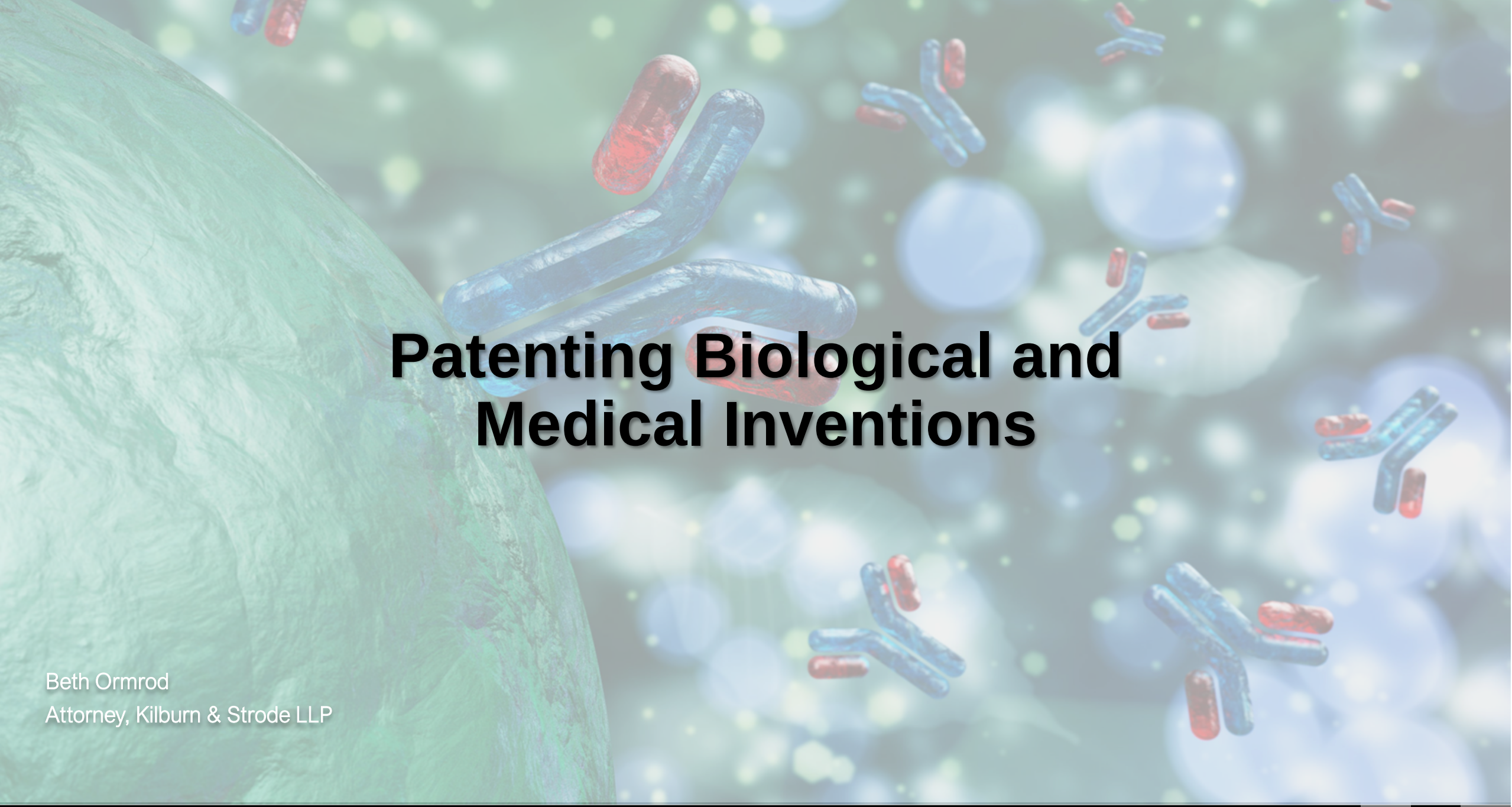
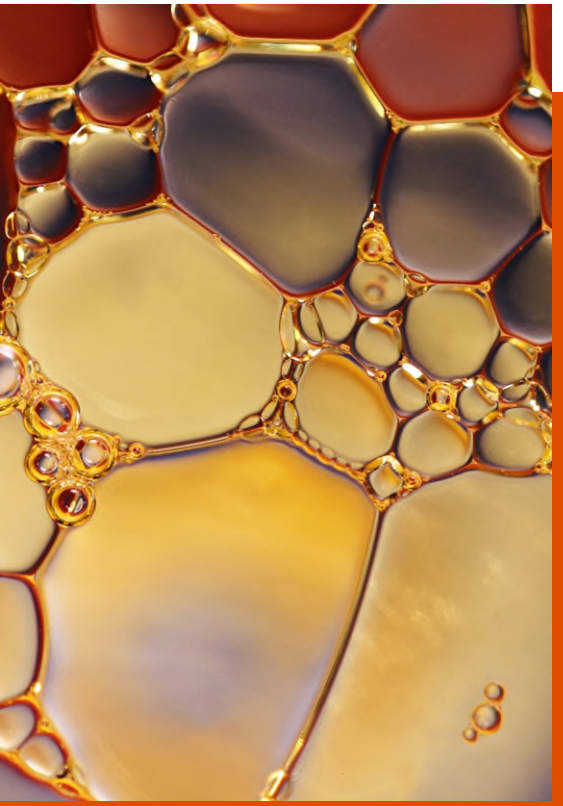


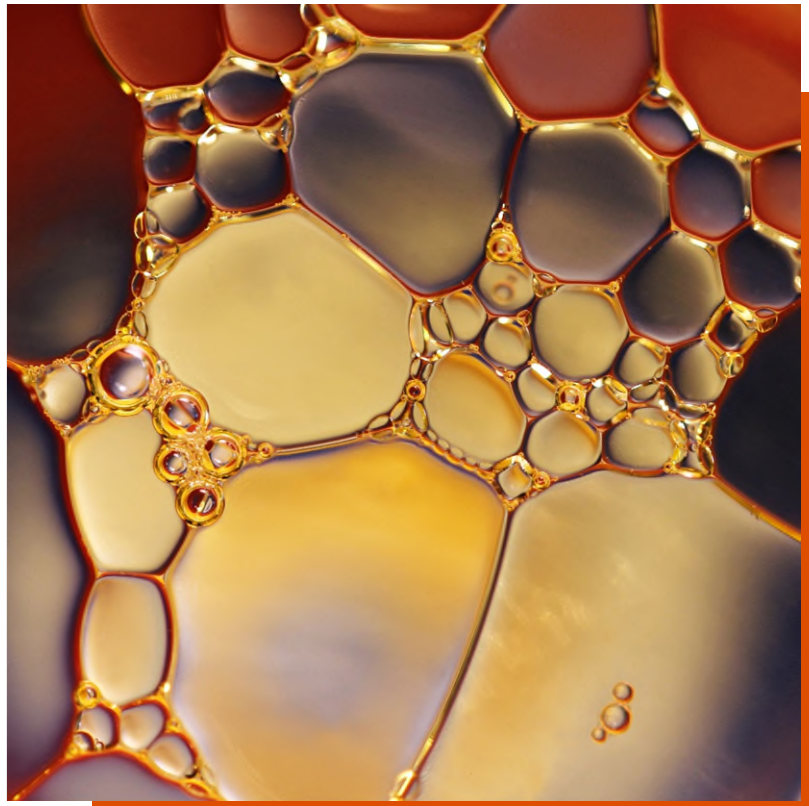
Patenting Biological and Medical Inventions

Beth Ormrod
Attorney, Kilburn & Strode LLP

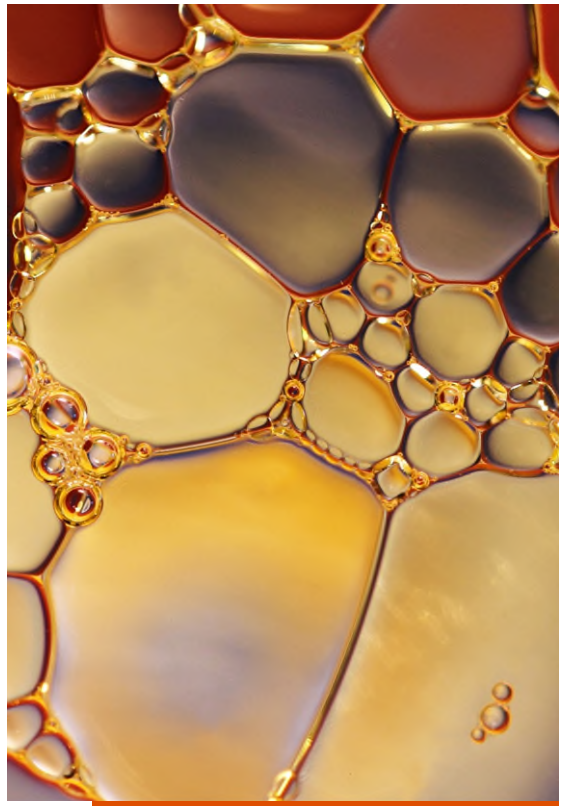
Contents

The Basics





Explore



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The Basics

- Novelty - Is it available to the public?
- Inventive step - Is it obvious to the skilled person?
- Sufficiency - Can the invention be reproduced?
- Support - Is the scope of claims justified?

(Articles 54, 56, 83 and 84 EPC)

The Basics (continued)

- Industrial application - Is it capable of use in industry?
- Morality - Not “contrary to ordre public” or morality?

(Articles 57 and 53 EPC)

Statutory exclusions

No patents on:

- methods for treatment of the human or animal body by surgery or therapy
- diagnostic methods practised on the human or animal body
- plant or animal varieties
- essentially biological processes for the production of plants or animals (but not microbiological processes)

(Article 53 EPC; Rule 26 EPC; G1/98; G1/04; G2/06; G1/07; G2/07; G1/08)
(Corresponding provisions under UK law but elsewhere may be different e.g. US)

Medicines

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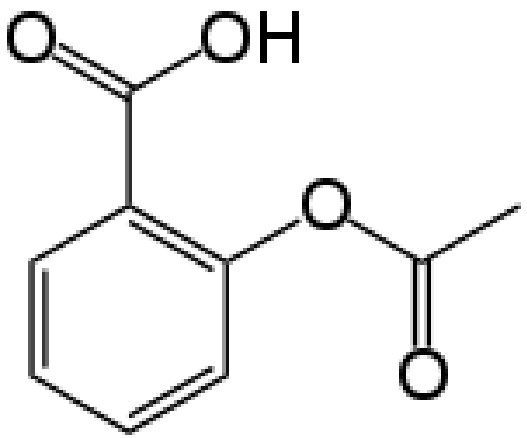
Medicines

Compounds defined by chemical formulae

A compound of formula



or a pharmaceutically acceptable salt thereof

First medical use claims

Product X is known in the art but only for non-medical uses

Claims

- Product X for use as a medicament
- Product X for use in therapy

(Article 54(4) EPC)

Second medical use claims

Product X is known in the art for a prior medical use Y

Second medical use claim (EPC 2000)

- Product X for use in the treatment of disease Z

(Article 54(5) EPC; G2/08 – as of 29 January 2011)

Old form of claim ("Swiss-type" claim)

- Use of product X in the manufacture of a medicament for the treatment of disease Z

(G5/83)
(Still the format used in some countries)

Method of treatment claims

A method of treating disease Y comprising administering an effective amount of compound X to a patient in need thereof.

(Article 53(c) EPC – not allowed)

(Allowed in US, AU)

Claim Reformulation

A method of treating disease Y comprising administering an effective amount of compound X to a patient in need thereof.

Compound X for use in the treatment of disease Y

New dosage regimen

Product X is known in the art for a prior medical use Y

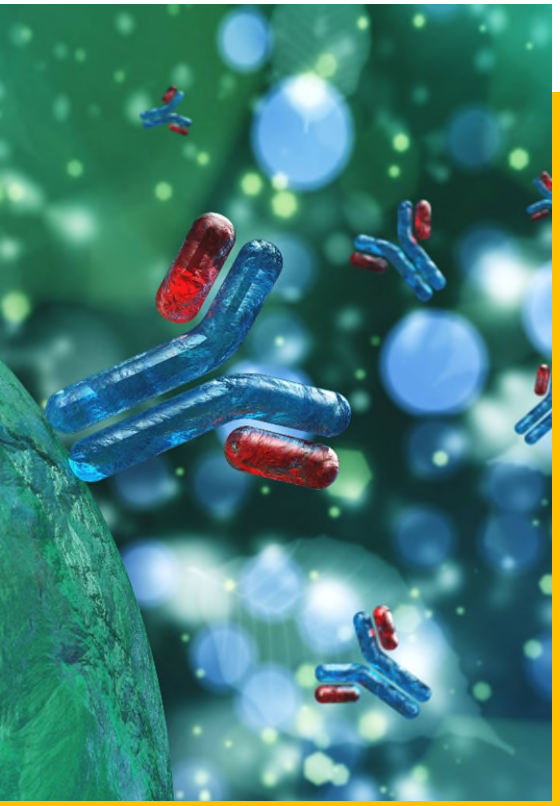
A new dose or mode of administration of the same drug for the same medical use might still be patentable

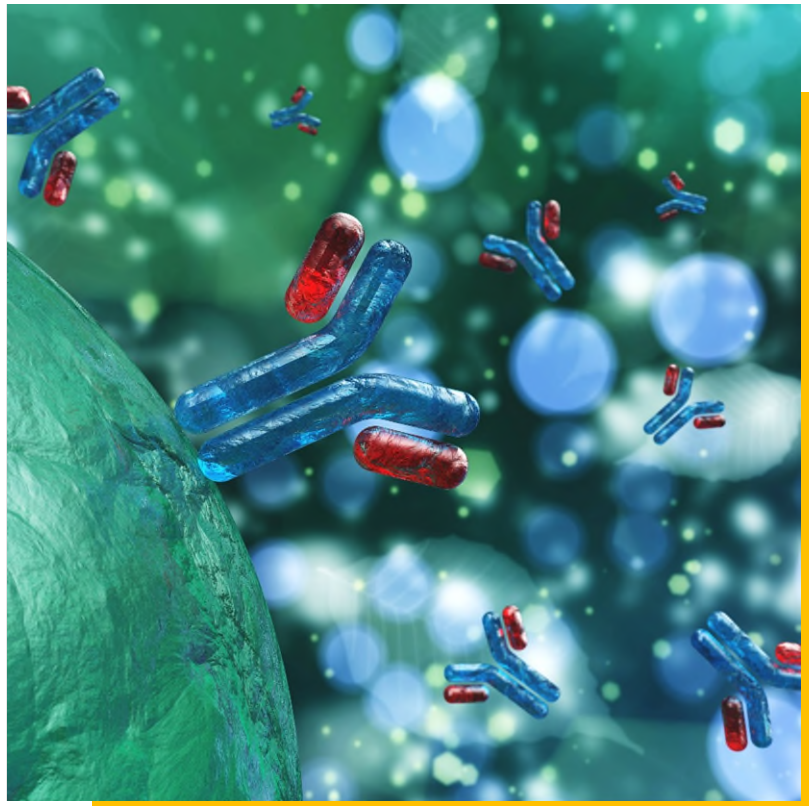
The use of nicotinic acid or a compound metabolised to nicotinic acid by the body selected from a group consisting of [named chemicals] for the manufacture of a sustained release medicament for *use in the treatment by oral administration once per day prior to sleep*, of hyperlipidaemia characterised in that the medicament does not comprise in admixture [disclaimed composition]

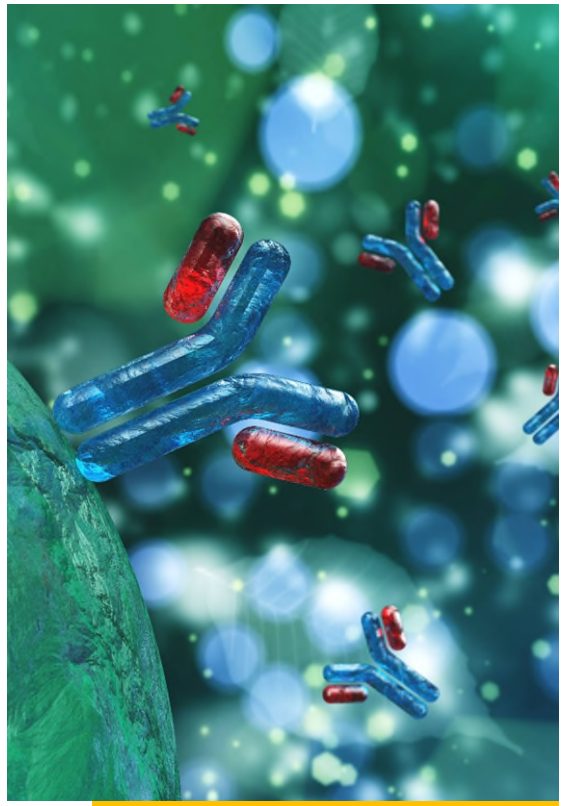
G2/08

But Actavis v ICOS [2019] UKSC 15

Biological molecules







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Biological molecules

Nucleic acid molecules

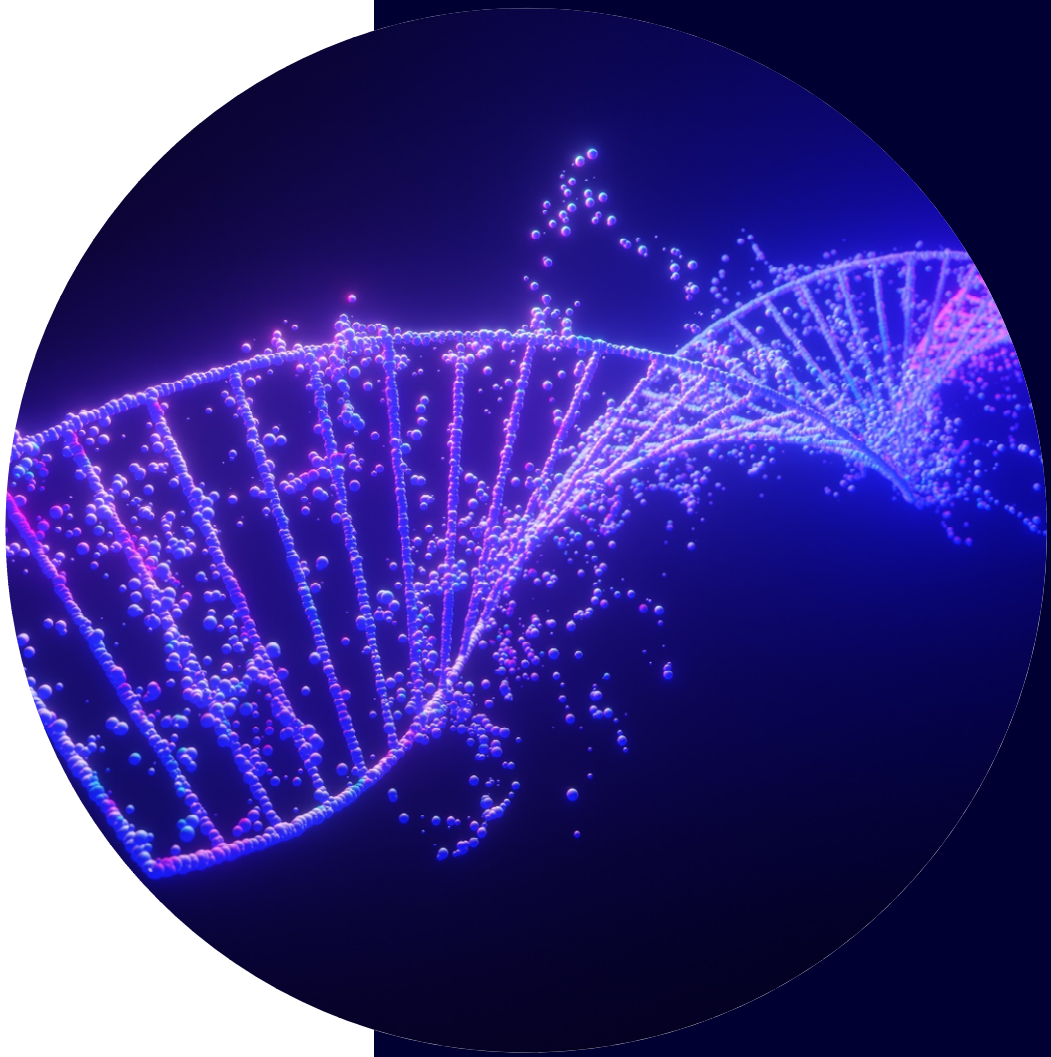
- DNA
  - cDNA
- RNA

Peptides

Polypeptides

Proteins

DNA → RNA → Protein



What is a DNA sequence?

```
caggtccagc tgcagcagtc tggacctgaa ctggtcaggc ctgggacttc agtgaagatg     60

tcctgcaagg cttctggata caccttcact aactactgga taggttgggc aaagcagagg    120

cctggacatg gccttgagtg gattggagat atttaccctg gaggtgatta tactaactac    180

aatgagaagt tcaagggcaa ggccacactg actgcagaca aatcctccag cacagcctac    240

atgcagttca gcagcctgac atctgaggac tctgccatct attattgtgc aagatggggg    300

ttaggatact actttgacta ctggggccaa ggcatcactc tcacagtctc ctca          354
```

```
<INSDSeq_sequence>caggtacagctgcagcagtcaggtccaggactggtgaagccctcgcagaccctctcactcacctgtgccatctccggggacagtgtctccagcaa
```

What is a protein sequence?

```
Asn Ile Val Met Thr Gln Ser Pro Lys Ser Met Ser Met Ser Val Gly
1               5                  10                  15

Glu Arg Val Thr Leu Thr Cys Lys Ala Ser Glu Asn Val Val Thr Tyr
            20                  25                  30

Val Ser Trp Tyr Gln Gln Lys Pro Glu Gln Ser Pro Lys Leu Leu Ile
        35                  40                  45

Tyr Gly Ala Ser Asn Arg Tyr Thr Gly Val Pro Asp Arg Phe Thr Gly
    50                  55                  60

Ser Gly Ser Ala Thr Asp Phe Thr Leu Thr Ile Ser Ser Val Gln Ala
65                  70                  75                  80

Glu Asp Leu Ala Asp Tyr His Cys Gly Gln Gly Tyr Ser Tyr Pro Tyr
                85                  90                  95

Thr Phe Gly Gly Gly Thr Lys Leu Glu Ile Lys Arg Ala Asp Ala Ala
            100                 105                 110

Pro Thr Val
        115
```

<INSDSeq_sequence>**SLQSGVPSRFSGSGSGTEFTLTISSLQPEDFATYYC**</INSDSeq_sequence>

Sequence listings

Needed by Patent Office to carry out search when application or claims relate to nucleotide or amino acid sequences

Sequence listing rules apply if:

- 10 or more nucleotides
- 4 or more amino acids

SEQ ID NOs

Sequence listings

- As of July 2022 the old WIPO Standard 25 was replaced with WIPO Standard 26
  - sequence listings in all new PCT and national/regional applications must comply with ST.26
  - if a PCT application filed before 1 July 2022 enters the regional /national phase after that date, the relevant standard is ST.25 – last of these 31m deadlines has now passed (all ST.26 now)
- File format is now .xml not .txt

- Need WIPO Sequence Suite to create, convert and easily view sequences

Sequence listings

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<212>  PRT
<213>  Homo Sapien

<400>  1

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1               5                  10                  15


Asn Ala Phe Thr Val Thr Val Pro Lys Asp Leu Tyr Val Val Glu Tyr
            20                  25                  30
```

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      </INSDSeq>
```

Sequence listings

- WIPO Sequence software may also be used to convert old ST.25 sequence listing into the new ST.26 XML format
- **Take care not to add subject matter** since the ST.26 standard requires more information than ST.25
    - Eg. ST25 required molecule type to be indicated (e.g. DNA, RNA, AA), but ST26 must also include a “moltype” qualifier to further define the molecule (e.g. “genomic DNA”, “other DNA”, “genomic RNA”, “mRNA”, “viral RNA”, “transcribed RNA”).

Patentability Issues

Europe

- Naturally occuring gene sequences are patentable in Europe as long as isolated

US – Myriad – isolated naturally occuring DNA sequences not patentable

- But cDNA is patentable

Claims to DNA and proteins

1. An **isolated** nucleic acid molecule comprising the nucleotide sequence shown in SEQ ID NO: 1.

2. A **purified** polypeptide comprising the amino acid sequence shown in SEQ ID NO: 2.

2a. A **purified** polypeptide encoded by the nucleotide sequence shown in SEQ ID NO: 1.

DNA and protein variants

```
AGCTGCCTGAG
**  *** * *
AGGAGCCAGTG
```

70% sequence identity

```
MGCTPSLKQ
**  *  *
MGGVPCIKN
```

50% sequence identity

(Need to state the algorithm, e.g. BLAST, CLUSTAL)

Claims to DNA and protein variants

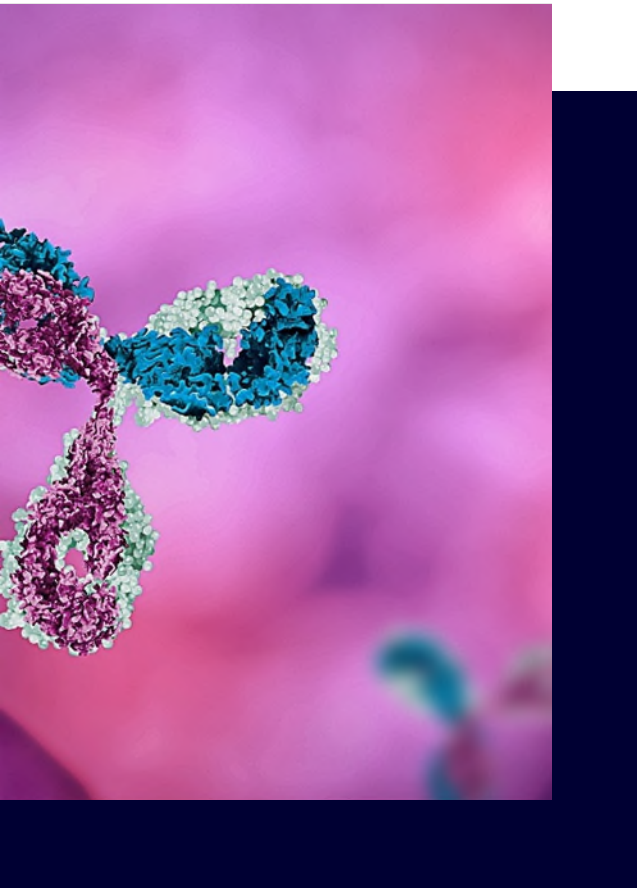
- A nucleic acid molecule having at least 90% sequence identity to SEQ ID NO: 1 and which encodes a melanocortin receptor.
- A polypeptide comprising an amino acid sequence having at least 95% sequence identity to SEQ ID NO: 2 and which binds FSH with a Ki of less than 10nM.

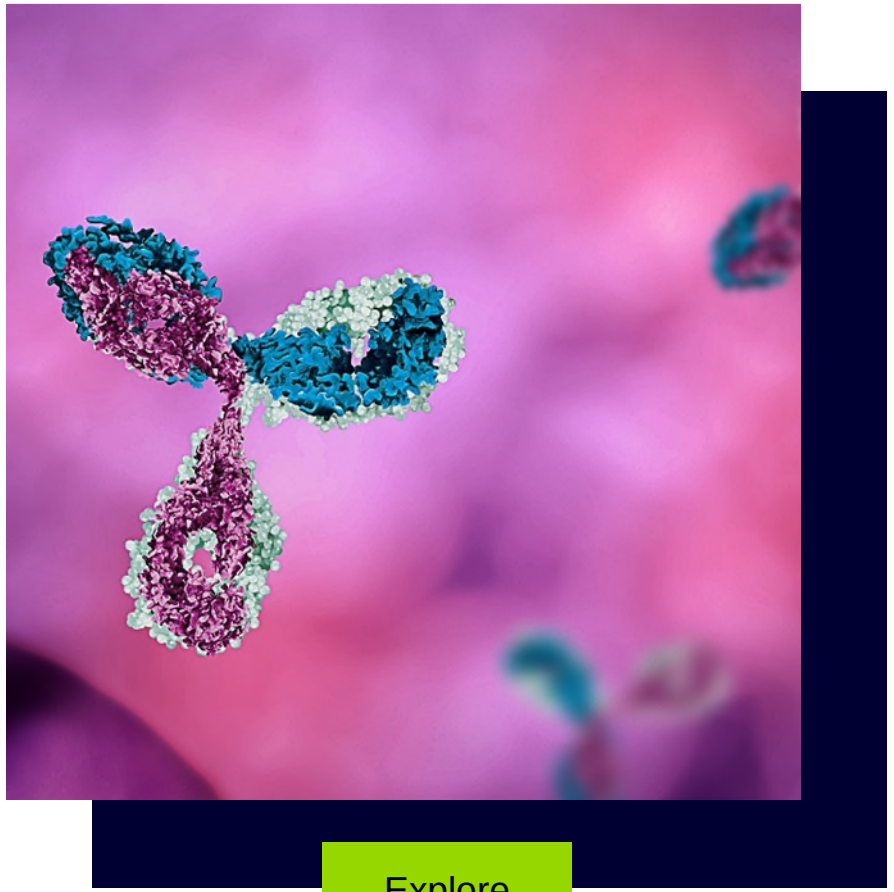
(Need to state the algorithm, e.g. BLAST, CLUSTAL)

Biological molecules – other claims

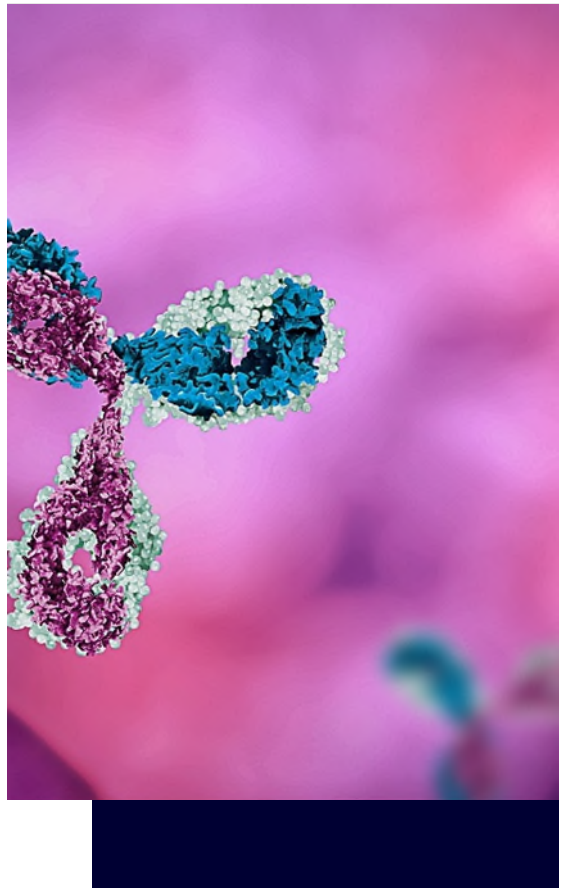
1. A vector which comprises a nucleic acid molecule as claimed in claim 1.
2. A host cell comprising a vector as claimed in claim 3.
3. An antibody which specifically binds to a polypeptide as claimed in claim 2 but which does not bind to a polypeptide having the sequence of SEQ ID NO: 5.
4. A pharmaceutical composition comprising a polypeptide as claimed in claim 2, optionally together with one or more carriers, adjuvants or excipients.
5. A vaccine comprising a nucleic acid molecule as claimed in claim 1, optionally together with one or more adjuvants.

Bacteria and cells





Explore



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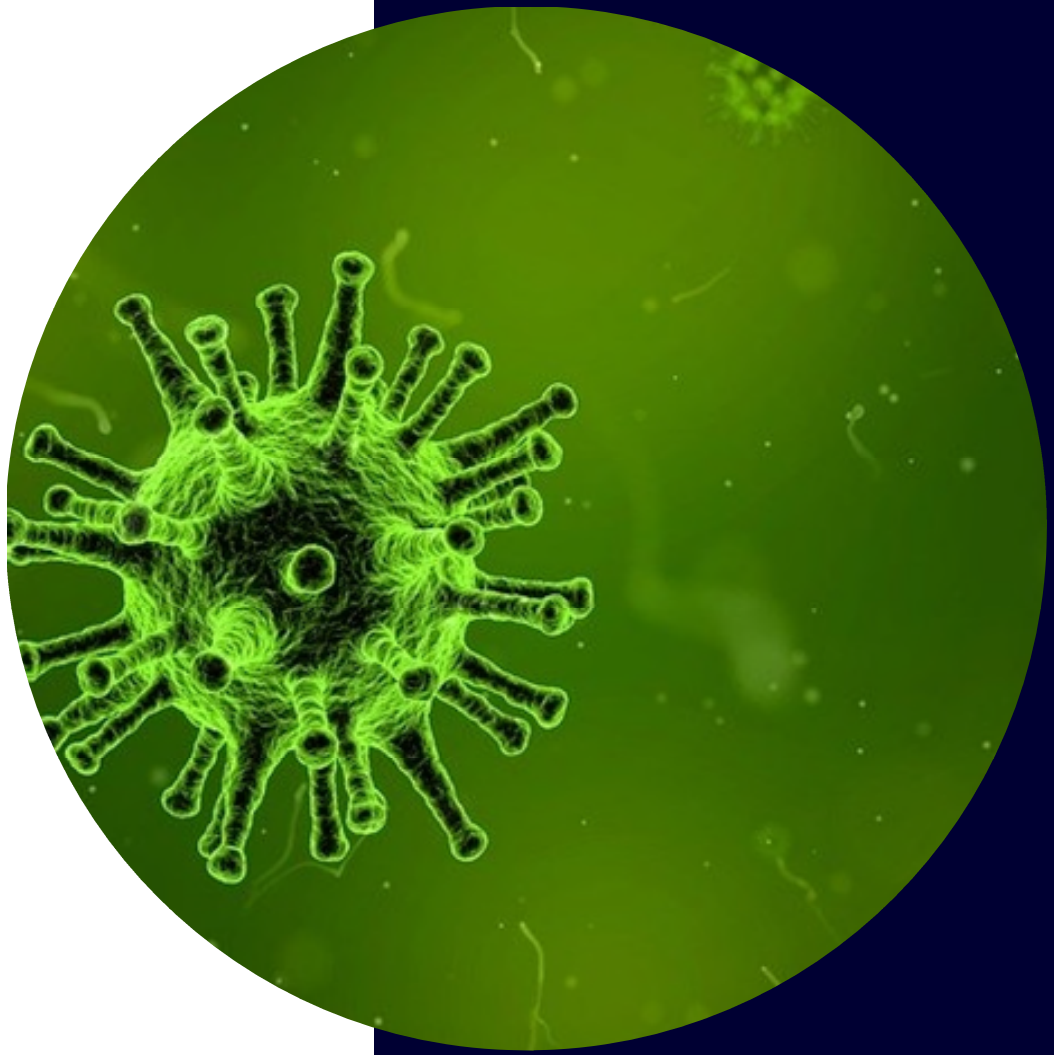
Bacteria and cells

Example of a claim to a bacteria

- An *E. coli* mutant

  which contains genes encoding proteins X and Y, and which is capable of producing ethanol.



Bacteria and cells (Continued)

How can you describe a new micro-organism?

- 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.
  - (Article 83 EPC)
  - Answer = Deposit of micro-organism at International Depository Authority under Budapest Treaty

- Various requirements in Europe to ensure that Article 83 EPC is complied with
- Different requirements for other countries

Plants & animals

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Plants

Example of a claim to a plant:

- A transgenic rice plant which produces vitamin A in its seeds at a level of at least 50mg vitamin A/gram seed.

Plant varieties

- European patents shall not be granted in respect of ... plant or animal varieties ...
- “Plant variety” means any plant grouping within a single botanical taxon of the lowest known rank ...
- Biotechnological inventions shall also be patentable if they concern plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety

(Article 53(b) EPC; Rules 26 and 27(b) EPC; G1/88)

Plants – other rights

Plant Variety Rights

- UPOV Convention
- Community Plant Variety Right
- UK Plant Variety Right

US plant patent

Essentially biological processes

Article 53(b) EPC

- European patents shall not be granted in respect of:
  - essentially biological **processes** for the production of plants or animals

Essentially biological processes

Article 53(b) EPC

- European patents shall not be granted in respect of:
  - essentially biological processes for the production of plants or animals

- But the **products** of such processes *may* be patentable
  - Broccoli and tomato cases – G2/07, G1/08, G2/12, G2/13
  - Commission Notice 8 Nov 2016, CA/D 6/17, Amended Rule 28(2), T1063/18.

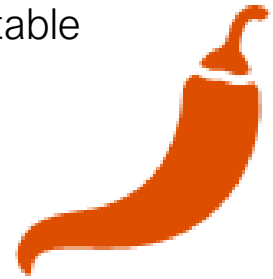
Essentially biological processes

Article 53(b) EPC

- European patents shall not be granted in respect of:
  - essentially biological processes for the production of plants or animals

- But the products of such processes *may* be patentable pre 1 July 2017
  - Broccoli and tomato cases – G2/07, G1/08, G2/12, G2/13
  - Commission Notice 8 Nov 2016, CA/D 6/17, Amended Rule 28(2), T1063/18.

- But the products of such processes *<u>are no longer</u>* patentable
  - on or after 1 July 2017
  - G 3/19.



Animals

Example of a claim to an animal

A transgenic cow comprising a nucleotide sequence encoding human insulin,

wherein the human insulin is secreted into the cow's milk.

Animal varieties

European patents shall not be granted in respect of ... plant or animal varieties ...”

Biotechnological inventions shall also be patentable if they concern plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety

(Article 53(b) EPC; Rule 27(b) EPC)

- But what is an animal variety?

Oncomouse

European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

(Article 53(a) EPC; Rule 28(d) EPC; T19/90; EU Biotech Directive EC/98/44)

Have to weigh up suffering of animal with substantial medical benefit to man or animal

More recently: T 1553/22

Claims to human beings

The human body, at the various stages of its formation and development, … cannot constitute patentable inventions.

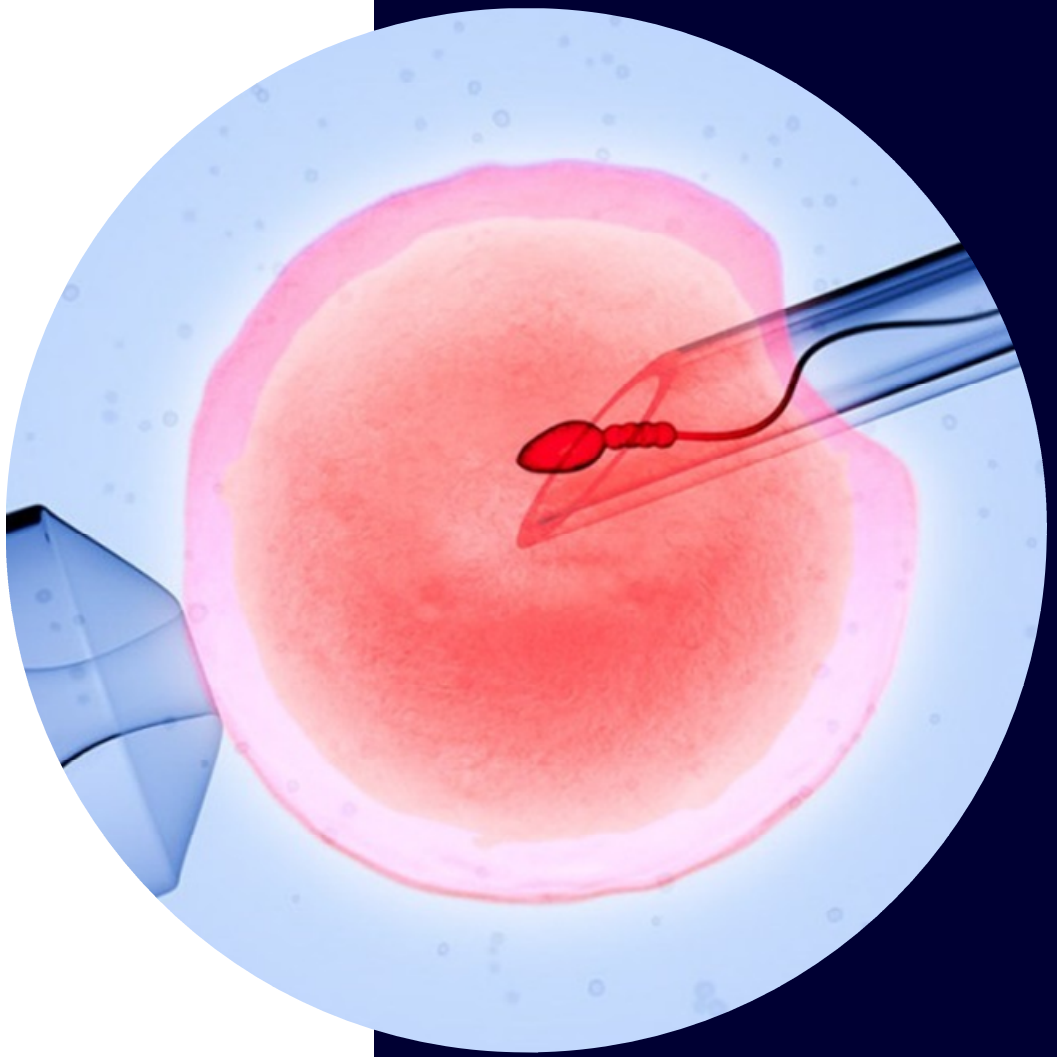
(EU Biotech Directive EC/98/44)

Embryonic stem cells

European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(c) uses of human embryos for industrial or commercial purposes.

(Rule 29 EPC; Rule 28(c) EPC; G2/06; CJEU decision C-34/10)



Reliance on the destruction of human embryos?

- You would be excluded if embryos were necessarily destroyed in order to implement your invention, even if destruction step is not mentioned in the application (C-34/10 *Brüstle v Greenpeace)*
- No exclusion if there was an alternative source of cells, such as parthenogenesis (C-364/13 *International Stem Cell Corporation ("ISCC") v Comptroller General of Patents*)
- Anything after the publication of WO03046141 (5 June 2003) should be OK

Methods of diagnosis

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Methods of diagnosis

No patents for

"diagnostic methods practised on the human or animal body ..."

1. Examination (collect data)
2. Comparison
3. Finding of a deviation (eg symptom)
4. Decision (attribute the symptom to a disease)

Does the method have to result in a diagnosis?

(Article 53(c) EPC; T385/86; T964/99; G1/04; G1/07)

What about in the US?

- *Mayo; USPTO Guidance Life sciences examples 28-33 (issued May 4, 2016); Vanda*

Methods and processes

Standard method and process claims:

- A process for producing a polypeptide of formula ... comprising the steps ...
- An *in vitro* method of assaying for the presence of *Staphylococcus* bacteria comprising ...
- Use of a nucleotide primer of SEQ ID NO: 1 for determining ...
- A method of producing a transgenic plant comprising ...
- A method of producing a transgenic animal comprising...

SPC

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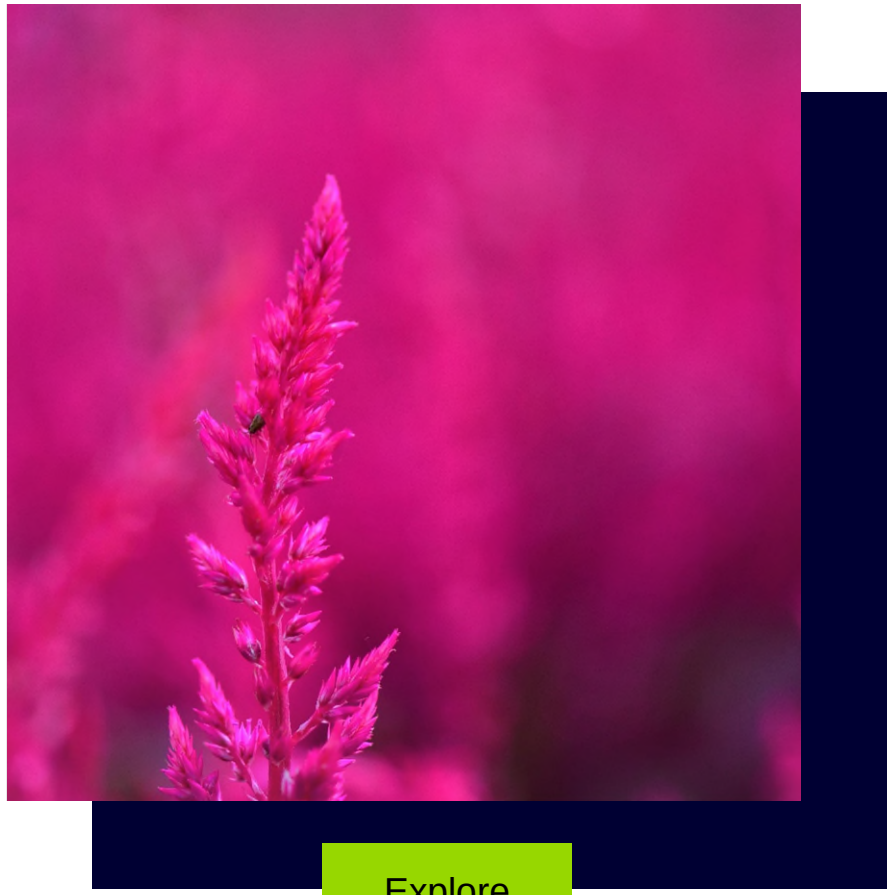
Supplementary Protection Certificates

Patent term extension offered for medicinal or plant protection patent

- SPCs can extend the term of a medicinal or plant protection patent by up to 5 years (possibility of a further 6-month extension term).
- SPCs are national rights
- Compensate patent owner for some of the patent term lost by regulatory trials and approval process
- An SPC may be based on any patent which protects:

  a) the active ingredient(s) of the authorised medicinal or plant protection product;
  b) a method of producing the active ingredient(s);
  c) an application of the active ingredient(s); or
  d) a preparation containing the active ingredient(s) (at least in the case of plant protection products).

Cross-sector



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What's next?

AI/ML

- Drug discovery
  - New targets
  - Patient stratification
  - Repurposing
- Diagnostics
  - Smart medical devices
  - Digital healthcare

Thank you

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