits (do good, by doing good)
- Set-up success for downstream transactions

Company – Company License Agreements

- Tend to be product or target focused
- Often include a license under a broad bucket of intellectual property for specific products, e.g.:
  - existing and future patents and know-how
  - that are necessary or reasonably useful for the licensed products
- Usually provide freedom-to-operate (with respect to the licensor and its affiliates) for the licensed products, at least within a specified field

University – Company License Agreements

- Tend to be intellectual property focused
- Often include a license under a very specific bucket of intellectual property, e.g.:
  - only existing patents and know-how
  - that are set forth on a schedule or, in the case of know-how, that arose out of a specific laboratory
- Do not provide freedom-to-operate – there may be intellectual property arising out of other university laboratories, or arising after the agreement effective date, that is not included in the license
- May find a bit more room for negotiation ex-U.S.

Process Overview – Engaging with the University

- Negotiations may involve two distinct offices at the university:
  - Technology Transfer Office – for licensing existing intellectual property
  - Sponsored Research Office – for sponsoring future research
- Negotiations are generally led by business personnel of the applicable office, with support from internal counsel
- External counsel is generally not involved except sometimes in the case of particularly large or complex transactions
- Process may go from a CDA, to an option, to a license

SECTION 02

UNIVERSITY-SPECIFIC POLICIES AND LAWS

University Mission

- Each university's mission provides a backdrop for negotiations:
  - MIT – "…to advance knowledge and educate students in science, technology, and other areas of scholarship that will best serve the nation and the world in the 21st century."
  - University of California – "…providing long-term societal benefits through transmitting advanced knowledge, discovering new knowledge…more specifically, includes…education, research, and other kinds of public service…"
  - Rutgers – "providing for the instructional needs of New Jersey's citizens ….conducting the cutting-edge research…and performing public service"

Reservation of Rights

- Universities typically reserve rights to:
  - Use licensed intellectual property for academic teaching, research and educational purposes
  - Grant other non-profits the same rights
  - Satisfy Bayh-Dole Act requirements
- Some universities have begun to extend their reservation of rights to allow access for humanitarian purposes in developing countries

Commitment to Publication

- Universities require the freedom to publish (publish or die for the PI)
- Licensee generally can:
  - Review publications in advance to remove licensee confidential information and for patentable subject matter
  - Delay publication for a limited time to allow for patent filings

University Intellectual Property Policies

- Patent Policy:
  - University inventors obligated to disclose inventions to technology licensing office
  - University inventors frequently receive a share of income generated by their inventions
  - Can ask to review these
- Know-How Policy:
  - Less clearly defined by many universities
  - Policy may not require disclosure of know-how
  - May cover copyrights in academic publications or software

Bayh-Dole Act*

- If licensed intellectual property was generated under funding by the U.S. government:
  - March-In Rights – government can step-in in certain circumstances (health & safety, not taking steps towards practical application)
  - Preference for U.S. Industry – if exclusive rights are granted, products sold in the U.S. must be substantially made in the U.S. (unless a waiver is granted)
  - Government License – government has a nonexclusive license to practice or have practiced for or on behalf of the U.S. throughout the world

* See 35 U.S.C. §§200-212, 37 C.F.R. Part 401

IRS Guidance

- In the U.S., facilities built with tax-free bonds cannot be used for "private" purposes*
  - In the case of company-sponsored research, universities cannot provide for an exclusive license, or otherwise transfer inventions, unless a "competitive price" is paid as determined at the time of license
  - Implication is that license terms for new intellectual property cannot be fixed, but universities have provided ranges of terms or alternatives based on stage of development and specific context

* See https://www.irs.gov/pub/irs-drop/rp-07-47.pdf

SECTION 03

LICENSE PROVISIONS – UNIVERSITY PERSPECTIVE

Scope of Grant

- Exclusivity
  - Patents – exclusive to a specific list of patents (subject to university's reservation of rights)
  - Know-How – varies by university, with some universities only granting non-exclusive rights to specifically listed know-how or know-how arising out of a specific lab
  - Tangible Materials – may be exclusive for certain materials (subject to university's reservation of rights)
- Field of Use
  - Varies based on deal
  - May be tied to diligence requirements

Sublicensing

- Approval
  - Universities may want to approve sublicenses
  - Look to limit the scope of relevant sublicenses rather than all
  - Provide copies for insight (redacted for unrelated matters)
- Appropriate flexibility to facilitate program advancement
  - Will a sublicensee object to terms that the licensee is willing to agree to?
- "Standby" licenses
  - A sophisticated sublicensee (e.g., big pharma) will want comfort if the original university license is terminated

Diligence Obligations

- Ties back to university mission
- General Obligations
- Specific Milestones / financial commitments
- Ability to extend
  - University perspective: diligence is significant to ensure continued development, but need to consider consequences of a failure (e.g., does University want technology "returned"?)
- Common pitfall is failing to adequately define
  - What are "Commercially Reasonable Efforts"

Payment Provisions

- Upfront (cash/equity)
- Maintenance Fees
- Milestones
- Royalties on Net Sales
- Sublicensing Revenues
- Reimbursement of Patent Costs
- Sponsored Research Commitment

Equity

- Increasingly common
- Non-lead investor
- Right to assign
- Triggers and limits
  - Fund raise of a certain size
  - Capped per round or total investment

Royalties on Net Sales

- Valid Claims – are payments based on pending or only issued claims?
- Know-How – given university right to publish, what know-how (if any), triggers a royalty obligation?
- Reductions – what adjustments apply?
  - Combination products
  - No valid claim
  - Third party licenses
  - Generic entry
  - Compulsory licenses

Sublicensing Revenues

- If other consideration (e.g., upfront, royalties, milestones) is sufficient, sublicensing revenue payments may not be required
- May not apply for limited sublicenses (e.g., country-specific sublicenses)
- If applicable:
  - Typically calculated as a percentage of sublicensing revenue (which may adjust based on time of sublicensing or stage of development)
  - Royalties may either be included as part of Net Sales or in Sublicensing Revenues
  - Payments not attributable to the sublicensing of university's IP are generally excluded (e.g., payments for equity or debt of the company, goods or services, or non-university IP)

Patent Prosecution / Enforcement / Defense

- Who leads
  - Directly or through outside counsel? With approval?
- Step-in rights
- Cooperation / review and comment rights
  - Obligation to be joined for standing

Representations

- Representations given by universities are often minimal, if at all:
  - Right to grant the license
  - Own the intellectual property
  - Other representations, if given, often qualified by knowledge of applicable personnel at technology transfer office

Indemnification

- By Licensee
  - Universities tend to require a broad indemnity from licensee, e.g., any liability resulting from the exercise of the license
  - Carve outs can include the university's breach, negligence or willful misconduct
- By University
  - If universities are not conducting ongoing activities, indemnification by the university is often limited or non-existent

Assignment

- When can the company assign without the university's consent?
  - Sale of substantially all of the assets of the company / to which the agreement relates
  - Affiliates

Choice of Law

- Limited discretion, particularly for public institutions, either:
  - Their state law
  - Silent

SECTION 04

AFTER SIGNING

New Intellectual Property

- Special Considerations
  - License grants generally limited to existing intellectual property
  - Reservation of rights allow universities to continue research
- Potential Solution
  - Sponsor ongoing research and receive an option to newly developed intellectual property

Sublicensing

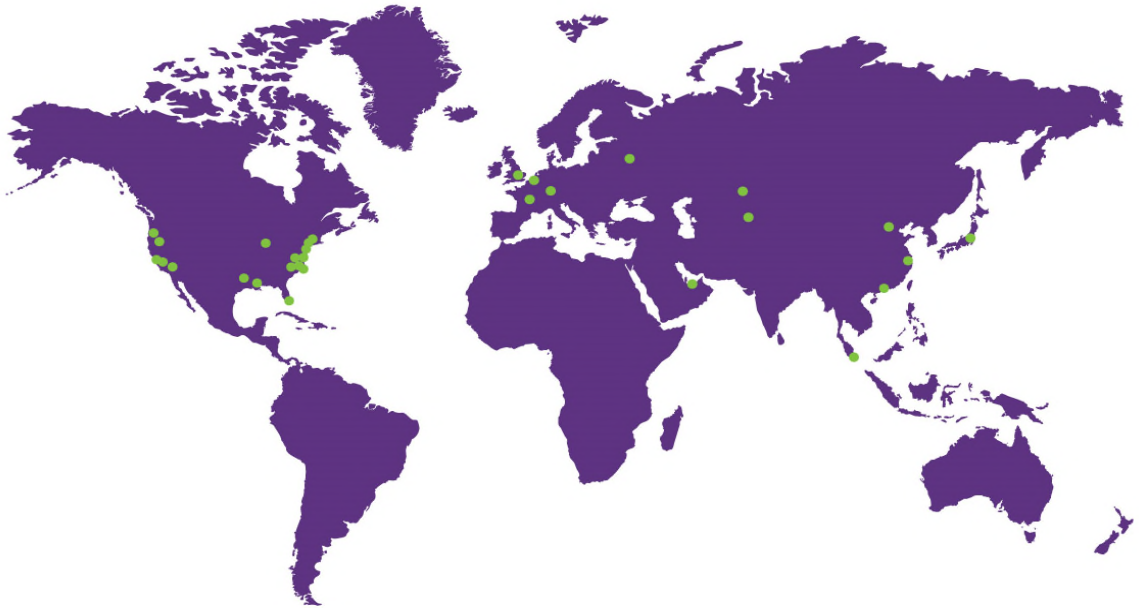
- Sublicensee Concerns
  - Sublicenses may not survive termination of license
  - Other required terms may need revision
- Potential Solution
  - Side letter executed by university, licensee and sublicensee

Our Global Reach

Africa
Asia Pacific
Europe
Latin America
Middle East
North America

Our Locations

Almaty
Astana
Beijing*
Boston
Brussels
Century City
Chicago
Dallas
Dubai
Frankfurt
Hartford
Hong Kong*
Houston
London
Los Angeles
Miami
Moscow
New York
Orange County
Paris
Philadelphia
Pittsburgh
Princeton
San Francisco
Shanghai*
Silicon Valley
Singapore
Tokyo
Washington, DC
Wilmington



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