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*Understanding the business development opportunity in  
Healthcare / Life Science.*

## **INTELLECTUAL PROPERTY LICENSING STRATEGY AND EXECUTION – Basics for Business Development**

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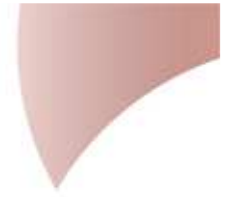
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# Intellectual Property Strategy and Execution

## – Get it right



- **IP principles and concepts for Business Development**
- **Best practice and pitfalls – what to avoid**
  - Five **Deadly** Sins of Patents (amongst others)
- **Uncovering Freedom to Operate (FTO)**
- **Patent licensing concepts**
- **Q&A**

# Mismatch Between IP and Business Model



Creates Tombstones

# A Fit Creates Sound Business



The  
Execution

The Products

The Revenue Model

The IPR



# IPRs Play a Vital Role in Creating Business with High Potential

## Legal

Foundations to build upon

Ability to block competition

Licensing/cross-licensing opportunities

## Business

Unique products

Higher pricing

Lead time advantage

Bigger market share/higher revenues

# What can you do with a Patent?

- A patent is an item of (intellectual) **property** - with a patent you may:
  - **Manufacture and sell** the patented invention **yourself**
  - **Sell or assign** all or part of your rights to the patent
  - **License** the patent to someone else which allows them to exploit it for a set price or royalties (or both) and for a set time

# What is a Patent?

- *A legal right to property.* It is intangible, but very real property right

| Commercial activity   | Your CAR    | A PATENT                                    |
|---|-------------|---|
| Sell to another party?  | Yes (sale)  | Yes (assignment)                            |
| Allow another party to use but not own in exchange for value? | Yes (lease) | Yes (licence)<br>Exclusive or non-exclusive |

- A granted patent gives the owner (*patentee*) a **negative right to exclude** others for 20 yrs from first filing date
  - Scope of right defined by patent claims (“picket fence”)

# Patent Strategy

## - building coherent portfolios

- The **importance of patent portfolios** to the small start-up
  - to protect the **intellectual capital** of a company
  - to defend against **competition**
  - in raising **finance**
- Use in forming research and development partnerships
  - “pre-agreement” discussions of patent applications **safer** – subject matter and ownership crystallised
  - in-licensed “Academic” patents can be **packaged** with out-sourced **research** for SMEs and royalties for the Institute
  - out-licensed “SME” patents to other SMEs and “BigPharma” can **share R&D costs and risks** en route to market and royalties
- Use in securing “know-how” assets in recognisable and reassuring form
  - to **attract investors** – portfolios and IP awareness attractive
  - to **demonstrate ownership** and scope of protection of technology to potential partners



# Five Deadly Sins of Patents

1. Publishing before considering a patent filing  
Publications can kill patenting options
2. Publishing/speculating wider than your first patent filing before filing International (PCT) application  
1<sup>st</sup> patent: invention A → Publication A\* or A+B → PCT can't protect A\* or A+B
3. **Naming every contributor as an inventor**  
**Authors ≠ Inventors**
4. **Making assumptions about invention/patent ownership**  
**Chain of title, chain of title, chain of title, chain of title, chain of title...**
5. I have patented my invention so I have Freedom to Operate!  
Not if someone else's patent(s) cover key elements or a generalized version of your product/process

# "I am an author on the paper... ... why am I not an inventor?"

- 'Author' and 'Inventor' not synonymous
- Authors write or contribute to writing a particular work. In science = designing or performing experiments or in writing the resulting manuscripts, recognition of hard work or even for financial support
- Inventors have to be legally determined according to patent law, by their **involvement in the original conception of the invention** – not just pairs of hands following instructions or the head of the relevant department!
- Rules differ from country to country
- Erroneously identified “inventors” not actually involved in the conception of an invention, or an omitted inventor, may have serious consequences
- In the extreme, such mistakes can result in the patent being invalidated

# Big Problems When Inventors Not Named

- Un-named inventors
  - May question patent validity
  - Ask for re-examination of patent
  - May assign rights to third parties without notifying co-owners (e.g. USA)
- = Headaches for your Co. and will make potential investors walk away

## Questions You Need to Ask

- Does inventor have a prior employment contract?
- Does she have a prior consulting agreement?
- Is there an obligation to assign a patent to a funding agency?
- Chain of title, chain of title, chain of title...
- Role of the TTO is to investigate all of this for university-owned technologies

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# Dominating Patents (Freedom to Operate?)

- Your company:
  - **US Claim 1:** A method for treating an infection comprising administering a therapeutically effective amount of Drug X to treat the infection
  - **EP Claim 1:** Drug X for use as an anti-infection medicament
- Your Competitor:
  - **US Claim 1:** A compound (Drug X) having the following structure: [chemical formula]

## FTO Issue - What to do?

- Easy but worse solution: ignore and hope it goes away
- Invalidate competitor patent (hard/costly)
  - Presumption of validity
  - Reexamination possible
  - Attempt to invalidate if sued
- Is your competitor a partner in disguise? Get licence from competitor to use Drug X (maybe easy or not)

# Uncovering Freedom to Operate: - considerations for the small biotech

- **Freedom to Operate: Analyse - Dealing with “problem” patent documents:**
- Assess **countries** covered to assess impact
- What is the **status**?
  - **Granted patent?**
  - Current / **likely claim scope?**
  - **Speak to your attorney!**
- What is **claimed**?
  - **Infringement opinion** advisable
  - **Speak to your attorney!**
- If it appears you **infringe**, is the patent **valid**?
  - **Speak to your attorney!**



# Uncovering Freedom to Operate: - considerations for the small biotech

- **Problem Patent? - Decide on Action (beware of expense)**
  - *THINK! : POSSIBLE PARTNER???*
  - Where?
  - Opposition?
  - Re-examination?
  - Revocation?
  - Attack patent on key process with any prior art to hand?
  - Attack all possible restrictive patents where killer prior art can be found?
  - Buy patent/patentee?
  - In/cross – license?
  - Stop potentially infringing activity...?

# Patent Licensing Concepts

- University wishes to spin-out a new company (NEWCO)
- NEWCO will commercialize the invention(s)
- University owns the technology NEWCO needs
- How to access it?
  - Licence

# What Is a Licence?

- Patent Licence: Agreement by ***Licensor*** not to sue ***Licensee*** in court for value, generally money in form of:
  - **Up-front payment**
  - **Revenue stream (royalty payment)**
- Patent Sale: Transfer all rights in the patent for value
  - Document is called an *Assignment*
- Licence (private) v. Assignment (often public)
  - Patent assignments available on USPTO and other patent office websites (where registered)

## To Sell or License?

- It depends...on the transaction
- Sale is transfer of all rights in one, several or all territories
  - **Assignor** transfers/assigns/conveys ownership to another (*Assignee*)
  - Simple transaction
- Licence- *Licensor* can transfer different rights in patent to the same (exclusive) or different *Licensees* (non-exclusive) in different *Fields* and *Territories*
- Licensor retains ownership
  - Flexible, lucrative (“multiple bites at the same apple”)

## Licence “must haves”

- Licence grant should address the right to:
  - “make, have made, use, sell, offer for sale, and import”
  - Patents and know-how
  - Exclusivity
  - Non-exclusivity
  - Field
  - What Licensee can do, not do
  - Territory
  - Can Sublicense be granted?

# NEWCO Needs A Technology Licence

- University owns valuable technology and “Newco” needs a Licence to commercialize
- Other examples:
  - Inventor makes an invention at University lab and wants to “in-license” his own technology for a startup
  - Established companies may ask University for a licence to access new technologies.
  - Why not ask University for an assignment of rights?

## Financial Terms

- Financial terms to consider:
  - Signing or licence initiation fee
  - Annual maintenance fee
  - Up-front payments vs. stock (e.g, 5%)
  - Royalties
    - 1-5% on sales (drug)
    - <5% (diagnostics, methods)
  - University should seek about 20-25% of profits
  - Milestone payments: patent grant, clinical success
  - Patent expenses
  - Sublicence income

# Thank You

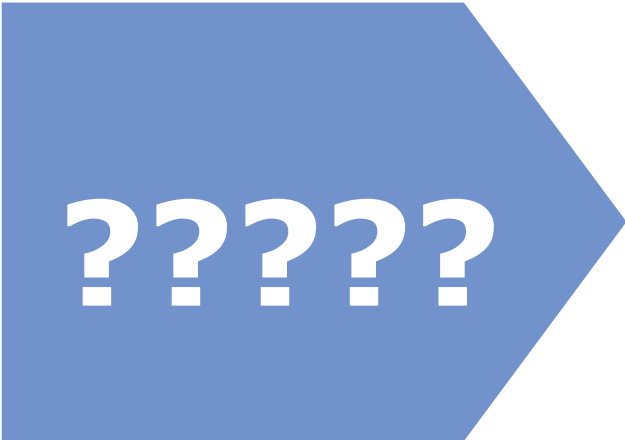


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## Q&A – Intellectual Property Licensing Strategy and Execution