

TECHNOLOGY TRANSFER

A Brief Survey: Facts, Strategies & Tactics

HISTORICAL PERSPECTIVE

- The federal government was originally responsible for licensing inventions made with public funding, in whole or in part
- The federal program was not very effective in promoting commercial development
 - Was a centralized, remote operation conducted by a group not known for its entrepreneurial thinking
 - Government felt it had to make the inventions as broadly available as possible and only offered nonexclusive licenses
 - By trying to make the technology available to all, it often made it available to none
- Some inventions require an exclusive license if a commercial developer is to be interested
 - Licensee needs to protect high cost, high risk technologies from being exploited by its competitors
 - Example: it costs a drug company \$800MM and 10 or more years to bring a new drug to market
 - No company will make this investment if its competitors are free to access the same technology under a nonexclusive licensing program.
- Bayh-Dole Act passed 1980
 - Grants universities to the right to take title to their inventions made with federal money, in whole or in part, and to take responsibility for licensing the rights as they see fit
 - Options, non-exclusive, co-exclusive, exclusive licenses possible
 - Applies only to patents (not copyrights or tangible property)
 - Has vastly improved the flow of innovation to commercial developers for public benefit
 - Certain government obligations apply
 - University must disclose the invention to the government within 2 months of inventor's disclosure to university
 - University has up to 2 years in which to take title to invention. If it takes title:
 - Government gets a nonexclusive, worldwide, nontransferable, irrevocable, fully paid-up license to practice or have practiced the invention for or on behalf of the US government.
 - University may not assign title to a third party, except a patent management organization (i.e. companies cannot own university inventions made with federal money even if company funded some of the research)
 - Licensed developer agrees to substantially manufacture the product in the US
 - Must give licensing preference to small companies; if large company funded the research, can license to the large company
 - University must share license income with inventor(s)

- Government can require the university to grant a license to a third party if invention not being developed in a timely fashion

UNIVERSITIES CREATE MANY TYPES OF INTELLECTUAL PROPERTY (“IP”)

- Ideas, designs
- Methods, processes
- Compositions-of-matter
 - Gene sequences
 - Chemical compositions
- Tangible materials
 - Biologicals
 - Devices
 - Instruments
- Works of authorship
 - Software
 - Web content

MANY INVENTORS DO NOT OWN THEIR INVENTIONS – IN ORDER TO LICENSE THE RIGHTS TO THE INVENTION, ONE MUST FIRST IDENTIFY THE OWNER

- Employee agreements assign title to employer as a condition of employment
- Consulting agreements assign title to client
- Under California labor law, inventions that employees make on their own time using their own resources may still be owned by the employer if:
 - The invention falls under the employer’s business interests
 - The invention falls under the employer’s current or anticipated R&D activities
- Some third party agreements may require title to inventions to be assigned to that party
 - Some Material Transfer Agreements
 - Some sponsored research agreements with companies

PROTECTING IP GIVES THE OWNER CERTAIN RIGHTS TO CONTROL HOW THE IP IS USED BY OTHERS AND CREATES A POTENTIAL LICENSABLE ASSET

- Types of IP protection
 - Trade secret
 - Generally not suitable for university inventions; environment too open to maintain the requisite secrecy to afford protection sufficient to satisfy a licensee
 - Copyright
 - Patent

COPYRIGHT

- Protects: expression of ideas
- Rights: owner can bar others from copying, distributing, making derivative works of, performing in public or displaying in public the work of authorship
- Protection is free and automatic and occurs at the time the work of authorship is fixed in a tangible medium for expression.
 - Can register the copyright with Library of Congress (\$30 fee) and derive additional benefits if litigation occurs (if prevail in an infringement trial, can collect damages and attorney fees)
- Term of copyright

- ↗ For work owned by the author: author's life + 70 yrs.
 - ↗ If made as a work-for-hire:
 - 95 yrs. from the date of publication
 - 125 yrs. from the date work was fixed in a tangible medium
- Fair use exemptions apply, but can be tricky. Seek legal advice before invoking.

PATENTS

- Protects: ideas
- Rights: owner can bar others from making, using, selling or importing the invention
- To qualify for a patent, the invention must be useful, novel, and nonobvious to others skilled in the art
- Term: 20 yrs. from filing date
- Certain actions by the inventor can result in loss of patent rights if a patent application has not first been filed
 - ↗ Public disclosure of invention
 - ↗ Offer for sale of invention
 - ↗ Public use of invention (research use exempt)
- Any one of these actions results in immediate loss of foreign rights, and loss of U.S. rights after one year
- Inventorship is a matter of law based on the claims that define the invention
 - ↗ Authors on a paper may not meet the legal requirements of inventorship if their contribution is not contained in one or more invention claims
 - ↗ Not having the proper inventors on the patent application can cause delays or result in the invalidation of the patent
- Who gets the patent?
 - ↗ U.S. – first-to-invent as shown by dated records (i.e. properly kept lab notebooks)
 - ↗ Rest of world – first-to-file the patent application with the patent office
- Protection is expensive: a patent, over its lifetime can cost:
 - ↗ U.S.: ~ \$25K
 - ↗ Foreign: ~ \$125K –250K
- Protection is unpredictable
 - ↗ Getting a patent is a negotiation with a patent examiner
 - ↗ Patent office might reject the patent claims; no patent issues, money lost
 - ↗ Allowed claims may be different from what was originally requested but are better than nothing
- Takes several years to issue (if at all); patent application will be published 18 months after the priority date before any claims are allowed (exceptions can apply)
 - ↗ In the meantime, others are free to commercially exploit the invention based on inventor's publications or presentations
 - ↗ A patent provides protection when it issues; some provisional rights accrue from the published patent application making it possible to get damages for infringement of the published patent application if certain conditions are met
 - The patent application must have issued
 - The infringer must have been aware of the published patent application
 - The infringed claim in the patent application must be the same as an issued claim
- Not all issued patents are valid
 - ↗ The only real test of patent validity is when a patent is challenged in a court of law

IT'S THE LICENSE THAT COUNTS!

- The objective of the technology transfer office is not to file patent applications for the sake of filing patent applications or appeasing inventors, but is to identify promising business opportunities for commercial development and put them in the hands of commercial developers so that the public that funded the invention may one day benefit from the technology and feel inclined to continue to fund academic research in the future
- Although much life science technology may very well be patentable, not all IP eligible for patent protection is licensable (i.e. affords value to a commercial developer)
 - Too early stage – more research needed before a company will be interested
 - Poor patent claims – too narrow to provide a competitive advantage or are unenforceable because it is difficult or impossible to identify infringers
 - Insufficient market or poor market dynamics
 - Product not sufficiently differentiated from competing technologies
 - Problems with manufacturing
- Clever science is not enough. The IP must:
 - Represent an attractive business and market opportunity
 - Afford a competitive advantage for the licensee
- The technology transfer office is therefore like any other investor that seeks a return on its investment. Investing in a patent application that is not licensable is a bad business decision and costs the university money that could have been better spent on research and education.

TIMING IS EVERYTHING

- The best time for an inventor to alert the licensing office about the invention is as soon as the invention is in hand and before the inventor begins writing the scientific manuscript for publication
 - The licensing office requires significant time (often months) to fully evaluate the invention and its licensability, and to develop and implement a management strategy that maximizes the value of the invention
 - Disclosing the invention to the licensing office at the last minute prior to public disclosure robs the licensing office of the time it needs to do its job well and means that any management decisions the office makes concerning the invention will be based on incomplete information and be more prone to error
- Work in partnership with the licensing office, and not at cross purposes with it; give the office the lead time it needs to do a thorough job. This lead time can translate into lead time for the licensee which can have significant impact on the value of the license.
 - Companies know academic researchers will rapidly publish their inventions and the licensee values getting access to the invention before its competition gets it from the literature.

PATENTING VS. MARKETING - WHICH COMES FIRST?

- High cost of patent protection means universities will generally file patent applications after they have found a licensee who will reimburse patent costs.
- Filing a patent application “at risk” (i.e. with no licensee in hand or in sight) can create significant financial exposure for the university

- ↗ Unreimbursed patent costs create a loss for the licensing office which is expected to make, not lose, money for the campus
 - ↗ Filing a patent application on an invention that the market does not want (i.e. for which there is no licensee either now or in the future) means that money that could have been spent on research and education is wasted on a bad investment.
- Waiting to file a patent application until after a licensee has been found has several additional advantages
 - ↗ The licensee can help write the patent application so that it gets the maximum protection for its specific business needs
 - ↗ The university gets maximum value from the license because the patent rights are developed in a way that is most important to the specific licensee
- Also, companies and universities have different objectives when it comes to filing patent applications
 - ↗ The company is in the business of building shareholder value
 - Failing to file a patent application on an invention puts its business at risk and at the mercy of its competition
 - ↗ The university is in the business of creating new knowledge and sharing it with others
 - Failing to file a patent application does not put its business at risk but can result in a lost business opportunity
 - Such lost opportunities are not often great considering:
 - ~ 98% of disclosed inventions earn less than \$100K/year, and most, substantially less and ~80% earn less than \$10K/year.
 - The net license income of even a highly successful university licensing office is only a few percent (i.e. low single digit) of the campus operating budget
- Nonetheless, “at risk” filings can occur under those circumstances where the risk is deemed acceptable in light of the business opportunity and competitive advantage the invention affords

COURTING AND CLOSING ON THE LICENSEE

- First market the technology nonconfidentially (to preserve patent rights)
- Negotiate secrecy agreements with parties expressing interest in getting confidential information about the invention
- Disclose confidential information under the secrecy agreement (to protect patent rights)
- As needed, provide material for testing using a Material Transfer Agreement
- Negotiate Letter of Intent for the license
 - ↗ University agrees to negotiate exclusively with the prospective licensee for a license for a certain period of time
 - ↗ Prospective licensee agrees to pay all patent costs incurred
- Commence patent work with outside patent counsel with input from the prospective licensee for maximum value to licensee (and therefore to the university)
- Commence license negotiations
 - ↗ First negotiate a Term Sheet, containing the principal license terms (1-3 pages)
 - ↗ Then draft an agreement containing these and other terms
- Complete the license negotiations via several rounds of revisions to the license document, with input from legal counsel on both sides

VALUATION – PRICING THE TECHNOLOGY

- Various models apply
 - Replacement value
 - What it cost to invent the technology
 - Market value
 - Compare to a similar technology at a similar stage of development that has been licensed and apply those financial terms (if that information is available)
 - Discounted cash flow analysis (a.k.a. net present value)
 - Estimated future value is discounted back to present time by adjusting for the risks associated with the technology's development to arrive at today's value
- Factors that influence technology value
 - Is the invention a seminal one that might create a new market or is it a "me-too" invention that simply allows the licensee to compete for market share?
 - Is the patent dominant or will it be dominated? Breadth of patent claims.
 - Are the patent claims enforceable? Not all inventions leave a "footprint", making it hard for a licensee to detect infringers and enforce the patent rights it paid to license.
 - How many years are left in the life of the patent?
 - Market size?
 - Market dynamics - growing, static, declining?
 - Potential market penetration?
 - Competitive products? The value of a new drug for an infectious disease could be diminished if there is a vaccine on the horizon.
 - Does the technology address a regulated market? (i.e. orphan drug status; does the competition have to get regulatory approval to market a competing product in which case the first company to get approval sets the bar for the competition in the eyes of the regulatory agencies)
 - Perceived value to the licensee's business; what might be very important to one company's business might be less important to another's and they pay accordingly. "Must-have" vs. "Nice-to-have".
 - What can the licensee afford to pay?
 - How many other technologies must the licensee pay to in-license in order to fully develop the invention? Royalty stacking may apply.
 - What stage is the technology? Early stage, high risk, high development cost vs. later stage, lower risk, less time to market.
 - Scope of license: exclusive, nonexclusive, co-exclusive? Field of use: world wide for all possible uses or limited to certain applications and/or certain geographical regions.
 - What "lead time" (head start over the competition), if any, does the licensee get as a result of taking a license, given that academic investigators rapidly publish their work and anyone can exploit it because the patent will not issue until well after the publication and affords no protection in the meantime?

THE LICENSE

- Is an important driver of value creation; provides an orderly means for technology transfer
- Owner grants permission to another party to use the property that belongs to the owner for a specified purpose and period of time

- This grant often contains a multiplicity of terms and conditions, including paying fair compensation to the owner for permission to use the technology for financial gain
- Typical license terms and conditions can include:
 - Definition of the patent rights to be licensed
 - Field of use – unlimited or restricted by application and/or geography
 - Duration of use – term of license (usually the life of the last-to-expire patent)
 - License grant - option, nonexclusive, co-exclusive, exclusive
 - Licensee to pay all patent costs
 - License issue fee
 - Annual license maintenance fee
 - Product development milestone payments
 - Minimum annual royalty
 - Earned royalty (percent of net sales of product)
 - Diligence provisions – company cannot “sit” on the technology; must advance it
 - Requirement for progress reports
 - Sublicense provisions and associated income
 - Limited warranty – university only warrants it has the right to grant the license and nothing more. It does not warrant the technology works, is good for anything or will not infringe someone else’s IP rights
 - Indemnification/liability – the university accepts no liability if damages or claims result from the technology, including product liability claims
 - Use of name - cannot use The Regents’ name for promotional purposes because it is property of the State of California
 - Infringement – the university does not want to be drawn into a lawsuit against its will if someone infringes the patent rights
 - Applicable law should problems arise (which state has jurisdiction?)
 - Preference for production of the product in the US for exclusive licenses
 - Termination provisions so the parties can exit their relationship if necessary
- An exclusive license document may be around 20-25 pages.

SOME COMMON LICENSING SITUATIONS

- Licensing to the Start-Up vs. BigCo
 - BigCos like to minimize paying royalties on net sales
 - Are large infrastructures with huge operating costs and do not like to share product sale income with licensors
 - Are generally well capitalized and prefer to pay upfront with cash in order to minimize royalty obligation. In this way they conserve sales revenue to fund their extensive operations and drive shareholder value
 - Start-Ups are cash-poor and like to avoid paying cash upfront and early on
 - The cash they have is expensive venture capital that is best spent on adding value to the licensed technology and not on license fees
 - Are more inclined to offer equity or an equity equivalent in lieu of some of the cash normally paid
- New ventures: the chicken vs. the egg
 - The problem
 - How to raise money without a license to the enabling technology?
 - Investors will not put money into a new company that has not established a proprietary position by in-licensing seminal technology

- How to obtain a license for the enabling technology without money?
 - The university has an obligation to the public to get fair consideration for publicly funded inventions and does not give its inventions away
- ↗ Some solutions
 - The Letter of Intent
 - The university agrees to negotiate exclusively with the new venture for the technology for a specified period of time, thereby giving the new venture a claim on the technology for a limited time, in return for paying patent costs at a future date, so that it can raise money.
 - A conditional license
 - The university issues a license to the new venture with an “affordable” license issue fee
 - The license obligates the founders to raise a certain amount of money by a certain time and to pay the balance of money that would be owed under a normal license when the financing closes
 - Failure to meet the financing requirement is grounds for termination that frees the university to license to another party.
- Drug discovery targets
 - ↗ It does not always make sense to file a patent application on a drug discovery target because companies often do not need a license to legally practice the invention
 - Academic investigators rapidly publish their work which appears in the public domain well before the corresponding patent issues and bars use of the target
 - Companies can develop a drug screen based on the publication, screen their libraries, find hits, and develop leads before the patent covering the target issues, and thereby have no need to license the patent rights because they have no need for the license