

# **Best practices to help growth stage companies build their IP portfolio**

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**IN VIVO**  
PATENT LAW

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# Growth Stage Company

- Continued R&D – product efficacy, safety, clinical trials, regulatory approvals, commercial scale up, manufacturing, etc.
- Cash flow – managing capital for R&D, commercialization, and business operations
- Hiring the right team – experienced management and talent

# Common strategies that come into play during the life of the Company:

- In-license IP to strengthen the portfolio, or allay infringement concerns
- Develop a product in-house for commercialization
- Out-license IP, form strategic alliances or partnerships to deliver products/services to market (various fields)
- ROI: sell, divest, joint ventures

**So how do we best serve the company?**

**Wear the business hat.**

**What are the company's business goals?**

Be the attorney who

Helps the  
Company raise  
capital

Protects the  
Company's IP

Aligns value in  
IP portfolio w/  
business goals

**...create VALUE at every step.**

# In-licensing patents

**Patents – bundle of rights** - right to exclude others from making, using, offering for sale, selling, or importing into the United States the invention claimed in the patent.

- **Exclusive License**
- **Non-exclusive License**
- **Exclusive Field License**
- **Hybrid Patent and Know-How License**

# In-licensing patents - Exclusive License from University

- Understand IP being sought:
  - patent family
  - scope of claims, prior art
  - stage of patent filing/patent term
  - additional know-how?
  - commercially viable technology? compatible?
  - confer with scientific advisors – vet the tech
  - any other related University IP/inventor IP necessary to make, use, sell products/provide services?

# In-licensing patents - Exclusive License from University

- Understand parties coming to the table
  - The Company - selling points, team, resources
  - Tech transfer licensing rep – experience level
  - Inventors – faculty
  - Other universities/co-owners/3<sup>rd</sup> party interests – IP that resulted from collaboration
    - ❖ Inter-institutional agreement?
    - ❖ Competing interests - startups by other universities?
    - ❖ Sponsored Research Agreements?



# In-licensing patents - Exclusive License from University

## - Understand non-negotiable University clauses

Bayh-Dole Act allows Universities to elect to retain title to and license inventions conceived or reduced to practice with the assistance of Federal funding. Certain obligations must be met. Some of these obligations correspond to provisions in University license agreements that are non-negotiable.

**2.3 Government Rights and Requirements.** Notwithstanding anything hereunder, any and all licenses and other rights granted hereunder are limited by and subject to the rights and requirements of the United States Government which may arise out of its sponsorship of the research which led to the conception or reduction to practice of the Invention. The United States Government is entitled, as a right, under the provisions of 35 U.S.C. §§ 200-212 and applicable regulations of Title 37 of the Code of Federal Regulations: (i) to a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on the behalf of the United States Government any of the Patent Rights throughout the world and (ii) to exercise march in rights on Patent Rights. Further Licensee agrees, as required by 35 U.S.C. § 204, that any Licensed Products used or sold in the United States shall be substantially manufactured in the United States.

# In-licensing patents - Exclusive License from University

## - Understand non-negotiable University clauses

University's mission typically is focused on education, research, and public service.

**2.2 Reservation of University Rights.** University reserves the rights to practice under the Patent Rights or Copyrights for its own internal research, public service, teaching and educational purposes, without payment of royalties, provided that the exercise of such reserved rights by University shall not (a) be subject to any intellectual property rights granted to any commercial third party nor (b) include any human use or clinical administration without prior written approval from Licensee, such approval not to be unreasonably withheld. University shall also retain the rights: (i) to make, use and provide Licensed Products to other academic and nonprofit research institutions for their own internal research, public service, teaching and educational purposes and (ii) to allow other academic and nonprofit research institutions to use Patent Rights or Copyrights for educational and research purposes, provided that University shall require of such third parties that the use of such Licensed Products or practice of the Patent Rights or Copyrights shall not (1) be subject to any intellectual property rights granted to any commercial third party nor (2) include any human use or clinical administration without prior written approval from Licensee, such approval not to be unreasonably withheld. University shall be free to publish the results of its research and educational activities as it sees fit.

(Some wiggle room to negotiate for review of publications to remove Licensee confidential information, and permit time for patent filings prior to publication)

# In-licensing patents - Exclusive License from University

## - Understand non-negotiable University clauses

Limited Reps and Warranties. . . do the up-front due diligence. . .

10.1 University makes no representations or warranties; (i) that any patent will issue on the Invention, or (ii) of the validity of any patent included in the Patent Rights or that practice under such patents shall be free of infringement.

10.2 University represents that, to its knowledge, as of Effective Date, (i) the entire right, title, and interest in the patent applications and patents comprising the Existing Patent Rights have been assigned to University free and clear of all liens, claims and encumbrances of any inventor or any nongovernmental third party, (ii) that University has all requisite power and authority to grant the licenses contained in this Agreement under said Existing Patent Rights and Copyrights, (iii) University has not entered into any agreements, other than grants from the U.S. Government which provide for the rights described in Section 2.3, with any third party with respect to the Existing Patent Rights, the technology claimed therein, or Inventions, (iv) University's execution and performance of this Agreement will not result in a breach of any other contract to which it is, or will become, a party, and (v) University has not received any notification, and does not possess any information reasonably indicating, that the Existing Patent Rights and Copyrights are invalid or that the exercise by Licensee of the rights granted hereunder will infringe on any patent or other proprietary right of any third party.

# In-licensing patents - Exclusive License from University

create Value in negotiations by:

- securing broad, reasonable scope of rights
- reducing unreasonable, onerous obligations

# In-licensing patents - Exclusive License from University

create Value by securing broad, reasonable scope of rights

- Term Sheet – focused on major terms; go/no-go...

- License Grant – as broad as possible

2.1 **Grant to Licensee.** University hereby grants to Licensee ~~and its Affiliates~~ to the extent of the Licensed Territory an exclusive license under the Patent Rights to make, use, sell, have made, have sold, offer for sale, and import Licensed Products and perform Licensed Services in the Licensed Field and, with the right to sublicense as set forth in Article 6, subject to all the terms and conditions of this Agreement.

Patent Rights – listed in Schedule

Territory – worldwide

Have made rights – e.g. right to have 3<sup>rd</sup> party make product for sale

Field – all fields

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~~Affiliates~~ – if the Company has no affiliates... potential issues re future Affiliates and sole right to sue

## Right to sublicense – right to grant sublicenses to 3<sup>rd</sup> parties

6.1 Licensee may sublicense any and all rights licensed hereunder, with such rights including the right to permit Sublicensees to further sublicense such rights. Licensee shall notify University in writing and provide University with a copy of each sublicense agreement entered into by Licensee granting Sublicensee rights to any and all rights licensed hereunder and each amendment thereto within thirty (30) days after their execution.

# In-licensing patents - Exclusive License from University

## A practice note about Definitions...

1.18 “**Licensed Products**” means any method or process, composition, product, service, or component part thereof covered in whole or in part by a Valid Claim contained in the Patent Rights or covered by Copyright. Licensed Products include Clinically-Approved Products, Licensed Services, and Other Products.

1.19 “**Licensed Service**” means a service provided by Licensee, Affiliate, or Sublicensee that uses a Licensed Product or that is itself a Licensed Product. Research and development carried out by Licensee, Affiliates, or a Sublicensee for the purpose of creating, developing, or commercializing Clinically-Approved Products or Other Products does not constitute a Licensed Service.

1.37 “**Valid Claim**” means a claim of any pending patent application or any issued, unexpired United States or granted foreign patent that has not been dedicated to the public, disclaimed, abandoned or held invalid or unenforceable by a court or other body of competent jurisdiction from which no further appeal can be taken, and that has not been explicitly disclaimed, or admitted by University in writing to be invalid or unenforceable or of a scope not covering Licensed Products through reissue, disclaimer or otherwise.

1.24 “**Net Sales**” means the total invoiced sales price for Licensed Products sold by Licensee, Affiliates, and Sublicensees less (a) sales taxes or other taxes (other than income taxes), (b) shipping and insurance charges, (c) actual allowances, rebates, credits, or refunds for returned or defective goods, (d) trade, quantity, and other discounts, retroactive price reductions, or other allowances actually allowed or granted from the billed amount and taken, (e) rebates, credits, and chargeback payments (or the equivalent thereof) granted to managed health care organizations, wholesalers, or to federal, state/provincial, local and other governments, including their agencies, purchasers, and/or reimbursors, or to trade customers, and (f) any import or export duties, tariffs, or similar charges incurred with respect to the import or export of Licensed Products into or out of any country in the Licensed Territory. Licensed Products will be considered sold when paid for.

# In-licensing patents - Exclusive License from University

create Value by securing broad, reasonable scope of rights

- **Improvements** – (1) any modification or improvement of the technology later developed by same faculty/inventor that relates to patents and owned by University, [and (2) inventions that would require a license under Patent Rights]

**Consider negotiating to add provisions:**

**Notice of Improvements** – notice of patent filings on Improvements with copy of patent application and sufficient info to evaluate Improvements

**License to Improvements** –

- Option to evaluate and Parties agree to negotiate in good faith terms and conditions of licensing any Improvements on a case by case basis.
- or Option to add Improvements patents/apps under Patent Rights/revise schedule



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## Consider sponsoring ongoing research under Sponsored Research Agreement

- w/ Non-exclusive, royalty-free license to Sponsored Research IP and
- Exclusive option to obtain exclusive license to Sponsored research IP

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create Value by securing broad, reasonable scope of rights

- Patent Prosecution/enforcement/defense... alliance management

8.1 Patent filings and prosecution **shall be by counsel of University's choosing** and shall be in the name of University. University shall keep Licensee advised as to the prosecution of such applications by promptly forwarding to Licensee copies of all official correspondence, (including, but not limited to, applications, Office Actions, responses, etc.) relating thereto. **Licensee shall have the right, and University shall provide Licensee a reasonable opportunity, to comment and advise University as to the conduct of such prosecution and maintenance**, provided, however, that University shall have the right to make the final decisions for all matters associated with such prosecution and maintenance.

# In-licensing patents - Exclusive License from University create Value by reducing unreasonable, onerous obligations

- Reimbursement of all past and future patent costs
  - Spread payment schedule of past patent costs according to realistic financial timeline... avoid having to amend payment schedule and make concessions
  - Understand general cost timelines for patent applications; maintenance fees/annuities... invoices billed monthly

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create Value by reducing unreasonable, onerous obligations

## - Royalties on Net Sales

- Conduct up-front due diligence for negotiating chips, and to understand how financial terms will come into play for Licensed Products and Licensed Services
- Relationship of defined terms: Licensed Products, Valid Claim, Net Sales
- Reduction provisions: Royalty Stacking, Combination Product, No Valid Claim
- Licensing Executive Society (LES) publishes royalty rates survey reports periodically, free to members

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## Balance Payment Provisions

- Reimbursement of Patent Costs
- Royalties on Net Sales
- License Issue Fee/Upfront payment/Equity
- Annual Maintenance Fee
- Milestone Fees
- Sublicense Revenue Fees

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## - Diligence obligations- set reasonable dates

### APPENDIX B

### MILESTONES

NOTE: The milestones below are proposed milestones.

Actual milestones will be negotiated based on the Licensee's business model.

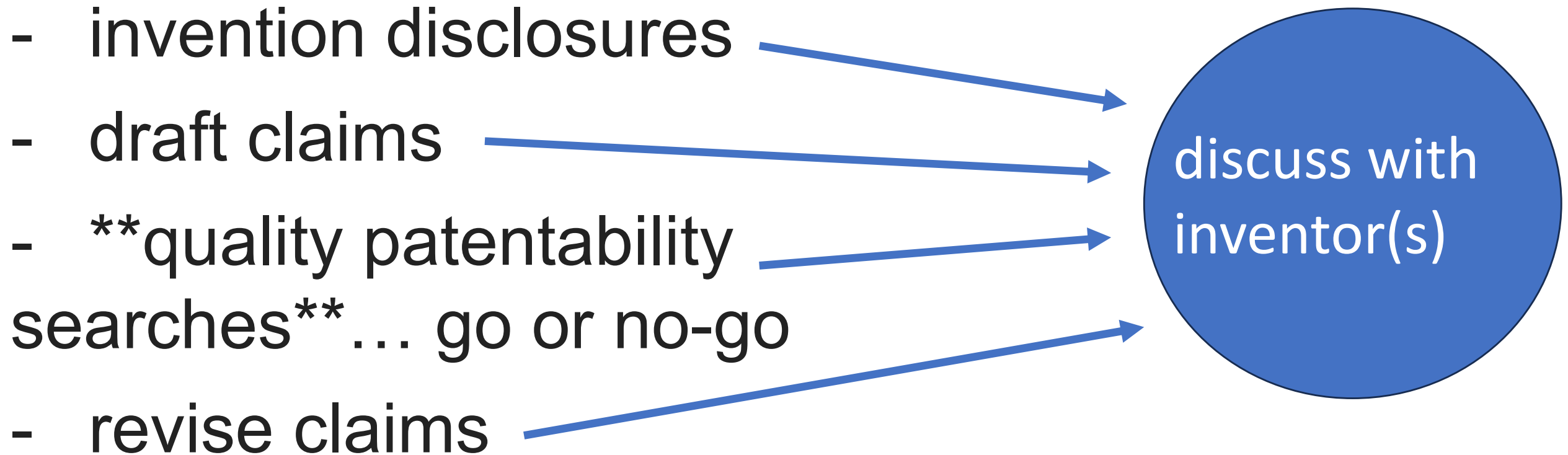
1. Licensee shall have a corporate management team in place by\_\_\_\_\_
2. Licensee shall have financing in the amount of\_\_\_\_\_ by\_\_\_\_\_
3. Licensed Product Development Milestones (i) (ii) (iii) (iv)
4. Licensee shall commence with commercial sales of License Product by\_\_\_\_\_

Dates are often extendible, University typically would not prefer to terminate the Agreement and have IP returned...

However, amendments to stretch dates likely will come with fees or concessions...

# Filing Patent Applications for Company Inventions

create Value by preparing a solid patent application from the start



# Filing Patent Applications for Company Inventions

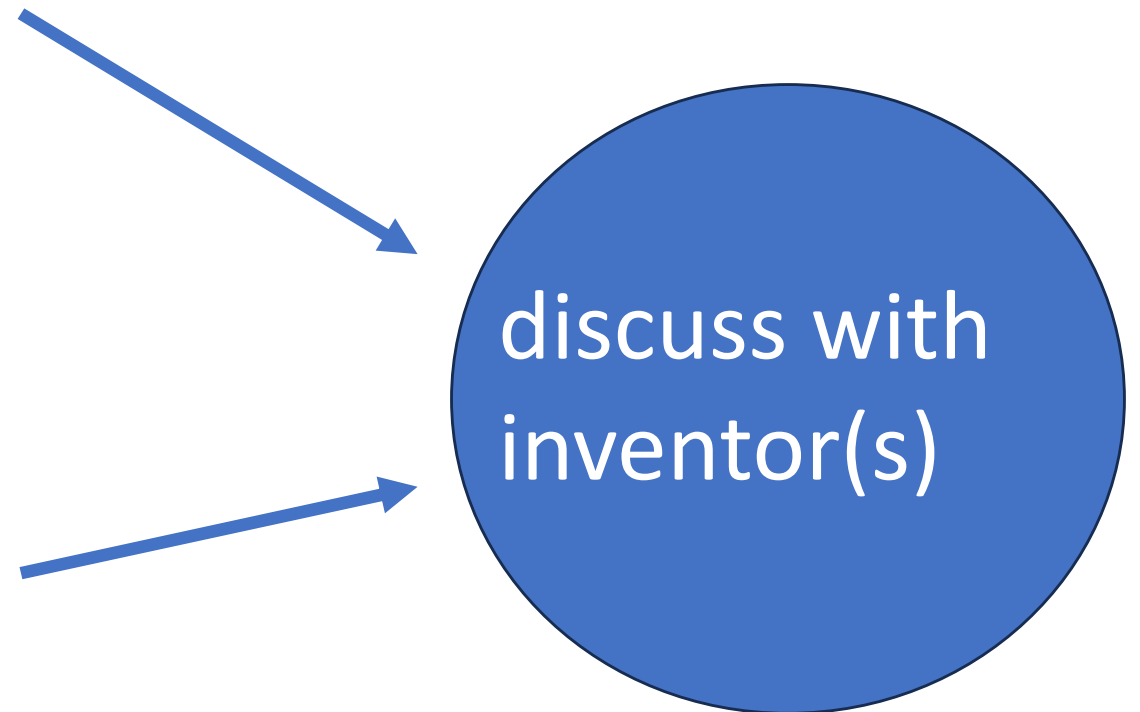
create Value by preparing a solid patent application from the start

- Independent claim scope

Balance between broadly covering all possible commercial embodiments v. what's enabled, heart of invention

- Alternative embodiments/dependent claims

Fall-back inventive features





# Filing Patent Applications for Company Inventions

create Value by preparing a solid patent application from the start

Tell a good [supported] Invention Story.

- Prior art problems/technical problems
- Invention solution to problem, highlight distinguishing features
- Drawings
- Data, data, data –
  - \*\*unexpected results,
  - \*\* substantial, significant results over the prior art

# Filing Patent Applications for Company Inventions

create Value by preparing a solid patent application from the start

Set-up for:

- **positive Examiner Interviews** (request Examiner Interviews often – before/after response filings, build positive rapport with Examiner)
- **fall back positions for claim amendments**
- **specification support for advantages over prior art to overcome obviousness rejections**

# Filing Patent Applications for Company Inventions

create Value by ensuring a clear chain of title

“I hereby assign...”

- Include Assignment of Inventions in Invention Agreements with Employees, Consultants, Advisors, Officers
- Confirming Assignments after provisional application is filed
- Recording Assignment for each application

# Thank You

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