

# **Topic 2 Patent Drafting Techniques** for Chemistry/Biotech Inventions

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# Ways to claim a chemistry/bio product

- Structure (Markush, sequence)
- Composition
- Parameters
  - But watch out: method specific parameters don't belong in a product claim unless you have a product-by-process claim

#### Markush claims – 1

Best way to cover multiple chemical structures sharing the same structural core

- Core structure
- Variable substituents listed as alternatives
- Position and number of substituents can be varied too



#### Markush claims – 2

A compound represented by formula (I)

wherein

X is C or S;

Y is N, O, or C;

Z is aryl, heteroaryl, cycloalkyl, or heterocycloalkyl;

R<sup>1</sup> represents independently for each occurrence hydrogen, halogen or C<sub>1-6</sub>alkyl;

R<sup>2</sup> is hydrogen or C<sub>1-6</sub>alkyl; and

R<sup>3</sup> is hydrogen or hydroxyl.



#### Markush claims – 3

Ensure you have defined each feature in the description



#### Parameters in claims

Often used for claiming polymers and in material science where it is difficult to claim structurally

An alkali metal catalyst on a basic support, in which basic support is a material which desorbs carbon dioxide at a temperature higher than standard alphaalumina.

If the product is new, then you might get broader protection with a product-by-process claim



#### Medical use claims

- Substance X for use as a medicament.
- Substance X for use in treatment of Y.
- Substance X for use in treatment of Z.



- An **isolated** polynucleotide ...
- A purified nucleotide ...
- cDNA ...
- "isolated" and "purified" allow differentiation from natural polynucleotides
- cDNA is by definition different from the corresponding DNA found in nature



An isolated polynucleotide which **hybridizes** to SEQ ID No. 1, or a **portion/fragment** thereof.

- When using "hybridization" ensure that a minimum degree of homology is defined:
  - "for example 60%, with higher homology being preferred (70%), most preferred (80%), particularly preferred (90%), especially preferred (95%)"
- Watch out when using the words "portion" or "fragment"
  - define what is meant otherwise may be considered as very small (and therefore readily anticipated)

An isolated polynucleotide having the sequence of one of SEQ ID No. 1, 3, 5, 7, 9, 11, 13, ...

- Type of claim protects many polynucleotide sequences
  BUT
- It may not be clear if all the sequences share a common inventive concept. If not, then each sequence may be considered a different invention and will need to be searched (extra costs)



- An isolated polynucleotide comprising SEQ ID No. 1.
- An isolated polynucleotide including a polynucleotide of SEQ ID No. 1.
- An isolated polynucleotide of SEQ ID No. 1.
- An isolated polynucleotide consisting of SEQ ID No. 1.
  - Increasingly narrower scope

# Protein/polypeptide – 1

A protein/polypeptide having the SEQ ID No. 1 or a variant, homologue, or portion/fragment thereof

- Homologous sequence is limited to having same properties as parent sequence
- Watch out when using "portion/fragment" wording

## Protein/polypeptide – 2

A polypeptide which is the product of method comprising steps ... (or according to claim X).

A polypeptide obtained by the method comprising steps ... (or according to claim X).

A polypeptide produced by the method comprising steps ... (or according to claim X).

A polypeptide obtainable by the method comprising steps ... (or according to claim X).

- Product by process claims
- Product must be new and inventive and there must be no other way of defining the product

May be able to get a broad claim in the following cases:

For newly identified target/difficult target for raising antibody:

"An antibody which specifically binds to <target>".

For new medical use:

"An antibody which specifically binds to <target> for use in a method of treating <new disease or condition>".



New and improved characteristic of an antibody

- For example to unexpected effect of antibody by way of structural information or functional information, such as
  - Affinity
  - Specificity
  - Epitope
  - Immunogenicity
  - Down-stream function

New and improved characteristic of an antibody (cont.)

- Will need to add supporting data to the application:
- Structural information for at least one exemplary antibody
- Functional data to show that the antibody specifically binds to the target
- Functional data to show that the antibody has unexpected technical effect/functional characteristics

New development of a known medical use

- Bispecific
- Patient group
- Drug conjugate
- Combination/administration
- Dose/formulation
- Administration regime/route
- Again, need to keep in mind that will need comparative data/supporting arguments



An antibody specific for the polypeptide of claim X

Very limited claim



# Reach through claims

- An isolated polypeptide identified by the method of claim X
- A polypeptide identifiable by the method of claim X
- A polynucleotide obtained by screening method of claim X
- Caution: these claims may lack support in certain jurisdictions (EP)



# Exclusions to patentability

Some jurisdictions don't allow some claim types:

- Diagnostic methods
- Therapeutic methods
- Surgical methods
- Plant, animal and biological processes for producing plants and animals



# Claim categories

- Check that you have claims to all the possible claim categories:
- Compound / product per se
- Intermediate(s)
- Composition comprising product(s)
- Use of product/composition
- Process for making product/compound/composition
- Process for making intermediate
- Process for making composition
- Kit of parts



#### Final checklist

- Check that claims do NOT cover embodiments in the prior art
- Check that claims do NOT cover embodiments that do NOT work
- Are all of the essential elements present in the claims? (e.g. are all of the features required to fulfill the technical effect in the claims?)
- Check that don't have too many limitations
- Check the scope of your product and method claims sometimes the method claims can be broader than product claims
- Check consistency between independent claims and dependent claims
  wipo

#### Thank you!

