Transferring Technology to the Commercial Marketplace

The Steps to Commercialization

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Step 1: Analyzing the Disclosure: Invention Disclosure and Checklist

- **Type of technology**
  - **Patent**
  - **Copyright/Software**
  - **Biological Materials**
- **Ownership issues**
  - **Identifying true inventors/authors and status when technology developed (required to assign/not required to assign)**
- **Prior agreement obligations – who is entitled to licenses**
- **Identifying any bars**, i.e. prior publication, use of third-party owned intellectual property or other encumbrances that would preclude transfer for commercialization

Step 2: Meeting with Inventor: Invention Disclosure and Patentability Evaluation

- Assessing stage of the invention? prototype, proof of concept, in vitro/vivo experiments?
- If technology patentable, is publication bar anticipated?
- What is novel about the discovery/potential commercial uses
- Does inventor know companies that may be licensees?
- What would the inventor like to do? Start-up possible?
- Setting reasonable expectations with the inventor as to:
  - **Filing patent applications**
  - **Understanding how to deal with patent attorneys**
  - **Marketing assistance, if any, expected from the inventor**

Step 3: Protecting the Invention

- Dangers on the way to patenting
  - **Enthusiastic Inventor discloses to 3rd parties, including colleagues and students**
  - **Inventor submits an article for peer review**
  - **Following the rules, Inventor discloses the invention to the TTO, but the TTO is careless about handling it**
  - **The TTO is not careless, but underestimates honesty of potential licensees**

Step 3.5: Ensuring the Invention is Protected

- Once Invention enters patent system – patent laws will provide protection against thievery for most part
- But, if Invention not yet in patent system – 2 possibilities for protection
  - **Trade secret**
    - o Protects Invention against misappropriation (theft)
  - **Contract**
    - o Protects Invention against misuse by potential licensees

Step 3.5: Ensuring the Invention is Protected

- If Invention (before patenting) qualifies a “secret” and is maintained . . .
  - **TTO does**
    - o Develop a nondisclosure agreement to cover
    - o Develop a non-confidential summary
    - o Consider filing patent application
  - **TTO does not**
    - o Put description of invention on its website
    - o Disclose invention to potential licensees without requiring nondisclosure agreement to be signed

Step 4: Protecting the Invention During Commercialization

- Protecting Invention from misuse by contract during licensing period
  - **Simple nondisclosure agreement not sufficient for pre-licensing negotiations**
  - Best practice**:** use a contract **to protect invention as an asset throughout the patenting period**
    - Avoids licensee misuse of invention if secrecy lost inadvertently or invention is published in patenting process
    - Provides continued protection if leaks occur
    - Allows Inventor to publish

Step 4: Protecting the Invention During Commercialization

- Essential terms of a Pre-Market or Option Agreement
  - **Parties**
    - o Authorized signatories
  - **Definition of Invention**
    - o May have changed – will need to include patent application, issued patent and patent-owner case or tracking identifier
  - **Reaffirm confidentiality obligations as long as Invention is not publicly known**

Step 4: Protecting the Invention During Commercialization

- More terms of contract
  - **Permitted uses**
    - Evaluation only
    - No use in company research
    - No use for or as commercial product
  - **No express or implied license, except evaluation; no obligation for license relationship on part of parties unless specifically included (see following)**
  - **Potential Licensee to make decisions/exercise option within specific time period**
  - **Add disclaimers of warranties and representations**

Step 4: Protecting the Invention During Commercialization

- Limit extent to which invention becomes known. The more people who know it the less likely it will have trade secret protection (remember, in pre-patent stage, no patent protection- so Trade Secret may be only legal protection available)

Step 4: Protecting the Invention During Commercialization

- Take effective protective measures
  - **Through education of faculty inventors & administrators**
  - **Provide nondisclosure agreement to inventor – just in case he/she contacts a company**
  - **Add non-disclosure provisions covering inventions to industrial research contracts**
  - **Release only non-confidential information for general/website marketing**
  - **Release enabling description of Invention to third party only under nondisclosure**

Step 5: Whether to Patent: Patentability Evaluation

- Assess patentability through literature search for prior art
- Get recommendation/cost commitment from outside patent attorney
- If dedicated patent firms (or attorney that the TTO or inventor prefer to use), involve them early in the process

Step 5: Whether to Patent: Product Characteristic & Market Potential

- Assessing commercial potential using a number of factors including
  - **Highest and best use**
  - **Weighing advantages over existing technologies**
  - **If new, weighing the barriers to market**
  - **Assessing the strength of competitors**
  - **Estimating market size**
  - **Determining strength of patent/can its use be policed?**
  - **If time and resources can do market study**
  - **If patent committee involved, send to patent committee with findings/recommendations**

Step 5.5: Patenting: Use Market Potential Evaluations (unless building inventory)

- Determine where to file based on early “best use” assessment
- File cheapest (PCT) if possible
- If possible, respond to early licensee preferences for geographic protection
- Make decision: Who will prepare application and file?
  - **University/research center**
  - **Licensee**
  - **Other ?**

Step 5.5: Patenting

- Finding Patent Funding
  - **Institutional budget – annual set aside based on budget forecast**
  - **“Pay as you go”/funds spent dependent upon royalties received and % retained in “royalty account”**
  - **Licensee commits to paying patent costs**
  - **Department, Lab, Center pays for its own patent filings**
  - **Industry research consortia members commit % of research funding to fund patenting**

Step 5.5: Patenting

- Finding Patent Funding
  - **Outside “captive” fund pays (may be a regional or national fund)**
  - **Any venture fund pays costs for selected candidates**
  - **Patent Fund “Start-up” Grant (most likely term limited)**
  - **Angel/inventor investors (for spinouts)**

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All About Marketing

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Step 6: Getting Ready to Market

- Prepare non-confidential abstract
- Follow-up leads from inventor or consultants
- Is outside marketing expert needed – determine early as marketing reports take time
- Decide on best marketing strategy
  - **<u>Targeted marketing</u> - focus on 1-3 companies**
  - **<u>Shotgun approach</u> – mass mailings, technology databases**
  - **<u>Timed approach</u> – beginning with targets and broaden if no show of interest by a certain date**

Step 6: Getting Ready to Market

- Prepare marketing information package including patent application if ready or filed
  - **Describe research**
  - **Have marketing tools in place**
    - Rolodex, invention abstract, patent search, corporate directories, trade journals, database access, NDAs, names of commercial assessment firms, if needed.

Step 7: Marketing: Marketing & Product Profiles, Company Comments

- Maintain constant contact with prospects
- Set up inventor/prospect meetings; send inventor out on licensee prospect visits (not alone)
- Make sure all necessary information is accessible and user friendly
  - **Results of patent search**
  - **Test data**
  - **Copies of publications**
  - **Manuscripts**
  - **Patent application**
- Have “basic terms” prepared on paper including royalty terms and supporting backup

Step 7: Marketing the Technology

- Expect difficulty in marketing to existing companies. What you can expect to hear:
  - **The "science" is unproven – no one believes it**
  - **The idea is too new – the market is unproven**
  - **Development costs too high and too risky**
  - **We have no R&D capability that can handle it**
  - **We are already over-committed on research and development; it competes with our own products**
  - **If we didn't invent it, we don't want it**
- Essential to find a champion within the company – VP New Products, VP Business Development, leading company scientist, or higher

Step 8: Negotiating the Royalties

- "The licensee determines the royalty by agreeing to pay it!"
- The Licensee and Licensor will both arrive at an acceptable royalty range.
  - **The licensee will use factors such as**
    - o Value of licensed product to end customer
    - o Cost of development
    - o Dynamics of the marketplace (how robust is it)
    - o Competition
    - o Its own financial forecasts

Step 8: Negotiating the Royalties

- The licensor will use factors such as
  - **The number/kind of IP assets licensed (or bundled)**
  - **The scope of the license rights**
    - Exclusive or non-exclusive
    - Geographical area covered
    - Field of use
    - License term
  - **Commercial potential**
  - **R&D to be carried out**
  - **Barriers to the marketplace**

Step 8: Negotiating the Royalties

- Walking away
  - **Each party decides its "walk away" price**
- Bargaining begins . . . . but, all forecasts are hypothetical
- Factors that may make a difference in "price"
  - **Importance of licensed technology to final product**
  - **Type of product and how unique it is**
  - **Typical profitability of the type of product**
  - **Strength and "reach" of the IP**
  - **Whether blocking IP requires additional licenses**
  - **Development cost & time to market**

Step 8: Negotiating the Royalties

- Overall “business” expertise needed to negotiate royalties
  - **Knowledge of product development, manufacturing process**
  - **Knowledge of markets**
  - **Knowledge of pricing for comparable technologies**

Step 8: **Sample Royalty Ranges (MIT)**

- License without equity
  - **License issue fee: $10,000-$200,000**
  - **Annual license fee (minimum royalties): $20,000>$200,000re**
  - **Milestone payments if applicable: $50,000>$1,000,000 (Upon FDA approval)**
  - **Running royalties: 0.5% - 7% (or higher for software and drugs)**

Step 9: Closing the Deal

- Control drafting of the license agreement
- Make sure you have authority to commit and so does the party across the table
- Make sure the inventor knows the deal – document it
- Make sure all stakeholders understand the deal and have the same expectations

Step 10: Follow Through: License Profile

- Get signed agreement
- Complete license file
- Place “trigger” dates into database
  - **Sending notices**
  - **Sending invoices**
  - **Due diligence reports due**
  - **Royalty reports due**
- Flag any encumbrances in the license
  - **Improvements licensed**
  - **First option to fund related research**
  - **Requirement to include updates to software, new applications etc.**

Alternative Commercialization Strategies

- Delaying the deal through use of the Option*
  - **Usually option is exclusive for a limited period of time (you are taking the patent application/patent off the market)**
  - **Prospective licensee/optionee pays patent costs and modest fee**
  - **Optionee agrees to confidentiality**
  - **May fund research if needed to "prove" invention**
  - **Optionee must exercise option by date certain or terminate it (avoid the open-option dilemma)**

Alternative Commercialization Strategies

- Licensing Trade Secrets
  - **First step: Analyze disclosure for trade secret properties (U.S. requirements)**
    - Non-public information
    - Owned by employer
    - Has economic value
    - Intent to maintain in secrecy

Alternative Commercialization Strategies

- Licensing Trade Secrets
  - **Second step: Define it with specificity**
  - **Third step: Disclose only under non-disclosure agreement**
  - **Fourth step: Consider step-down license if information is known**
  - **Fifth step: Set up management system**

Alternative Commercialization Strategies

- Licensing Know-How – A few pointers:
  - **Must be carefully defined with rights retained, if needed**
  - **Must assign a value to it (needs to qualify as “consideration”)**

Alternative Commercialization Strategies

- Licensing Know-How – A few pointers:
  - **Combining with patent license takes planning**
    - o Pluses: Adds value to patent license and may extend life of the license beyond the patent term
    - o Minuses: If patent license terminated or breached is know-how license also terminated or breached and vice-versa?
  - **Best practice: Combine a non-exclusive know- how license with an exclusive patent license**

Alternative Commercialization Strategies

- Licensing Biological Materials – A few pointers:
  - **Exclusive license removes them from institutional use unless continuing research rights are reserved**
  - **Must reserve rights for research/experimentation if publishing or journals will not accept article**
  - **Non-exclusive licenses may be enough although will be at reduced royalty**
  - **Consider licensing for research but require additional license for commercial use**

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Collaborating with Industry

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University-Industry Relationships in the U.S.: The Many Options

- Single sponsor/single SOW research projects
- Consortia (many companies funding together)
- Cooperative Research (government funded with company)
- Master/Umbrella Agreements
- Long-term Alliance Agreements
- Joint Studies/no cost
- Visiting Scientist Exchange Agreements
- Material Transfer Agreements

Standardized Terms Generally Found

- Inventions are owned according to U.S. patent law
  - **Mine, yours, ours**
  - **No accounting or licensing approvals required where patents are jointly owned through co-inventorship**
  - **Invention ownership is not assigned to industry: fairly universal rejection by universities of "we paid for it so we own it" philosophy**
- Same with copyrights and all other IP
- Publication delays only for sponsor confidential information and potential patents
  - **Usually a 90 day limit**

More Standardized Terms

- Research sponsors do receive license grants
  - **Most common: Royalty-free, non-exclusive license without right to sublicense; option to negotiate a royalty-bearing exclusive license**
  - **Uncommon: Royalty-bearing license to be negotiated**
  - **Middle ground: Royalty-free, non-exclusive for non-commercial purposes**
- Royalty rates
  - **Most common: Fair and reasonable to be negotiated**
  - **Uncommon: Pre-set in research agreement**
  - **Possible middle ground: Floor > Ceiling set in research agreement**

And, More Standardized Terms

- Who Files?
  - **Common: University files through patent counsel of choice**
  - **Not quite so common: University permits industry sponsor to file provided university has right of review and comment**
  - **Issue: Who is the client?**

And, More Standardized Terms

- Payment of patent costs
  - **Most common: Sponsor/licensee to pay if license is exclusive**
  - **Uncommon: University undertakes obligation to file and always pays**
  - **Middle ground: Sponsor to pay to ensure patent application is filed; otherwise discretionary with university**

Identifying Clauses That Play a Role in Technology Transfer

- The parties (who will be the “licensee” if IP is developed)
- Typical clauses involving intellectual property rights/obligations
  - **Definitions of “invention” and other IP**
  - **Requirement to disclose**
  - **Patent filing obligations; foreign filing elections and who pays**

Identifying Clauses That Play a Role in Technology Transfer

- Typical clauses involving intellectual property rights/obligations
  - **License rights- patents/copyrights/software/trp**
    - o Vesting under research contract (“hereby grants” vs. “agrees to grant”)
    - o Option periods
    - o License terms
  - **Background rights**
  - **IP warranties, representations**

The Background Rights Dilemma

- Background rights – rights to university's pre-existing, concurrently developed and in some cases "to be developed" IP outside of the scope of the research program.
- Typical clause requires university to give/license the sponsoring company rights to use any other IP owned by the university that is necessary for/useful for practicing inventions/copyrights or all research results developed during the project. Right is usually open-ended – no time limit on the obligation or exercise of it

The Problem with Background Rights: A Clearer View

- Impossible to speculate what university IP will be encumbered because:
  - **Invention to which background rights are tied hasn't been made yet**
  - **Impossible to know how the sponsor may at some future time use an invention, copyright or other research result**
- Provides industry with entitlement to unfunded IP
- Ties up IP developed by investigator who never took sponsor funding –diminishes the rights/expectations of unsuspecting inventor

The Problem with Background Rights: A Clearer View

- Guts university tech transfer program because background is not licensed for benefit of the public (but is used defensively for benefit of a single company). Requires collateral IP (if identifiable) to be put “on hold”
- Impacts future sponsored research. One company’s background is anther company’s reason to sponsor

Crawling Out of the Background Rights Dilemma

- Limit to inventions of named research team – not entire university
- Limit to “required” for commercialization of licensed inventions – not “useful” for commercialization of research results
- Limit to “extent university has right to license”
- Put time limitation on – e.g. inventions made one year after termination of research contract
- Require royalties to be paid; no consideration for royalty-free