Patenting Biological and Medical Inventions

CIPA Informals Lecture – 15 February 2021

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Content

- The basics
- Medicines
- Biological molecules
- Bacteria and cells
- Plants
- Animals
- Methods of diagnosis
- Cross-sector

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The basics

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 – Cont'd

- 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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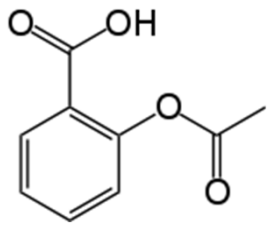
Medicines

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)

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)

Second Medical Use Claims

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

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)

New form of claim (EPC 2000)

Product X for use in the treatment of disease Z

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

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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

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Biological molecules

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Biological Molecules

Nucleic acid molecules

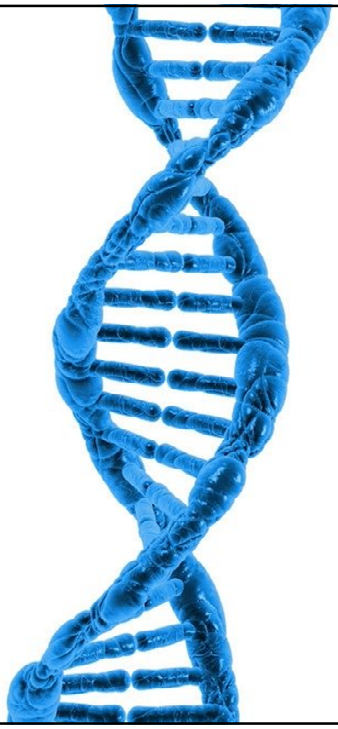
- DNA
  - cDNA
- RNA

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
```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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
```


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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

WIPO Standard 25 (ST26 is coming eventually – "Big Bang" in January 2022)

EPOJ Special Edition No. 3 (2007), Decision of President dated 28 April 2011, Notice from EPO dated 18 October 2013

PatentIn version 3.5 / BiSSAP

Patentability issues

Europe

Naturally occurring gene sequences patentable in Europe as long as isolated

- Biological material isolated from its natural environment or produced by means of a technical process patentable (Art 3(2) Biotech Directive, Rule 27(a) EPC)

US – *Myriad* - isolated naturally occurring DNA sequences not patentable

But cDNA is patentable

Implications for other natural products? USPTO's latest Guidance – "Nature-based product examples 9-18 (issued December 16, 2014)"

- "Differences in Culture: Expanded Cells Held Patent Eligible in the US"; Newton (2019) EIPR 41(2), 123-126

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.

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DNA and Protein Variants

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

70% sequence identity

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

50% sequence identity

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

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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

3. A vector which comprises a nucleic acid molecule as claimed in claim 1.
4. A host cell comprising a vector as claimed in claim 3.
5. 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.
6. A pharmaceutical composition comprising a polypeptide as claimed in claim 2, optionally together with one or more carriers, adjuvants or excipients.
7. A vaccine comprising a nucleic acid molecule as claimed in claim 1, optionally together with one or more adjuvants.

Bacteria and cells

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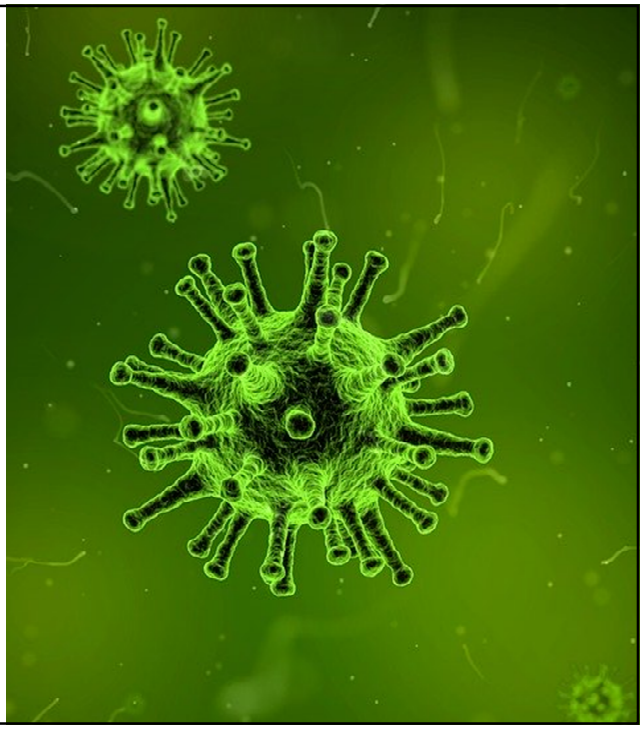
Bacteria and Cells

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 Cont'd

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

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

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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.

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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.

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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

35

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)

36

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 ..."

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...

Cross-sector

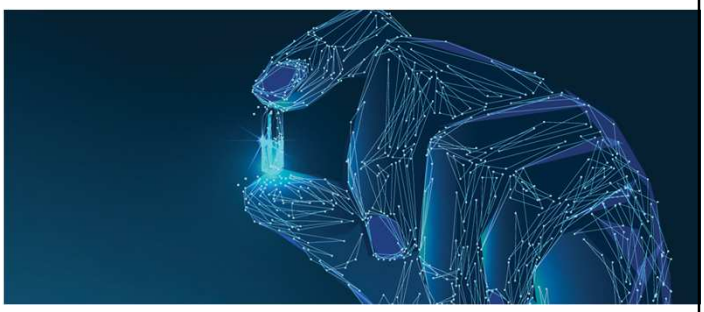
What's next?

AI/ML

- **Drug discovery**
  - New targets
  - Patient stratification
  - Repurposing
- **Diagnostics**

Smart medical devices

Digital healthcare



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