Patentability of gene sequences with no plausible function indicated in the application

- no invention, rather a discovery (Art.52(2))
- no industrial applicability (Art.57)
- no problem to be solved (Art.56)
Patentability of gene sequences with no plausible function indicated in the application

In cases where a substance, naturally occurring in the human body, is identified, and possibly also structurally characterised and made available through some method, but either its function is not known or it is complex and incompletely understood, and no disease or condition has yet been identified as being attributable to an excess or deficiency of the substance, and no other practical use is suggested for the substance, then industrial applicability cannot be acknowledged. Even though research results may be a scientific achievement of considerable merit, they are not necessarily an invention which can be applied industrially (T 0870/04)
Patentability of gene sequences with no plausible function indicated in the application

The indicated function must be specific and credible / plausible (level of overall sequence identity, level of characterization of molecules with structural similarity)

The experimental data should render credible the activity based on which the subject-matter is claimed

Sequences with function assignments based on sequence comparisons (in silico) e.g. based on consensus sequences or sequence identities indicating the belonging to a certain family
Patentability of gene sequences with no plausible function indicated in the application

What if the Applicant files a speculative application, based on very preliminary data, which may then be confirmed or "adjusted" by later filed technical evidence / experimental data?

What if I the Applicant introduces in the application all possible hypothetical functions of a polypeptide, so that at a later stage at least one can be confirmed?
Patentability of gene sequences with no plausible function indicated in the application

- The relevant arguments and evidence to be considered by the Examiner for assessing Inventive Step may either be taken from the originally-filed patent application or submitted by the Applicant during the subsequent proceedings (EPO Guidelines C-IV 11.10)

- Care must be taken whenever new effects in support of inventive step are referred to. Such new effects can only be taken into account if they are implied by or at least related to the technical problem initially suggested in the originally filed application (T 0386/89; T1306/04)

Wish list / Laundry list / Cherry picking approach
Patentability of gene sequences with no plausible function indicated in the application

• human sequences are limited

• coverage of prior art of natural (human) sequences approaching completeness

• Less room for **novel / inventive** sequences *per se* against developing prior art

• Only room for further uses

• Medical type claims (first and further medical use of known products) use-limited anyway
Outline of the presentation

• Introduction
• Exclusions (Art.52 EPC)
• Exceptions (Art.53 (a) EPC)
  • Rule 28 EPC
  • Rule 29 EPC
• Exceptions (Art.53 (b) EPC)
• Exceptions (Art.53 (c) EPC)
  • Art.54 (4) (5) EPC
• Conclusions
Is everything patentable?
Article 53 EPC - Exceptions to patentability

European 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 essential biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

(c) methods for the 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.
Patentability of Plants

A plant variety such as durum wheat type wh222 deposited at a seed depository

A transgenic plant and its seeds containing an exogenous bacterial gene encoding Bt toxin

Seeds follow the same requirements as for the plants
patentability of animals

Yes,
• If the subject-matter is not covered by the terms “animal variety”, “race animale”, “Tierrasse” or feasibility not confined to them (Rule 27(b), T19/90)

No,
• If a specific animal variety is claimed per se (Art. 53(b), Rule 27(b)&(c))
Is everything patentable?
Article 53 EPC - Exceptions to patentability

European 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 essential biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

(c) methods for the 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.
"microbiological process" means any process involving or performed upon or resulting in microbiological material fermentation

"micro-organisms" all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory (GL: C-IV, 4.7.1)

Viruses
Unicellular Fungi
Yeast
Algae
Protozoa
Human, animal and vegetal cell(s) (lines)
plasmids, vectors
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Therapeutical / surgical / diagnostic methods (Art.53(c), 54(4)(5))

A patent confers a monopoly to the Proprietor; however, in the pharmaceutical/medical field no freedom to operate?

Medical practice must not be hindered by protection rights (need to ensure medical care for the population). The doctors must be free of practising their profession.

Even though it may be commercial in nature, the medical profession is not a branch of industry.
Article 53(c) EPC - therapy

- therapy covers also prophylactic treatment such as vaccination (T 0019/86) and removal of plaque (T 0290/86)

- non-therapeutic treatments (cosmetic, treatment of sheep / cows to promote growth or quality of wool / milk)

- Treatment of dead bodies
Compound X is new

(a) compound X for use as a medicament
(b) compound X for use in treating disease Y
(c) composition A containing X for use in treating disease Y
(d) medicament containing the compound X
(e) use of X in a composition A for the treatment of disease Y
(f) use of X as a medicament for the treatment of disease Y
(g) use of X for the treatment of disease Y
(h) use of X for preparing a medicament
(i) use of X for the manufacture of a medicament for treating disease Y
(j) process for the preparation of a medicament for treating disease Y using compound X as an active ingredient
(k) method of treatment of disease Y using X
Article 53(c) EPC - therapy

Compound X is **not new**, but **no** medical use

(a) compound X for use as a medicament
(b) compound X for use in treating disease Y
(c) composition A containing X for use in treating disease Y
(d) medicament containing the compound X
(e) use of X in a composition A for the treatment of disease Y
(f) use of X as a medicament for the treatment of disease Y
(g) use of X for the treatment of disease Y
(h) use of X for preparing a medicament
(i) use of X for the manufacture of a medicament for treating disease Y
(j) process for the preparation of a medicament for treating disease Y using compound X as an active ingredient
(k) method of treatment of disease Y using X
Article 53(c) EPC - therapy

Compound X is not new and known as medicament

(a) compound X for use as a medicament
(b) compound X for use in treating disease Y
(c) composition A containing X for use in treating disease Y
(d) medicament containing the compound X
(e) use of X in a composition A for the treatment of disease Y
(f) use of X as a medicament for the treatment of disease Y
(g) use of X for the treatment of disease Y
(h) use of X for preparing a medicament
(i) use of X for the manufacture of a medicament for treating disease Y
(j) process for the preparation of a medicament for treating disease Y using compound X as an active ingredient
(k) method of treatment of disease Y using X
Article 53(c) EPC - therapy

- mechanism of action
- dosage
- route of administration
- patient group
- disease
- 2nd medical use
- 1st medical use
- dosage regimen