



IP Management

Intellectual Property Teaching Kit

IP STRATEGY

IP strategies for universities and businesses

- Universities
 - teaching
 - fundamental and applied research
 - technology transfer (i.e. no in-house production and sales)
- Businesses
 - own development, manufacturing and/or sales of products and services
 - commercialisation of technologies (out-licensing, IP sales)

IP strategy approaches

- Developing and protecting IP
 - particularly relevant to university activities
 - also relevant to businesses
- Creating a competitive advantage by optimising and using IP
 - relevant to university spin-out companies
 - relevant to businesses

Developing and protecting IP

Strategic objective	Tactic
"Monopolising" the technology	<ul style="list-style-type: none">– Publish and ensure wide access, or– Protect with patents and other IP forms, or– Maintain as secret know-how
Managing the IP filing strategy	<ul style="list-style-type: none">– Maintain application for a limited duration– Decide which territories should be protected
Enhancing the status of the technology	<ul style="list-style-type: none">– Develop complementary technologies– Create portfolio of related patents & other IP

Creating a competitive advantage

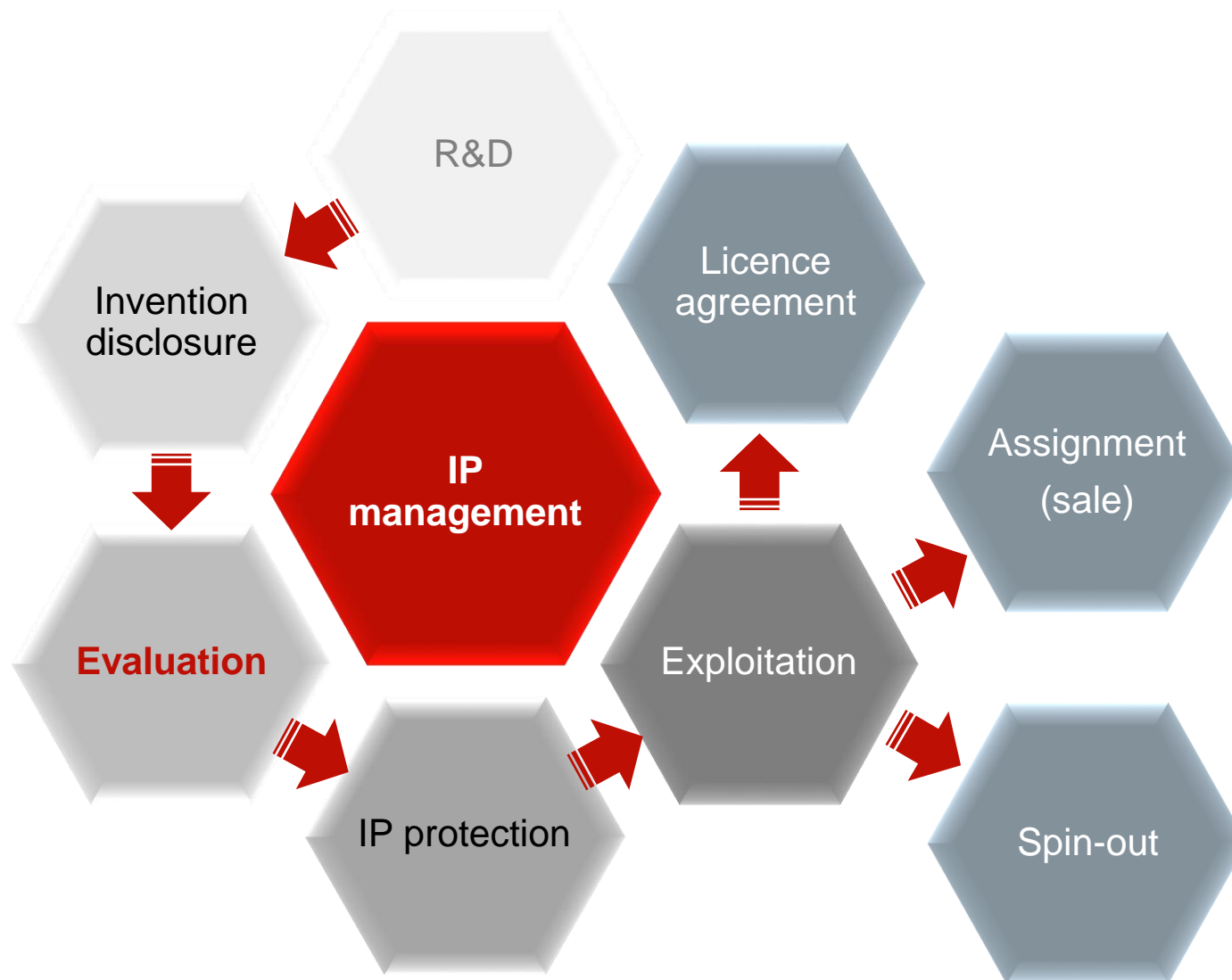
Strategic objective	Tactic
Creating a “monopoly”	<ul style="list-style-type: none">– Be aware of IP landscape (competitors)– Ensure freedom-to-operate– Police infringers– Defend "monopoly"
Managing competitors	<ul style="list-style-type: none">– Create defensive patents– Trade IP for cross-licensing deals
Securing finance	<ul style="list-style-type: none">– Build IP portfolio to attract investment
Monetising the IP portfolio	<ul style="list-style-type: none">– Consider out-licensing, sale of IP, spin-outs
Sourcing new IP	<ul style="list-style-type: none">– Use collaborations, in-licensing, acquisitions

COMMERCIALISATION OF IP

Technology transfer

- University objective
 - to make innovative research results and technologies available for wider use by means of technology transfer
- Possibilities for technology transfer
 - publications, people and artefacts
 - collaborations
 - contract research
 - licensing
 - sale
 - spin-outs

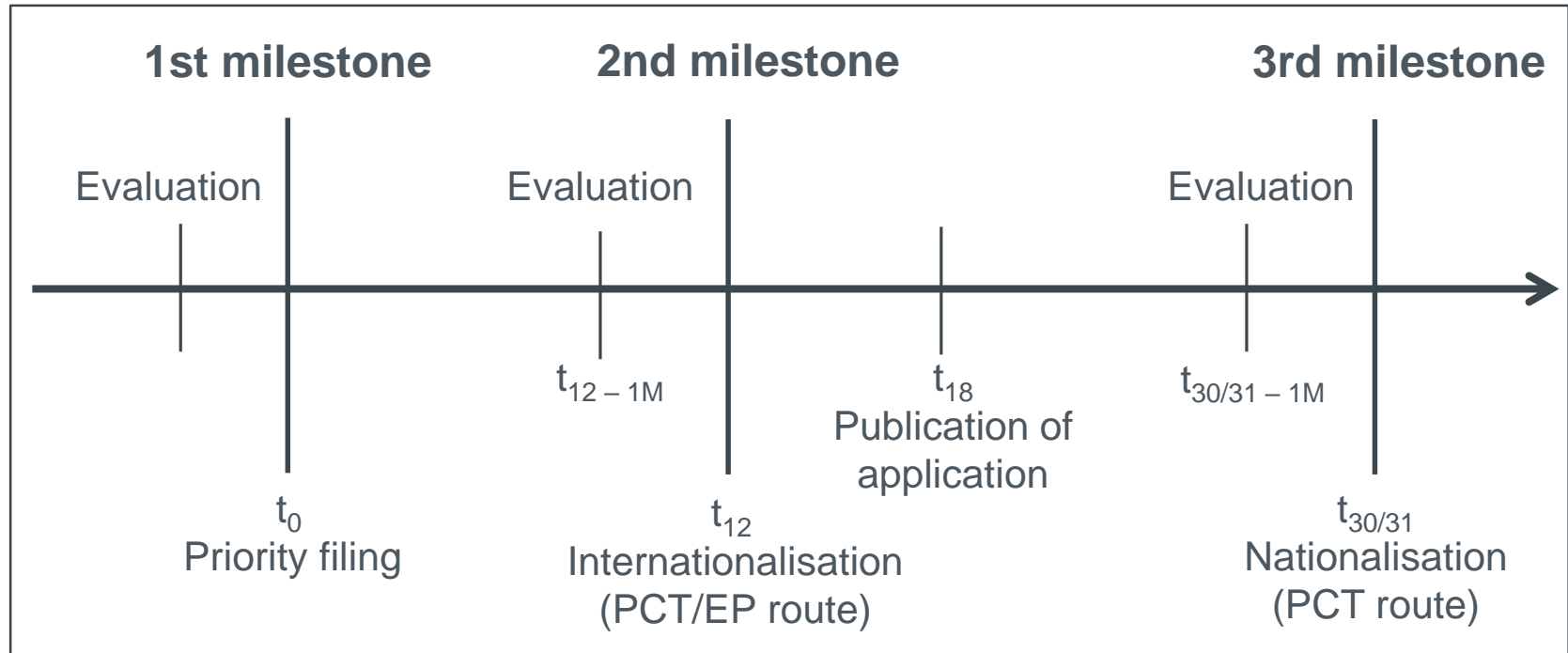
How universities can exploit IP



Evaluating IP

- Legal status
- Technology
- Market conditions

IP evaluation process

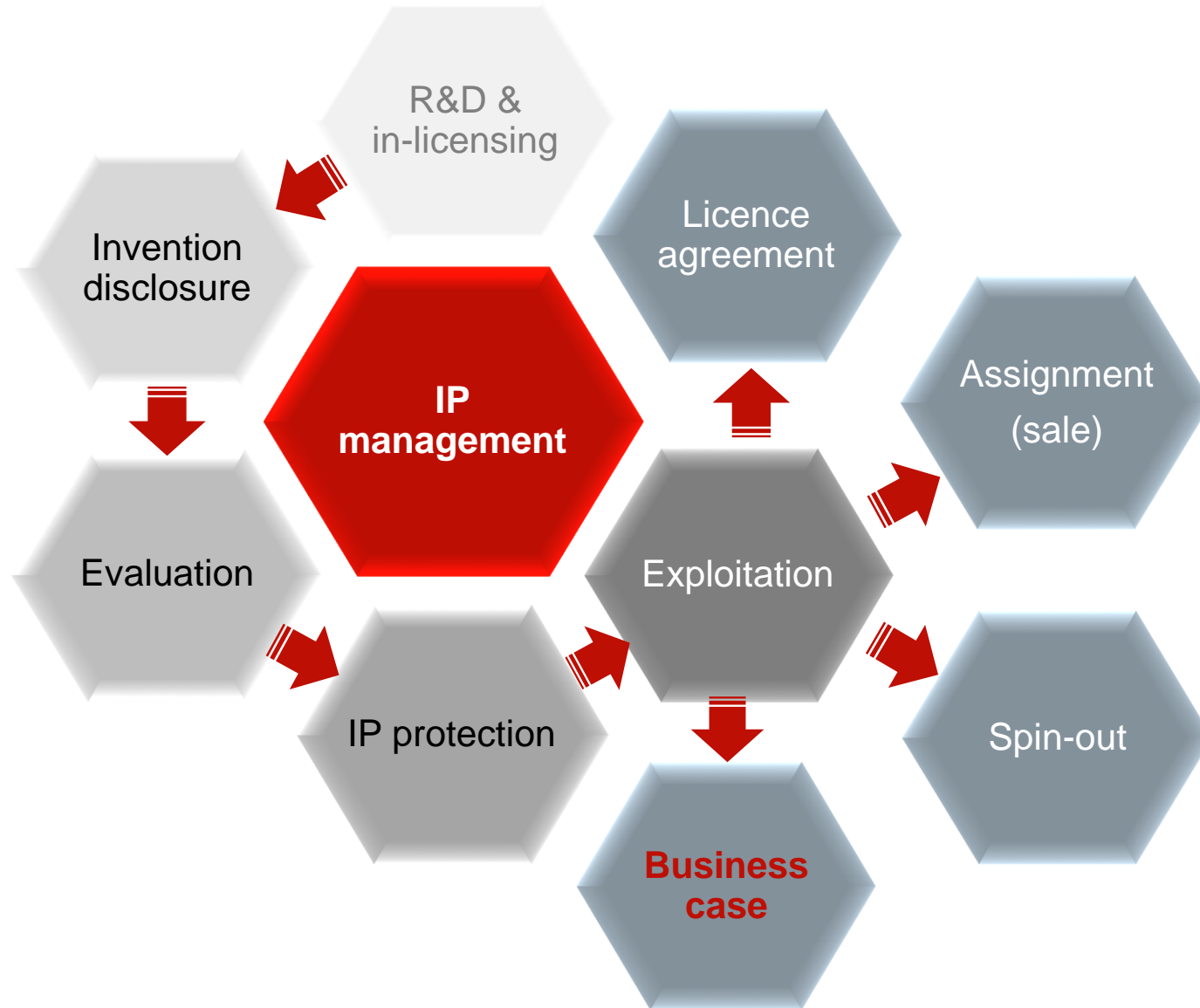


t_0 Patent priority filing: start of priority year

t_{12} Deadline for internationalisation: 12 months after t_0

$t_{30/31}$ Deadline for nationalisation: 30/31 months after t_0 (PCT route)

How businesses exploit IP



Licensing IP

- Intellectual property rights
 - prevent others from using your inventions and creations
- Licences (contractual agreements)
 - allows others to use your inventions and creations
 - in accordance with specific terms and conditions
- Requirements for a legal contract
 - mutual exchange of a bargain
 - consideration (payment) exchanged for something of value (IP)



Benefits of licensing

Licensor	Licensee
<ul style="list-style-type: none">▪ Create new source of revenues▪ Access new territories and markets▪ Influence market acceptance for technology and products▪ Create production and supply partnerships	<ul style="list-style-type: none">▪ Gain access to new technologies, turn-key products and processes and new markets▪ Reduce or avoid R&D costs and associated risks▪ Provide competitive advantage and IPR protection▪ Increase asset value of business

IP and spin-outs

- Decision to set up university spin-outs and new technology start-ups relies mainly on:
 - A demonstrated technology
 - Good commercial potential
 - Validly protected IP position
 - Strong management skills and expertise
- Investment
 - Start-ups generally lack positive cash flows.
 - Value lies in IP assets.
 - Investors base decision on strength of team and IP to protect future earnings.

IP MANAGEMENT CASE STUDY

Background

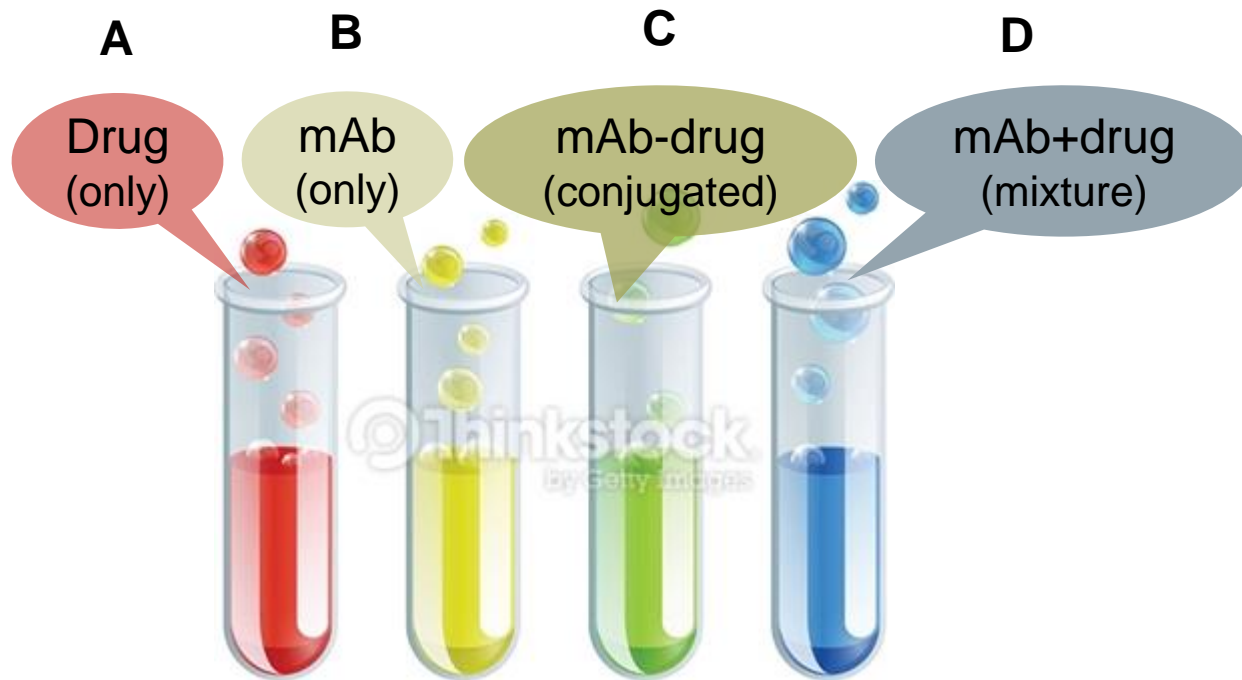
- Scientists at the Weizmann Institute conduct research on using antibodies as carriers to target treatment for specific cancers.
- A former colleague provides materials for use in experiments.
- Promising results are obtained.
- A patent application is filed.
- The patent is licensed to a biopharma company.
- Ownership of the patent is disputed.
- Litigation proves costly.

The research programme

- Objective: to target cancer cells with a chemotherapeutic drug.
- Sela's research group at the Weizmann Institute received two monoclonal antibodies (mAb) from former colleague Professor Schlessinger.
- mAb binds to specific site on cancer cells (selective targeting).
- One mAb selected for experiments.
- Drug chemically linked to mAb (conjugated).
- Effects targeted delivery of chemotherapeutic drug.

The experiments

Treatment of tumour with mAb and chemotherapeutic drug



A = some effect

B = some effect

C = some effect

D = significant inhibition

The results

- Expectation that **experiment C** would show best results
 - mAb should carry drug directly to tumour and destroy cancer cells.
- **Experiment D** shows a surprising effect
 - Free mixture of chemotherapeutic drug and mAb creates synergistic effect on inhibiting growth of cancer cells.
 - Unpredicted result demonstrates "inventive step".

The publication

- Sela did not consider filing a patent application
 - mAb owned by Schlessinger's employer, Rorer Biotechnology.
 - Might give rise to complex negotiations.
 - Happy to disseminate results in *Journal of the National Cancer Institute*.
- Sela's group prepares publication
 - Draft of paper shown to Schlessinger on next visit.
 - Schlessinger also named as author for contribution of mAb.
 - Paper published in December 1988.

The patent application

Schlessinger discusses results with colleagues at Rorer:

- Clinical studies initiated.
- Patent application prepared.
- Claimed "antibodies" + "antibody/drug mixtures" in cancer treatment.
- Inventors named are all Rorer employees.
- US patent application filed September 1988 (unbeknown to Weizmann).

The licence

- 1994: Rorer grants exclusive licence to ImClone.
- ImClone invests USD 190m in developing cancer therapy.
- 1999: Aventis acquires Rorer and patent after series of mergers.
- "Erbix" receives FDA approval:
 - 2004: colorectal cancer
 - 2006: head and neck cancer
- 2007: sales of "Erbix" in the order of USD 400m per year.

The patent dispute

- 2001: Patent granted and published (US6217866):
 - US patent limited to claims for mAb/drug mixture.
 - Other territories grant claims to mAb only and to mixture.
- 2002: Sela becomes aware of patent and raises concerns.
- Yeda (technology transfer company for Weizmann Institute) enters discussions with Aventis and ImClone → no resolution.
- 2003: Yeda starts court proceedings against Aventis and ImClone.

Litigation

- Yeda's case
 - Experiments and inventive concept originated solely from Sela's group.
 - Data and figures for patent specification drawn from draft publication.
- Defendants' case
 - Provided mAb for the experiments.
 - Schlessinger advised Weizmann scientists on the project.
 - Had already contemplated mixture of mAb and drug.

The court decision

- Weizmann scientists are sole inventors of US patent.
- Inventorship of patent corrected at USPTO.
- Yeda becomes owner of patent.
- Out-of-court settlement reached 2007:
 - Yeda owns US patent.
 - Yeda and Aventis jointly own patents in other territories.
 - Aventis and ImClone pay USD 60m each to Yeda.
 - ImClone pays Yeda royalty on sales in US.
 - ImClone pays Yeda and Aventis royalty on sales outside US.

Note on inventorship

Judge Buchwald: *"Conception is the touchstone of inventorship, the completion of the mental part of invention."*

- The inventors are those who conceived of the idea of using the mAb in an unconjugated mixture in order to treat human tumour cells.
- The provision of mAb alone does not give entitlement to inventorship.
- There was no evidence of collaboration or contribution to conception or reduction to practice of the invention by Schlessinger's group.

Discussion

What procedural steps might have been introduced in the two organisations involved that could have prevented the situation of incorrect inventorship arising?

Lessons learnt

- Exercise caution in disclosing research results → use an **NDA**.
- Clarify terms for exchange of materials → use an **MTA**.
- Complete an invention disclosure form (**IDF**) to help inventors focus.
- Keep **notebooks** to provide convincing documentary evidence.