



BOEHMERT & BOEHMERT
ANWALTSPARTNERSCHAFT mbB

Patentability criteria and their application to pharmaceutical, medical and biotech inventions



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Patentability requirements



Patents are granted:
for inventions, in all fields of technology,

if

- they are **new**,
- Involve an **inventive step**/
are **non-obvious**,
- And are susceptible of
industrial application



Example Europe

European Patents shall be granted for any inventions in all fields of technology provided that they are

- **new**
- involve an **inventive step** and
- are susceptible of **industrial application**.





Example Brasil

To be patentable an invention must meet the requirements of

novelty,

inventive activity and

industrial application



Exclusions & Exceptions



NON-PATENTABLE INVENTIONS

Exclusions

Exceptions



Activities which do not aim at any technical results.
They are not inventions



They are inventions but they have not been allowed for other reasons

"non-inventions" Example Europe



The following in particular shall not be regarded as inventions:

- (a) **discoveries, scientific theories and mathematical methods;**
- (b) **aesthetic creations;**
- (c) **schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;**
- (d) **presentations of information.**



6	1	3	5	8	9	2	4	7
5	4	2	7	1	3	9	8	6
S	U	D	O	K	U	5	1	3
4	3	8	9	C	A	C	H	E
2	7	6	4	5	1	8	3	9
9	b	y	M	U	N	D	S	2
1	6	5	8	7	2	3	9	4
8	9	7	3	6	4	1	2	5
3	2	4	1	9	5	7	6	8

"non-inventions" Example India



The following are not inventions within the meaning of the Act:

- (a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;
- (b) an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health to the environment;
- (c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature;



6	1	3	5	8	9	2	4	7
5	4	2	7	1	3	9	8	6
S	U	D	O	K	U	5	1	3
4	3	8	9	C	A	C	H	E
2	7	6	4	5	1	8	3	9
9	b	y	M	U	N	D	S	2
1	6	5	8	7	2	3	9	4
8	9	7	3	6	4	1	2	5
3	2	4	1	9	5	7	6	8

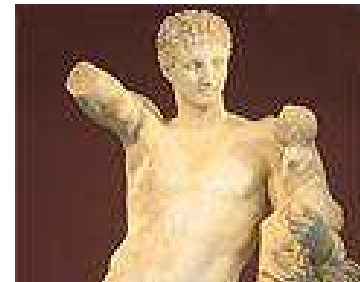
"non-inventions" Example India



The following are not inventions within the meaning of the Act:

- (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 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.

For the purposes 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 the same substance, unless they differ significantly in properties with regard to efficacy;



6	1	3	5	8	9	2	4	7
5	4	2	7	1	3	9	8	6
S	U	D	O	K	U	5	1	3
4	3	8	9	C	A	C	H	E
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1	6	5	8	7	2	3	9	4
8	9	7	3	6	4	1	2	5
3	2	4	1	9	5	7	6	8

"non-inventions" Example India



The following are not inventions within the meaning of the Act:

- (e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
- ...
- (i) any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or ... of animals to render them free of disease or to increase their economic value
- (j) plants and animals in whole or any part thereof
- ...
- (p) an invention which in effect, is traditional knowledge...



6	1	3	5	8	9	2	4	7
5	4	2	7	1	3	9	8	6
S	U	D	O	K	U	5	1	3
4	3	8	9	C	A	C	H	E
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9	b	y	M	U	N	D	S	2
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3	2	4	1	9	5	7	6	8

“exclusions“ Example US



No statutory provisions of exclusions, BUT:

- Abstract ideas
- Natural phenomena
- Products of nature
- Laws of nature

excluded by case law



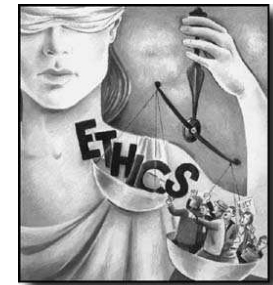
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8	9	7	3	6	4	1	2	5
3	2	4	1	9	5	7	6	8



Exceptions to patentability (Europe)

Patents shall **not** be granted in respect of:

- (a) inventions the commercial exploitation of which would be contrary to "**ordre public**" or **morality**; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
- (b) **plant or animal varieties** or **essentially biological processes** for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;
- (c) **methods for treatment** of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.





Pharma subject matter

Physical entities:

- substances, compounds, compositions, formulations

Activities:

- methods of synthesis, methods of manufacture, methods of formulating, methods of treatment
- Uses, incl. use as a medicine in general (“1st medical indication”), use as a medicine for the treatment of specific disease (“2nd or furthermedical indication”)



Pharma subject matter

Physical entities claimed in:

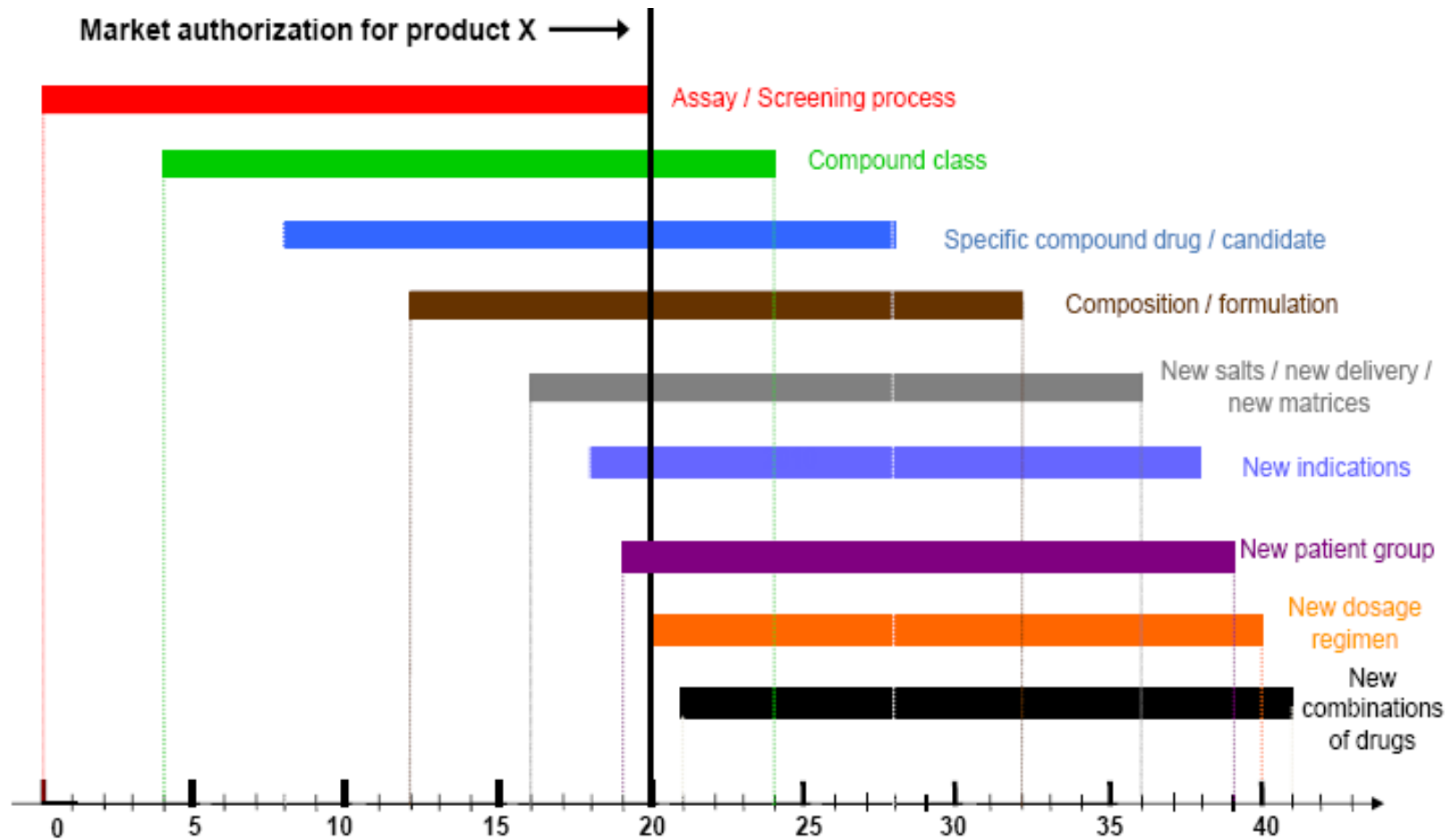
- Product claims (substance, compound, salt, crystal form, solvate etc.)

Activities claimed in:

- Method claims
- Process claims
- use claims



Pharma subject matter



Novelty



- (1) An invention shall be considered to be **new** if it does not form part of the state of the art.

- (2) The state of the art shall be held to comprise **everything made available to the public** by means of a written or oral description, by use, or in any other way, before the date of filing of the (European) patent application.

Everything Made Available to the Public



An invention is available to the public if

- there is a theoretical (more than hypothetical) possibility of accessing the information.
- it is not necessary that the information actually has been accessed
- there is no explicit or implicit obligation to maintain secrecy.

Everything Made Available to the Public



Technical content of an item of prior art is interpreted

- as understood by the person skilled in the art
- including all explicit and inherent features
- not including equivalents

The State of the Art



When determining novelty of an invention, individual items of prior arts may **not** be **combined**.

The State of the Art



Example: claim has features: a, b, c, d

document 1

a

b

c

e

Not novelty destroying

The State of the Art



Example: claim has features: **a, b, c, d**

document 1 document 2

a	a
b	x
c	y
e	e = d

Not novelty
destroying

Not novelty
destroying

The State of the Art



Example: claim has features: **a, b, c, d**

document 1 document 2

a	a
b	x
c	y
e	e = d

novelty	<u>Not</u> novelty
destroying	destroying

The State of the Art



Example: claim has features: **a, b, c, d**

<u>document 1</u>	<u>document 2</u>	<u>document 3</u> <u>embodiment I</u>
a	a	a
b	x	b
c	y	d
e	e = d	f
novelty destroying	<u>Not</u> novelty destroying	<u>Not</u> novelty destroying

The State of the Art



Example: claim has features: **a, b, c, d**

<u>document 1</u>	<u>document 2</u>	<u>document 3</u> <u>embodiment I</u>	<u>document 3</u> <u>embodiment II</u>
a	a	a	a
b	x	b	c
c	y	d	d
e	e = d	f	g
novelty destroying	<u>Not</u> novelty destroying	<u>Not</u> novelty destroying	<u>Not</u> novelty destroying

The State of the Art



Example: claim has features: **a, b, c, d**

<u>document 1</u>	<u>document 2</u>	<u>document 3</u> <u>embodiment I</u>	<u>document 3</u> <u>embodiment II</u>	<u>document 4</u>
a	a	a	a	a
b	x	b	c	b
c	y	d	d	c
e	e = d	f	g	d*
novelty destroying	<u>Not</u> novelty destroying	<u>Not</u> novelty destroying	<u>Not</u> novelty destroying	novelty destroying

Public Prior Use



- **What** has been used, **when** and **how**?
- Questions need to be answered and proven completely and consistently.
- Possibly also, **who** and **where**?

Novelty

selection from generic formula



Prior art:

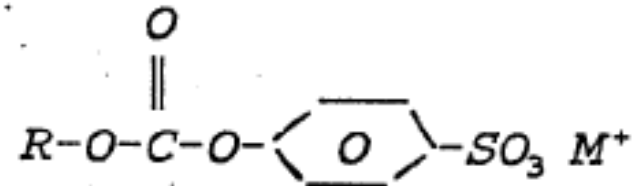
A compound having the structure



wherein R is C₁-C₂₀ hydrocarbyl.

Claim:

A compound having the structure



Wherein M⁺ represents a cation, and R represents n-hexyl, n-octyl, 2-ethylhexyl, 3,5,5-trimethylhexyl, or n-decyl → novel

Novelty

new forms/parameters



Scenario: Prior art discloses amorphous form and a crystalline form of compound A

Invention: specific polymorph which has specific characteristics as determined by XRPD, IR, DSC, mp

- Disclose such characteristics in the application
- Disclose also alternative characteristics (secondary bands, peak intensities, peak patterns, spectra, recording conditions of such characteristics)

Novelty

new forms/parameters



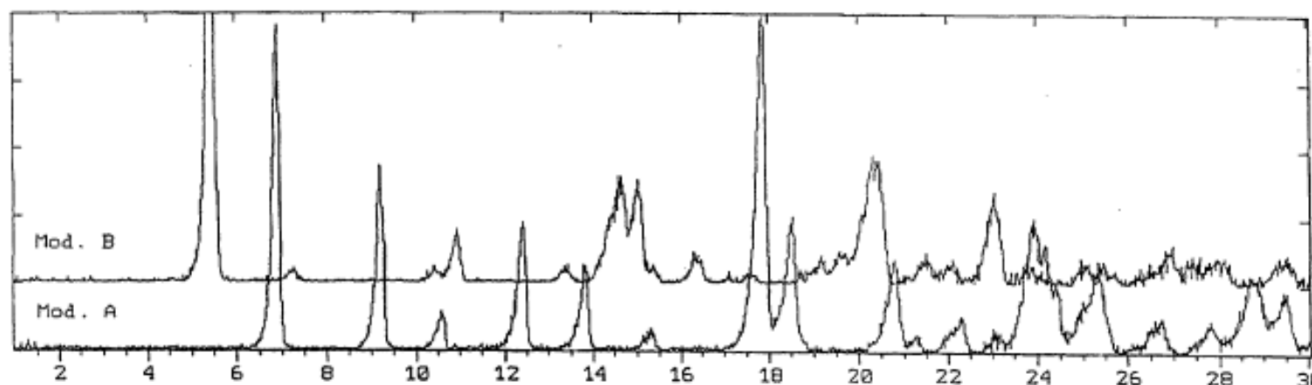
- Disclose also method of production of new polymorph (→ product-by-process claim)
- Include discussion of advantages and/or unexpected effects associated with such polymorph (because of T0777/08)
- Include comparative data (or be prepared to obtain and procure them)

Novelty purity



Scenario: Prior art discloses mixture of two crystalline forms A and B of a compound; pure form A is not described/disclosed in the prior art

Invention: method for the production of pure form A



Novelty purity



Method for the production of pure form A

Pure form A of compound ..., obtainable by a method comprising the steps ...

Beware of T990/96 and related decisions: *“A document disclosing a low molecular weight compound and its manufacture makes normally available this compound to the public in all degrees of purity “*

Include in the application a rationale why pure form was so far not available

Novelty

Second medical use claims



Use of compound X (for the manufacture of a medicament) for the treatment of y

(G005/83, G006/83, EPC 2000)

„Swiss-type claims“

Second medical use claims



Scenario:

Pharmaceutical substance is known but its suitability for the treatment of a disease is not known in the prior art.



US: Method of treatment claims

EP: Second medical use claims in „EPC-format“

India: not patentable (*„not an invention... the mere discovery of any new property or new use for a known substance ...*)

BR: „Swiss-type claims“

MX: „EPC format“

Excursion: Novelty

Second medical use claims in Europe



Claim 1 of EP 0903148:

„Use of ribavirin for the manufacture of a pharmaceutical composition for treating a patient having chronic hepatitis C infection to eradicate detectable HCV-RNA by a method comprising administering an effective amount of ribavirin in association with an effective amount of interferon alpha for a time period of 40 - 50 weeks, wherein **the patient is one having failed to respond to a previous course of interferon alpha therapy**, characterised in that the patient has **a viral load of greater than 2 million copies per ml** of serum as measured by HCV-RNA quantitative PCR of a **HCV genotype 1 infection**.“

Excursion: Novelty

Second medical use claims in Europe



Prior art to EP 0903148:

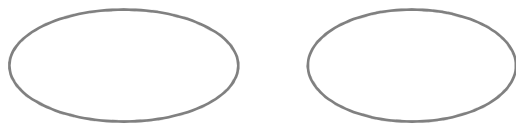
- relapsers and non-responders to monotherapy
- 77.5% infected with genotype 1
- mean serum HCV-RNA titer = 3.4 million copies/ml

Opposition division:

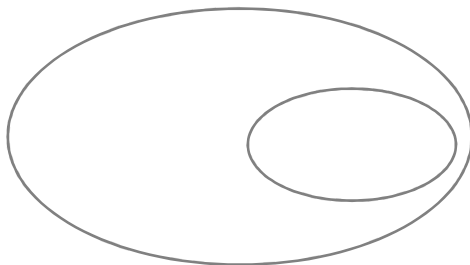
„Among the patients according to the prior art, there must be at least one patient that fulfills all features of the opposed claim(s). At least some prior art patients fall in the group of patients of the opposed claims and therefore an overlap exists.“

Excursion: Novelty

Second medical use claims in Europe



T19/86, T893/90 allowed



T233/96, EP 0903148

refused (in 1st
instance)

Excursion: Novelty

Second medical use claims in Europe



Situations of novelty in EPO case law:

- | | |
|-------------------------------------|---|
| a) Further medical indication | novelty found |
| b) Different groups of subjects | novelty found |
| c) Overlap of subjects | no novelty |
| d) Different mode of administration | novelty found |
| e) Different biological mechanism | no novelty |
| f) Different technical effect | novelty found - T 836/01 |
| g) Different prescribed regimen | novelty found - T1020/03
confirmed by G02/08 |

Excursion: Novelty

Second medical use claims in Europe



T 1319/04

European patents shall not be granted in respect of methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions for use in any of these methods. (Art. 53(c) EPC))

Excursion: Novelty

Second medical use claims in Europe



T 1319/04

“Use of nicotinic acid ... for the manufacture of a sustained release medicament for use in the treatment of hyperlipidaemia **by oral administration once per day prior to sleep ...**”

Excursion: Novelty

Second medical use claims in Europe



“...can a known medicament be patented ... for use in a different, new and inventive treatment by therapy of the same illness?”

“...is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regimen?”

Questions referred to Enlarged Board of Appeal as
G02/08

Excursion: Novelty

Second medical use claims in Europe



1. “Where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness.
2. Such patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art.
3. Where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim, as instituted by decision G5/83.

Excursion: Novelty

Second medical use claims in Europe



1. New second medical use claim format:
“Compound x for use in a method of treatment of disease y” (Article 54(4)(5) EPC)
2. Claim wording of already filed *applications* should be changed. (Art.123(2) EPC).
3. New applications should be drafted using new claim format. (for other jurisdictions think of other applicable formats, though, and include such format in the description!)

Inventive step/non-obviousness

Example Israel



The invention does not appear
obvious
to an average skilled person
in the light of information published before the
filing/priority date

Inventive step/non-obviousness

Example Europe



An invention involves an inventive step, if

- having regard to the state of the art
- it is not obvious to a person skilled in the art

Inventive step/non-obviousness

Example India



A feature of an invention

that involves technical advance

As compared to the existing knowledge

Or

Having economic significance

Or both

And that makes the invention not obvious to a person skilled in the art

Inventive step/non-obviousness

Example China



The invention has prominent substantive features and represents a notable progress as compared with the prior art.

The prior art is defined as technology known to the public before the filing/priority date in China or abroad.

Inventive step/non-obviousness

How do you judge this?



US:

determination of the following questions of fact to resolve the issue of obviousness:

- the scope and content of the prior art;
- the level of ordinary skill in the art;
- the differences between the claimed invention and the prior art
- Consider indicia of non-obviousness

Inventive step/non-obviousness

How do you judge this?



Objective secondary indicia:

- The invention's commercial success
 - Long felt but unresolved needs
 - The failure of others
 - Skepticism by experts
 - Praise by others
 - Teaching away by others
 - Recognition of a problem
- Copying of the invention by competitors

Inventive step/non-obviousness How do you judge this?



Objective secondary indicia in legal provisions in India:

A feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art

Other obviousness criteria also in Indian Patent Act:

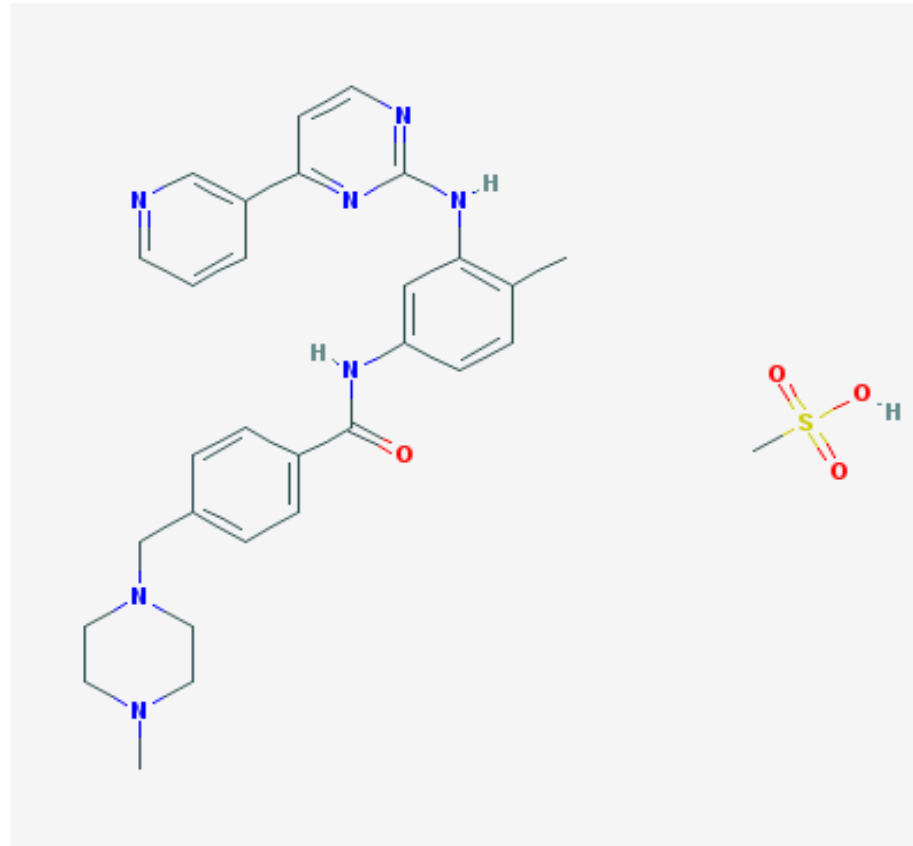
...the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance.... For the purposes of this clause, salts, esters, ... shall be considered to be the same substance, **unless they differ significantly in properties with regard to efficacy**

Inventive step/non-obviousness

How do you judge this?



India: The „Glivec story“



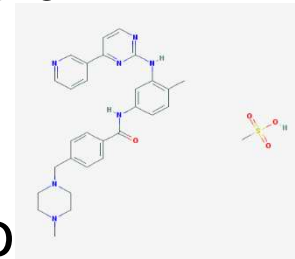
Inventive step/non-obviousness

How do you judge this?



Imatinib („Glivec“) exists as „free base“ and various salts. These various salts may adopt different crystal forms.

Novartis filed a patent application in India directed at β -crystalline form of imatinib mesylate.



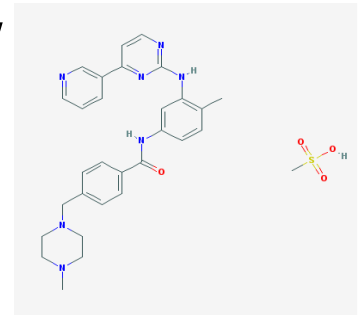
Patent application was rejected by IPO referring to section 3d) of Indian Patent Act, according to which the mere discovery of a new form of a known substance which does not result **in the enhancement of the known efficacy** of that substance cannot be patented

Inventive step/non-obviousness How do you judge this?



Novartis took the matter to the Chennai High Court and the Supreme Court;

Novartis produced data showing a 30% increase in bioavailability in the body and furthermore argued that the β -crystal form had better storability, flow properties and longer shelf life.



The Supreme Court ruled that efficacy means „pharmaceutical efficacy“ which is not the same as „bioavailability“. The Supreme Court also found that better storability etc. has nothing to do with „pharmaceutical efficacy“.

Inventive step/non-obviousness

How do you judge this?



Other jurisdictions:

Caselaw

Secondary indicia

„Problem-solution approach“

and combinations thereof

Example: Inventive step under the EPC



Problem - Solution - Approach

Example: Inventive step under the EPC



Problem - Solution – Approach

Step 1 Determination of the „closest prior art“

Example: Inventive step under the EPC



Problem - Solution – Approach

Step 1 Determination of the „closest prior art“

Step 2 Determination of the technical difference

Example: Inventive step under the EPC



Problem - Solution – Approach

Step 1 Determination of the „closest prior art“

Step 2 Determination of the technical difference

Step 3 Determination of the technical effect of the technical difference

Example: Inventive step under the EPC



Problem - Solution – Approach

Step 1 Determination of the „closest prior art“

Step 2 Determination of the technical difference

Step 3 Determination of the technical effect of the technical difference

Step 4 Determination of the objective problem

Example: Inventive step under the EPC



Problem - Solution – Approach

Step 1 Determination of the „closest prior art“

Step 2 Determination of the technical difference

Step 3 Determination of the technical effect of the technical difference

Step 4 Determination of the objective problem

Step 5 Is there a teaching in the prior art inciting the skilled person to modify the closest prior art so as to arrive at the claimed subject matter?

Example: Inventive step under the EPC



Claim 1 of EP 0 787 743:

“A monoclonal antibody that binds specifically to a human stem cell factor (SCF) receptor, characterised in that the antibody is produced and released by hybridoma cells that were deposited, under No. DSM 2247, at the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH, DSM, in accordance with the Budapest Treaty, and which are designated A3C6E2.”

Example: Inventive step under the EPC



Prior art discloses:

- monoclonals specific to SCF-receptor of type IgG 2A
- methods of production of monoclonals

Invention uses:

specific cell line for production of monoclonal

- produces different type of monoclonal (IgG 1)
- monoclonal is easier to purify (no cross reactivities)
- has higher affinity to its natural ligand

Example: Inventive step under the EPC



Someone skilled in the art had:

no incentive to use specific cell line,

no reasonable expectation of success of obtaining a specific antibody with very specific qualities

Example: Inventive Step under the EPC



Confirming a reasonably expected result experimentally does not give rise to inventive step: T 249/88.

The reasonable expectation of success should not be confused with the hope to succeed: T 296/93, T 923/92, T 207/94 and T 430/96.

The mere completion of experiments foreshadowed in the prior art at a theoretical level is not sufficient to establish inventive step: T 915/94.

On the other hand, certainty is not required to deny inventive step: T 338/97.

Example: Inventive step under the EPC



1. The triazole sulphonamides of the formula:



and salts thereof, where:

R¹ represents hydrogen, alkyl of 1 to 6 carbon atoms, phenyl, or substituted or unsubstituted pyrimidin-2-yl;

R² represents hydrogen, alkyl of 1 to 6 carbon atoms, phenyl, amino, alkylamino of 1 to 4 carbon atoms, or 2,5-dimethylpyrrol-1-yl; and

R³ represents optionally substituted phenyl;

with the following provisos:

- (a) **R¹** and **R²** are not simultaneously hydrogen;
- (b) when **R¹** represents hydrogen and **R³** simultaneously represents phenyl or 4-methylphenyl, **R²** does not represent phenyl;
- (c) when **R¹** represents hydrogen, **R²** does not represent amino.

Example: Inventive step under the EPC



Applicant: **All** compounds with alleged herbicidal activity; however, experimental evidence only available for very few

Board of Appeal: Even small structural modifications may cause major differences in biological activity; the Board is not satisfied that substantially all compounds are likely to be herbicidally active.

“The question whether or not such a technical effect is achieved by all the compounds may arise under Article 56 EPC, if this technical effect turns out to be the sole reason for the alleged inventiveness of these compounds.”

A nighttime photograph of a cityscape. In the foreground, a modern glass-walled building is illuminated from within, with several windows glowing with a bright green light. To its right is a large, multi-story classical building with many windows. The background shows a city skyline under a dark sky with a bright moon or sun. The overall scene is dark, with the primary light sources being the building's interior lights and the celestial body in the sky.

Thank you !

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Boehmert & Boehmert