

THINK GLOBALLY!

*European Patenting Practice
... with a view on USPTO Differences*

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*»Patents add the fuel of interest to
the fire of genius«*

Abraham Lincoln

Overview

- The European Patent Office
- European Patents
- Patentability Requirements
- Practical Aspects
- Recent Developments

European Patent Office - EPO Headquarters in Munich



Source: www.epo.org

The EPO

- is a public supranational authority created 1977 with headquarters in Munich, Germany
- has administrative and financial autonomy
- is not legally bound to the European Union (EU)
- grants European (EP) patents under the European Patent Convention (EPC) with effect for its 38 contracting states
- Norway, Switzerland and Turkey are examples for countries which are not EU members but EPC contractors



Red: The 38 EPC contracting states

Grey: The 2
»Extension States«
Bosnia/Herzegovina,
Montenegro

Source: www.epo.org



What is a European Patent?

The EP patents granted under the EPC are

- not EU patents or even Europe-wide patents, but are
- a bundle of 38 patents conferring the same rights as a national patent granted by the respective states

Post-grant Validation

The national law may require filing of a translation of the EP patent into the national official language for validation

Under the »London Agreement« (2008) some states

- have fully waived translations (e.g. France, Germany, Great Britain) or
- require a national language translation of the claims only or
- require a national translation of the claims and an English translation of the specification

What is patentable in Europe?

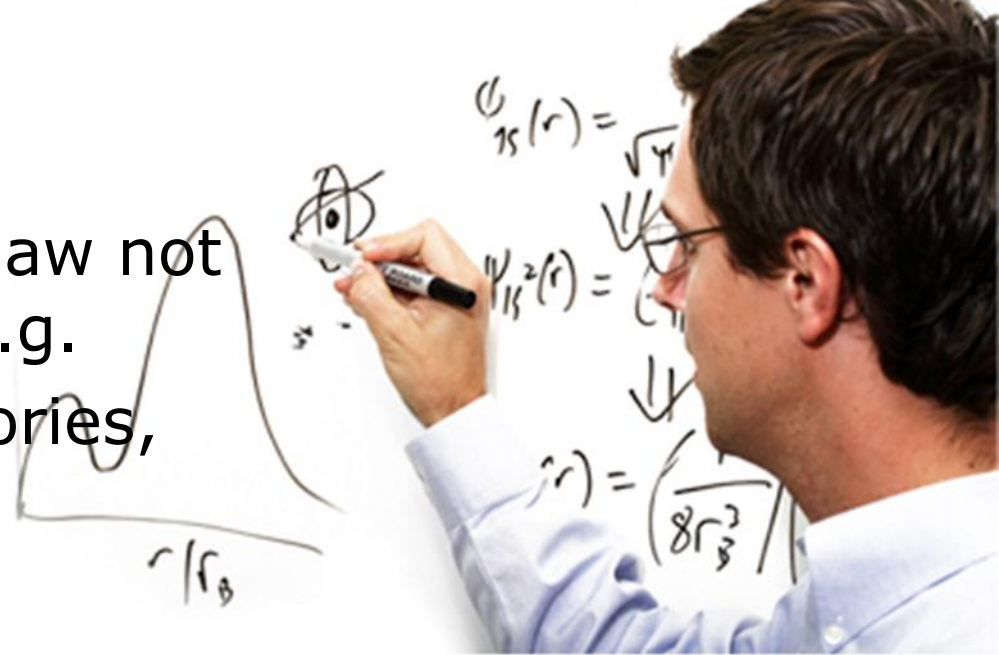
»... anything under the sun that is made by man«?
- Diamond vs. Chakrabarty (1980) -



No sorry, in the EPO you cannot climb into the ring with everything!

Under the EPC

some innovations are by law not regarded as inventions, e.g. discoveries, scientific theories, mathematical methods, and



some inventions are by law not patentable, e.g. if the commercial exploitation would be contrary to morality

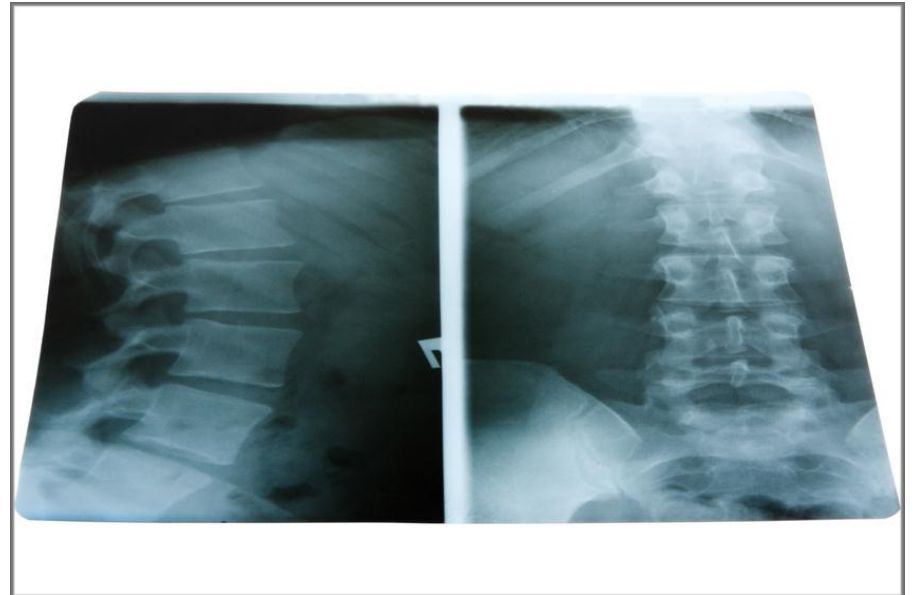
The EPC requires that a patentable invention must be a technical one.

»A technical invention is an instruction for plan-conformant action, utilizing controllable forces of nature to reproducibly achieve, without interposition of intellectual acts, a causally overseisable result.«



Important Non-patentable Inventions

- Business methods
- Computer software »as such«
- Methods for diagnostics or therapeutical treatment
»performed directly on the body«



Patentable Pharma Inventions

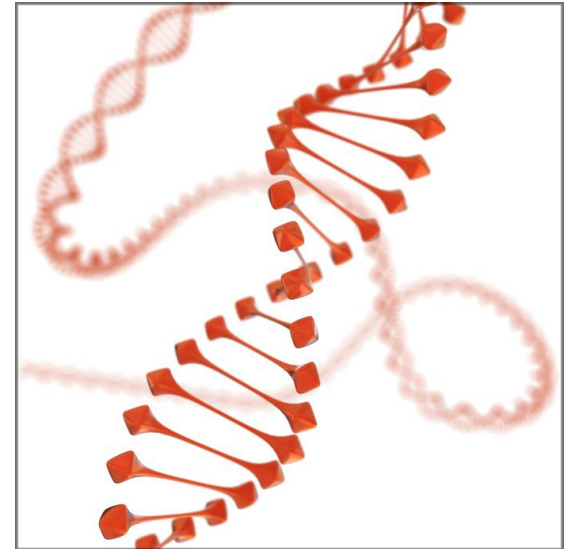
For example:



- Drugs
- Novel compositions or formulations of drugs
- Novel formulation aids for drugs
- Novel medical uses of known drugs
- Methods for preparing drugs or formulations
- Screening methods for receptor antagonists
- Animal models for drug testing
- Marker genes for drug responsiveness

Patentable Biotech Inventions

For example:



- DNA/RNA sequences
- Vectors containing DNA sequences
- Recombinant proteins
- Antibodies (difficult after Köhler/Milstein)
- Genetically engineered host cells
- Transgenic plants or animals
- Bio-Chips

Novelty (Anticipation)

Relevant Prior Art:

- Any written, electronic or oral description
- Public prior use
- No territorial or temporal restriction

Important differences to USPTO Law:

- No grace period for disclosure of the invention by the inventor itself
- No »swearing back of reference«
- No »Applicants admitted prior art«


Novelty ... cont.

The EPO's novelty approach is »photographic«

- Implicitly disclosed features are only to be considered if directly and unambiguously derivable from the prior art
- »Equivalents« and the »common general knowledge« of the skilled artisan are not to be considered

Novelty ... cont.

For chemical inventions novelty cannot be established by:

- Applying a new parameter for the identification of a product already known *per se*
- Preparing a product already known *per se* by a new method
 - ... but: a novel product may be defined by the process used for its preparation:  »Product-by-Process« claims
- Providing a product already known *per se* at a higher level of purification

Inventive Step (Non-obviousness)

»Problem-Solution-Approach«

- Step 1: Determination of the »closest prior art«
- Step 2: Establishing the »objective technical problem«
- Step 3: »Could/would« test: Would the invention starting from steps 1 and 2 have been obvious for the skilled artisan?

No *ex post facto* judgement (retrospective view)

Inventive Step ... cont.

Secondary Considerations or »indicia« for inventive step

Examples (from strong to weak):

- unexpected/surprising results (e.g. synergism)
- failure of others (technical difficulties to overcome)
- satisfaction of a long-felt want or need in the art
- copying by others
- mercantile success

Inventive Step ... cont.

No significant differences to the USPTO practice:

- »Obvious to try« with
- »reasonable expectation of success« and
- »undue burden of experimentation«

... renders the invention obvious!

Under the EPC no *prima facie* obviousness due to structural similarity alone!

Sufficient Disclosure

Article 83 EPC: »The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.«

»Clarity« means particularly:

- No relative or vague expressions in the claims, e.g.: low, high, strong, weak, etc., about (with numerical ranges)
- No multiple independent claims in one claim category (product, method, apparatus)

Sufficient Disclosure/Clarity ... cont.

- No »omnibus claims« (claims referring to the description or the drawings)
- No reference to the »scope and spirit of the invention«

Sufficient Discl./Completeness ... cont.

»Complete« means particularly:

- Sufficient examples supporting the »full breadth of the claims« - 1 example may be sufficient under the circumstances
- Data about effects can be submitted later
- No undue burden of experimentation for the skilled artisan

The »catch-all clause« ... »herein incorporated by reference« does not constitute »original« disclosure suitable for amendments/limitations

Sufficient Disclosure ... cont.

Important differences to USPTO Practice:

- No differentiation between »Written Description« and »Enablement«
- No »Best Mode« requirement
 - Patent cannot be invalidated for this reason

Claim Drafting

Use open »Means plus function« language where possible and appropriate!

Advantages:

- Very open definition of the elements by their functions
- Often easier to write
- Covers »any means« for doing the function, not only those »means« stated in the description
- Covers »equivalents«

Claim Drafting ... cont.

Some Problems with »Functional Claim Language«:

EPO Examiners often object that the claims:

- Only define the invention by the problem to be solved with no explicit technical teaching
- Cover embodiments not showing the inventive effects
- Are in »breadth« not fully supported by the description (i.e. examples)

Claim Drafting ... cont.

Problems with »Reach-through« Claims:

- Lack of clarity and support
- No sufficient disclosure over the entire scope
- No proper assessment for novelty possible

Result:

- Incomplete or no search by the EPO
- Claims must be restricted to specific embodiments

Claim Drafting ... cont.

Two »Golden Rules« of claim drafting are:



1. Avoid »Selection Inventions« where possible

2. Avoid the so-called »Formstein« defense where possible

Selection inventions

deal with the selection of individual elements, sub-sets, or sub-ranges, which have not been explicitly mentioned, within a larger known set or range

Selection inventions ... cont.

A selection is considered novel if:

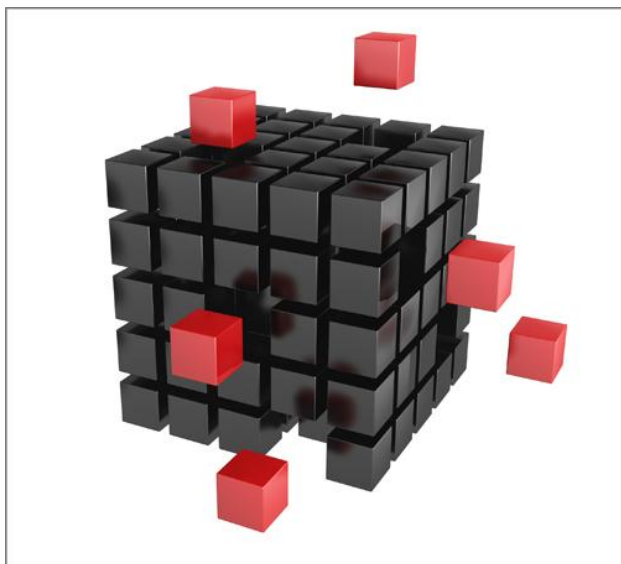
- the selected sub-range is narrow compared to the known range
- the selected sub-range is sufficiently far removed from any specific examples disclosed in the prior art and from the end-points of the known range
- the selected range is not an arbitrary specimen of the prior art, i.e. not a mere embodiment of the prior art, but another invention (purposive selection, new technical teaching).

Selection inventions ... cont.

Examples in the chemical field

- individual chemical compounds from a known generic formula whereby the compound selected results from the selection of specific substituents from two or more »lists« of substituents given in the known generic formula.
- specific mixtures resulting from the selection of individual components from lists of components making up the prior art mixture

How to avoid Selection Inventions?



Make your own selection!

- Disclose specific sub-ranges
- Disclose specific single values within the sub-ranges
- Disclose specific substituents
- Disclose specific combinations of substituents

The »Formstein« Defense

Since 70 % of all European patent litigation cases are heard by German courts, the landmark decision »Formstein« (Molded Curbstone) of the German Federal Supreme Court (BGH - 1986) should be kept in view when drafting claims:

»The defense that the embodiment alleged to be an equivalent would not be patentable over the prior art is admissible«



What does it mean?

The Formstein defense, if successful, reduces the equivalence range of the main claim such that the infringing product is outside the scope:

Main claim: A + B

Sub-claim: A + B + C

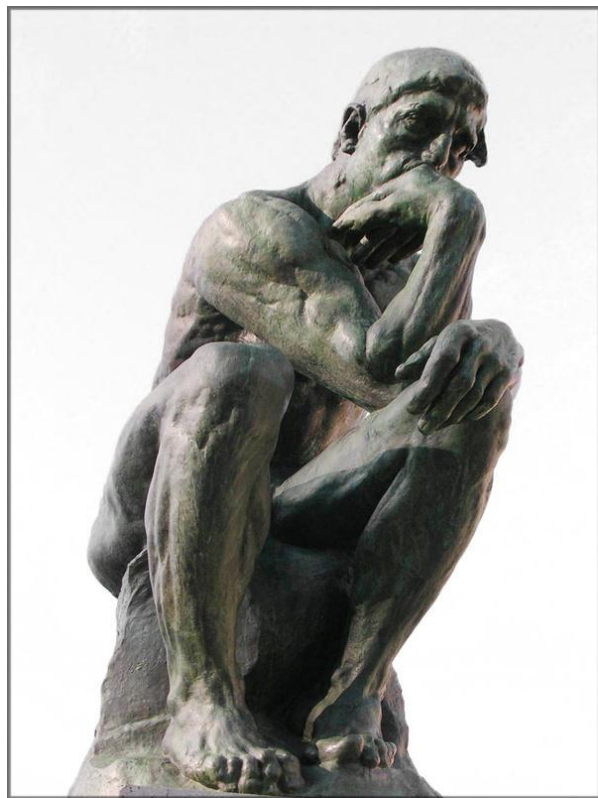
Infringing embodiment: A + B' + C'

wherein: B' and C' are equivalent elements, A + B' is not patentable, and A + B' + C' is patentable

Then, according to Formstein, A + B' + C does not infringe the main claim, but infringes the sub-claim!

How to avoid the Formstein Defense?

Sub-claims, sub-claims, sub-claims ...!



- Claim specific sub-ranges and specific single values within the sub-ranges
- Claim specific substituents and specific combinations of substituents
- Claims all specific embodiments of the invention your client wants to sell

Further Differences EPO/USPTO



Before the EPO:

- First-to-file not First-to-invent
- Public prior use also outside the EPC territory is novelty-destroying
- Sales offers not disclosing the invention or with No Disclosure Agreement are not novelty-destroying

Further Differences EPO/USPTO ... cont.

- Information Disclosure Statement can be requested, but violence of duty of disclosure is no »inequitable conduct« and establishes no *prima facie* case of unpatentability
- Indefiniteness (lack of clarity) of the claims is no reason for revokation in opposition or nullity proceedings
- Multiple-dependency claims are allowed
- No patent term adjustment

Important Recent EPC Amendments

- The EPO search will be focused on only 1 independent claim per category (product, method, apparatus or use). If the applicant makes no election in due time, the EPO will search the first independent claim in each category.
- Replying to a negative preliminary opinion on patentability issued with a European search report is now obligatory within a 6-month term.
- Divisional applications (comparable to continuation applications in the US) must be filed within a **24-month time** limit after either the first substantial official action or a specific non-unity objection, whichever is later.

Thank you for your attention!



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