

# Protecting Advances in Antibody Technology

## **LakePharma – Antibody Engineering Symposium**

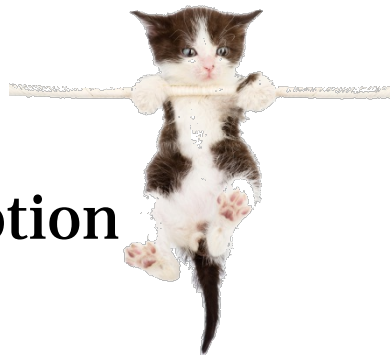
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**Experience**  
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# Introduction and Overview

- Types of intellectual property
  - patent basics
- Patent portfolio management/development
- Protecting antibody-based technologies
- Exclusivity considerations
- Hang in there
- Cocktail reception



# Types of Intellectual Property

## Trademark

- A word, logo, design, shape, etc. that is used to distinguish your product or service from another's (e.g., Tysabri<sup>®</sup>)

## Copyright

- Common copyrightable materials include, for example, advertising materials, product package inserts, computer programs, **scientific publications**, etc.
- Copyrights owned by author, unless a “work for hire” (i.e., scientific publications)
- Copyright transfer forms

# Types of Intellectual Property

## Trade Secret

- A “trade secret” is something that is not known in the trade that has value to the owner
- Valuable to the owner because it provides an advantage over competitors...that value disappears when competitor becomes aware
- Negative results can be a valuable trade secret

## Publication

- Publication of scientific information/data creates “prior art” against potential competitor >>>> no patents!!!

# Types of Intellectual Property

## Patent

- A patent describes and claims an “invention”, which is either a:

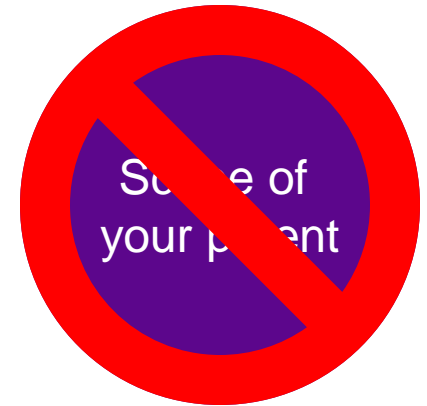
Product – a tangible thing that has a physical structure (e.g., an antibody or chemical structure, a transgenic animal, a drug formulation, a device, a combination of two or more known things, etc.)

Process – a method for doing something useful (e.g., treating or diagnosing a disease, purifying a protein or chemical compound, culturing a cell, novel assays, a new use for a known compound, etc.)

# Patent Basics

- **What does a patent do and not do?**

- gives patentee the right to exclude others from making, using and selling an invention (scope of patent claim)  
[Caveat: *exclusivity*  $\neq$  *freedom to use*]



- **Some of the requirements for patentability**

- novelty – must be new—not disclosed publicly prior to patent filing
- not obvious – must not be obvious from what is already known [beware of your own *unhelpful* statements!]
- useful – must be applicable to a legitimate use, e.g. therapy
- enabled – must be adequately described and demonstrated to work

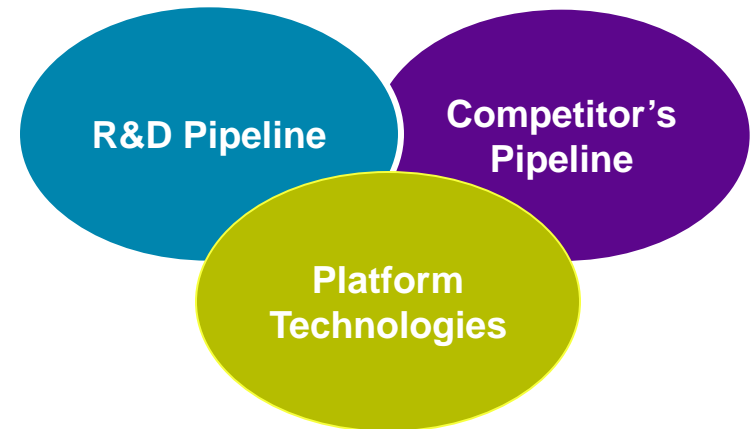
- **Inventorship  $\neq$  Authorship**

# Patent, Trade Secret, or Publish?

- Whether to file a patent application depends in part on:
  - Value to the company
    - cover a commercially important product or method?
    - potential for out-licensing?
  - Scope of patentable claims
    - Ease of designing around?
  - Enforceability and potential monetary damages
  - Level of competition in the field
  - Ease of independent discovery?

# Patent Portfolio Management

- Protect inventions at all stages of product development
  - Traditional inventions
  - Non-traditional inventions
- Monitor competitors
  - FTO issues
- Regularly review portfolio
  - Insure portfolio aligned with business objectives
    - Assess value changes due to legislation/case law
    - Cross-licensing





# Patent Portfolio Development



Compound (Broad) / Mechanism of action

Compound (Specific) / Synthesis / Method of use

Formulations

Manufacturing processes

Additional indications

Additional drug information (safety)

Polymorphs / salts / metabolites

Dosing regimen

Patient sub-populations

Biomarkers

Combinations

Improved formulations

Label-based claims

# Antibody-based Patent Strategies

- **Function-based claims**

- **Broad:**

- Bind specific protein, therapy, combination therapy, increased therapeutic efficacy, binding affinity

- **Narrow**

- Inhibit receptor function, ligand binding, inhibit protein binding

- **Epitope/competition-based claims**

- Binding to specific epitope, compete for binding with mAb defined by sequence or deposit

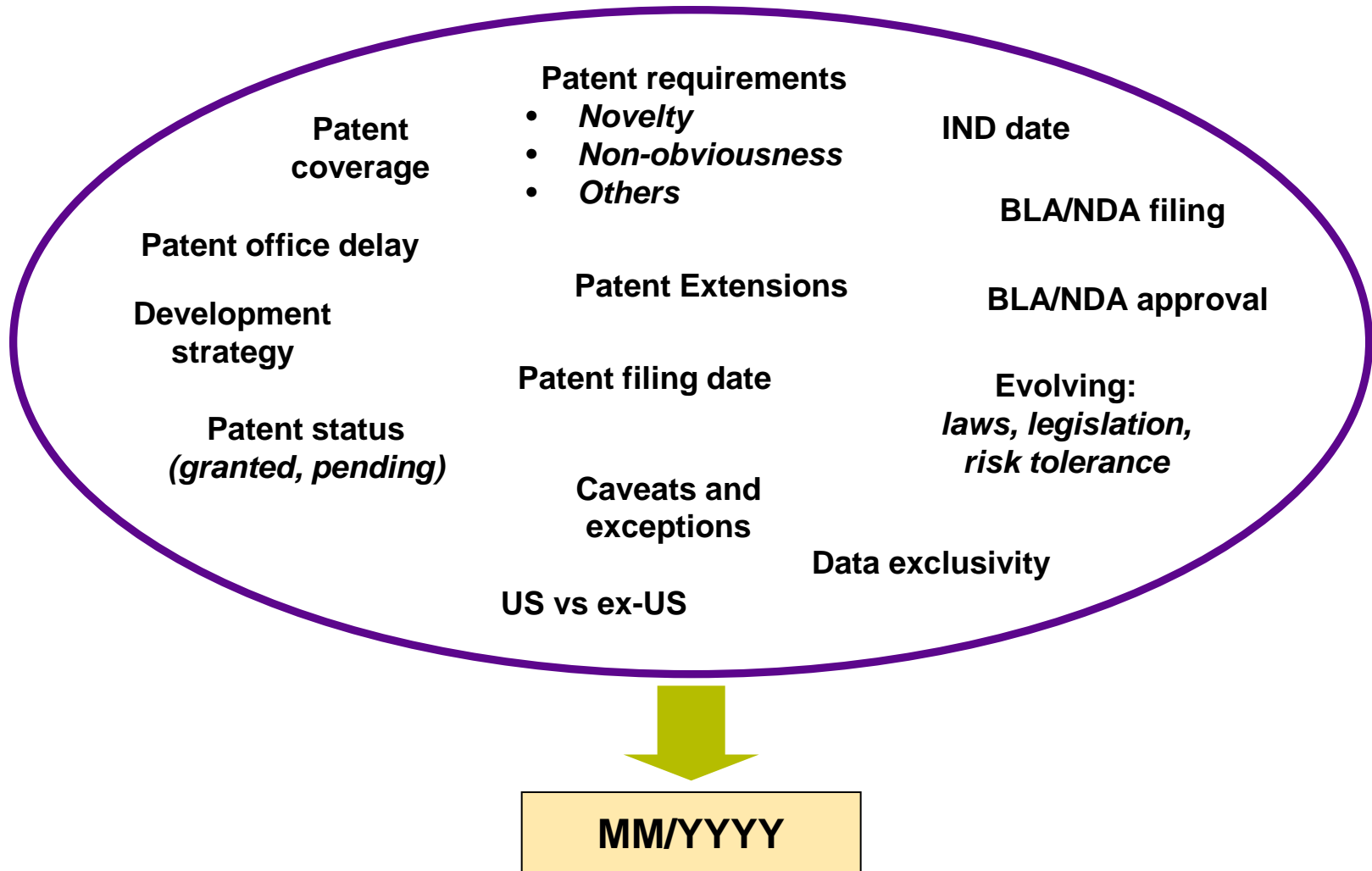
# Antibody-based Patent Strategies – continued

- **Ab structure claims**
  - **Broad:**
    - **Single CDR, complete variable region, consensus sequence, % identity**
  - **Narrow:**
    - **All CDRs, VH only, VL only, VH and VL, murine/chimeric**
- **Claiming specific properties**
  - **Glycosylation, variants/impurities**
  - **Formulations**

# Antibody-based Patent Strategies – continued

- **Claim methods of manufacture/purification/expression**
  - Aggregation, potency issues
  - Vectors, promoters, markers
- **Platform Technologies**
- **Personalized medicine**
  - Companion Dx
- **Bio-better/2d generation**

# Loss of Exclusivity Date (LOE)



Questions?



Thank you!

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