

Patents & Biotech/Pharma

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What We Will Cover

Biotech Patent Issues

- Examination practice
 - Description
 - Enablement
 - patentable subject matter
- Business Matters
 - Searching/FTO/Validity
 - Invention Management

Examination Practice – The Reality

- Immature case law and examination practice
- USPTO Practice and the CAFC swings between extremes and then settles
 - Uncertainty is in the air
 - Myriad; Ariad v. Lilly; Bilski
- Large numbers of filings, backlog and turnover of Patent Office staff

Description and Enablement

- Full description of the invention in exchange for monopoly
- Unlike mechanical inventions, biotechnology inventions are
 - difficult to describe and may be unpredictable
- Biotechnology inventions have a greater burden of description – 35 U.S.C. 112, First Para
 - 20 vs 200 page specifications
 - “Written description”
 - “Enablement”

Written Description

- Must describe the invention in sufficient detail to demonstrate that the inventors were “in possession” of the invention at the filing date
 - Describing not just the exemplified compounds/methods but what is claimed
 - How do you provide information to support human efficacy?
 - How do you provide information to support modifications?
 - How do you describe microorganisms?
 - Budapest Treaty
 - Deposit Rules
 - How do you describe DNA/RNA/protein/polysaccharide sequences?
 - How do you describe platform technologies?

Enablement

- Other aspect of 35 U.S.C. 112, first paragraph
- Sufficient description to enable a person of skill in the art to make and use the invention across the entire scope of the claims
- How do you enable a human therapeutic?
 - Need to demonstrate how an *in vitro* or animal model result can predict and foreshadow a human application

Dealing with Description

- Time and resource consuming – data, data, data.
- IP protection strategy should drive the research strategy, not *vice versa*
 - avoid the science project approach
- Keeping inventors aware of issues arising from their publications
- Patenting strategies for complementary, some times narrower, protection of different aspects of invention

Searching

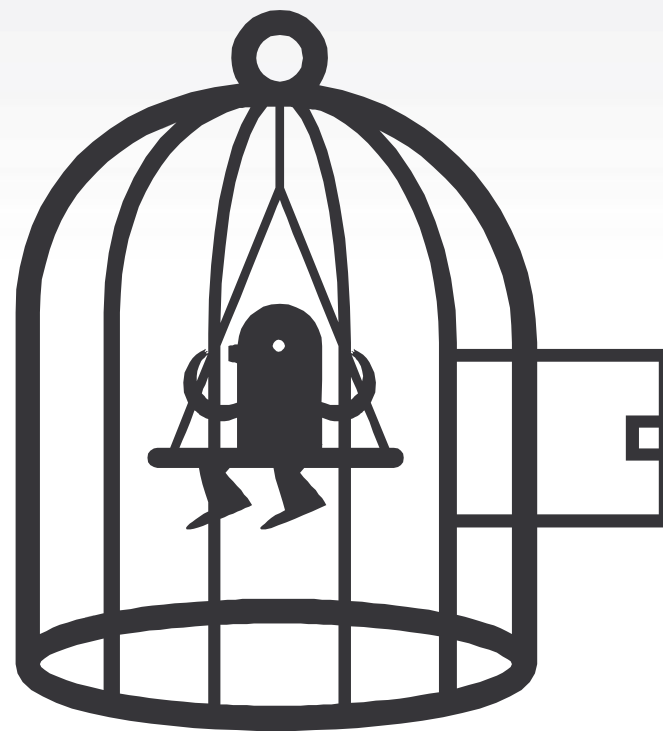
- Patentable inventions must be novel and inventive
- The Biotech/Pharmaceutical art is crowded
- Scientists may be aware of non-patent literature
- Patent literature may be in advance of scientific publications
 - Examination is a different standard to peer review
- Searching of patent literature
 - Both for freedom to operate and for novelty/inventive step
 - Don't forget to look at all sources of publications

Invention Management Strategy

1. Capture
2. Categorization
3. Disposition

Capture

- Conception
- Reduction to Practice



Categorization

- (a) core technology/platform technology
- (b) feature technology
- (c) alternative technology
- (d) related to end use
- (e) unrelated product



Core/Platform Technology

- Invention is fundamental to product function or manufacture
 - E.g. a novel promoter for increased protein expression

Feature Technology

- A feature not necessary to produce the product but adds a feature to add to its appeal
 - A construct comprising a novel promoter operatively linked to a protein of interest

Alternative Technology

- An invention that relates to solving a problem a different way than the current product
 - Rather than a promoter to increase efficiency of expression; an enhancer element to increase expression in a construct

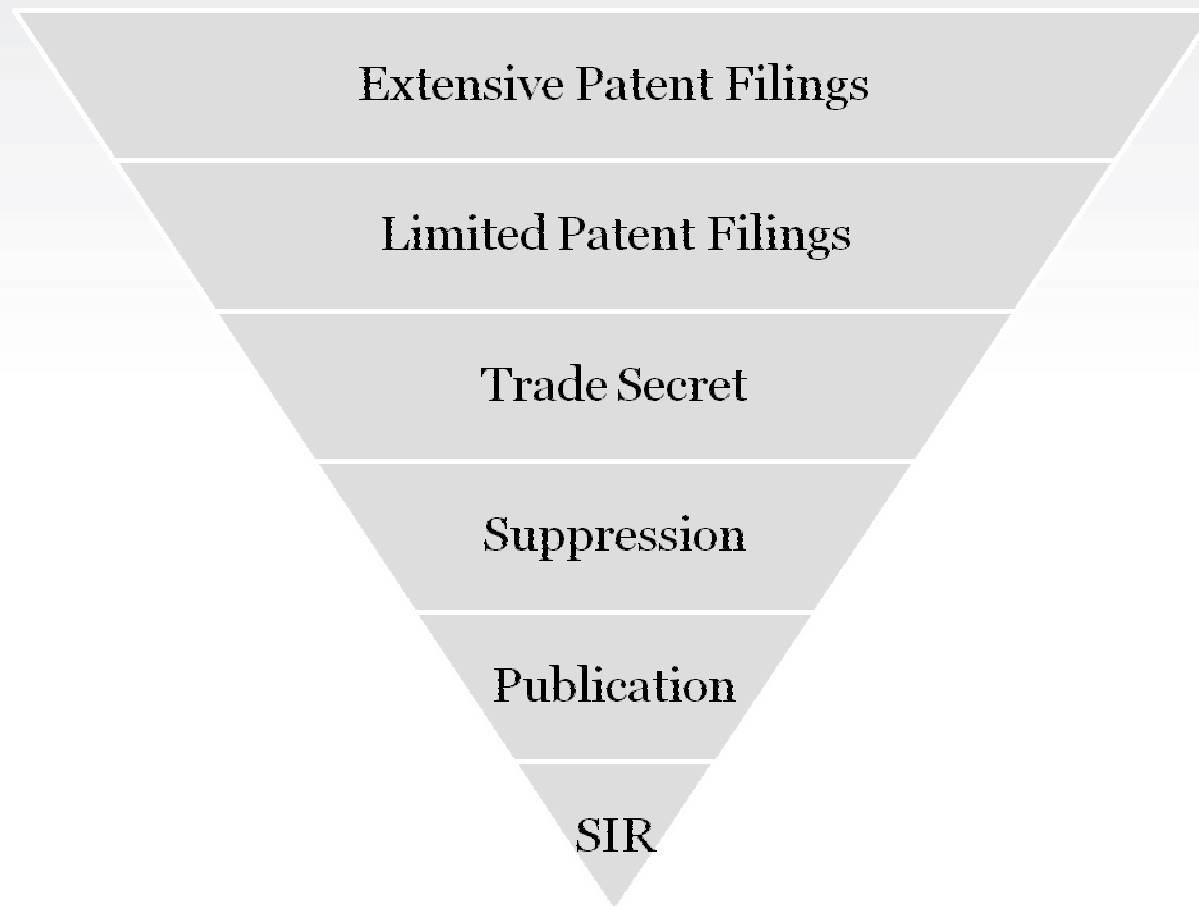
Production/End Use Technology

- Inventions which relate to the end use of the product or the materials or processes of making the product
 - Method of making a protein using the novel promoter/construct

Other Technology

- Technology not directly related to enhancing the competitiveness or managing the risk of the company but may represent a significant improvement in a different industry (alternative revenue stream)

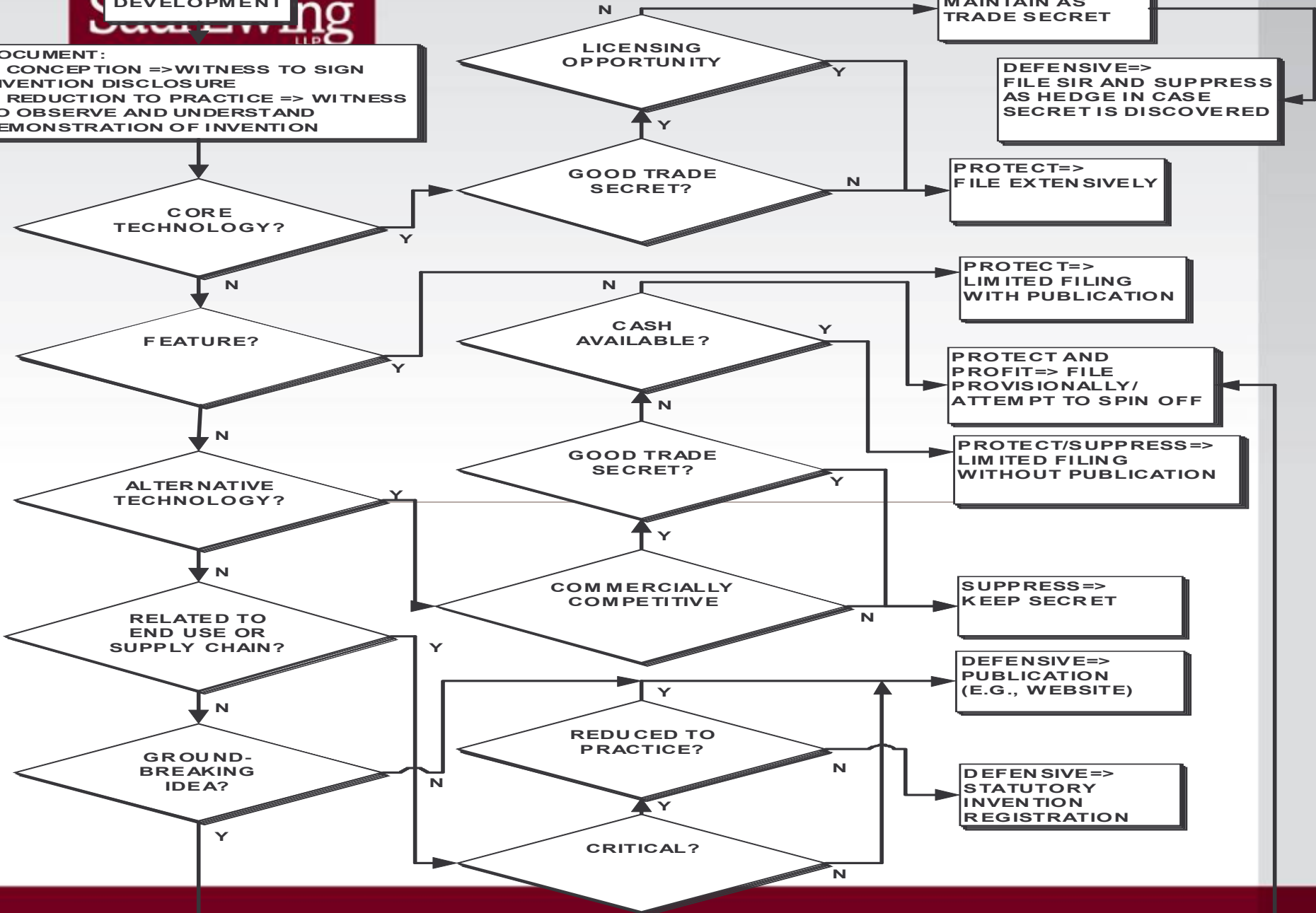
Disposition



NEW DEVELOPMENT

INVENTION MANAGEMENT

DOCUMENT:
 1) CONCEPTION => WITNESS TO SIGN INVENTION DISCLOSURE
 2) REDUCTION TO PRACTICE => WITNESS TO OBSERVE AND UNDERSTAND DEMONSTRATION OF INVENTION



Summary

- Moving target of case law and practice
- Burden of description falls on applicant
 - Strategies to deal with this
- Different claims in different countries
- Searching to provide guidance for patentability and for freedom to operate
- IP management to drive monetization and asset development

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