

## Drafting & Prosecuting Pharmaceutical Patents at the EPO

Robert Watson  
April 2007

## Overview

- Introduction
- Claim types
  - And the law associated with them
- Particular EPO issues
- Questions

## Mewburn Ellis LLP

- A large firm ...
  - 37 qualified patent attorneys
  - 14 patent assistants
  - 3 lawyers
  - Plus trade mark attorneys, paralegals, patent administrators & searchers
- ... with quality people ...
  - Emphasis on training

## The firm & our people

- ... having a broad range of technical backgrounds ...
  - Mechanical & electrical engineers
  - Physicists & material scientists
  - Chemists & biochemists
  - PhDs, e.g.
    - Opto-electronics & carbon nanotubes
    - Molecular biology & pharmaceutical chemistry

## The firm & our people

- ... and experience working for a variety of clients ...
  - Major UK, EP, US, JP & IN companies
  - UK charities, universities & research organisations
  - UK start-ups/spin-outs & SMEs
- ... offering a hands-on, pro-active service

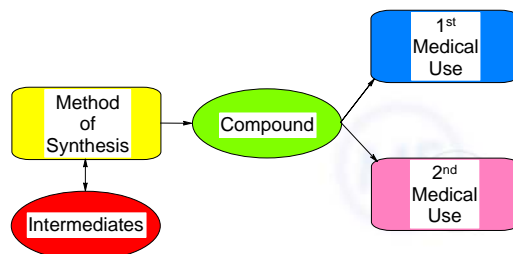
## Robert Watson

- Partner in London Office
- Majority of work is in Pharmaceuticals
- Particularly for UK 'small' companies
  - SpiroGen Limited
  - KuDOS Pharmaceuticals Limited

## Claim Types - Overview

- Molecules
- Combinations
- Isomers
- Forms
- Libraries

## Claim Types - Molecules



## Claim Types - Molecules

- A compound of Formula I, and isomers, salts, solvates, chemically protected forms and prodrugs thereof.

## Claim Types - Molecules

- A compound of Formula I, and pharmaceutically acceptable salts thereof for use in a method of therapy.
- A pharmaceutical composition comprising a compound of Formula I, and pharmaceutically acceptable salts thereof, and a pharmaceutically acceptable carrier or diluent.

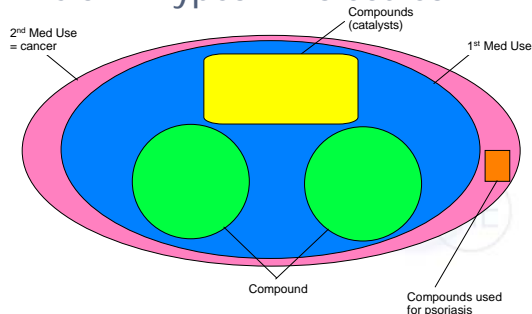
## Claim Types - Molecules

- Use of a compound of Formula I, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for the treatment of disease X.
- A compound of Formula I, or a pharmaceutically acceptable salt thereof, for use in treating disease X.

## Claim Types - Molecules

- A method of synthesising a compound of Formula I comprising the steps of:
  - (i) ...
  - (ii) ...
  - (iii) ...
- A compound of Formula I'.

## Claim Types - Molecules



## Claim Types - Molecules

- Clarity – Article 84 EPC
- Claims must be
  - Clear
  - Concise
  - Supported by the description

## T 860/93

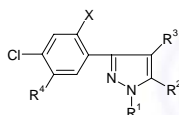
- “A water-soluble cellulose ether derivative that has attached to it a long-chain alkyl group as a hydrophobic modified is characterized in that ...”
- Rejected under Art 84 EPC due to “water-soluble”
- Decision appealed

## T 860/93 (continued)

- Distinguished relative terms from parameters
- Evidence that term was understood
- Requirement to interpret claims in their context
- Able to use description and common general knowledge

## T 337/95

- “A 3-(substituted phenyl) pyrazole derivative or a salt thereof, of formula:



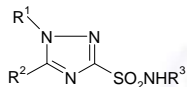
- wherein R<sup>1</sup> denotes lower alkyl or lower haloalkyl”

## T 337/95 (continued)

- Refused – lower alkyl unclear
- Term has different meanings in different reference sources
- Specification said “lower alkyl group such as methyl, ethyl, propyl or butyl”
- Term is too vague
- Case allowed with R<sup>1</sup> = methyl!

## T 939/92

- “The triazole sulphonamides of the formula:



- where R<sup>3</sup> represents optionally substituted phenyl”

## T 939/92 (continued)

- “Substituted” to be given its normal meaning, i.e. “substituted by absolutely anything”
- Not an objection under Art 84 if the term is very broad

## Claim Types - Molecules

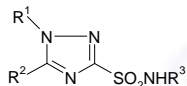
- Claim Scope
- Sufficiency – Article 83 EPC
  - Clear & complete to enable invention to be carried out
- Inventive Step – Article 56 EPC
  - Must not be obvious to the skilled person

## T 805/93

- Relates to a claim with viscosity limits
- Refused due to lack of defined temperature for measurements
- Appellant argued that must be at room temperature, but was not supported by evidence
- T 960/98 – not a sufficiency issue

## T 939/92

- “The triazole sulphonamides of the formula:



- where R<sup>3</sup> represents optionally substituted phenyl”

## T 939/92 (continued)

- “Substituted” to be given its normal meaning, i.e. “substituted by absolutely anything”
- In view of prior art, compounds claimed had to exhibit herbicidal properties
- Not established that all claimed compounds would!

## 2<sup>nd</sup> Medical Use Claims

- G 5/83 – traditionally define a new medical indication (specified) for a known medicament (specified)
- ‘Swiss’ claim:
  - Alternative to method of treatment claim
  - Use of drug X in the manufacture of a medicament for treatment of disease Y

## 2<sup>nd</sup> Medical Use Claims

- Developments:
- T4/98, novelty can be in:
  - the illness or disease treated;
  - nature of therapeutic compound;
  - subject to be treated/ class of patient
- T0290/86 – the further medical indication should be **based upon a different technical effect** which is both new and inventive

## 2<sup>nd</sup> Medical Use Claims

- T 1020/03 –
  - The Board decided that a novel dosing regimen is permissible subject matter for a 2<sup>nd</sup> medical use claim, provided the claims meet the other requirements of patentability
  - Opens the door to use 2<sup>nd</sup> medical use claims for any novel therapeutic use provided the novel use is not defined purely by the mechanism of action

## 2<sup>nd</sup> Medical Use Claims

- Some granted claims...
  - The use of an xxxx receptor antagonist in the preparation of a medicament for use in the treatment of a primary headache disorder or drug-induced headache.
- and
- Use of an inhibitor of soluble xxxx hydrolase or microsomal xxxx hydrolase for the manufacture of a medicament for the treatment of inflammatory disease.

## Claim Types - Combinations

- No special law
- Combination needs to be:
  - Novel – not usually a problem
  - Inventive – more difficult
    - If obvious to combine, need synergy to show ‘surprising advantage’

## Claim Types - Isomers

- Enantiomers
  - Disclosure of racemic form does not destroy novelty of specific enantiomer (T1048/92)
- Diastereoisomers
  - Achieving higher level of diastereomeric purity does not provide novelty (T990/96)

## Claim Types - Forms

- Salts
- Prodrugs
- Polymorphs
  - No equivalent to Section 3(b)
  - Same requirements as compounds
  - For polymorphs – rebuttable IS presumption

## Claim Types - Libraries

- Claims directed to "A collection of compounds of formula X"
- Recent EPO Board of Appeal decision
  - T 1057/03 & T1173/03
  - Refused by Examining Division as not all compounds showed anti-cancer activity
  - Overturned by Appeal Board

## Claim Types - Libraries

- "Was it obvious to provide the collections of compounds in order to speed up the process of identifying a compound having a specific biological activity in comparison with the classical method of synthesizing compounds one by one and separately testing each compound in a specific screening test?"

## Particular EPO Issues

- Added subject matter
- Priority
- Multiple Independent Claims
- Multiple Dependent Claims

## Added Subject Matter

- Article 123(2) EPC
  - "A European patent application or a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed."

## Added Subject Matter

- Many amendments allowable in USA are not accepted at the EPO
  - Must be "directly and unambiguously derivable..."
  - Not "fair basis"
  - Not "reasonably apprehend..."
  - Examples, tables, figures almost never provide support

## Added Subject Matter

- Obsessive examination
  - pre-grant
  - even more so post-grant & appeal
- Ground of Invalidity
  - prosecution no defence
  - burden of proof on the patentee
  - “beyond reasonable doubt”

## Priority

- G 2/98 – Tight Priority
  - Referred due to conflicting lines of decision of Boards of Appeal
  - Paris Convention key to decision
  - Priority only if claim unambiguously derivable from previous application as a whole

## G 2/98 (cont.)

- Very similar to added matter test
  - “... only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole.”
- Need to think about EPO when drafting priority application

## Multiple independent claims

- Rule 29(2) EPC
  - “... a European patent application may contain more than one independent claim in the same category (product, process, apparatus or use) only if the subject-matter of the application involves one of the following:

## Multiple independent claims

- ...
- (a) a plurality of inter-related products;
  - (b) different uses of a product or apparatus;
  - (c) alternative solutions to a particular problem, where it is not appropriate to cover these alternatives by a single claim.

## Multiple independent claims

- Intended to reinforce existing EPO practice
- Previously rejected under Clarity
- Some cases – only 18 published cases refer to Rule 29(2)

## Multiple Independent Claims

- Need to be able to draft a single independent claim in each claim category
- If the 'new' claim is not explicitly recited, then
- Expect an added subject matter objection
- Therefore, the single independent claim should be in the PCT application (somewhere) and in the priority application
- Avoid divisional applications

## Multiple dependent claims

- Claim 1 – A
- Claim 2 – Claim 1 + B (A+B)
- Claim 3 – Claim 1 + C (A+C)
- Claim 4 – Claim 1 + B, C & D (A+B+C+D)
  
- Cannot add A+B+C!
- But if claim 3 was also dependent on claim 2, then no problem

## Some suggestions

- **REMEMBER!**
  - PCT application is the European application
  - (And the application elsewhere)
  - Added matter rules apply with reference to PCT application as filed
  - Tight priority – consider the issues in the priority application

## The "EPO Friendly" Application

- Independent claims
  - Assume you will need a single independent claim in each category at EPO
  - Which claim will it be?
- Multiple dependent claims
  - Use them!
  - Or provide basis for them in description
  - No claims fees in a PCT filing

## Drafting & Prosecuting Pharmaceutical Patents at the EPO

robert.watson@mewburn.com  
T: +44 20 7240 4405 F: +44 20 7240 9339

Mewburn Ellis LLP  
York House, 23 Kingsway, London WC2B 6HP, United Kingdom