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The forward-looking IP firm

Shooting yourself in the foot

…or how not to

Adam Gregory, D.Phil.
Partner, Patent Attorney
MEWBURN ELLIS LLP

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Outline

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- Patentability and the state of the art
- Common problems with own prior art
  - Weak initial filings, intervening disclosures
  - Foreshadowing
- When disclosures ‘don’t count’
  - Grace Periods & Confidential Disclosures
- Final Thoughts

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Patentability and the state of the art

Novelty & Inventive Step

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An invention must not form part of the state of the art…

…and must not be an obvious development, in view of the state of the art

The state of the art includes:

"all matter (whether a product, a process or information about either, or anything else) which has at any time… been made available to the public…by written or oral description, by use or in any other way"

ALL non-confidential disclosures form part of the state of the art…

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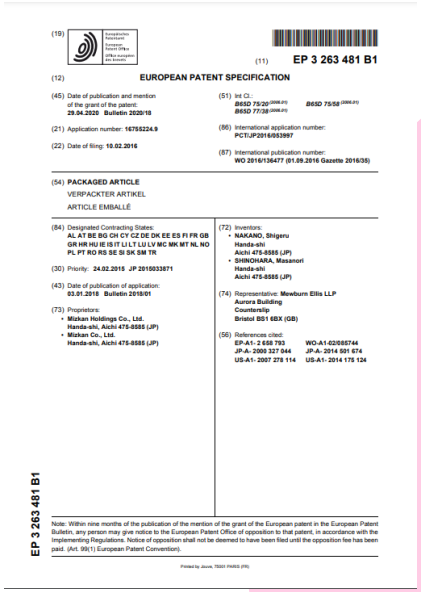

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(73) Proprietors:
- **Mizkan Holdings Co., Ltd.**
  Handa-shi, Aichi 475-8585 (JP)
- **Mizkan Co., Ltd.**
  Handa-shi, Aichi 475-8585 (JP)

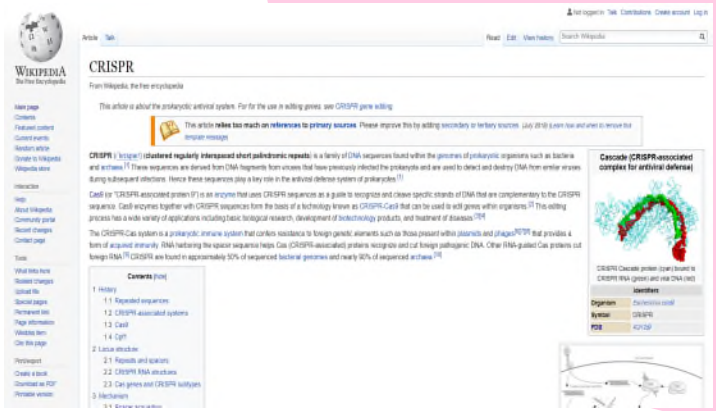
(72) Inventors:
- **NAKANO, Shigeru**
  Handa-shi
  Aichi 475-8585 (JP)
- **SHIMOHARA, Masanori**
  Handa-shi
  Aichi 475-8585 (JP)

(74) Representative: **Mewburn Ellis LLP**
Aurora Building
Counterslip
Bristol BS1 6BX (GB)

(56) References cited:
EP-A1- 2 638 793 **WO-A1-02/085744**
JP-A- 2000 327 044 **JP-A- 2014 501 674**
US-A1- 2007 278 114 **US-A1- 2014 175 124**

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

EP 3 263 481 B1

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Common Problems:
Weak initial filings, intervening disclosures

Priority – refresher

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- An applicant that has filed a patent application for an invention (A1) has a period of 12 months from the date of filing within which to file further patent applications claiming priority to the first filing.
  - The subsequent filing (A2) enjoys the benefit of the filing date of the first application (A1), in respect of subject-matter contained in A1.
  - Disclosures made between A1 and A2 are not available as prior art for the evaluation of novelty and inventive step of the claims of A2 entitled to the priority of A1.

Priority – refresher

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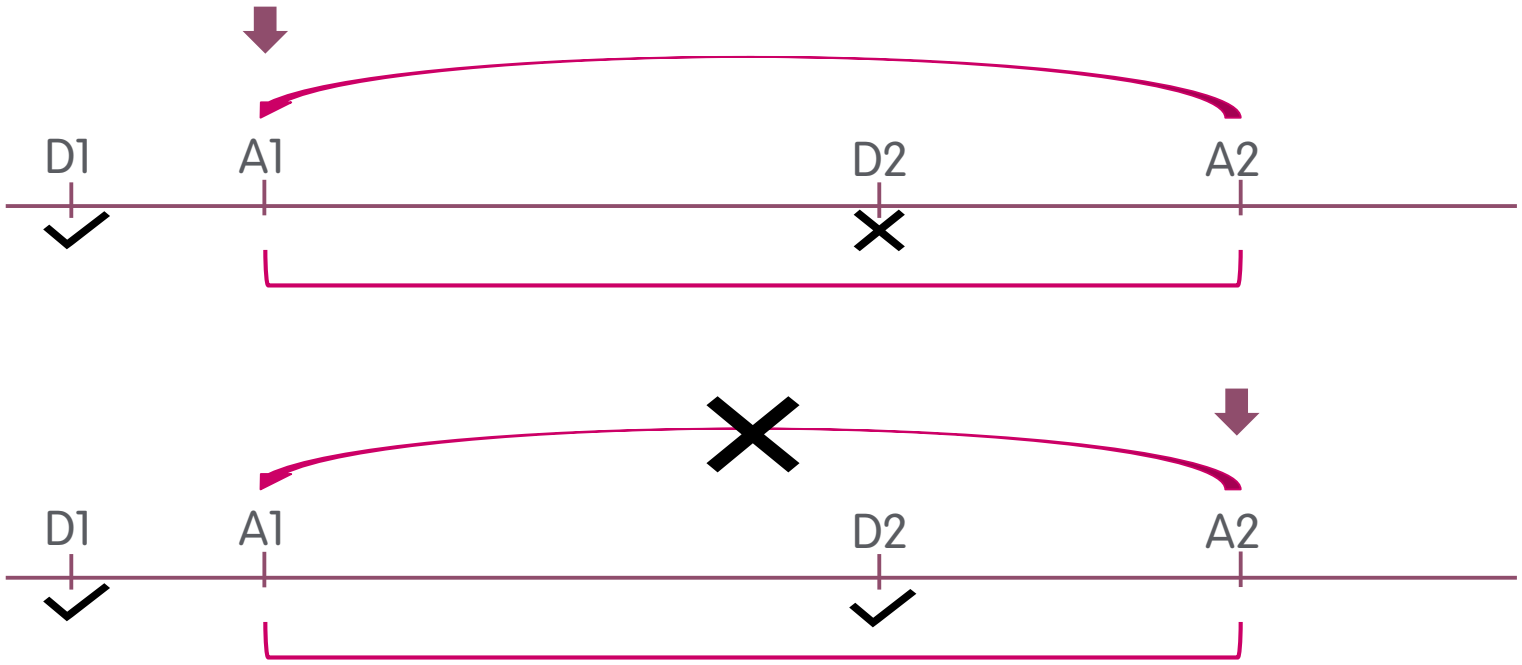
- The subsequent filing (A2) enjoys the benefit of the filing date of the first application (A1), in respect of subject-matter contained in A1.
  - A1: Aspects X, Y
  - A2: Aspects X, Y, Z
  - A2 claims…
    1. X
    2. Y
    3. Z
    4. X + Z
    5. Y + Z



Weak initial filings, intervening disclosures

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- Example 1: **Broad** weak initial filing

Weak initial filings, intervening disclosures

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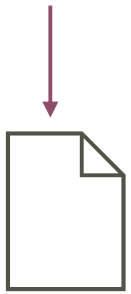
- Example 1: Broad weak initial filing
- A1: Minimally-drafted initial filing
  - Directed to an antibody that binds to domain III of protein A (broadly)
  - No sequence information or other fallbacks

A1: 1. An antibody that binds to domain III of protein A



Weak initial filings, intervening disclosures

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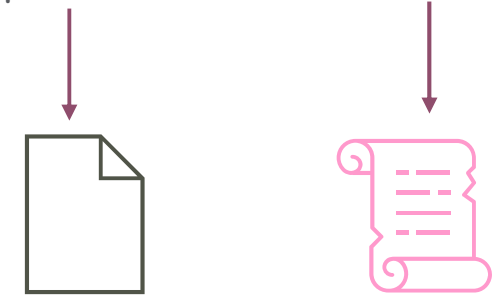
- Example 1: Broad weak initial filing
- Inventor: Can I publish? We've filed a patent application, right? Gotta hit those KPIs!
    - Comprehensive disclosure of the technology, including antibody sequence information

A1: 1. An antibody that binds to domain III of protein A

Paper disclosing antibody sequences and experimental data



Weak initial filings, intervening disclosures

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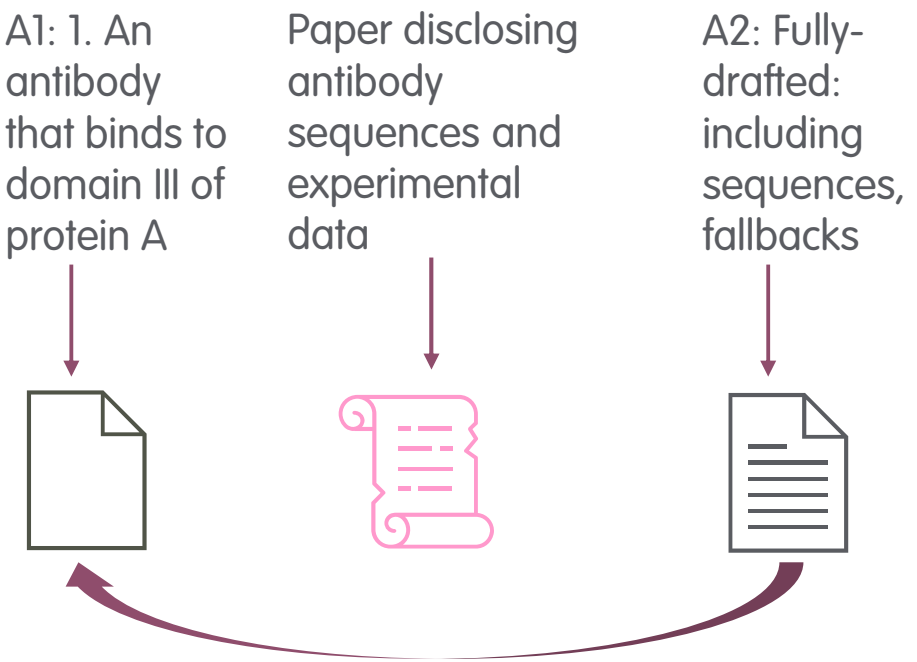
- Example 1: Broad weak initial filing
- A2: Fully-drafted PCT application, claiming priority to A1
  - Properly describing the antibodies, their sequences, variants, fallbacks, *etc.*



Weak initial filings, intervening disclosures

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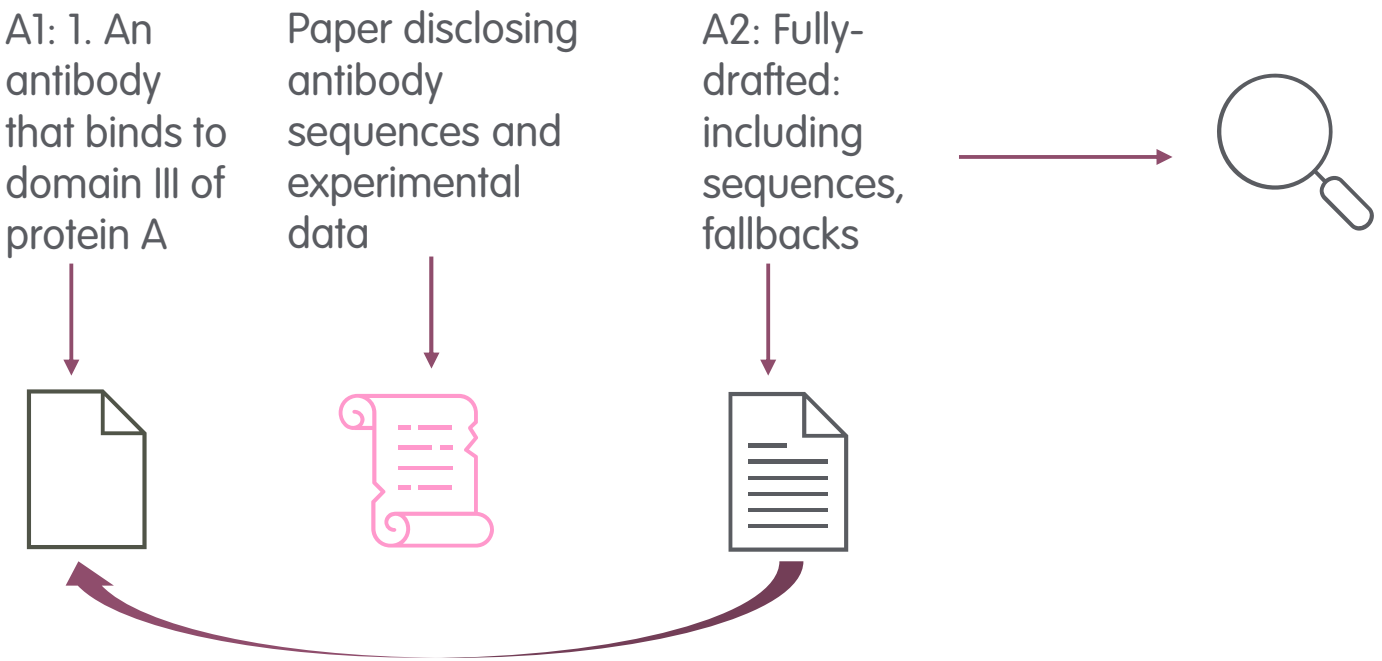
- Example 1: Broad weak initial filing
- Examination of A2, broad claims not allowable…
  - *E.g.* Prior art doc (pre-A1) → domain III-binding antibodies were known
  - *E.g.* Broad claim unsupported across its scope



Weak initial filings, intervening disclosures

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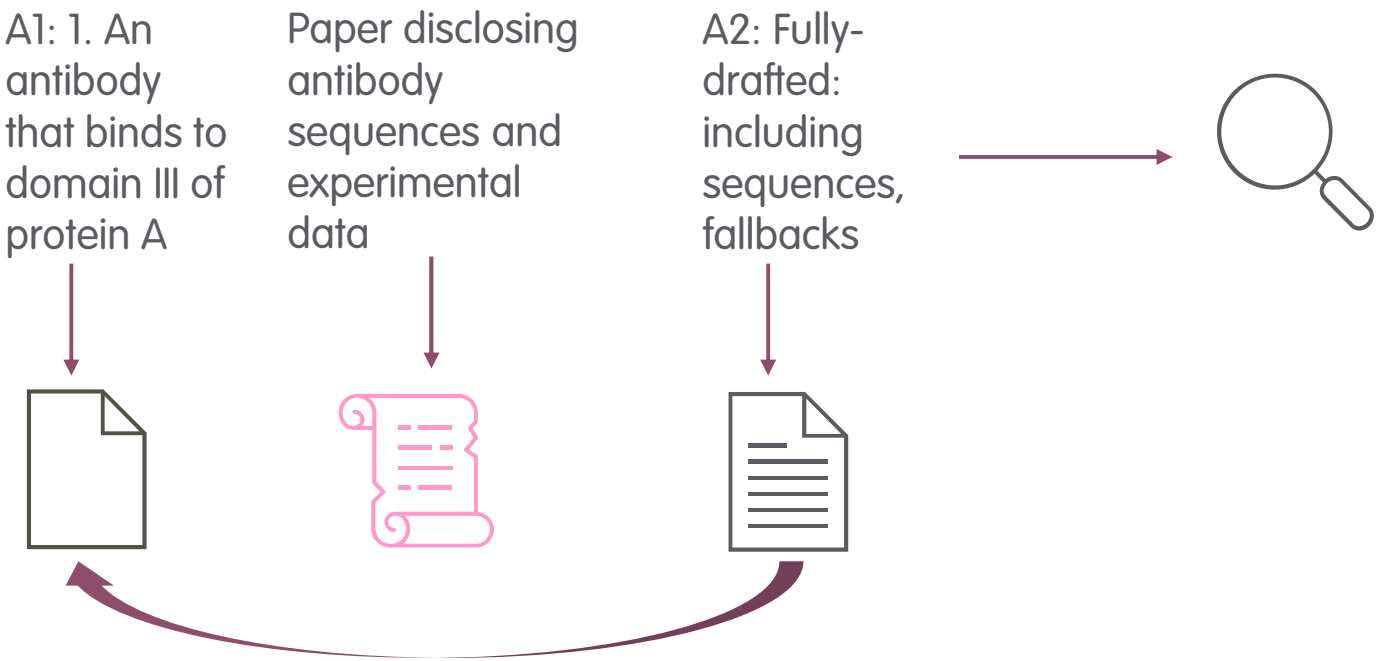
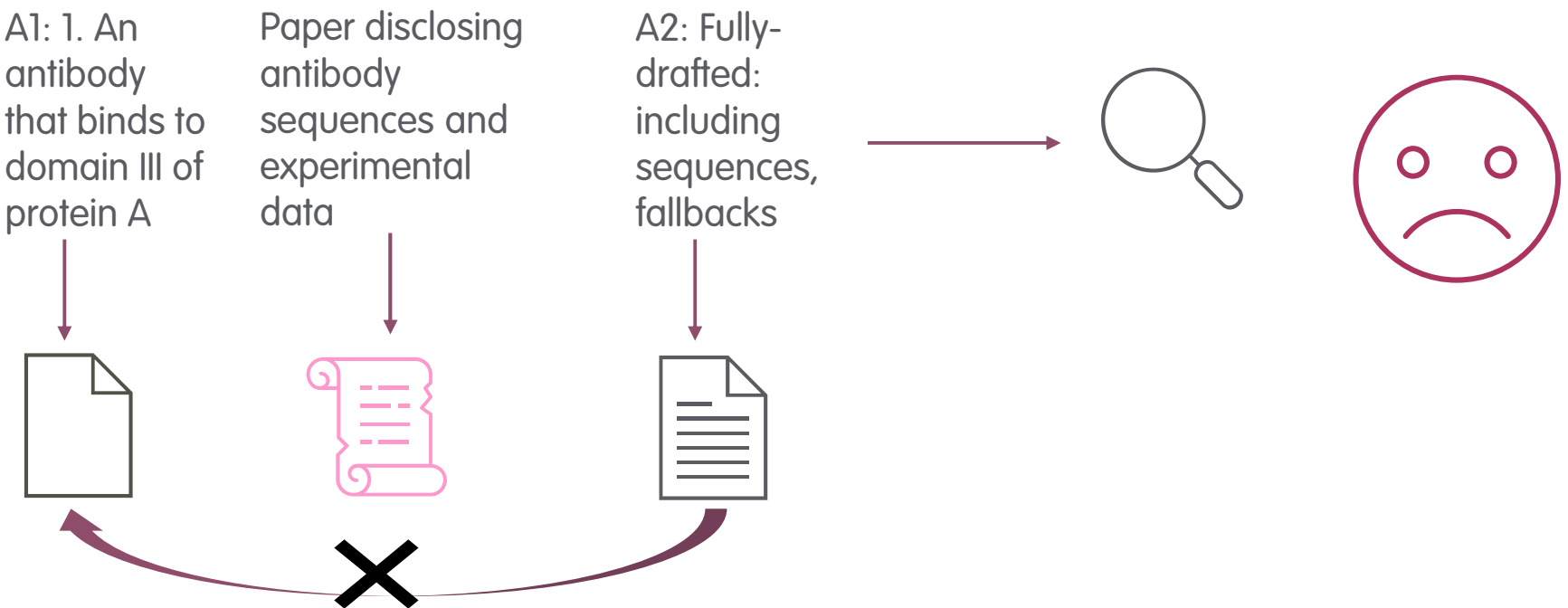
- Example 1: Broad weak initial filing
- Examination of A2
  - Need to narrow the claims to novel/supported subject-matter, *e.g.* antibodies defined by reference to their sequences



Weak initial filings, intervening disclosures

- Example 1: Broad weak initial filing
- Examination of A2
  - …But this subject-matter lacks a valid claim to the priority of A1
  - Lacks novelty over the paper, which discloses the antibody sequences



Weak initial filings, intervening disclosures

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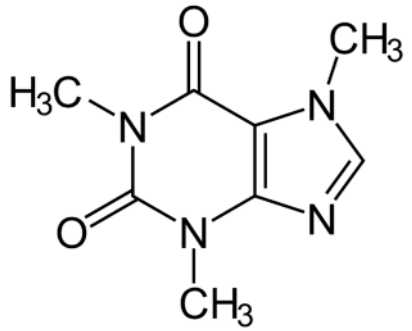
- Example 2: **Narrow** weak initial filing

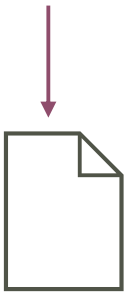
Weak initial filings, intervening disclosures

- Example 2: Narrow weak initial filing
- A1: Minimally-drafted initial filing
  - Directed to a particular, novel compound X
  - No variants

X =



A1: Novel compound X (only)

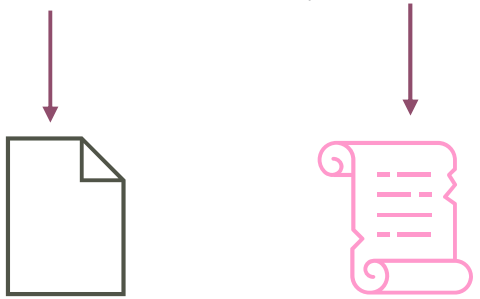


Weak initial filings, intervening disclosures

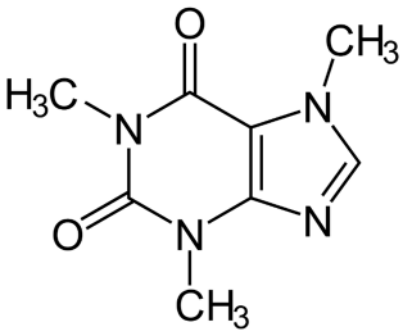
- Example 2: Narrow weak initial filing
- Inventor: publishes PhD thesis
  - Comprehensive disclosure of the technology
  - Describes X, and also related compounds X^1 and X^2

A1: Novel compound X (only)

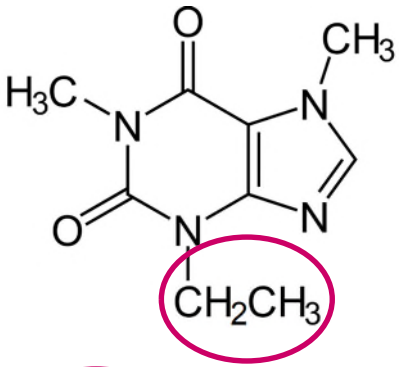
Inventor PhD thesis disclosing X and related compounds (X^1, X^2, *etc.*)



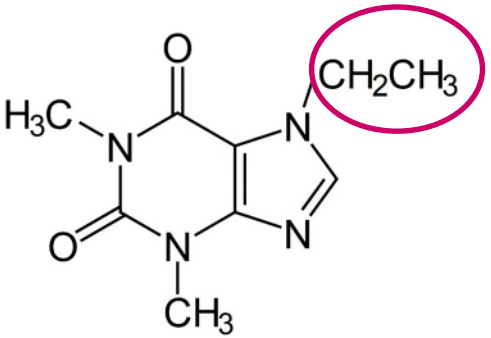
X =



X^1 =



X^2 =



Weak initial filings, intervening disclosures

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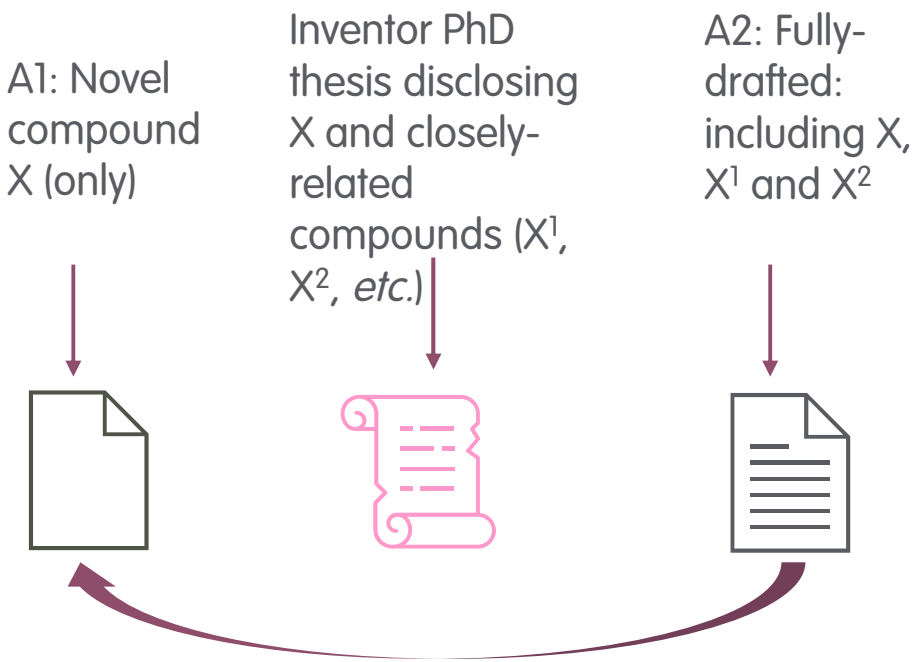
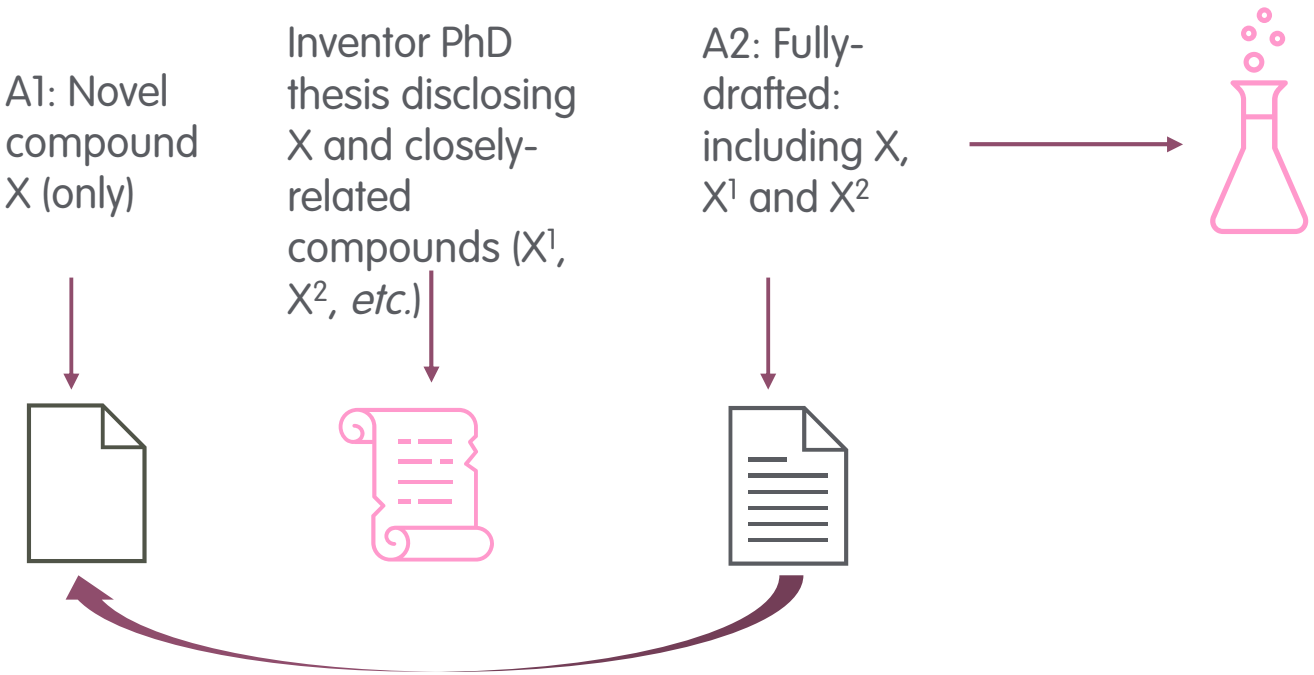
- Example 2: Narrow weak initial filing
- A2: Fully-drafted PCT application, claiming priority to A1
  - Properly describing X and related compounds, variants including X^1 and X^2



Weak initial filings, intervening disclosures

- Example 2: Narrow weak initial filing
- Further experimental work
  - *E.g.* X^2 is the preferred compound, X doesn't work very well



Weak initial filings, intervening disclosures

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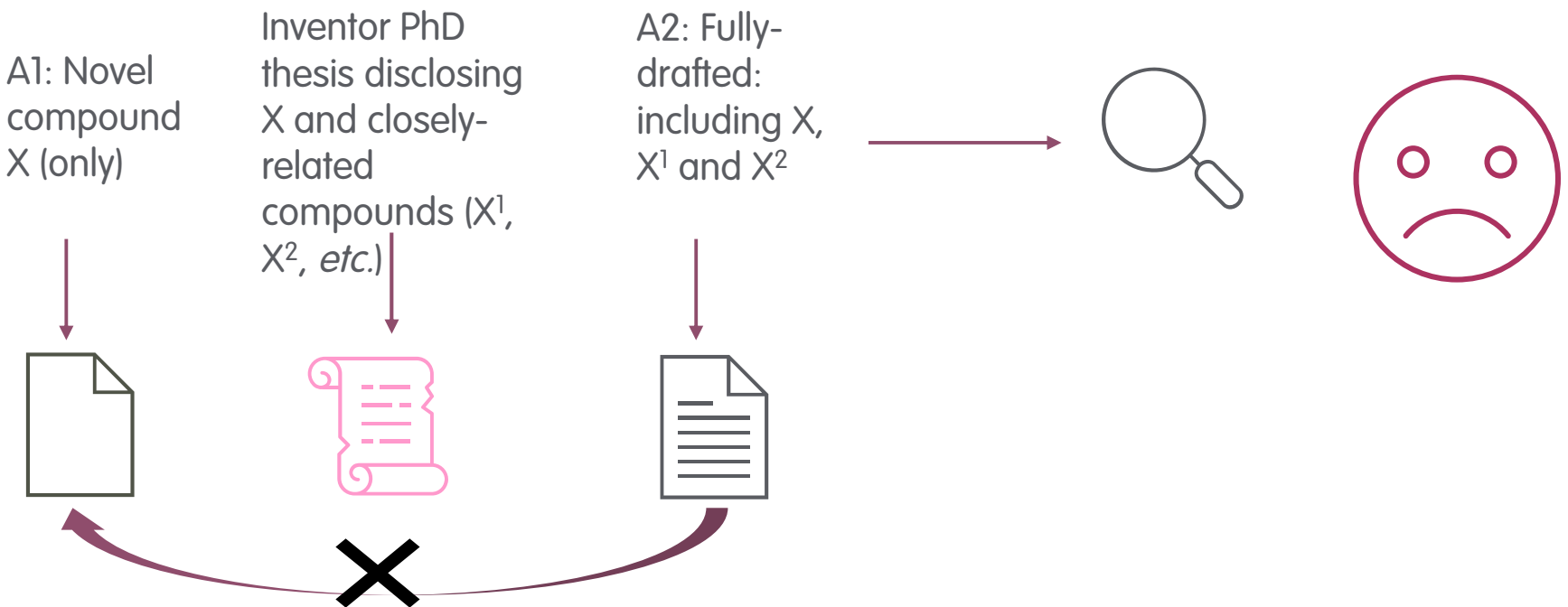
- Example 2: Narrow weak initial filing
- But claims directed to or encompassing X^2 aren't entitled to the priority of A1
- So the PhD thesis is destroys the novelty of claims to our lead compound



Weak initial filings, intervening disclosures

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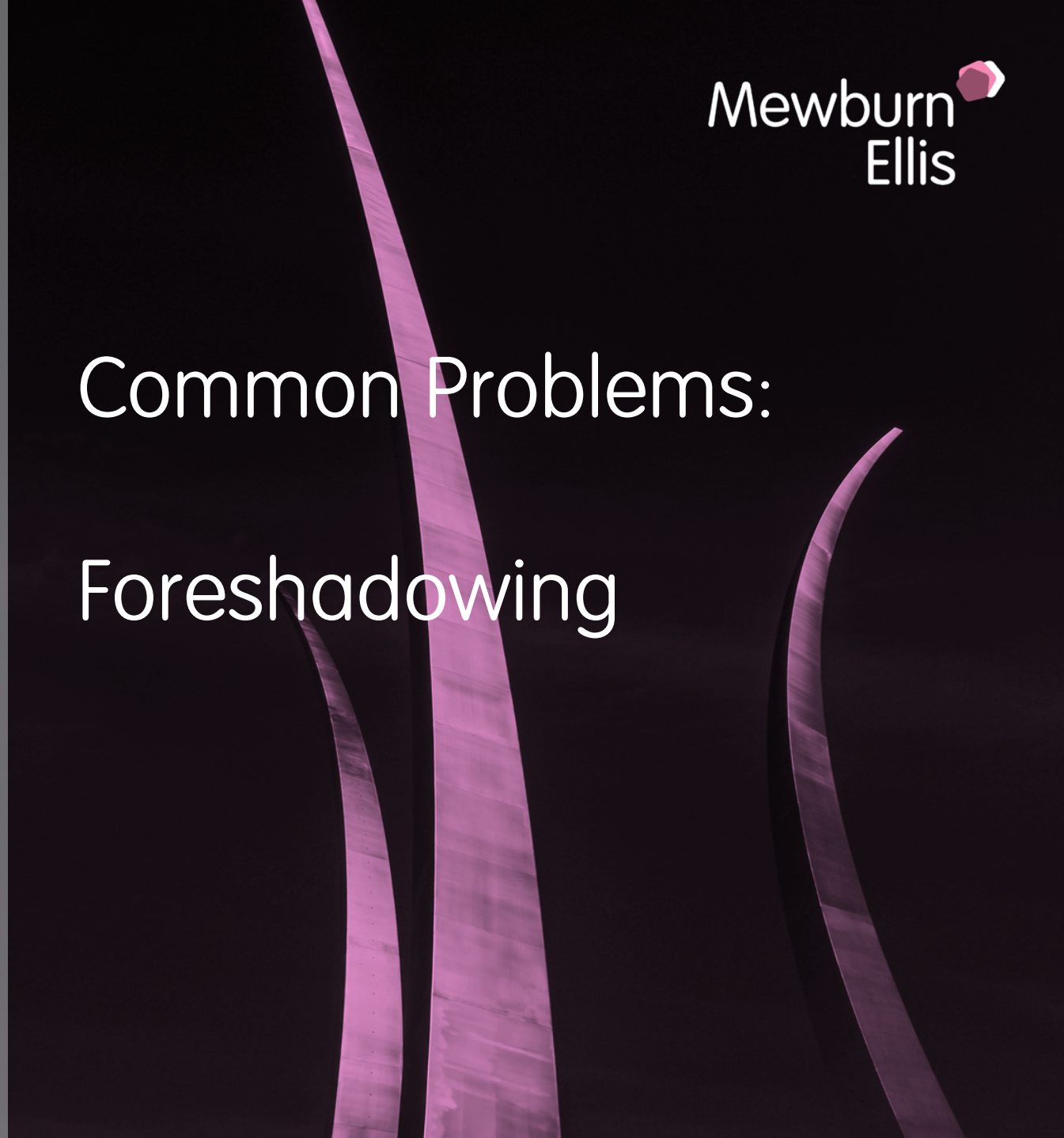
- Why does this happen?
  - Weak initial filings usually due to financial constraints
    - Lots of IDFs, uncertain commercial value, hard to know where to commit the resource
  - Disclosure during the priority year usually due to pressure on inventors to publish, and the assumption that this is OK as long as a patent application has been filed
- What can be done to avoid the situation?
  - Invest more in initial filings? (not easy)
  - Stop inventors from disclosing until after a comprehensive filing? (also not easy)
  - Strong lines of communication between inventors and TTO/IP counsel, educate inventors about the risks of disclosures during the priority year
  - Ideally, require that any disclosure relating to an invention must be reviewed and approved by TTO/IP counsel (even after an application has been filed) → possible to change their content/file top-up application in advance



Common Problems:

Foreshadowing

Foreshadowing

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- Earlier patent filings in a programme
- Other disclosures of information that could be relevant to obviousness for a future filing

Foreshadowing

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- Earlier patent filings in a programme
  - Important that applications are comprehensively-drafted…
  - ….but also must take care not to include information that could undermine patentability of claims of a future filing in the programme

- Example
  - Application A directed to the use of antagonists of target protein X to treat rheumatoid arthritis
  - All data relates to the use of different modalities (antibodies, small molecules, siRNA) to inhibit target X, in *in vitro* and *in vivo* models of arthritis
  - The inventors think the approach could work *e.g.* for treatment of psoriasis too, but no data in the application relating to this aspect
  - Nevertheless, describe the use of antagonists of target protein X to treat psoriasis in Application A

Foreshadowing

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- Earlier patent filings in a programme
- Example
  - Later, the inventors obtain data demonstrating the use of antagonists of target protein X to treat psoriasis and – after publication of Application A – file Application B, directed to this subject-matter
  - Application A is available as prior art, and presents a significant obstacle to obtaining granted claims to the use of antagonists of target protein X to treat psoriasis in Application B
  - Application A lacks supporting data for this aspect, so it's challenging to obtain claims to treatment of psoriasis out of Application A too

Foreshadowing

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- Other disclosures of information that could be relevant to obviousness for a future filing

Foreshadowing

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- Other disclosures of information that could be relevant to obviousness for a future filing
- Example 1
  - Application A (fully-drafted) relating to the use of antagonists of target protein X to treat rheumatoid arthritis is filed
  - After careful consideration, decide not to include speculative statements relating to treatment of psoriasis, with a view to a future filing
  - Inventors then publish a paper, share it on LinkedIn…

Foreshadowing

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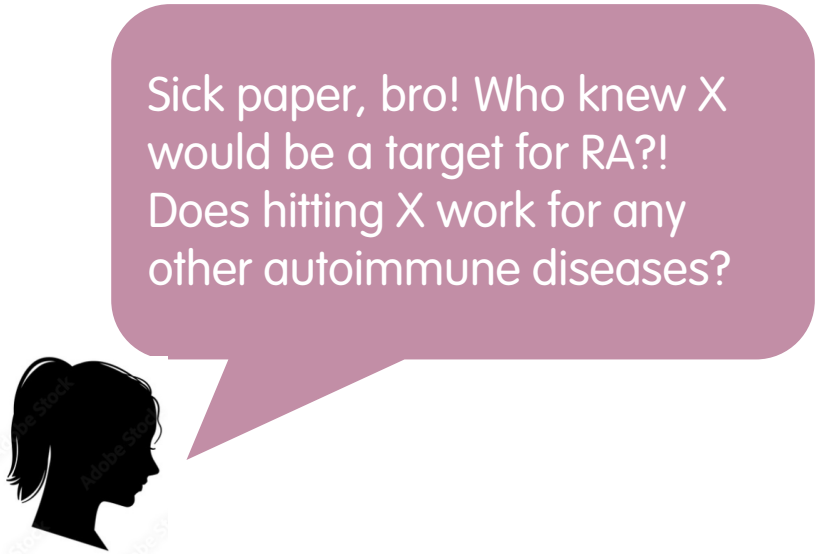
- Other disclosures of information that could be relevant to obviousness for a future filing
- Example 1

  LinkedIn exchange:



Foreshadowing

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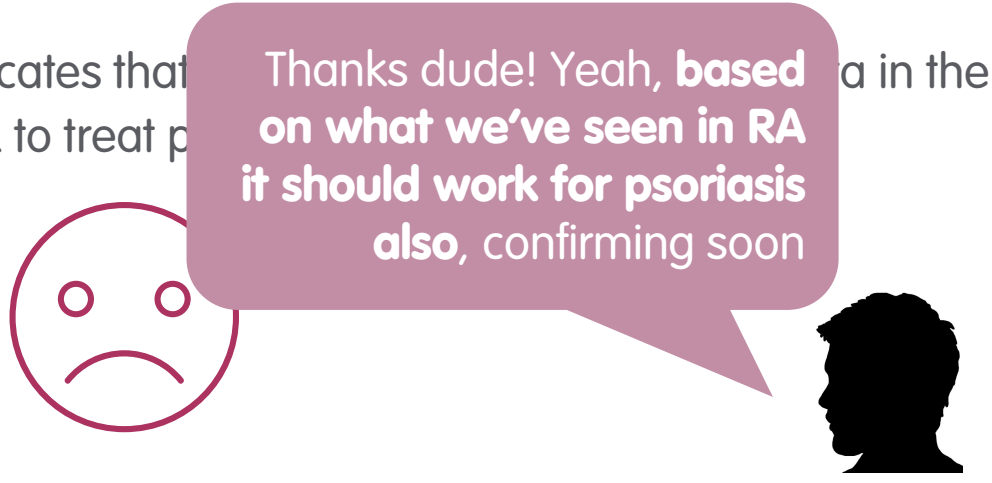
- Other disclosures of information that could be relevant to obviousness for a future filing
- Example 1
  - Later, the inventors obtain data demonstrating the use of antagonists of target protein X to treat psoriasis and file Application B, directed to this subject-matter
  - They obtain granted claims to the treatment of psoriasis from Application B
  - Years later, a third party seeking to invalidate the psoriasis patent finds the exchange on LinkedIn
  - Successfully argues that this indicates that a in the paper that targeting X would also work to treat p



Foreshadowing

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- Other disclosures of information that could be relevant to obviousness for a future filing
- Example 2
  - Inventors identify novel antibody Q that binds to target X with high affinity, and inhibits growth of pancreatic cancer cells
  - Not ready to file patent application for antibody Q…
  - …but really want to present their awesome data at ASCO Annual Meeting
  - They reason it's OK to show their data provided they don't include antibody sequences → no-one would be able to make the antibody based on the disclosure

Foreshadowing

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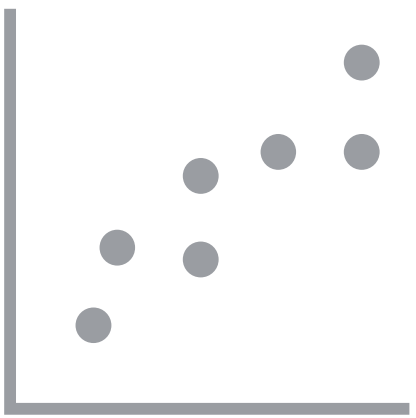
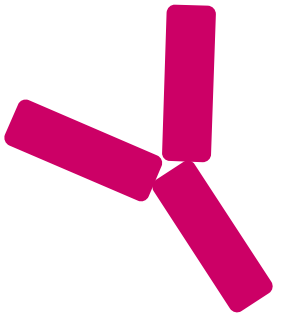
- Other disclosures of information that could be relevant to obviousness for a future filing
- Example 2





  - Present a poster at ASCO including data showing potency of antibody Q to inhibit pancreatic cancer cell growth, and affinity of binding to X

Foreshadowing

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- Other disclosures of information that could be relevant to obviousness for a future filing
- Example 2
  - Later file a patent application directed to antibody Q
  - During prosecution in EP, SG, CN, JP, *etc.* the patent offices object that antibody Q is a mere alternative to known antibodies that bind to target X, and claims to this antibody therefore lack an inventive step
  - Argue that antibody Q is inventive as it is more potent and binds with greater affinity to X than prior art antibodies…
  - …but the patent offices cite the ASCO poster as evidence that antibodies to X achieving such technical effects were known prior to filing the application to antibody Q

Foreshadowing

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- What can be done to avoid the situation?
  - Strong lines of communication between inventors and TTO/IP counsel
    - Forward-looking IP strategy, taking account of plans for future experiments, timelines for obtaining data
    - Updates on technical developments, commercial plans
    - Ideally, require that any disclosures relating to the programme must be reviewed and approved by TTO/IP counsel (even after an application has been filed) → possible to change their content/file top-up application in advance
  - Educate inventors about the risks of their own disclosures

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When disclosures ‘don’t count’

Grace Periods & Confidential Disclosures

Grace Periods

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- Some jurisdictions provide 'grace periods' whereby certain disclosures are not considered to form part of the state of the art if they're made within a specified period preceding the date of filing
  - *E.g.* US, JP, KR, SG, CA, AU, EA, CL, RU, AL, SM
  - Time-limited – 12m (US, JP*, KR, SG, CA, AU, CL) / 6m (JP*, EA, RU, AL, SM)
  - Limited factual circumstances – typically only inventor-derived disclosures
    - EXTREMELY narrow circs. in some countries → EP = evident abuse
  - Onerous administrative requirements in some countries
    - Direct filing, not a priority filing
    - Some countries require that you identify disclosure(s) at time of filing (*e.g.* JP)
  - Grace period provisions not harmonised
- We should NEVER be planning to rely on grace periods!

Confidential Disclosures

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- Prior to filing, inventors/applicants may wish to share information with third parties about the invention
  - When trying to license/sell rights to the invention, secure investment, *etc.*
- While confidential disclosures are not available as prior art, take appropriate measures to protect your position → CDAs
- Any communication relating to an invention with an external party (prior to filing) brings risk
  - Even when under CDA, you've lost control
- Ideally, file patent application before sharing any information, even under CDA


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Final Thoughts

Final Thoughts

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- Own disclosures having adverse effects usually happen when there's a disconnect between IP strategy and inventor/applicant activities
  - Develop strong lines of communication between inventors and TTO, so that they keep you informed of planned disclosures (well in advance)
  - Educate inventors about the risks associated with their own disclosures (even where an application has been filed)
  - Ideally, require prior review and approval of inventor disclosures by TTO/IP counsel
- Never plan to rely on grace periods
- Even when sharing information relating to an invention under CDA, consider filing in advance to minimise risk


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Thank you for listening
Any questions?


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