PLAUSIBILITY IN SMALL MOLECULE CASES

EPO

RSC CASE LAW SEMINAR 2017

Dr. Joe Lenthall
SUMMARY

OUTLINE

• Brief overview of plausibility at the EPO

• Discussion of T 488/16

• Discussion of T 950/13

• Conclusion
PLAUSIBILITY AT THE EPO
LEGAL BASIS

Plausibility is derived from case law

Inventive step and sufficiency
  • Depending on claim type

Both sufficiency and inventive step judged
  • On date of filing
  • From the application as filed and common general knowledge
LEGAL BASIS

• Inventive step
  • Must be plausible from the application as filed that the problem is solved, i.e. that the therapeutic effect is present for the claimed compound(s)
  • If not, problem must be reformulated or inventive step denied

• Sufficiency
  • Plausible that the therapeutic effect is provided by
• Absolute proof not necessary (i.e. *in vitro* trials not needed)

• No requirement in EPC for experimental data to be provided

• Theoretical reasoning may be enough for plausibility

• But where exactly is the line....
APPEAL CASE

- Patent – EP1169038
- Bristol Myers Squibb Ireland – Patentee
- Apotex – Opponent
- Hearing date - 01 February 2017
- Board - 3.3.01
- Claims – Dasatinib or salts thereof
PROSECUTION

- Patent granted with a broad genus claim
- Over 500 example compounds
- Supporting evidence showing inhibitory activity was filed during prosecution to support inventiveness
ISCLOSURE IN THE APPLICATION

Dasatinib is not singled out in the application

The application states that the compounds exhibit protein kinase inhibition

Single statement regarding experiments:

“Compounds described in the following Examples have been tested in one or more of these assays, and have shown activity.”

Application contain no activity data
PPONENT

Argues the skilled person would not consider that dasatinib is an inhibitor of PTKs from the teaching of the application.

Therefore, the technical effect is not plausible from the application as filed.

So, post published evidence can’t be used to support the technical effect.
Skilled person would understand that each and every one of the examples had been tested
Expert evidence submitted to support this statement
Claims narrowed to a single chemical compound - dasatinib
Agreed with the Opponent

“The patent in suit does not contain any evidence that the problem formulated has been successfully solved. There is no evidence at all that any compound of the example, let alone dasatinib, had been tested for Src activity inhibitory activity”

Some of the post-filed data showed compounds from the original application did not have activity

Dismissed the expert evidence on the basis that highly skilled experts do not reflect the skilled...
APPEAL CASE
• Patent – EP1610780
• Bristol Myers Squibb Ireland – patentee
• Apotex – Opponent
• Hearing date - 03 February 2017
• Board - 3.3.01

• Claims – Dasatinib for the treatment of Chronic Myelogenous Leukemia (CML)
DISCLOSURE IN APPLICATION

• Dasatinib singled out and specifically claimed in the application as filed
• Specific statements that dasatinib can be used for treatment and is preferred
• Specific protein tyrosine kinase targets identified
• CML treatment based on activity against these specific PTKs
• Analogy between dasatinib and imatinib
• Application contains activity data
KNOWLEDGE AT FILING DATE

- Filing date in this case was 4 years after T0488/16 application
- Known that there was a link between inhibition of the specific PTKs mentioned and CML treatment
- Widely known that Imatinib (structurally similar compound) was useful in treating CML
OPPONENT

Argues that the skilled person would not have considered that all of the compounds in the application were inhibitors (of the specific PTKs)

Known that structural changes can have effect of PTK inhibition

Therefore, not plausible that dasatinib has the technical effect claimed

Lack of sufficiency cannot be remedied by post-published data
PATENTEE

- Argues that the application makes it plausible that dasatinib has the required activity
  - Based on the disclosure of specific PTKs
  - The focus on dasatinib
  - The analogy to imatinib and statement that dasatinib inhibits specific PTKs that are immune to imatinib
T0950/13

APPEAL BOARD (contrary to the Opposition Division)

• Agrees with the patentee.
• The board was persuaded by:
  • The analogy to imatinib
  • The more specific disclosure of dasatinib in the application and its specific link to CML treatment
  • The known link between the specific PTKs and treatment of CML
“The application does not contain experimental evidence for dasatinibs BRC-ABL kinase inhibitory activity. However, the disclosure of the experimental results in the application is not always required to establish sufficiency, in particular if the application discloses a plausible technical concept...”
CONCLUSIONS
CONCLUSIONS

T0488/16

- No activity data
- Many compounds, no focus on dasatinib,
- No plausible theory about why the compounds would have activity

T0950/13

- No activity data
- Clear focus on dasatinib
- Plausible explanation and direct statement for
A lot of discussion around T0488/16 and concerns that now we need some data to meet plausibility. T0950/13 shows it's still possible to have no data and meet the plausibility threshold.

Provide good theoretical reasoning that the therapeutic effect can be achieved if no or limited data.

Focussing some discussion on preferred compounds if possible.
CONCLUSIONS

T0488/16 – BMS have filed a petition for review
Arguing that the Board of Appeal did not properly identify the common general knowledge of the skilled person

Watch this space!

[Huge thanks to Eleanor Maciver]
ANY QUESTIONS?

Dr. Joe Lenthall
Joseph.Lenthall@Mewburn.com

22 – 24 Queen Square
Bristol BS1 4ND
Tel: +44 (0)117 945 1324