UNIVERSITY OF MINNESOTA
Driven to Discover℠

Office for Technology Commercialization

"How to not kill your invention"

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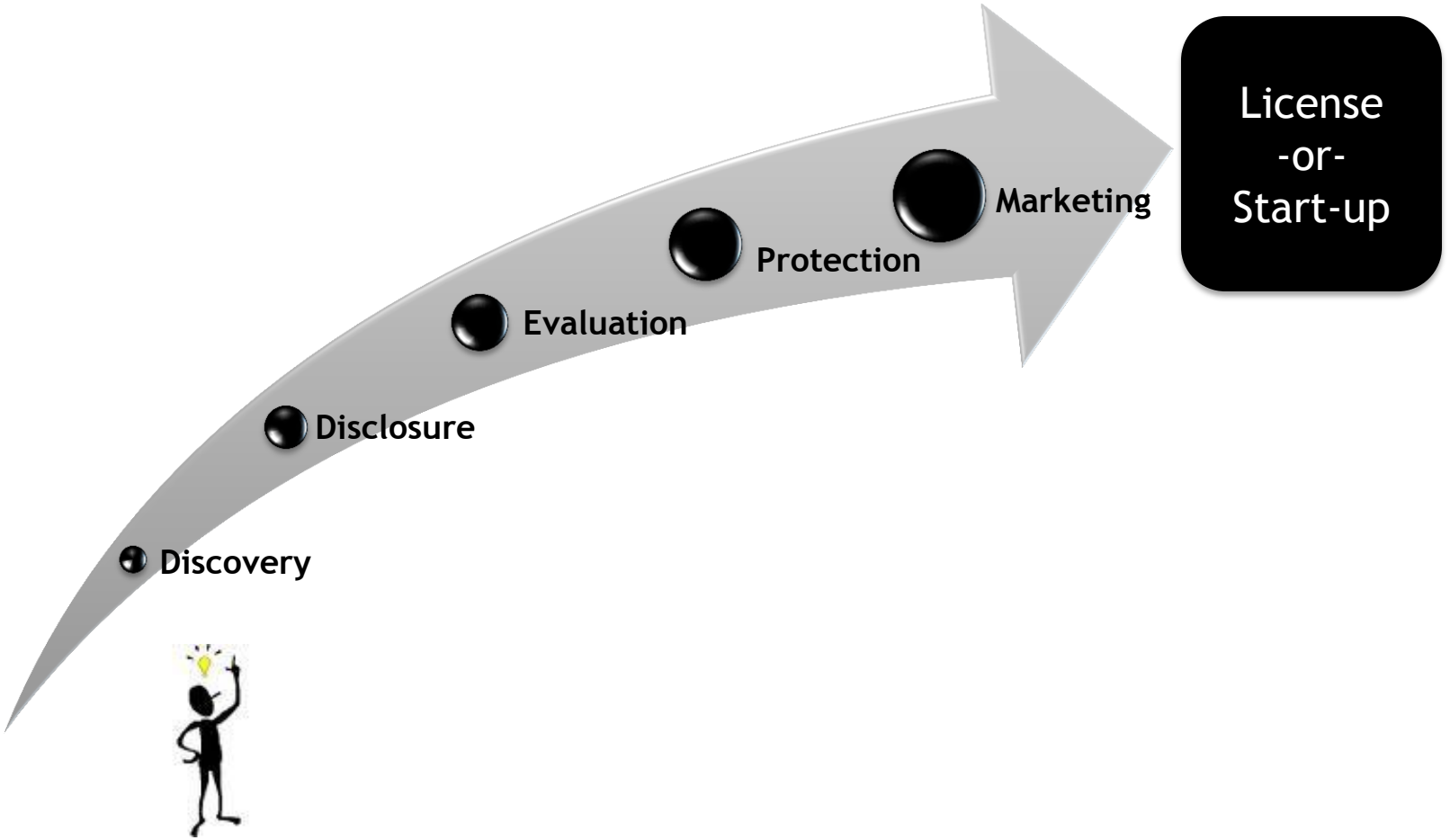
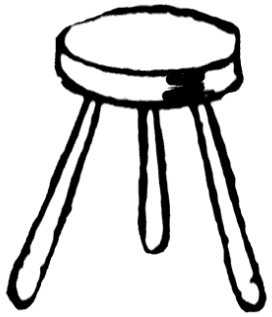
Learning Objectives

- Understanding “technology commercialization”
- How to protect your intellectual property
- Importance of protecting intellectual property
- Challenges unique to academic technology development

Generic Commercialization Process



Technology Evaluation



Strength of Invention:
- What problem is solved?
- Is there a technical advantage?
- Easy to work around?
- Additional work required?
- Enough funding to complete?
- Leader in the field?

Commercial Potential:
- Who are the customers?
- Addresses an unmet need?
- How big is the market?
- Competing technologies?
- Expected time to market?
- Dominating IP?
- Supportive VOC?
- Third-party strings?
- Commercial interest?

*Patentability:
- Surprising and unexpected results?
- Novel/Non-obvious?
- Discovery or invention?
- Public disclosures?
- Patent landscape?
- Publication landscape?

***In consultation with a patent attorney.**

Strength of Invention	+	−	+	+
Commercial Potential	+	+	−	+
Protectable	+	+	+	−

Discuss with inventor/attorney/VOC

↓

Can we overcome the obstacle?

YES → • Pursue Patent
• Begin Marketing

NO

↓

CLOSE

How to protect IP

Trade secret

- Just don’t tell anyone about your IP!
- Only works when the entire flow of information is controlled.
- Does not work in academia.
- There is always a risk of losing confidentiality and reverse-engineering by competitors.

Copyright

Protects idea fixed in a tangible medium of expression

- Examples – music scores, books, photographs, recordings, software, art works, movies, etc.

Must be original and have at least minimal creativity

Copyright begins automatically, but registration with the US government gives additional rights and protections.

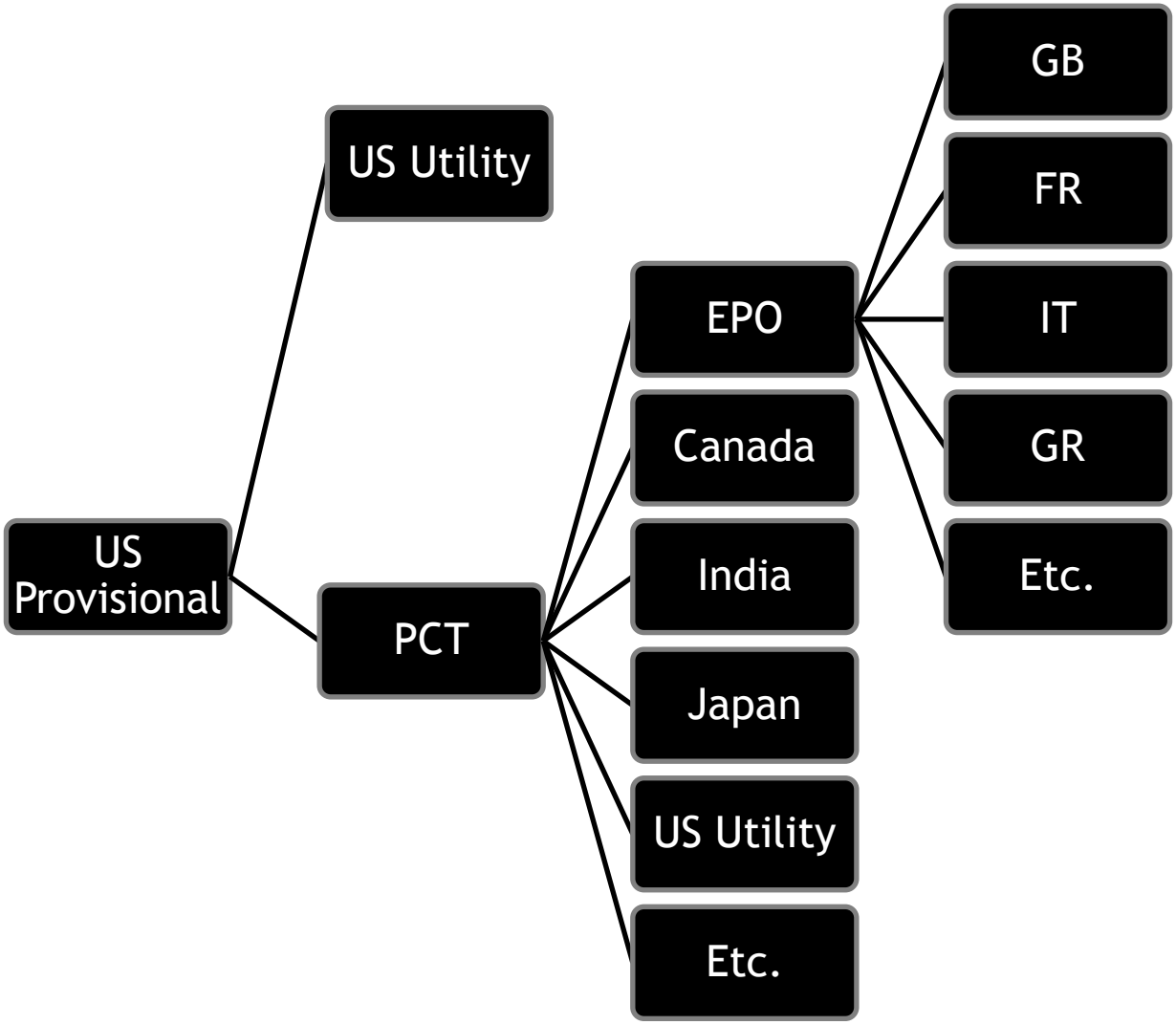
Trademarks

- Symbols, names, images and designs used in commerce
- Protection begins automatically with its use, but to fully secure its protection, it must be registered with the USPTO.
- ™ vs ®
  - TM indicates intent to register
  - ® after trademark has been registered

Patent Basics

Patents

- Protects processes, machines, articles of manufacture, inventions, etc.
- Property rights granted by a government to exclude others from making, using, offering for sale, selling or importing the invention.
- Patents expire 20 years after initial filing.
- It can take 2-10 years to get an allowed patent.


US Provisional
US Utility
PCT
EPO
Canada
India
Japan
US Utility
Etc.
GB
FR
IT
GR
Etc.
1 Year
2.5 Years

- Patent protection is expensive:
  - ~$1-10,000+ (Initial U.S. application)
  - ~$25-50,000+ (U.S. lifetime cost)
  - “Hundreds of thousands” to “millions” for global rights

- The U has limited resources, so not all technologies can be patented.

Inventions must meet these criteria:

- **Demonstrate utility**
  - They must have a use and benefit mankind
- **Have novelty**
  - They must not have been previously known publicly
- **Be non-obvious**
  - The invention must not be obvious to anyone "skilled in the art" & exhibit "surprising and unexpected" results
- **Enabled**
  - The invention has to work and do what you claim it does

"Non-obvious" versus "Novelty"

The technology:

- People have been using Drug-X for years to kill flies, ants, and mosquitoes.
- Our researcher has determined for the first time that Drug-X also kills beetles.

Is this technology:

- **Novel** – "Yes" because no one has ever killed beetles w/ Drug-X.
- Is it **non-obvious** – "No" it worked on every other kind of bug tested, so why not beetles.
- Is it **patentable**?

Probably not:

- It would be "obvious" for someone to test Drug-X on beetles, given its track record with other bugs.
- So it is not "surprising and unexpected" that Drug-X works on beetles too.

"First to invent" versus "First to file"

- Prior to **March 2013**:
  - The US was a "First to invent" country, while the rest of the world was "First to file".

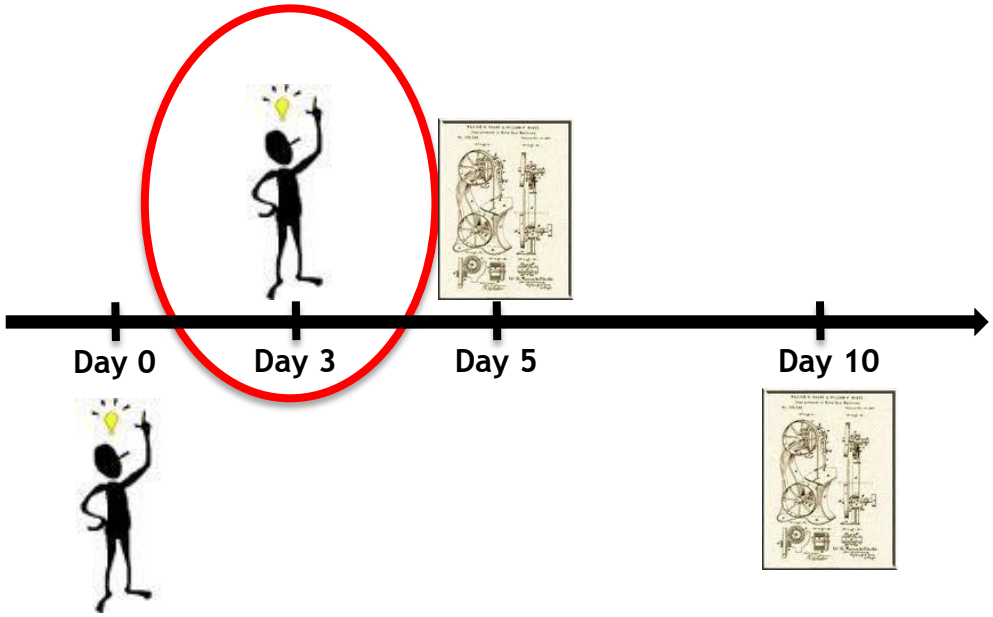
- After **March 2013**:
  - The US became a "First to file" country.

- This change harmonized the US with the rest of the world in some ways, but we still have some quirky provisions.

Under the new "first to file" rules…who gets the patent?

Inventor A

Inventor B

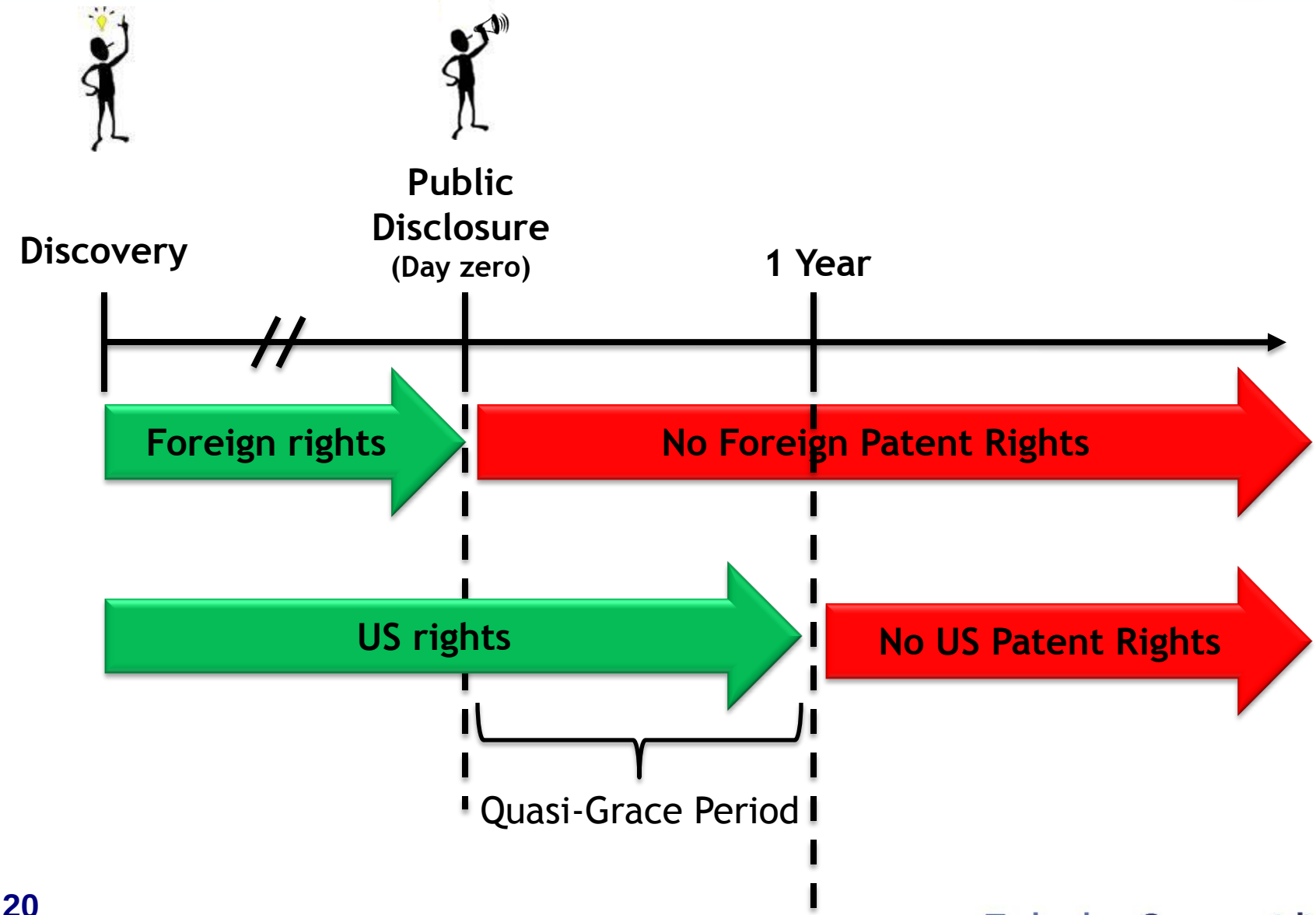


Quickest way to kill your IP?

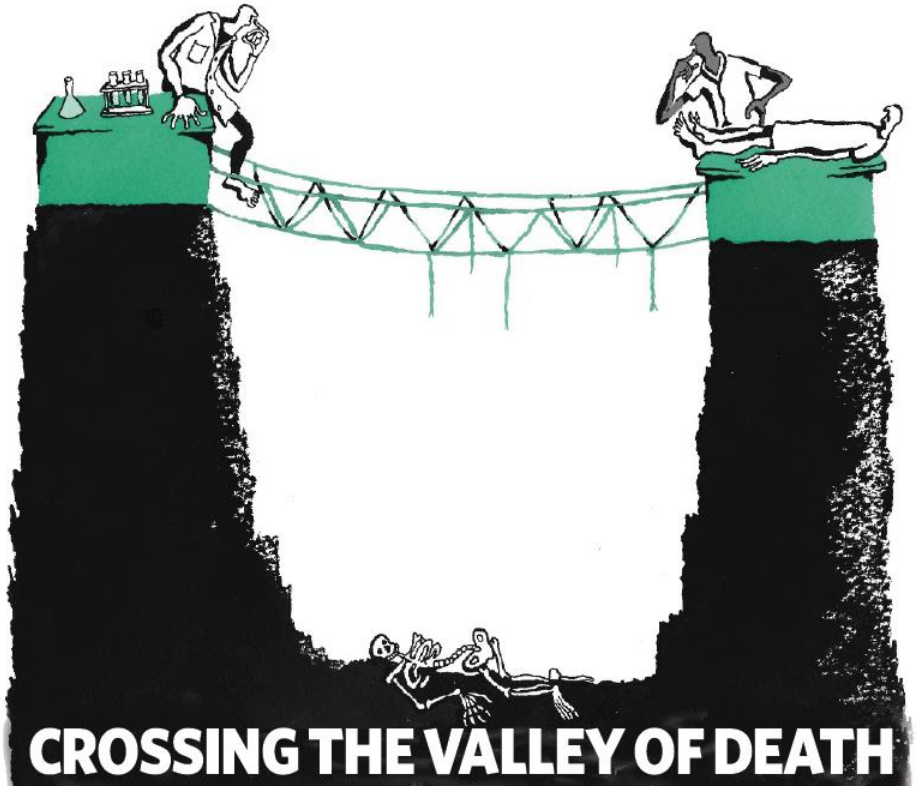
"Publicly disclose it"

• Class presentations • Posting on Facebook • Information on non-secure websites • Telling people about your invention • Publications • Sharing data with collaborators • Poster presentations	• Research talks at meetings • Graduate theses • Department Seminars • Info from awarded grants • Technical updates for grants • Talking to company without a CDA • Research Abstracts

Why is this important?


Discovery
Public Disclosure
(Day zero)
1 Year
Foreign rights
No Foreign Patent Rights
US rights
No US Patent Rights
Quasi-Grace Period

Tech commercialization in academia



Why academic technologies fail

Too early:

1. Preliminary data only
2. Discovery ≠ invention
3. No funding to conduct further research

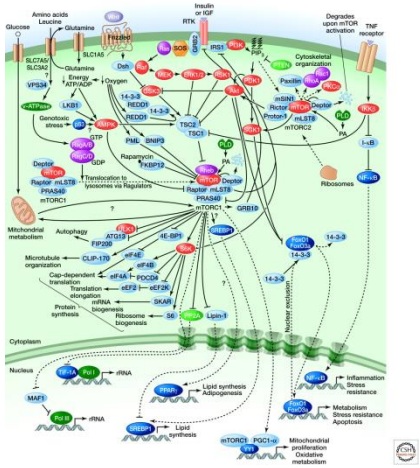
Weak IP:

1. Tech is only an incremental improvement
2. "Method only" patent claims
3. IP damaged by public disclosures
4. Severe obviousness hurdles
5. Mechanism of action discovery

Weak market potential:

1. End "product" is not clearly defined
2. Market doesn't exist
3. Lack of commercial interest

Discovery ≠ Invention



Technology disclosure

- Discovered that PT5 is a negative regulator of the mTOR signaling pathway.

The researcher wants to patent the following:

- Use of PT5 as a biomarker for cancer
- Drugs that modulate the activity of PT5

What is patentable?

- Nothing.
- This is a discovery of a natural process, but not an invention.
- The researcher has not demonstrated PT5 is a cancer biomarker.
- The researcher has no data showing PT5 is a viable drug target, nor has identified any drug candidates.

Next steps

- Suggested to the inventor –
  - Determine if the presence of PT5 levels correlate with the presence of cancer or its progression/outcome.
  - Seek experts within the U to help with drug screening.

Early discovery – not yet enabled

Technology disclosure

- A professor has an idea to treat bacterial infections of the lung by the inhalation of “drug-X”.

What the inventors want to patent

- The use of “drug-X” for the treatment of lung infections.

What is patentable?

- Nothing at this point.
- No data has yet been created.
- The patent office requires “enablement” of technologies.

Next steps

- Recommend the inventor test his/her hypothesis and generate data.

"Discovery" versus "Invention"

Here is what we know:

- Drug-X has been used to kill bugs for 20 years, but nobody knows how it works.
- Our researcher has determined that Drug-X works by destroying protein-Y (pY).

What is patentable?

- Nothing.
- Drug-X was destroying pY long before we knew how it worked ("inherency").
- Just because the researcher figured out the mechanism of action doesn't mean he/she can block others from now using Drug-X to kill bugs.

How to make this into an invention:

- Create novel analogs of Drug-X that have better activity.
- Use the protein structure of pY to logically create a new family of drugs.
- Develop drugs that target other proteins in the same pathway as pY.
- Create a novel formulation for that is better at delivering Drug-X.
- Etc., etc., etc.

The commercial realities of academic tech development

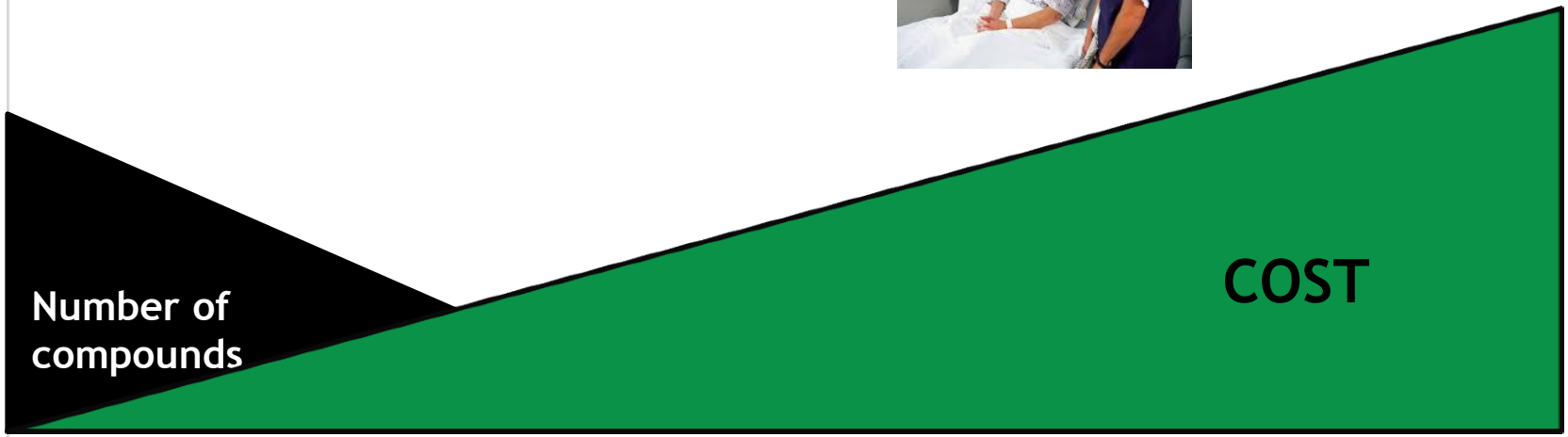
Example - Drug development

Research → Preclinical → Phase I Clinical → Phase II Clinical → Phase III Clinical → FDA Approval → Product Launch → Profit

Biochemical and cell-based testing

Animal Testing

Human Testing



The reality of drug development

	Preclinical	Phase I	Phase 2	Phase 3
Risk of failure	>95%	88%	83%	62%
Cost	$1-10M	$32M	$40M	$113M
Time (months)	37	22	26	31

Sources: US Bureau of Economics – Federal Trade Commission - July 7th, 2003; Health Affairs25(2) 420-428, 2006.

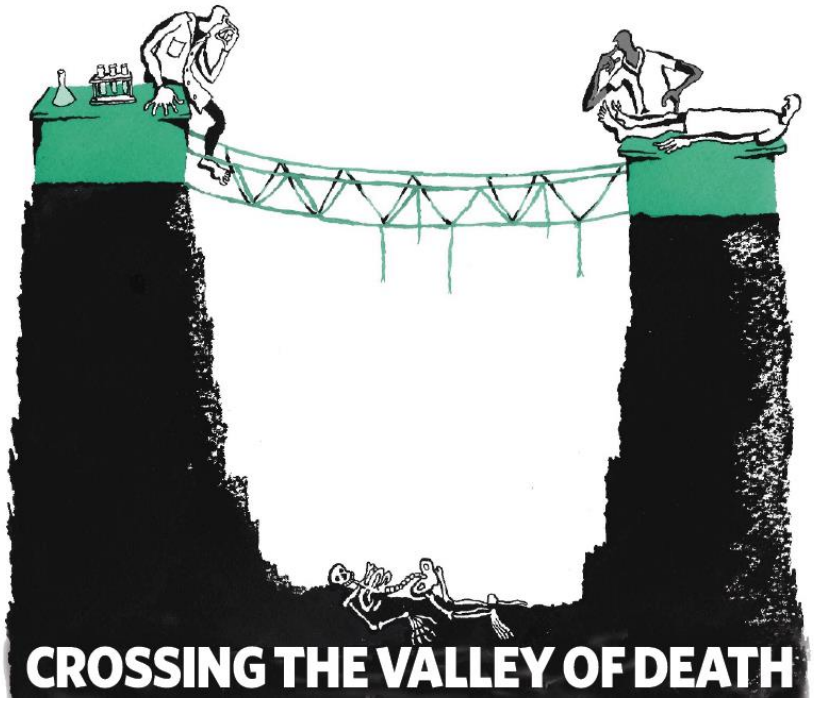
Drug companies get their new drugs from one of two places:

1. INTERNAL - They have their own research and development groups.
2. EXTERNAL - They "in-license" IP from others (or buy the company).

If you were a drug company, when would you want to in-license a drug candidate?

a) Preclinical
b) Phase I
c) Phase II
d) Phase III

Under today's terms biotech companies naturally prefer late-stage deals . . .

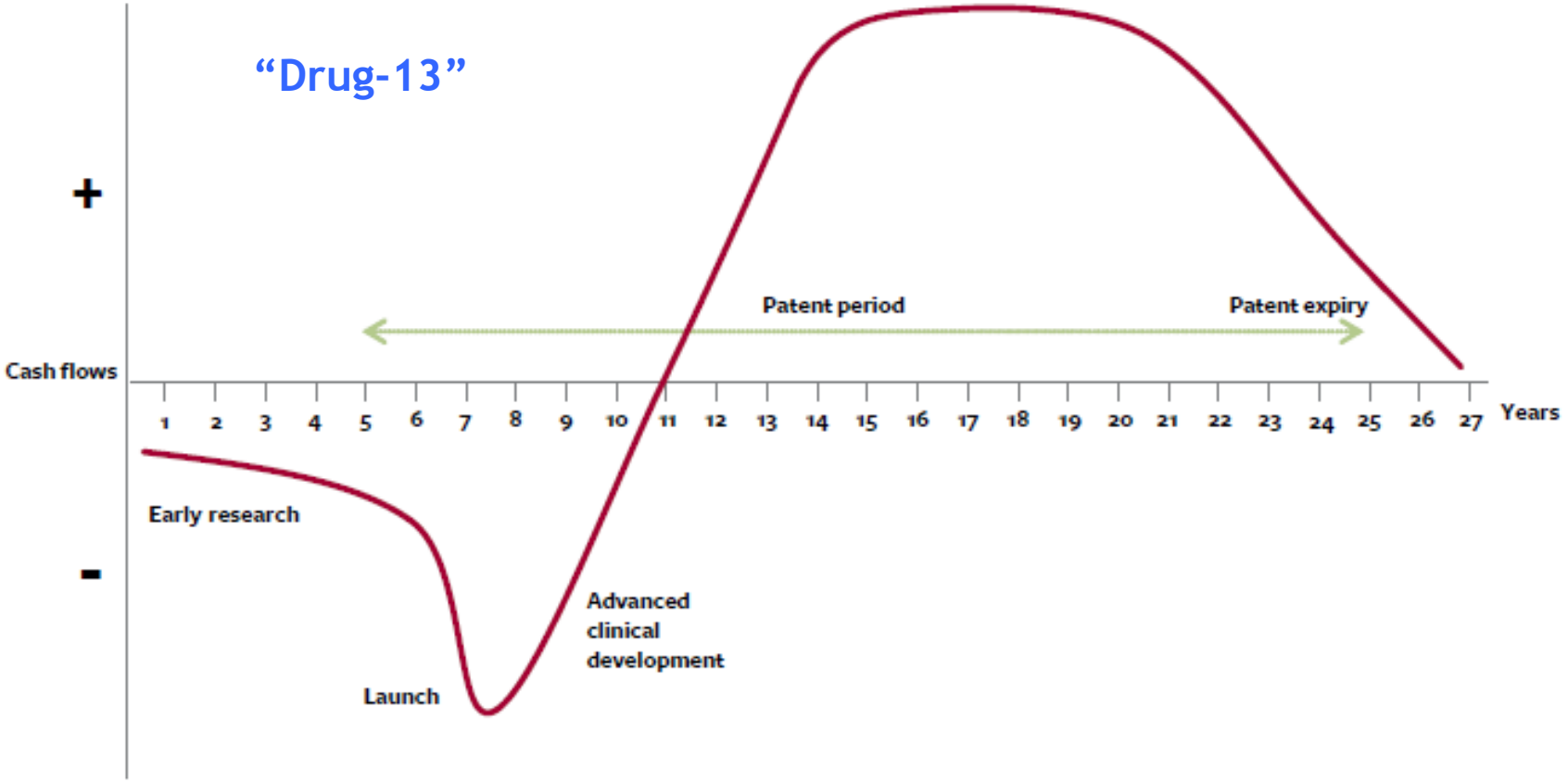


Companies want this…

…but academia is usually here!

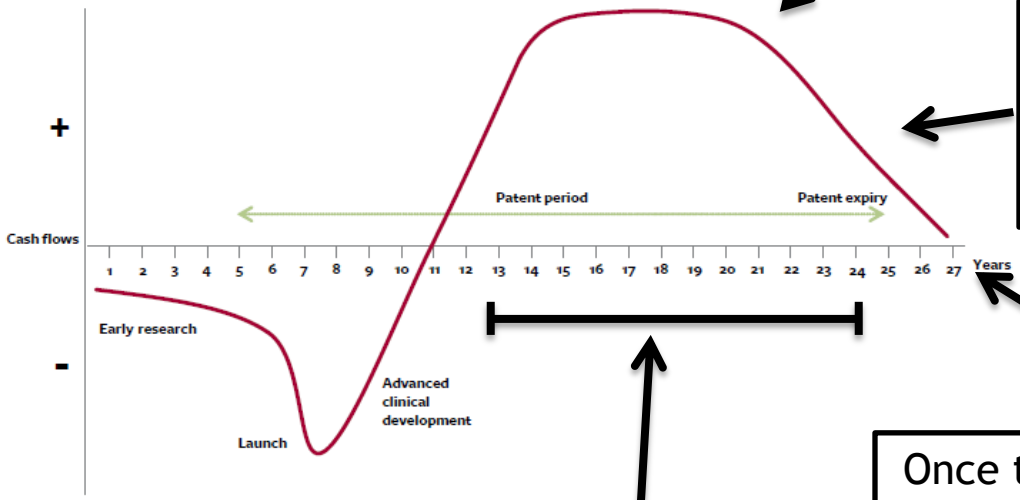
Note: This figure is based on the licenses that the top 12 pharma companies negotiated from 1991-2002 – The "THE McKINSEY QUARTERLY" 2002 NUMBER 4

Drug development lifecycle from a cash flow perspective



"Drug Development - valuing the pipeline" - Mayer Brown, LLP - March 2009

All of this revenue has to cover the development costs of Drug-13, as well as the costs associated with previous failures (Drugs 1-12).



Protection can be increased via things such as "extended release" formulas and seeking orphan indications.

Once the patent expires - generics and other competition will erode the revenue.

By the time the drug hits the market there may only be ~10-12 years of patent life to recoup the costs.

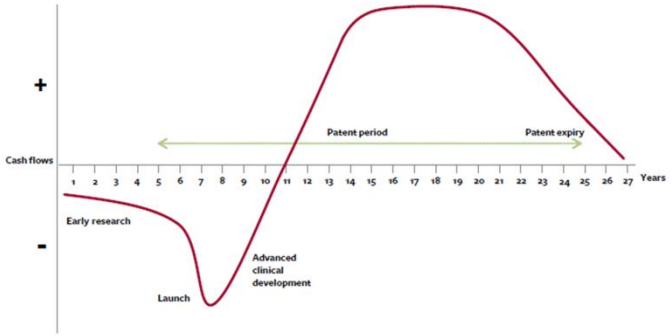
Another hurdle…early patenting

5 years

In academia we need to publish, write grants, collaborate with colleagues, etc. which requires us to patent much earlier!

Companies can wait a long time to file a patent because they can control the public disclosure of their materials.

Patent Timing Impacts Revenue



Total Sales ($Millions)

Date of drug discovery	Date of patent filing	Date of drug approval	Years 10-15	Years 15-20	Years 20-25	Total Sales	Net Return*
2000	2000	2015	$100	$450	$50	$600	-$200

* Assumes development costs of $800M

How can we cross the valley?

- Secure large government grants –
- University funded clinical research –
- Sponsored research –
- Private donors –
- Work on “orphan diseases” -
- License to small biotech companies that are less risk adverse -

Commercialization – tips and best practices

Engage with your TTO early

- We can work with a emerging/developing IP, but we can't do much with IP that is already publicly disclosed – earlier is better than later.
- It is our job to help educate you on commercialization, so don't worry if you are completely "green"!

Get in the drivers seat!

- Each TTO has hundreds of tech's it must manage, they can't give each one extensive attention or financial support.
- One of the most critical factors in commercialization success is an active and engaged inventor.
- Self-market your technology as aggressively as possible, you are the best champion for your technology.
- Most licenses and sponsored research funding result from your networking efforts with companies.

Keep it simple

- Make sure you can clearly communicate what your invention is and what the final product/service will look like.
- Don’t get bogged down in the nitty-gritty details of the science.
- People like getting behind what they can understand!

Seek a mentor

- Find individuals within your institute that have successfully navigated the TTO-waters.
- Each TTO is a unique animal – your experience at one place won't be the same at your next.
- See if your TTO provides workshops or inventor training opportunities.

Be active in the patent process

- Review the patent application before it is filed to be sure it properly captures your IP.
- Stay engaged in the “back-and-forth” review process between the patent office and the patent attorney.

It is a marathon

- From “invention” to “license” can take many years, so don’t expect immediate results.
- “Commercialization” won’t “save” your lab if you are struggling with funding.
- Wait a few years between the time you disclose your IP and when you put money down on a new Ferrari.

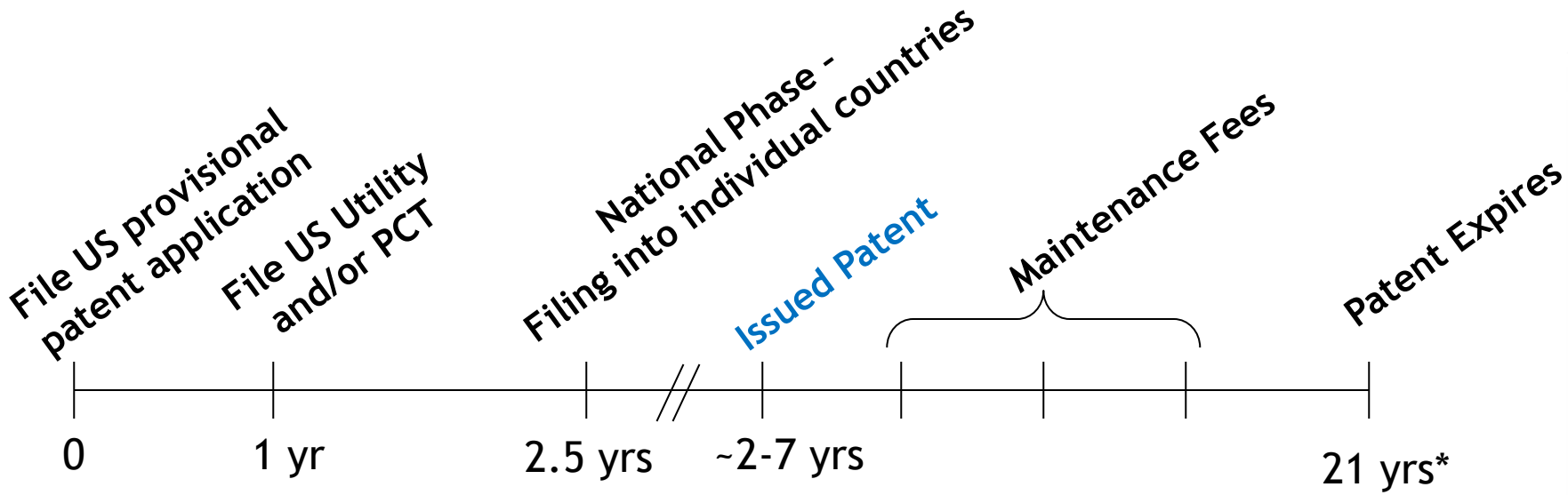
Agreements are important

- Make sure you have the proper “confidentiality” and “material transfer” agreements in place when working with companies and other institutes.
- Read the fine print on all sponsored research agreements – more than ever “funding agencies” have hooks into your IP and the revenue stream.

Thank-you!

Extra Slides

The life of a patent = 20 years



* Includes the “provisional patent” time

Types of patents - US

US Provisional

- Secures a priority date only.
- Is not actually reviewed within the patent office.
- Automatically expires 1 year from the filing date.
- If abandoned, it does not publish.

US Utility (non-provisional)

- "Official" patent application reviewed by the USPTO.
- The USPTO will respond to it with formal "office actions".
- Publishes 18 months after the earliest filing date (usually the provisional).

Types of patents - International

PCT – "Patent cooperation treaty"

- The "international" patent system.
- Provides simultaneous protection in 148 countries.

National stage

- 30 months after the initial filing date, you have to select which of the 148 countries you wish to pursue.