WEBINAR: Exploring the Patentability of Life Sciences Inventions in Europe and China

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AWA

China Case Studies
Patentable Subject Matter

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Patentable Subject Matter in China

Subject matter	Description	Patentable?
Microorganisms	Exist in nature without any technical treatment by humans, belong to "scientific discovery"	NO
	Separated into pure cultures and have specific industrial uses - must be deposited before filing date/ priority date	YES
Genes or DNA fragments	Found in natural form, belong to "scientific discovery"	NO
	Isolated or extracted from nature for the first time, accurately characterized, and have industrial uses	YES
Peptides or proteins	Isolated or extracted from nature for the first time, accurately characterized, and have industrial uses	YES

Patentable Subject Matter in China

Subject matter	Description	Patentable?
Genetically modified animals and plants	Still belong to the category of "animal species" or "plant species"	**NO**
Animal embryonic stem cells	Belong to the category of "animal species"	**NO**
Human stem cells	Human embryonic stem cell and preparation method thereof	**NO**
	Inventions implemented with human embryonic stem cells that are derived from mature commercial human embryonic stem cells	**YES**
	Inventions based on stem cells isolated or obtained from human embryos within 14 days of fertilization that have not undergone *in vivo* development	**YES**
	Adult stem cell and preparation method thereof	**YES**

Patentable Subject Matter in China

Subject matter	Description	Patentable?
Methods of disease diagnosis	Methods (1) practiced on a living human or animal body with (2) a direct purpose of obtaining disease diagnosis results or health conditions	NO
	Methods of pathological anatomy practice on a dead human or animal body; methods with a direct purpose of obtaining information as intermediate result	YES
Methods of disease treatment	Surgical and drug treatment methods, psychotherapy, other methods for therapeutic purposes	NO
	Various immunization methods implemented to prevent diseases	NO
	Methods for manufacturing prostheses, methods for disposing dead human or animal bodies, and the like	YES

Patentable Subject Matter in China

Subject matter	Description	Patentable?
Medical use inventions	Substance or composition X for use as a medicament/ in therapy or in vivo diagnostics or surgery/ in treating disease Y	-
	Use of substance or composition X in preparation of a medicament for treating disease Y (Swiss-type claim)	**YES**
	- Indication, subject of administration, mode and route of administration	**Having limiting effect**
	- Dosage, dosing regimen	**Having no limiting effect**

Patentable Subject Matter in Europe

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Patentable Subject Matter in Europe*

Subject matter	Description	Patentable?
Biological material, e.g. cells, microorganisms, proteins, DNA including genes and fragments	Isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature	YES
Human stem cells	If, at the filing date, could only be prepared by a method which necessarily involved the destruction of human embryos, even if the said method is not part of the claims	NO
	Embryonic stem cells, if can be made without destroying embryo, e.g. by single blastomere biopsy process (“SBB”), or induced pluripotent stem cells (“iPS cells”)	YES

* here, ”in Europe” means ”under the European Patent Convention, EPC”

Patentable Subject Matter in Europe

Subject matter	Description	Patentable?
Animals and plants, including stem cells	If the technical feasibility of the invention is not confined to a particular plant or animal variety	YES
	Methods for genetic modification of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and animals resulting from such processes	NO
	Exclusively obtained by means of an essentially biological process (e.g. traditional crossing and breeding)	NO

Patentable Subject Matter in Europe

Subject matter	Description	Patentable?
Methods of surgery and treatment	If have curative purpose and are performed on a living human or animal body	NO
	Surgery which involves substantial health risk, even if not curative purpose	NO
	Other methods which handle human beings or animals or are used for measuring or recording characteristics of the human or animal body	YES
Methods of diagnosis	If method includes both i) a step of interaction with human or animal body and ii) a step of a deductive medical decision	NO
	Any other diagnostic method, e.g. *in vitro* methods	YES
Product for use in an excluded method	Even if previously known *per se* or for use in other excluded method	YES

China Case Studies
Support Requirement
Supplementary Data

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Claims for Biomaterials – Supported by Specification?

Claims for Biomaterials (protein, or DNA) defined by sequences

- Open claims are generally rejected for lack of support of specification
  - Case 1, Chinese Patent Application No. 201180068019.4
    - Open claim ➔ Closed claim

- Claims defined by deletion, substitution or addition of residues, or by homology
  - Case 2, Chinese Patent Application No. 201410443899.4
    - Rejected for lack of support of specification
  - Case 3, Chinese Patent No. 200980137647.6
    - Granted for being supported by specification

Claims for Biomaterials – Supported by Specification?

- Open claims are generally rejected for lack of support of the specification

  Chinese Patent Application No. 201180068019.4

  - Original claim 1:
    - A fusion protein, wherein the fusion protein comprises circularly permuted form of TRAIL and oligopeptides located at the N-terminus and/or C-terminus of the permuted form, the oligopeptides contain a repeating sequence consisting of 3-10 histidine residues, and (omitted).
  - Granted claim 1
    - A fusion protein, wherein the fusion protein consists of circularly permuted form of TRAIL and oligopeptides located at the N-terminus and/or C-terminus of the permuted form, the oligopeptides consist of (1) a repeating sequence consisting of 3-10 histidine residues or (2) a Met-Gly amino acid sequence and a repeating sequence composed of 3-10 histidine residues, and (omitted).

Claims for Biomaterials – Supported by Specification?

- Claims defined by deletion, substitution or addition of residues, or by homology

  Chinese Patent Application No. 201410443899.4

  - Rejected claim 1
    - A protein, or a salt thereof, having a structure of (N-CRD)-Linker-(C-CRD), wherein N-CRD is a polypeptide having the amino acid sequence of SEQ ID NO:3, a variant thereof differing from the amino acid sequence of SEQ ID NO: 3 by a deletion, substitution or addition of 1 to 8 amino acid residues and having substantially equivalent SEQ ID NO:3 polypeptide activity, or a variant thereof having an amino acid sequence at least 90% homologous to SEQ ID NO:3 and having substantially equivalent SEQ ID NO:3 polypeptide activity; (omitted)
  - Granted claim 1 of relevant patent of the same patent family
    - A protein, or a salt thereof, having a structure of (N-CRD)-Linker-(C-CRD), wherein N-CRD is a polypeptide having the amino acid sequence of SEQ ID NO:3; (omitted)

Claims for Biomaterials – Supported by Specification?

- Claims defined by deletion, substitution or addition of residues, or by homology

  Chinese Patent No. 200980137647.6

  - Granted claim 1
    - An aptamer that binds to NGF and inhibits binding of NGF to an NGF receptor……the sequence of the aptamer is any one of the following nucleotide sequences (a), (b) and (c):

      ……

      (c) a nucleotide sequence having more than 90% identity with the nucleotide sequence of SEQ ID NO: 62, wherein the uracil may be thymine, and wherein the nucleotide sequence UGAAAGAAACC is the same.

Claims for Biomaterials – Supported by Specification?

- Claims defined by deletion, substitution or addition of residues, or by homology

  Chinese Patent No. 200980137647.6

  - Claim 1
    - The mutations are clearly excluded from UGAAAAAAACC
  - Specification
    - Provides tens of sequences comprising consensus sequence UGAAAAAAACC
    - Proves that consensus sequence UGAAAAAAACC is essential to the function of binding to NGF and inhibiting binding of NGF to an NGF receptor
  - The Reexamination board's opinion
    - It can be predicted that the mutant sequence can still have the technical effect of binding to NGF

Supplementary Data after Filing: China Position

Prior to April 2017, supplementary data was NOT acceptable whatsoever

In April 2017, China revised the Patent Examination Guidelines, and supplementary experimental data can be accepted on conditions

In January 2021, China revised the Patent Examination Guidelines, and supplementary experimental data can be accepted on relaxed conditions

Supplementary Data after Filing: China Position

Prior to April 2017, supplementary data was not acceptable whatsoever

- It is indicated that: "…experimental data submitted after the date of filing shall NOT be considered"

In April 2017, China revised the Patent Examination Guidelines, and supplementary experimental data can be accepted conditionally

- The condition for acceptance: "the technical effect proved by the supplementary experimental data should be one deducible by a person skilled in the art from the disclosure of the patent application as filed"
  - the alleged technical effect to be proved by the supplementary data should be explicitly disclosed in the original application as filed, AND
  - relevant data should also be disclosed in the original application

- The expected relaxation on the standard of acceptance of post filing data, if any, was very limited, as compared with the practice before April 2017

Case Studies

Novartis Case, CN201110029600.7

- Discloses:
  - Experimental methods, including animal models, administration methods, daily doses, and detection indicators
  - Conclusive text, "the obtained results indicate that the combination of the present invention has an unexpected therapeutic effect"
- No any specific experimental data or results
- All claims invalidated

Elan Pharmaceuticals Case, CN02826786.9

- Discloses:
  - Preparation Examples providing hundreds of specific compounds, and Biological Examples providing procedures of cell assays
  - Conclusive text, "the compounds of the present invention exhibited an IC_{50} of less than or equal to 20 µM"
- No any specific experimental data or results
- Application rejected

Supplementary Data after Filing: China Position

In January 2021, China revised the Patent Examination Guidelines

- It is stated in the revised Patent Examination Guidelines that: “with respect to experimental data submitted after the date of filing to meet the requirements of Article 22, paragraph 3 and Article 26, paragraph 3 of the Patent Law, they should be examined by the examiner. The technical effect proved by the supplementary experimental data should be one deducible by a person skilled in the art from the disclosure of the patent application as filed”
- Article 22, paragraph 3 relates to inventive step
- Article 26, paragraph 3 relates to sufficient disclosure of specification

Has China’s unfriendly attitude to supplementary experimental data changed?

Supplementary Data after Filing: China Position

The interpretation of acceptance conditions actually becomes more relaxed

Example 1: a patent application relates to compound A with hypotensive effect

- Specification describes preparation examples, hypotensive effect and experimental methods for measuring hypotensive activity of compound A
- NO experimental data is recorded

- Supplementary data showing the hypotensive effect of compound A are filed
- Supplementary data are accepted and considered
  - The alleged technical effect to be proved by the supplementary data can be obtained from the original application as filed
  - No need for experimental data to be disclosed in the original application

Supplementary Data after Filing: China Position

Example 2: a patent application relates to antitumor compounds of general formula

- Specification describes general formula I and preparation method thereof, and preparation examples of specific compounds A, B, and the like
- Specification describes antitumor effect of general formula I, experimental methods for determining antitumor activity, and experimental results showing IC_{50} values of the example compounds in a range of 10-100 nM

- Supplementary data showing a IC_{50} of 15 nM of compound A, and a IC_{50} of a compound of reference document is 87 nM are filed
- Supplementary data are accepted and considered
  - Compound A and its antitumor effect have been disclosed in the original specification
  - The alleged technical effect to be proved by the supplementary data can be obtained from the original application as filed

Supplementary Data after Filing: China Position

Has China's unfriendly attitude to supplementary experimental data changed?

YES!

Reaccommodate to provide in the specification at filing:

- Identification of chemical or biological materials to be claimed, and preparation method thereof
- Chemical or biological activities thereof, experimental methods for determining the activities, and experimental data including but not limited to *in vitro* cell experimental data; animal experimental data; or clinical trial data

Minimum to be provided in the specification at filing:

- Identification of chemical or biological materials to be claimed, and preparation method thereof
- Chemical or biological activities thereof, and experimental methods for determining the activities
- Supplementary experimental data are acceptable after filing

Support Requirement in Europe

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Support Requirement – The European* perspective

Article 83 EPC:

“The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.”

…i.e. an invention must be **sufficiently disclosed over the whole claim scope**

* again, ”European” here means ”under the European Patent Convention, EPC”

Support Requirement – The European perspective

Article 56 EPC:

"An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art."

From the EPO's case law, Article 56 also requires that a technical problem is solved by the invention, and that **the solution is applicable to the whole claim scope**

Support Requirement – The European perspective

Both sufficiency and inventive step require the application to show

i) that a technical problem has been plausibly solved, and

ii) that any claimed generalization can plausibly be reached from the teaching of the application.

"Plausibility" is a real buzz-word these days…

Support Requirement – The European perspective

Important case #1: T 1329/04 – “Factor 9/Johns Hopkins”

“The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve.”

-> No inventive step!

Support Requirement – The European perspective

BUT: T 2371/13 – “Two colorants/L’Oréal”

The fact that an effect had to be regarded as implausible because it was not backed up in the application was not a good enough reason to disregard comparative tests filed later with a view to proving it.

-> Inventive step OK!

…in other words, this reinforces that supplementary data may be useful

Support Requirement – The European perspective

Important case #2: T 609/02 – “AP-1 complex/Salk Institute”

“If the description of a patent specification provides no more than a vague indication of a possible medical use for a chemical compound yet to be identified, later, more detailed evidence cannot be used to remedy the fundamental insufficiency of disclosure”

”[the] application must disclose the suitability of the product […] for the claimed therapeutic application.”

-> No sufficiency of disclosure

Support Requirement – The European perspective

BUT: T 950/13 – “Dasatinib in leukemia/BMS”

Here, the invention was made plausible by the application through the similarity between the claimed compound and a known compound. The later filed data served as proper evidence to support patentability of a concept that what was already made plausible in the application.

-> Sufficiency of disclosure OK!

Questions

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