

# Problems in obtaining adequate protection for your invention

A biopharmaceutical perspective

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# The basic problem

- Molecules can be structurally different but functionally equivalent
- Written description:
  - Sufficient to allow skilled persons to know what was invented and to show that the inventor had possession of the invention
- Enablement:
  - Enable skilled persons to make and use the invention without undue experimentation
- A disclosure may be
  - Sufficient to satisfy both requirements
  - Sufficient to allow others to design around the claims
  - But insufficient to support claims that cover such design-around alternatives

# In other words:

- A patent disclosure may allow others to derive a substantial benefit from the invention that cannot be covered by the claims
- Risk: The patentee is forced to disclose more than he has a right to claim
- Accordingly, claim drafting sometimes tries to dominate future developments and inventions that rely on the earlier invention – claims try to “reach through” to future developments, using functional limitations
- Assumption: compounds with a common function share a common structure, and vice versa.
- Risk: patent claims could cover alternative designs that were never contemplated and could not have been known, dominating a whole developing technology field: a disincentive for developing improvements.

# Some limitations on the scope of protection

- Claim support in patent disclosure
  - Written description
  - Enablement
- Doctrine of equivalents
- Claim construction
- Remedies for infringement

# Written description

- Example:
  - Disclosure teaches a cDNA encoding protein X, and two complimentary sequences that hybridize to it;
  - The claim is directed *generally* to nucleic acid molecules that hybridize to the cDNA under high stringency conditions
- Example:
  - Disclosure teaches the purification of antigen X, but no specific antibody that binds to it
  - The claim is directed to an isolated antibody capable of binding to antigen X
- Example:
  - Disclosure teaches a method for identifying whether a compound specifically inhibits enzyme E, but no specific compound
  - The claim is directed to a method for inhibiting enzyme E in a human by administering a compound that selectively inhibits enzyme E

# Written description

- Functional claim limitations, aimed at covering variants of the disclosed structures, can meet the written description requirement
- The functional claim limitation must be known to be sufficiently **correlated** to a **particular, known structure**
- A nucleic acid sequence that hybridizes under stringent conditions to a disclosed complementary sequence - yes
- An isolated antibody that binds specifically to antigen X – yes, maybe
- A method for treating a patient with a compound capable of inhibiting enzyme E - no

# Enablement

- Must teach skilled person how to make and use the full scope of the claimed invention without undue experimentation
- Scope of enablement provided by the disclosure must be commensurate with the scope of protection sought by the claims
- Predictable fields like mechanics or electronics: broad claims more easily enabled
- Unpredictable fields: hard to enable across the entire scope of a broad claim

# Enablement

- Example: claim is directed to all possible DNA sequences that will encode a polypeptide sufficiently duplicative of protein E to possess the biological activity of x. The specification teaches only a few analog genes.
- *“Details for preparing only a few analog genes are disclosed. This disclosure might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for patentee’s desire to claim all protein E gene analogs. There may be many other genetic sequences that code for protein E-type products. Patentee has told how to make and use only a few of them and is therefore not entitled to claim all of them.”*
- Example: claim is directed to all possible DNA sequences that will encode the specifically-disclosed amino acid sequence of protein E.
- May meet enablement requirement (but written description?)

# “Reasonable royalty” damages – today and tomorrow

## TODAY

- Basis: invention as patented
- 15 *Georgia-Pacific* factors, and others
- Can base damages on value of entire infringing product if “functionally related;” patented component forms “basis for market demand.”
- Can award damages for derivative or conveyed sales

## TOMORROW

- Basis: patent’s “specific contribution over the prior art”
- Subtract value attributable to prior art and other features that add value to infringing product
- Can base damages on value of entire infringing product only if patentee shows that “specific contribution over the prior art” is the “predominant” basis for market demand
- Can consider other factors as well

# Apportionment: why / why not?

- Proponents
  - Many patents potentially apply to one product (multiple recovery problem)
  - “Overclaiming”
- Opponents
  - Prior art subtraction is profoundly unclear when applied to some products, drives up litigation costs
  - Unfair, because patentee had to prove presence of all claim elements in litigation
  - Makes infringement cheaper; front-end squeeze on negotiated licensing agreements.

**Thank you!**