Plausibility at the EPO: Selected Recent Case Law

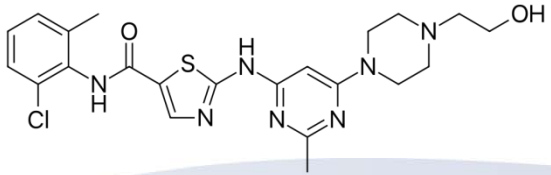
European Patent Attorney, partner

Selected Recent Case Law

- Biotech/pharma cases
- Little or no supporting data in the application as filed

T 488/16* (Dasatinib/BRISTOL-MYERS SQUIBB)

- 580 compounds including dasatinib originally covered
- Claim 1 as granted restricted to dasatinib



- No evidence for the purported technical effect (PTK inhibitor) in the application as filed, in particular not with respect to dasatinib

T 488/16* (Dasatinib/BRISTOL-MYERS SQUIBB)

- The purported effect was not supported by common general knowledge
- Post-published evidence was disregarded
- Problem reformulated as “provision of a further chemical compound”
- No inventive step

T 488/16 (Dasatinib/BRISTOL-MYERS SQUIBB)

- Extensive references by the appellant to EPO Case Law, national decisions from EPC contracting states and US case law.

- Referral to Enlarged Board denied:
  - No diverging Case Law
  - The question of whether a problem is plausibly solved is a technical question to be addressed by the technical Board of Appeal

T 488/16 (Dasatinib/BRISTOL-MYERS SQUIBB)

- Post-published **evidence in support that the claimed subject-matter** solves the technical problem the patent in suit purports to solve **may be taken into consideration, if it is already plausible from the disclosure of the patent that the problem is indeed solved**

- In the board's judgement, **it is not acceptable to draw up a generic formula, which covers millions of compounds, vaguely indicate an "activity" against PTKs and leave it to the imagination of the skilled reader** or to future investigations to establish which compound inhibits which kinase and is therefore suitable to treat the respective diseases associated therewith.

T 1322/17 (Ibandronate/ATNAHS)

- Claim 1: “A medicament comprising 150 mg of ibandronic acid [...] for use in the prevention or treatment of osteoporosis by administration as a single dose.”

- Proprietor invokes the effect of reduced incidence rate of bone fractures and relies on post-published evidence

T 1322/17 (Ibandronate/ATNAHS)

- The application referred to the "ibandronate clinical development program". This program is not identified further.

- The results of this program were not included in the application and not made publicly available at or before the filing date.

- **Results only known to the inventors** derived from studies of unknown set-up **cannot be considered when assessing the plausibility** of certain effects.

T 1322/17 (Ibandronate/ATNAHS)

- It is noted that experimental evidence is not limited to clinical data.
- It is also noted that experimental evidence is not always necessary to render a certain effect plausible.
- A **mechanistic explanation** and/or common general knowledge may be sufficient in certain instances.

T 1322/17 (Ibandronate/ATNAHS)

- However, in this case, there were no supporting circumstances
  - Post-published evidence disregarded
  - Arbitrary choice
  - Not inventive

T 108/09* (Fulvestrant/ASTRA ZENECA AB)

1. Use of fulvestrant in the preparation of a medicament for the treatment of a patient with breast cancer who previously has been treated with an aromatase inhibitor and tamoxifen and has failed with such previous treatment.

- The sole example of the patent was a protocol for a clinical trial (not the clinical trial itself).

- Post-filed document 10 showed the results of the trial.

T 108/09 (Fulvestrant/ASTRA ZENECA AB)

- The board notes that the present case is different from the situation described in decision T 1329/04.

- In the present case, it was already known that fulvestrant was effective as a second-line agent in the treatment of breast cancer.

T 108/09 (Fulvestrant/ASTRA ZENECA AB)

- Document (10) is not the only source of information regarding the question whether fulvestrant is useful as a third-line agent

- The data contained in document (10) may be used in the evaluation of whether or not the problem underlying the present invention has been plausibly solved.

- Inventive

T 0536/07 (Co-expression soluble PACE/GENETICS INSTITUTE)

1. A mammalian host cell comprising

a recombinant DNA sequence encoding the mammalian paired basic amino acid converting enzyme PACE lacking a transmembrane domain, operably linked to a heterologous expression control sequence permitting expression of said PACE; and

a polynucleotide encoding a precursor polypeptide, wherein the precursor polypeptide is a substrate for the encoded PACE which is operably linked to a heterologous expression control sequence permitting expression of the protein product of the precursor polynucleotide by the host cell.“

T 0536/07 (Co-expression soluble PACE/GENETICS INSTITUTE)

- No working examples for the claimed subject-matter
- The objective technical problem was formulated as the provision of an **alternative system** to those disclosed in documents D5 and D9
- Post-published evidence D21, D22 demonstrated the feasibility of the proposed solution.

T 0536/07 (Co-expression soluble PACE/GENETICS INSTITUTE)

- Board: *"the present situation differs from that underlying decision T 1329/04"*

- In that case, relevant structural differences between the claimed product and related products described in the art **did not allow the former to be identified as a bona fide member of a family defined by the latter**...

T 0536/07 (Co-expression soluble PACE/GENETICS INSTITUTE)

- In the present case, there is **no indication whatsoever of a possible prejudice** in the art **or of foreseen difficulties** in carrying out the proposed solution.

- …no further information is found in the post-published evidence **that was not already made available to the skilled person by the contested patent**

- Inventive

“Reversing” the plausibility argument

- T1760/11* – no a priori reasons for the skilled person to regard the information in the application as filed as **implausible**

- T863/12* – no indication in the common general knowledge of a lack of plausibility

How far does plausibility stretch?

T2371/13* (Association de deux colorants cationiques/L'OREAL)

1. **Use as direct dyes** in, or for the manufacture of, direct dyeing compositions for...**in particular the hair** ...of **a combination comprising**

   (i) at least one cationic dye chosen from (I) Basic Brown 17, Basic Brown 16, Basic Red 76, Basic Red 118, (II) Basic Yellow 57, (III) Basic Blue 99 and

   (ii) at least one cationic dye of the following formulas (IV) or (VI)...

T2371/13* (Association de deux colorants cationiques/L'OREAL)

- The application as filed contained 4 “virtual examples”.

- Tests filed by the respondent during the examination procedure on September 29, 2004 and May 23, 2006 showed that the combination of cationic direct dyes as claimed **actually resulted in a improved selectivity**.

T2371/13* (Association de deux colorants cationiques/L'OREAL)

- Opponent: referred to Case Law around plausibility...

The results of all experimental tests filed by the respondent **after the date of filing** of the patent in suit **should be excluded from the discussion of inventive step** and therefore not be taken into account for the demonstration of the effect obtained on the uniformity of coloring.

T2371/13* (Association de deux colorants cationiques/L'OREAL)

- Board: It is customary to assert under inventive step a technical effect which is not explicitly mentioned in the application as filed.

- ...in the present case, **disregarding tests** intended to demonstrate an improvement in the uniformity of the colors **would be incompatible with the problem / solution approach** which requires defining a document as the state of the art, which is not necessarily that cited in the patent application

T2371/13* (Association de deux colorants cationiques/L'OREAL)

- The question of whether the invention had been plausibly made at the time of filing was a question of **sufficiency**.
- But **this ground had not been raised** by the opponent...
- Opponent had themselves filed examples, to challenge those filed by the patentee
- Board: the problem is not credibly solved across the entire scope = lack of inventive step.

Summary

- Plausibility is to be assessed on a case-by-case basis
- Try to link the invention to the common general knowledge in other ways, e.g. mechanistic explanation
- It may be possible to ”reverse” the burden of proof with respect to the common general knowledge.
- So far, plausibility is (probably) limited to biotech and pharma cases.