



INTELLECTUAL PROPERTY EXPERTS



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Freedom to Operate

the Flipside of Patents



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FREEDOM TO OPERATE

- What is it
- How to do it
- When to do it
- Start
- Scope & intensity
- Analysis
- Result
- What to do with the result
- Dealing with 3rd party IP

WHAT IS IT?

- Freedom to Operate:

*“The ability to proceed with the research, development, commercial production of a new product/process with a **minimal risk** of infringing third party IP”*

Infringing:

*“**make, offer, use or sell ...**”*

- Goal: minimise risk of infringement
- Side effect: Identify partners/licensors/licensees/competition



HOW TO DO IT?

- Deconstruct the process/product
(it is a bit like making apple pie)



HOW TO DO IT?

- Deconstruct the process/product

- Gene
- Target
- Lead
 - Small molecule, protein, antibody
- Screening tools
 - Libraries, assays, platforms,
- Technologies
 - Processes, methods (chemistry, biotech)
 - Ingredients
- Derivatization
 - Antibody-drug conjugates, delivery vehicles, linkers, pegylation, ...
- Formulation/application
 - Excipients, adjuvants, linkers,
- Clinical indication



Start selecting the
essential elements

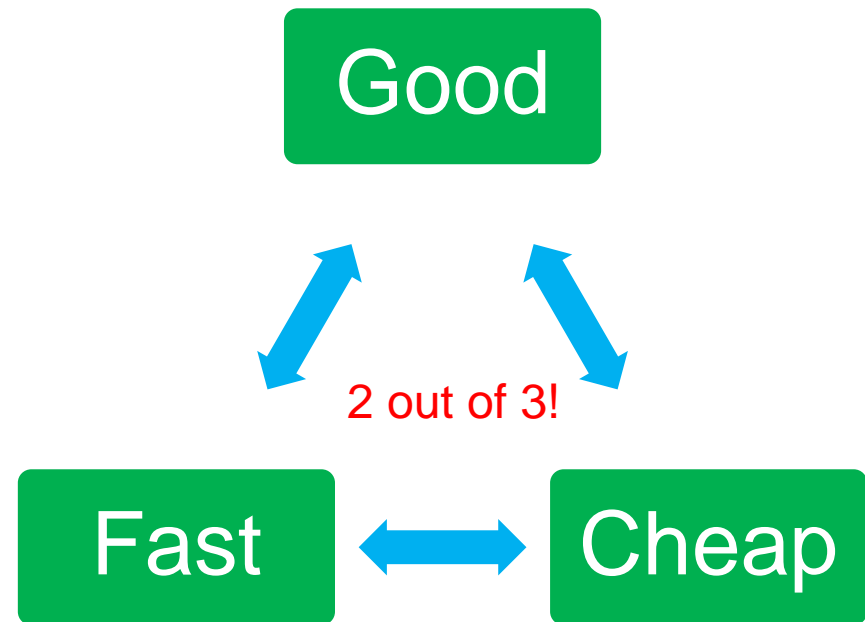
*“make,
offer,
use or
sell ...”*

WHEN IN TIME?

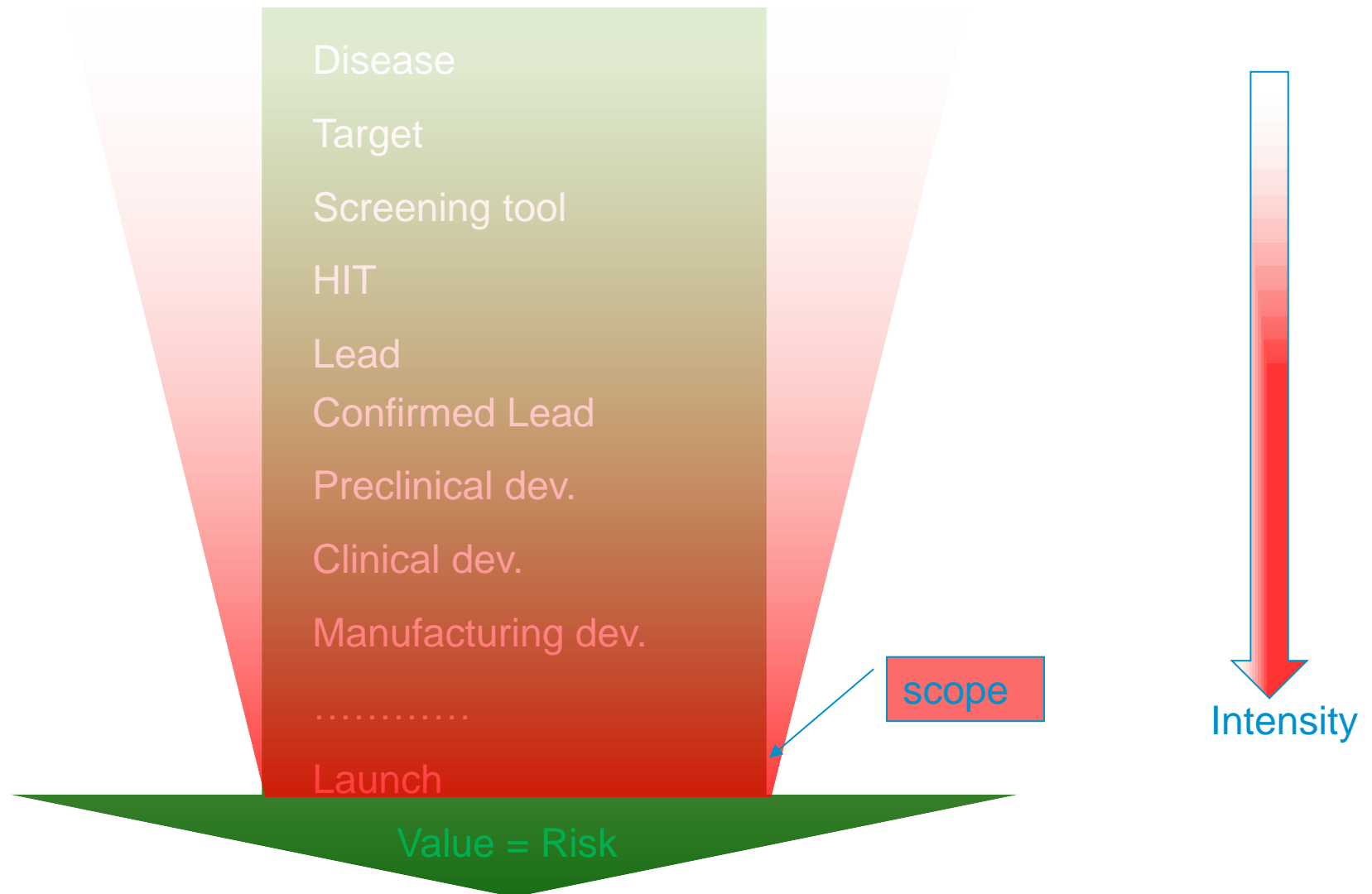
Before:

- Investment rounds
- Market entry

3-6 mo. prior to closure



WHEN IN DEVELOPMENT?



START

- Intelligence Collection
 - Business Intelligence
 - companies, startups, universities, conferences
 - authors, inventors, applicants
 - IP Intelligence
 - Technology landscaping
 - Cited references
 - *Citing references*



From day 1.

START FOR REAL

- Collect initial intelligence



- Define the essential elements



- Create/test search profiles for each element

- Technology/keywords
- Business/people based

“make, offer, use or sell ...”

SCOPE & INTENSITY

- Define Geography & Status

1. EP, US, WO: Granted & Applications
2. EP, US, WO, JP, CN: Granted & Applications
3. EP (DE, GB, FR, NL...) US, WO, JP, CN, KR: Granted & Applications
4. EP (DE, GB, FR, NL...) US, WO, JP, CN, KR: Granted & Applications + actual register status
5.

WHERE do you
plan to “*make,
offer, use or sell
...*” ?

ANALYSIS

What do you
plan to
*“make, offer,
use or sell ...”* ?

- Selection criteria
 - Assume validity of claims
 - Interpret claims in the broadest way possible
 - When in doubt: keep it in
- Define ranking criteria
 - Relevant
 - Essential elements are within scope of claim
 - Moderately relevant
 - Essential elements are within scope of claim, but claim is broad and may change (application)
 - Not relevant
 - Essential element is outside scope of claim or claim contains limitation



14

NOW WHAT?

- Not relevant → Ignore
- Moderately relevant → Monitor the patent
(every 6 months)



- Relevant →



WHAT TO DO?

- Detailed reanalysis
- Validity check

If problem persists:

- Avoid the patent
- Find alternatives
- Design around



DEALING WITH 3RD PARTY IP

- Negotiate (cross)license
- Buy
- Opposition
- Third party observations
- Litigation

Thank You

Questions?

The EP&C team

