Abel+Imray

CIPA Informals – Patenting in the Chemical Area

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Introduction

- Abel & Imray are a full service IP firm with offices in London, Bath and Cardiff.
- Dr Paul Commander, Senior Associate, background in biochemistry and molecular biology.
- Dr Katy Pellow, Part Qualified Attorney, background in chemistry.

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Topics to be covered

- Chemical subject matter & types of claims
- Data & examples
- Claiming methods of treatment & diagnosis
- Ranges
- Selection inventions
- Disclaimers
- Supplementary Protection Certificates (SPCs)
- Questions

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Chemical Subject Matter & Types of Claims

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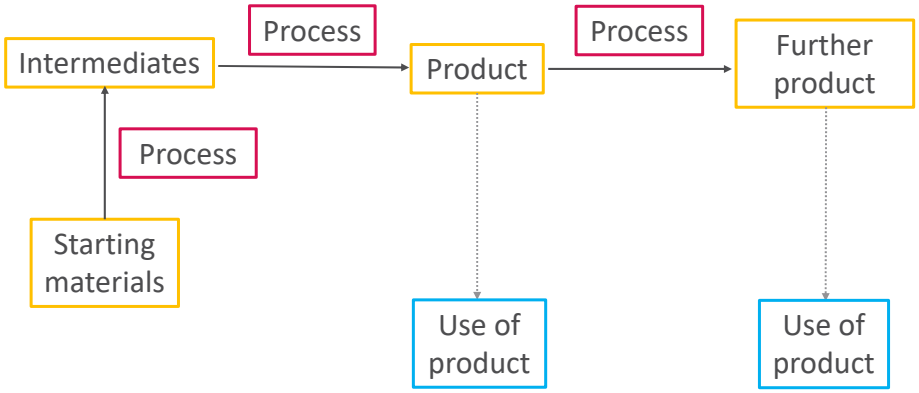
Chemical subject matter



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Product claims

- *Product X comprising .....*
- *Product X for use as [a colourant in a moldable composition] comprising.....*
- *Product per se defined in terms of chemical structure*
- *Product per se defined in terms of physical parameters (include test method e.g. ASTM)*
- *Product per se obtainable by the process according to claim X* (be careful with product-by-process claims – the product itself needs to be patentable and cannot be described in any other way)

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Process, use and apparatus claims

- Process for making the product
  - *A process for making X comprising the steps of…….*
  - May also claim the starting material or intermediates as product claims if they are patentable
- Use of the product
  - *Use of compound X for ……*
  - *A method of……using compound X comprising the steps of…….*
  - For example, a method for manufacturing polymer A using catalyst B
  - Method for extracting an oil from biowaste comprising the steps of …….
- Apparatus (or part of an apparatus)
  - *Apparatus for use X comprising…….*
  - Is there a new apparatus to make the product?

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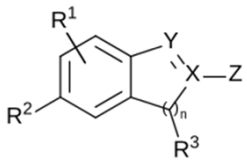
Markush claims



- Means of claiming functionally equivalent entities e.g. a series of compounds
- **Markush formulae/structures** are a pictorial representation of a large number of compounds in one formula
- Multiple independently variable groups
- No need to detail every atom of every compound of interest and can claim chemical space between examples
- General claim means the exact compound an applicant is interested in doesn't need to be revealed to competitors

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Data & Examples

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Sufficiency

'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**.' Art. 83 EPC
c.f. Section 14(3) Patents Act

- Balance between the proprietor gaining a monopoly and disclosing the invention to the public
- Skilled person can conduct routine work and experimentation and cope with occasional failures, but getting the invention to work should not be an undue burden e.g. require a research program
- Later, more detailed evidence cannot be used to remedy an original insufficiency of disclosure but could be used in support of an inventive step

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Examples

'The description of the patent application shall describe in detail at least one way to carry out the invention and use examples where appropriate' R. 42(1)(e) EPC

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Examples

- How many examples do I need?
  - The broader the claim the more likely multiple examples will be needed
  - Aim for examples scattered across the breadth of the claim
  - Is the technical effect a feature of the claims?
    - *A composition comprising A and B* – invention can be reproduced if a composition comprising A and B can be prepared based on examples of application and cgk
    - *Composition comprising A and B for use in treating diabetes* –need examples and data to show that the composition is likely to be effective in treating diabetes

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Examples – other things to consider

- Is there any known information contradicting the invention?
  - If the invention goes against established understanding in the field i.e. clear technical prejudice, then may need more examples
- Can influence when you file a patent application

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Plausibility

- Not mentioned in the EPC or UK Patents Act
- Origins in case law
- '*Plausibility is to exclude speculative patents, based on mere assertion, where there is no real reason to suppose the assertion is true*' Actavis v Eli Lilly [2015] EWHC 3294
- '*Although the disclosure need not definitively prove the assertion that the product works for the designated purpose, there must be something that would cause the skilled person to think that there was a reasonable prospect that the assertion would prove to be true.*' Warner-Lambert LLC v Generics Ltd t/a Mylan [2018] UKSC 56, pt 37

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Plausibility

+ Composition comprising A and B for use in treating diabetes
  - Need to show through data and examples that the composition is likely to be effective for the therapeutic indication i.e. it needs to be plausible
  - Examples that show that the claimed compound has a direct effect on metabolic mechanism involved in the disease are needed. But this does not mean that clinical trials and toxicology studies are required.
  - Data submitted also relevant for the evaluation of inventive step i.e. supporting a technical effect that is achieved over the prior art
  - Later data can be used to confirm an effect (to support an inventive step) but cannot be used to overcome a lack of sufficiency

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Claiming Methods of Treatment & Diagnosis

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Exclusions to patentability

- Methods of treatment by surgery or therapy and diagnostic methods are excluded from patentability.
- Intention of exclusion is to avoid medical practitioners being prevented from using such methods by patents.
- Art. 53(c) EPC
  - 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**.

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European medical use claims

- **Art. 54(4) EPC**
  - Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.
- **First medical use claim based on Art. 54(4) EPC**
  - Substance X for use as a medicament/for use in therapy.
  - Substance X for use in *in vivo* diagnostics.
- **Art. 54(5) EPC**
  - Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.
- **Second (& further) medical use claim based on Art. 54(5) EPC**
  - Substance X for use in the treatment of [specific] disease Y.
  - Substance X for use in a specific *in vivo* diagnostic/surgical application.
  - Specific use may be a new disease or a new treatment of a disease where use of substance X for treatment of that disease is known.

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Worked examples

- **Substance X is known as a herbicide, but new anti-cancer property is discovered.**
  - Substance X for use as a medicament.
  - Substance X for use in the treatment of cancer.
- **Substance Y is known for treating cancer, but new anti-diabetic property is discovered.**
  - Substance Y for use in the treatment of diabetes.
- **Substance Z is known for treating lupus using a regimen of 10 mg/kg administered weekly, but drug found more effective with fewer side effects if administered at 5 mg/kg monthly.**
  - Substance Z for use in the treatment of lupus, wherein substance Z is administered at a dose of 5 mg/kg once per month.

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Medical use claims & unity

- If a novel substance X is discovered & shown to have therapeutic applications for diseases Y **and** Z, the following independent claims are possible:
  1. Substance X.
  2. Substance X for use as a medicament.
  3. Substance X for use in the treatment of Y.
  4. Substance X for use in the treatment of Z.
- In this situation, there should be no *a priori* unity objection, nor an objection under R. 43(2) EPC [different uses of a product – R.43(2)(b) EPC].

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European medical use claims

- 1st & 2nd MU claims represent an exception to the general rules regarding novelty.
- Generally, "a known product for a new use" is not novel under Art. 54(1) EPC (cf. EPO-GL, F-IV, 4.13).
- Reference to "substance or composition" in Art. 54(4) & (5) does not generally extend to medical devices.

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Non-permitted claim formats

- **Both a US-style medical method claim and a use claim fall foul of Art. 53(c) EPC**
  - A method of treating disease Y comprising administering a therapeutically effective amount of substance X to a patient in need thereof.
  - Use of substance X for treating disease Y.
- **Second medical use (pre-EPC 2000/Swiss-type)**
  - Use of substance X for the manufacture of a medicament for use in the treatment disease Y.
  - Not allowed in applications having a filing/priority date of 29 Jan 2011 or later.

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Methods of diagnosis & surgery

- Key Enlarged Board decision for diagnostic methods is G 1/04.
- Exclusion only applies if method includes **all steps** necessary to make a diagnosis & all technical steps are "practised on the human or animal body".
- *In vitro* diagnostic method not excluded.

- Method of treatment including **at least 1 step** of treatment by surgery is excluded.
- Definition of what constitutes a method of surgery established in G 1/07.

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Ranges

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Novelty of ranges

+ Claimed range vs prior art range

  – Outside prior art range

  – Partially overlapping with prior art range

  – Lying within prior art range

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Inventive step of ranges outside prior art range

– Inventive step hinges on:
  • Distance between 55 and 60 ˚C
  • Absence or presence of unexpected technical effect

1. If there is no technical effect then mere alternative; small difference between 55 and 60 ˚C; no special technical effect so reasonable to expect the prior art range to be extended and still work; solution is obvious
2. If there is an unexpected technical effect then the problem is an 'improvement'; although gap is small, surprising effect in new range; solution is not obvious

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Amending ranges

- A process for the preparation of X characterised in that:

Temperature (˚C) 50 — 200
Preferably 80 — 140

Can amend by adding the preferred range and either the upper or lower part of the broad range (T2/81 and GL H-IV, 2.4):

80-200 ˚C; 50 — 200
80 — 140

or,

50-140 ˚C 50 — 200
80 — 140

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Amending ranges

- Amendment to the end ranges is more difficult

50-80 ˚C 50 — 200
80 — 140

or

140-200 ˚C 50 — 200
80 — 140

- T 1170/02
  - Would the skilled person **seriously contemplate** working in that range? Some sort of pointer in the description to an advantage of that range

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Selection Inventions

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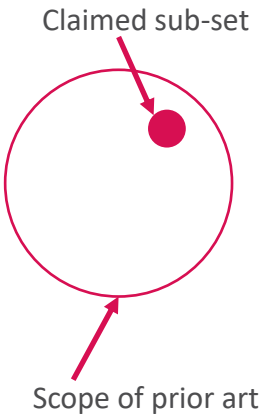
What is a selection invention?

- A selection invention is the identification of a sub-set of subject-matter from a larger known set of subject matter, wherein the sub-set has an improved technical effect.
- Selection invention patentability based on principle that disclosure of a genus does not destroy novelty of a species falling within that genus, whereas disclosure of a species takes away the novelty of a genus.
- Disclosure of **metal** would not take away the novelty of a claim to **copper**, but prior disclosure of **copper** would destroy novelty of claim to **metal**.
- Question to be asked is whether the selected element is disclosed in an individualised form in the prior art (T 12/81).



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Novelty of selection inventions – two lists principle

- Selection from a **single list** of specifically disclosed elements does not confer novelty.
- Thus if the prior art discloses fluorine, chlorine, bromine and iodine, selection of chlorine would not be novel.
- Selection of features from **two or more lists of a certain length** in a prior art document does lead to novelty ("two-lists principle").
- Example would be selection of individual compounds (or small genus) from a known generic formula, for example:
  - R_1 may be H, C_{1-4} alkyl, C_{1-4} alkenyl, OH, SH, F, Cl, Br or NH_2 and
  - R_2 may be H, aryl, acetyl, COOH, CHO, COCl or C_{1-4} alkynl.
  - Selecting R_1 to be OH and R_2 to be COOH should be novel.

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Novelty of selection inventions

- A **sub-range** selected from a **broader numerical range** of the prior art is considered novel if the following criteria are met:
  - Selected sub-range is **narrow** compared to the known range.
  - Selected sub-range is **sufficiently far removed from specific examples** in the prior art and from the end-points of the known range [case by case basis].
- E.g. prior art discloses 15-95°C, with specific examples at 25°C and 30°C.
  - Claiming 70-75°C would likely be novel.
  - Claiming 40-90°C or 20-24°C would not be novel.

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Disclaimers

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What are disclaimers?

+ Disclaimers are negative limitations

+ Negative limitations such as disclaimers may be used only if adding positive features to the claim either would not define more clearly and concisely the subject-matter still protectable or would unduly limit the scope of the claim

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Types of disclaimers

- Disclosed disclaimers:
  - The absence of the feature can be deduced from the application as filed
  - The absence of the feature may be implicitly disclosed

- Disclaimer excluding disclosed subject-matter:
  - The subject matter of the disclaimer is disclosed as a positive feature but the disclaimer as such is not disclosed

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Types of disclaimers

- Undisclosed disclaimers:
  - Neither the disclaimer nor the excluded subject matter is disclosed
  - Restore novelty by limiting a claim against state of the art under Art. 54(3) EPC
  - Restore novelty by delimiting a claim against accidental anticipation
  - Disclaim subject-matter which is excluded from patentability for non-technical reasons

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Supplementary Protection Certificates (SPCs)

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What is an SPC?

- An SPC is an extension of protection for a particular approved medicinal product.
- Not an extension of the patent *per se*.
- Purpose is to compensate patent holders for delays related to regulatory approval for the new medicinal product.
- No pan-European SPC application – a separate application must be made in each state.
- Key legal provision is Regulation (EC) No. 469/2009.

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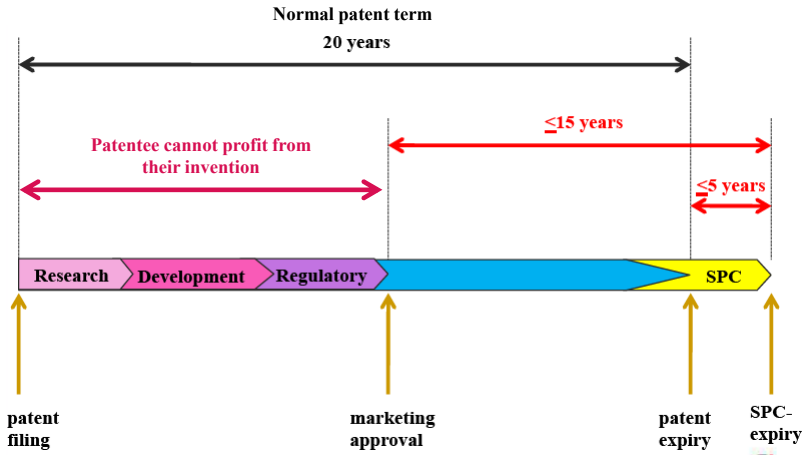
Principle of an SPC



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Formal Requirements for obtaining an SPC*

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market has been granted in accordance with the relevant EP law;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market.

** = Art. 3 of the Regulation*

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Timing*

You must apply for an SPC within:

1. six months of the date of authorisation;

OR

2. where authorisation is granted **before** the basic patent is granted, you must apply **within six months** of the date on which the patent is granted.

* = Art. 7 of the Regulation

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Duration of the SPC*

+ Term = ([date of 1st MA in the EEA] - [date of filing of corresponding patent]) - 5 years

+ If <5 yrs between patent filing date & date of 1st MA then no SPC.
+ If >10 yrs elapse between patent filing date & date of 1st MA then full 5 yr SPC available.
+ 6m extension available to the SPC if holder of MA has carried out paediatric trials.

* = Art.13 of the Regulation

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Questions?

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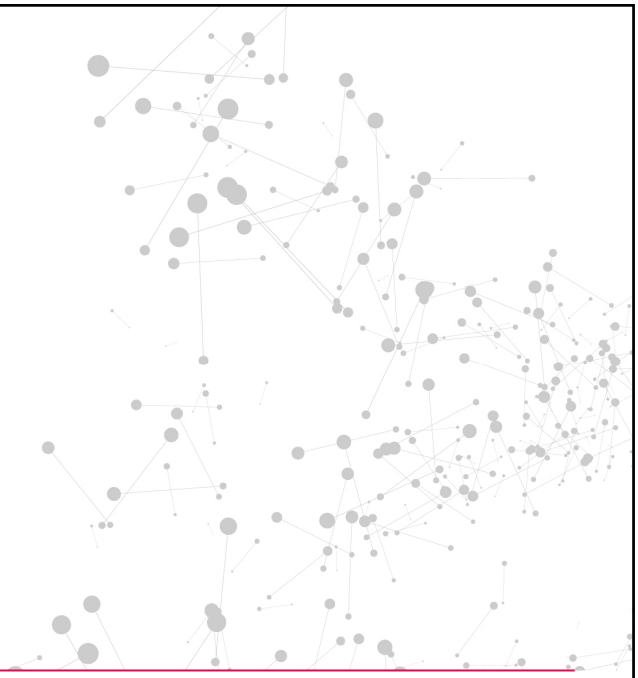

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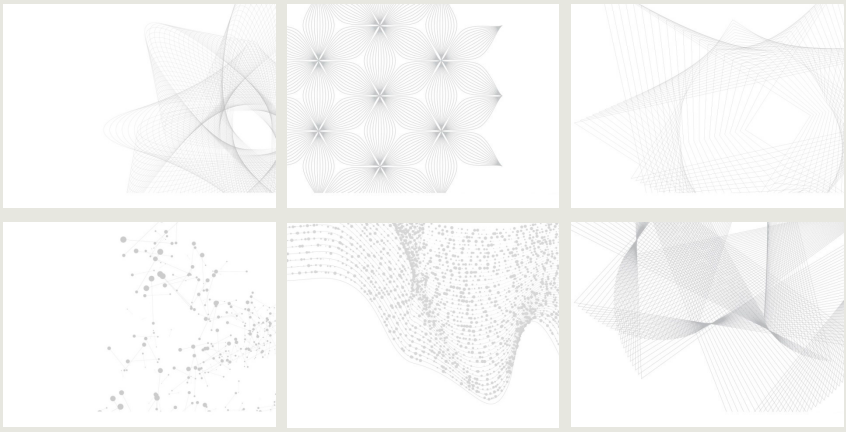

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