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When is an invention ripe for patenting?

Particular issues with therapeutic use claims.

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Particular issues with therapeutic use claims:

- How much information about the potential use of the product needs to be disclosed in the application?
- Is it enough to disclose a theoretical / prophetic use?
- Is data required?
  - Cellular assays?
  - Animal model?
  - Preliminary human data?
  - Clinical trials?
- In the absence of supporting data can the claim to a therapeutic use be “sufficient”?

When is the claim scope determined? - At trial.

- Germany – infringement only

- UK – validity and infringement

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Construction of therapeutic use claims

- Eg Use of an antibody that binds to receptor X for treatment of Y…..
- “for” = “suitable for”
- “suitable for the effective treatment”

Hospira v Novartis

- “does in fact achieve the claimed therapeutic efficacy”

Eli Lilly v Janssen

- “suitable and intended for” ie claim is to an effective treatment of the disease

Hospira v Genentech

Salk T609/02 - Approved by UK Court of Appeal in *Regeneron v Genentech*

- Acknowledged that proving the suitability of a given compound as an active ingredient in a pharmaceutical composition might require years and high development costs...
- For sufficient disclosure of a therapeutic application, it is not always necessary that the results of applying the claimed composition in clinical trials, or at least to animals are reported...
- Nevertheless must show, for example, by appropriate experiments *in vitro,* that the product has an effect on a disease process so as to make a claimed therapeutic effect plausible.
- Once this evidence is available from the patent then post-published evidence may be taken into account to "back up" the disclosure in the patent application

Lilly v Janssen

- Janssen was the proprietor of a second medical use patent claiming:
  - A pharmaceutical composition containing an antibody to the amyloid-β peptide
  - for use in preventing or treating a disease characterised by amyloid deposit (ie Alzheimer's and related diseases)
- Specification included *in vivo* animal data and Phase I and Phase II trial designs
- Lilly sought to "clear the way"

Sufficiency: *Lilly v Janssen*

- *In vivo* data was enough to overcome plausibility threshold, but only for certain antibodies
- The primary criterion for determining efficacy was Phase II clinical trials
- Phase III trials are the “best guide”
- Post published evidence that Phase III trials had failed - classical insufficiency
- Claim was excessively broad and not enabled across scope → *Biogen* insufficiency

Hospira v Novartis

- Novartis was proprietor of two dosage regime patents claiming:
  - the use of zoledronic acid
  - for the treatment of osteoporosis
  - by intravenous administration
  - at a range of doses
  - with dosing intervals of at least 6 months.
- Phase II trial included in examples in the specification
- Hospira and Mylan sought to “clear the way”

Sufficiency: *Hospira v Novartis*

- Scope of open-ended claims should be interpreted to extend to doses and dosage intervals that worked
- Still "quite broad" and placed an "undue burden on the skilled team to find out what doses and dosage intervals work" → *Biogen* insufficiency
- *Hospira* → Phase II data not enough to disclose efficacy (although *obiter* appellate comments suggest otherwise)

Hospira v Genentech

- Genentech was the proprietor of a patent claiming:
  - Use of an anti- ErbB2 antibody
  - For treating a human patient diagnosed with breast cancer characterised by overexpression of ErbB2
  - Administered iv at an initial dose of 8mg/kg
  - Followed by a plurality of doses at 6mg/kg, 3 weeks apart.
- The treatment of HER2 +ve breast cancer is a functional technical feature
- Patent disclosed clinical trial data 4 + 2 q1w iv dosing regime and prophetic example based on 8 + 6 q3w iv regime.

Sufficiency: *Hospira v Genentech*

- Did the disclosed data plausibly support the claimed use?
- On the expert evidence, skilled team would not have carried out a clinical trial to test whether it would work.
- [Squeeze with obviousness over prior art FDA label]
- Patent did not render the claimed effect plausible

Priority: *Hospira v Genentech*

- Must be an enabling disclosure of the claimed invention
- For it to be enabled, must be possible to make a reasonable prediction the invention will work
- Where this requires a therapeutic effect there is a requirement for plausibility – rejecting EPO approach in T903/05 *Gemvax*
- Same test for priority as sufficiency
- Priority document disclosed no plausible therapeutic effect

Is clinical trial data needed?

- Claimed invention must be plausibly disclosed to establish arguable enablement (and same in the priority application.)
- Is this the same level of plausibility for inventive step?
- Is the experimental burden getting higher to establish plausibility?
- Clinical data seems preferable.
- But clinical trial transparency risks prior disclosing?

- Balance risks of filing later (competitors/ prior art) with obtaining more supporting data (establish plausibility).

And beware trying to reshape scope of the invention during prosecution….

extent of disclosure still key.

EPC Art 123(2) Added matter

Disclosure of the invention: Added matter

- Article 123 EPC:

  The application /patent may not be amended in such a way as to add subject matter = has the invention changed?

- G2/10: amendments are permitted within the limits of what the skilled person would derive directly and unambiguously, using common general knowledge from the application as filed.....after the amendment the skilled person may not be presented with new technical information.

- Consistent with UK CoA approach eg *Napp v Sandoz*

Added matter – a softer EPO Approach?

- Meticulous literal examination has been a problem with some TBAs: strict literal basis in the application as filed required for any amended claim wording
- New Guidelines for Examination:
- *"literal support is, however, not required by the wording of Art 123(2)"*
- A number of decisions emphasise the test is whether new technical subject matter has been added
- Would skilled person derive any technically relevant information from the amended version? T1906/11

T1676/08– an extreme case?

- Protracted opposition appeal proceedings:
  - Divisional patent's granted claim to dosage regime rejected by OD on A123(2)/A76 EPC grounds arising from a disclaimer (introduced to avoid double patenting with parent case).
  - 3 rounds of oral proceedings as TBA first stayed pending Kos (dosage regimes)
  - The EBA decision in G2/10 then set out the test for added matter – requires the skilled person's understanding of the claim after introduction of the disclaimer to be assessed.
  - TBA refused to admit any evidence of the skilled person's understanding of the claim, or to explain the grounds and/or evidence upon which it proposed to decide the issue and declined to refer to Enlarged Board.

T1676/08

- Went on to hold the granted claim invalid under A123(2) on a construction not raised by the opponent or discussed with the parties; the relevant argument was revealed for the first time in the decision.
- Patentee given no indication of actual objection to claim or chance to address it
- Petition for review filed under A112a EPC alleging breach of A113 (right to be heard)
- Initial EBA hearing found the petition not clearly unallowable, and it will be considered by a full 5-member EBA panel later this year.

Thank you for listening!

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