Pharma and Biotech patents

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DRAFTING OF BIOTECH PATENTS

DEFINITION OF BIOTECHNOLOGY

Biotechnology is the broad area of **biology** involving living systems and organisms **to develop or make products**, or "any technological application that uses biological systems, living organisms, or derivatives thereof, **to make or modify products or processes for specific use"** (UN Convention on Biological Diversity, Art).

DRAFTING OF BIOTECH PATENTS

Definition of life sciences

- The branches of **science** that study living things are referred to as the **life sciences**. A scientist who works in the **life sciences** would be interested in learning more about plants, animals, human beings or even tiny microscopic organisms. Biology is the foundation of the **life sciences**. OR
- a branch of **science** (such as biology, medicine, and sometimes anthropology or sociology) that deals with living organisms and **life** processes.

INVENTIONS NOT PATENTABLE

- An invention, which is frivolous or which claims any thing obviously contrary to well established natural laws;
- An invention, the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;

INVENTIONS NOT PATENTABLE

- The mere discovery of a scientific principle or the formulation of or discovery of any living thing or non-living substance occurring in nature;
- A method of agriculture or horticulture;
- Any process for the medicinal,surgical, curative,prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products;

INVENTIONS NOT PATENTABLE

- Plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological process for production or propagation of plants and animals;
- An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components;

Patents and boundaries to Ethics

- Ethics are about what is regarded right or wrong by a society
- Ethical norms and values may vary from culture group to culture group, or even from country to country
- Ethical norms and values may change over time
- Technology may progress over time

Patents and boundaries to Ethics

- Since ethical standards may vary, only those inventions should be excluded from patentability for *ordre public* or morality reasons, for which there is a clear consensus in overwhelming parts of society that the underlying activities are contrary to ethical standards
- According to TRIPs, WTO-members may exclude from patentability inventions in order to protect *ordre public* or morality, provided that such exclusion is not made merely because the exploitation is prohibited by their law (see TRIPS, Art. 27.2)
- Illegality of an activity is not sufficient to exclude it from patentability for *ordre public* or morality reasons

MANDATORY REQUIREMENTS IN THE SPECIFICATION

PREAMBLE

When an applicant mentions a biological material which may not be described in such a way in the specification so as to satisfy to fully and particularly describe the invention and its operation or use and method by which it is to be performed and disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection shall;

MANDATORY REQUIREMENTS IN THE SPECIFICATION

- Deposit such mentioned biological material with an international depository authority under the Budapest Treaty
- Shall deposit before the date of filing patent application in India
- Reference of such deposition shall be made in the specification either on the filing date or within 3 months from the date of filing the specification.

MANDATORY REQUIREMENTS IN THE SPECIFICATION

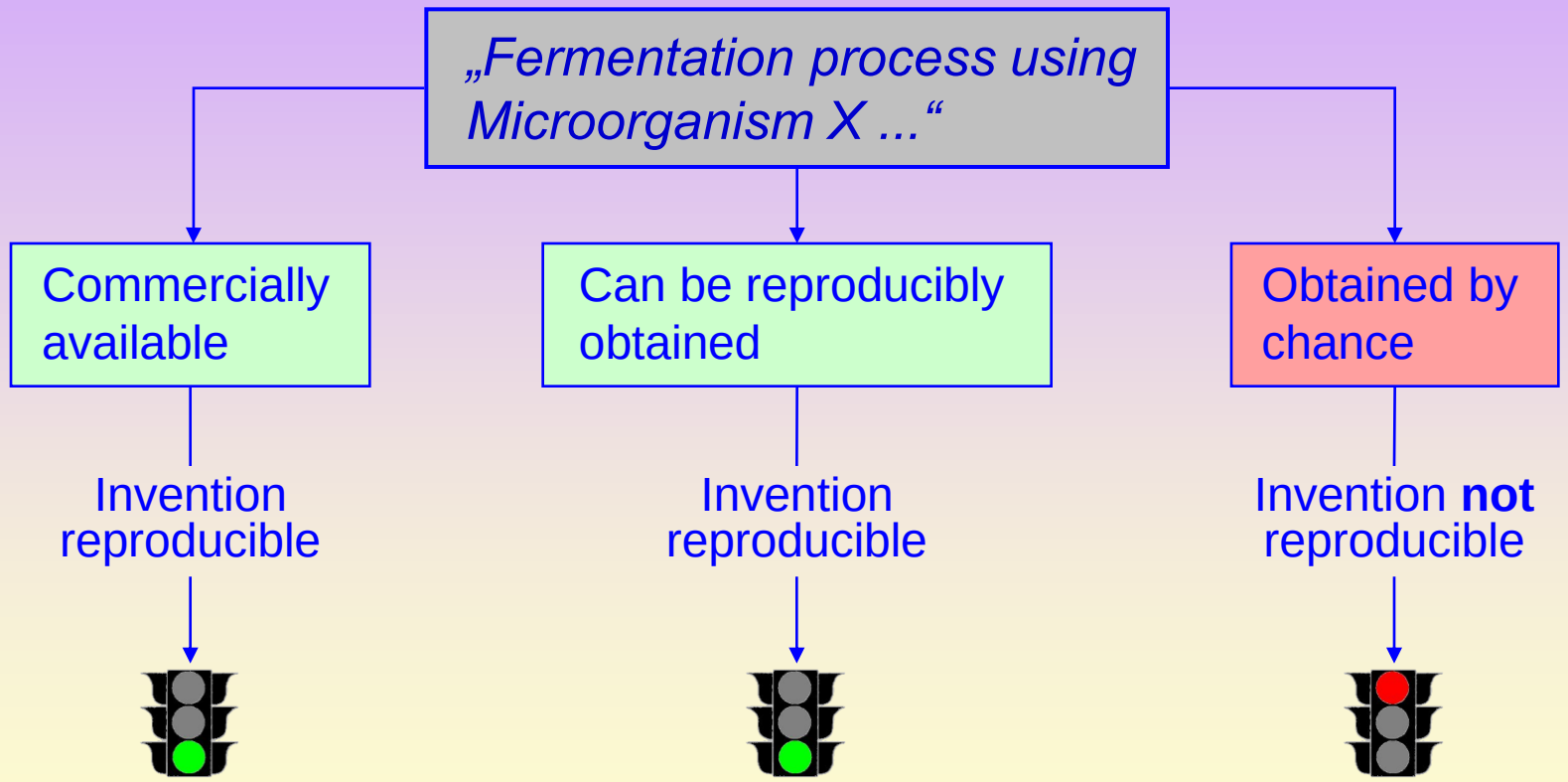
All the available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit [Accession number] of the material at the institution

MANDATORY REQUIREMENTS IN THE SPECIFICATION

- Access to the material is available in the depository institution only after the date of the application for patent in India or if a priority is claimed after the date of priority;
- Disclose the source and geographical origin of the biological material in the specification, when used an invention.

Sufficient description of biological material

If an invention involves biological material, the public **must** have access to it. Example:



PROVISIONS OF RULE 9 OF THE PATENTS RULES 2003

- Any document including drawing,if any, MAY also be filed in electronic form along with a copy of it on white paper;
- Provided further that in case the application for patent discloses sequence listing of nucleotides and or amino acids, the same shall be filed in electronic form.

Technical grounds of patentability also act as important safeguards of the public interest, aimed at ensuring that patents are only granted on genuine advances in knowledge, and are not used to exclude access to material in the public domain.

[to ensure the "principle of non-patentability of humans, their genes or cells in their natural environment;" and asserting that the human genome should be freely available for research purposes]

MANDATORY REQUIREMENT

Approval From National Biodiversity Authority Under section 19 (2)

Any person who intends to apply for a patent or any other form of intellectual property protection whether in India or outside India referred to in sub section (1) of section 6, may make an application in such form and in such manner as may be prescribed to the National Biodiversity Authority

THE INDIAN BIO-DIVERSITY ACT --- 2002

The Indian Bio-diversity Act, 2002 addresses the basic concerns of access to, and collection and utilization of biological resources and knowledge by foreigners, and sharing of benefits arising out of such access. Section 6 or the Act provides that any person seeking any kind of IPRs in or outside of India for any invention based on any biological resource or information on a biological resource obtained from India, is required to obtain prior permission of the NBA, which may determine benefit sharing fee or royalty for the benefits arising out of the commercial utilization of such rights.

HYPHOTHICATED EXAMPLES

I claim a genetically modified bacterial cell which is capable of expressing a novel protein having the desired characteristics as described herein.

- Not allowable as there is no mention of deposition of such biological material.
- Not clear how the GM bacteria has been obtained. In other words questioning the INVENTIVE STEP.
- Not clear with respect to which problem is solved with which solution.

Probable redraft of the claim

I claim

A genetically modified bacterial Cell identified by Accession Number ATCC 11111 which is capable of expressing a novel enzyme capable of hydrolyzing ……

The genetically modified bacterial cell as claimed in claim 1 wherein the modification is carried out by irradiation.

EXAMPLE

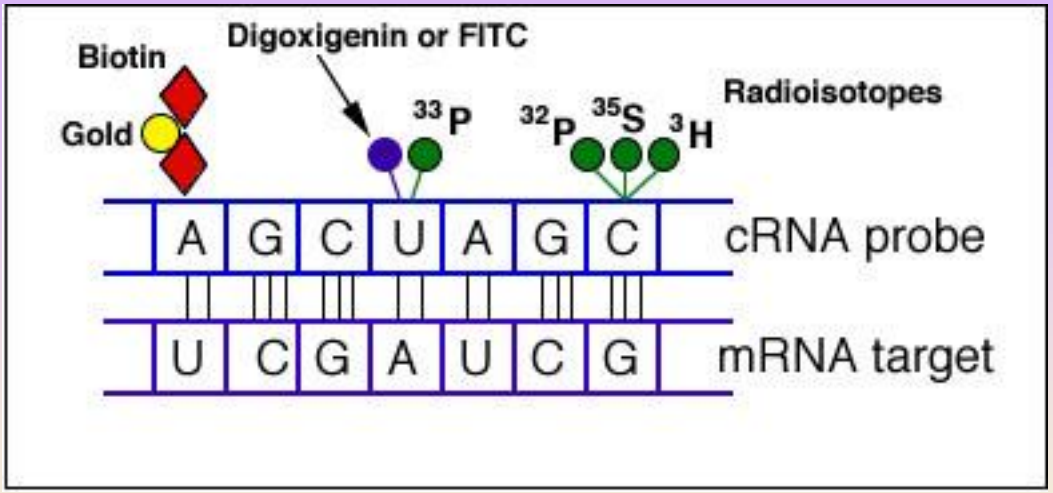
I CLAIM
An isolated DNA having the sequence as shown in SEQ.ID No. 1

DRAWBACKS

It appears that the isolated DNA may be novel but probably a discovery.

The use or functionality of the DNA is not mentioned.

Probes



- Examples of differently labelled probes

Examples of probe Claims

- Claim 1: A nucleic acid probe comprising the following sequence: ATTCGGGTTCCAGGCTCTCTAA

- Claim 2: A nucleic acid probe (suitable) for identifying the gene to red hair.

Problems with these claims

- Claim 1 uses the word comprising and not consisting with the result that any plasmid or even the gene to which the probe binds is encompassed within this claim. Consequently use the word consisting or (more likely) REFORMULATE AS:
- Claim 1: A probe having the following sequence: ATTCGGGTTCCAGGCTCTCTAA

Problems with these claims (cont.)

- Claim 2 is undefined as the probe is merely suitable for the red hair gene. Consequently the claim may not be novel as another sequence (I.E. the gene itself) may be novelty destroying.
- Practical advice: Include sequence data

Sequences

- Sequences which encode a gene may be written as either a DNA sequence or an amino acid sequence, examples are:
- Claim: The following amino acid sequence encoding human recombinant insulin: lys.lys.ser.glu.glu.tyr.glu.cys.. or the nucleic acid sequence coding said protein

EXAMPLE

- **Routine**: A new antigen (protein „X“) is isolated and the claim is directed to any Ab against the antigen;
  - **Claim**: „Monoclonal antibody against protein „X“;
- **Trial & Error and Testing**: The application gives guidance on how to select an antibody with the claimed feature(s). In fact, it discloses a method which has a good probability of selecting Abs with the claimed affinity;
  - **Claim**: „Monoclonal antibody against protein „X“ having a binding affinity of 10nM

- **Undue burden**: An antibody with the claimed affinity was obtained by chance. No guidance on how to obtain other Abs with the same affinity. In this case the applicant can only have the specific antibody which must have been deposited;
  - **Claim**: „Monoclonal Ab against protein „X“ having a binding affinity of 10nM“ (**not allowable**);
  - **Claim**: „Monoclonal Ab against protein „X“ having a binding affinity of 10nM which is produced by the hybridoma deposited under the accession number ATCC 2001“ (**allowable**);
- **Chance**: An antibody with the claimed affinity was obtained by chance. Only a claim to the specific, deposited antibody is allowable

EXAMPLE

A process for the extraction of the Active Pharmaceutical Ingredient from the roots of a herb [botanical name e.g. Azardicta indica] comprising the steps of;

(a) Chopping of the roots
(b) Cutting the roots into small pieces
(c) Drying the cut roots from 30 to 50 degree C for 1 to 4 h
(d) Powdering the roots
(e) Use of a solvent [e.g. an alcohol] to extract the extracts
(f) Filtering and
(g) Isolating the desired compound.

DRAFTING OF PHARMA PATENTS

- No patents were granted for CHEMICAL AND FOOD PRODUCTS till 31st December 1994.
- Filing of chemical and food product patents were allowed and the examination was kept in abeyance without rejection of such applications from 1999 but made effective from 1st January 1995.
- Grant or refusal of such patents was carried out since 1st January 2005
- EMRs were granted in the interim period.
- Since Food and Medicine are prime requirements of the Public the allowance of Product patents in these fields gathered a large amount of interest, discussions and debates.

SECTION 3 (d)

The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance

or

the mere discovery of any new property or the new use for a known substance

or

of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

SECTION 3 (d)
Act 39 of 1970[15 of 2005] with effective from 01-01-2005

The mere discovery of a **new form** **of a known substance which does not result in the enhancement of the** ***known efficacy*** of that substance or the mere discovery of any new property or new use for a known substance or of the mere new use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

EXPLANATION

For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be same substance unless they differ significantly in properties with regards to efficacy.

KNOWN EFFICACY

(1) Not defined in the Act

(2) Courts have concluded that if the product is a drug then it is “therapeutic efficacy” in other words other effects are excluded

ENHANCEMENT

(1) Again not defined in the Act

(2) Enhancement as shown in any units is a fit case for getting a grant.

CAUTION: What about allowable percent of errors in an experiment?

Test for Enablement

- Determine of scope of the claimed invention
- Ascertain if the teachings in the specification are commensurate in scope such that one of skill in the art could practice the invention (over its full scope) without undue experimentation

Undue Experimentation

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue.

Wands Factors

- the nature of the invention
- the state of the prior art
- the predictability or lack thereof in the art
- the amount of direction or guidance present
- the presence or absence of working examples
- the breadth of the claims
- the relative skill of those in the art
- the quantity of experimentation needed

Undue Experimentation and Enablement

- It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others.

- The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole.

EXAMPLES

- PROVIDES THE ACTUAL WORK DONE BY THE INVENTOR / APPLICANT
- ATLEAST ONE EXAMPLE FROM EITHER END OF THE RANGE CLAIMED
- COMPARITIVE EXAMPLES TO SUBSTANTIATE THE ALLEGED INVENTION
- IF INVENTION RELATES TO A MACHINE A PERFORMANCE COMPARISION MAY BE GIVEN
- EFFICACY STUDIES, FLOW CHARTS, COMPARITIVE TABLES MAY BE PART OF EXAMPLES.

CLAIMS INTERPRETATION

– Is the careful consideration of

– **each and every word**

– in a claim to determine what the claim covers

- Claims must be given their **broadest reasonable** interpretation **consistent** with the supporting description
- A claim must be interpreted in light of the specification **without** reading limitations into the claim.

Definition of Terms

- Words and phrases in claims must be given their
- **“plain meaning”**
- as understood by one having ordinary skill in the art
- **UNLESS**
- defined by applicant in the specification with “reasonable clarity, deliberateness, and precision”.

When is a Claim Term Limited by a Definition in the Specification?

- The specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision.

  Exemplification is not an explicit definition.
- Even “explicit definitions” can be subject to varying interpretations.

What if there is No Explicit Definition in the Specification?

Look to:

- The claims themselves and the context of the surrounding words
- The prior art
- Dictionaries
- Encyclopedias
- Treatises

Tips

- Provide Claim breadth commensurate in scope with the disclosure.
- Provide claims directed to the inventive concept.
- Avoid reach-through claims.

REACH THROUGH CLAIMS

- “ Reach-throough claims” are claims to future inventions based on currently disclosed inventions.
- These include claims directed to candidate compounds that might be identified by using basic screening methods and to downstream uses of such candidate compounds.

REACH-THROUGH CLAIMS

- Examples of such claims are those drawn to include all possible pharmaceutical candidate compounds identified by assaying and claims to methods of using such candidate compounds
- Example claim

  Small molecule per se claim, where the molecule is defined as binding to target but not yet identified (e.g. "A receptor [X] agonist").

Red Flag Terms

- Fragments thereof
- Analogues thereof
- Derivatives thereof
- Or derivatives or analogues thereof
- Derived from
  - "A compound of formula II…and its pharmaceutically acceptable salts *or derivatives* thereof."
  - "A is *derived from* a group…''

Physical Properties Differ Among Various Polymorphs

- Molar volume and density
- Refractive index
- Melting and sublimation temperatures
- Enthalpy (i.e., heat content)
- Solubility
- Vibration transitions (i.e., infrared absorption spectra and Raman spectra)

Physical Properties Differ Among Various Polymorphs (contd)

- Dissolution rate
- Stability
- Hardness
- Compatibility
- Handling, flow, and blending

Claiming A Polymorph

- Include name or structure of the chemical compound.
- Apply a “standard” convention to designate and name the polymorphic form and distinguish it from other polymorphic and pseudomorphic forms already in the art.
- Incorporate comparison and characterization data.

Polymorphs May Be Unobvious Over Prior Art Forms (contd)

- It may not be obvious, and not possible to predict
  - How many different crystal forms can be prepared
  - How to prepare any, as yet unknown, crystal forms
  - The properties of any, as yet unknown, crystal forms

  Therefore, new crystal forms are potentially patentable entities

Include Available Polymorph Comparison and Characterization Data Such As:

XRPD

Single crystal x-ray

Infrared absorption

Raman spectroscopy

Solid state NMR

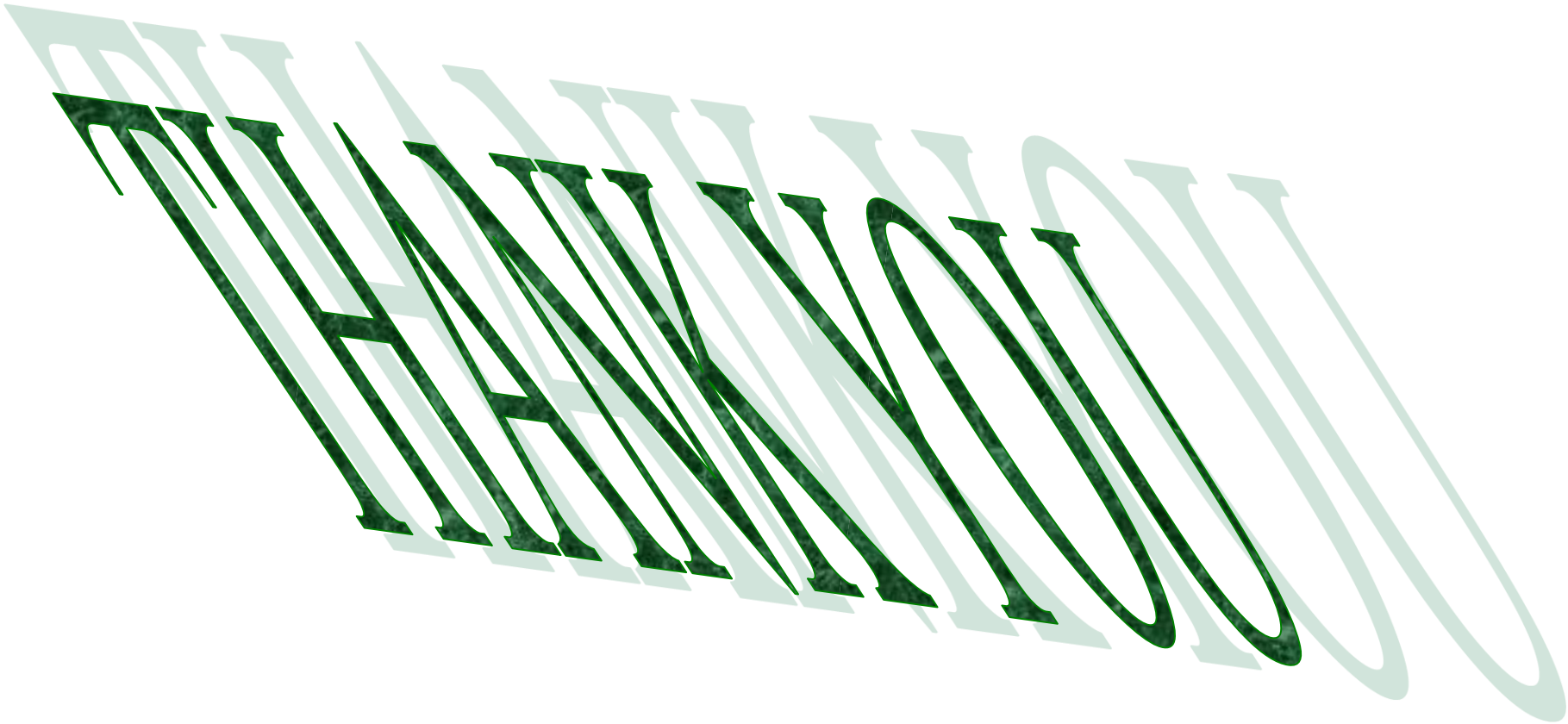
Morphology determination

Include All Available Polymorph Characterization Data Such As: (contd)

- Beyond having a diverse collection of characterization data, the data for a novel polymorph should be analyzed to demonstrate how it distinguishes over other disclosures including the compound per se, and more particularly, over other polymorphic forms.

Include all available polymorph characterization data such as (contd)

- Furthermore, characterization data that evidences unexpected or superior properties over properties of the compound per se, and other polymorphic forms, could make the prosecution easier.


THANK YOU