

Plausibility: a mess in the making

Young EPLAW congress

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Introduction

- 1474: Venetian Patent Statute
- 1624: The English Statute of Monopolies
- 1791: Patent Law in Revolutionary France
- 1817: First Dutch patent act
- 1883: Paris convention for the protection of industrial property
- 1910: Second Dutch patent act
- 1970: PCT
- 1973: European Patent Convention
- 1995: TRIPS agreement
- 1995: Third Dutch patent act

- 2001: First time use of term plausibility as a threshold test in PSA at EPO
- 2017: Plausibility plays a role in:
 1. Inventive step
 2. Novelty
 3. Sufficiency
 4. Priority
 5. Industrial applicability

521 years of patent law:

- Plausibility not mentioned in the law
- Plausibility does not play a role when applying the law



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Plausibility: origin and development at EPO

Art. 56 EPC: Inventive step

Agrevo (T 0939/92) – 1995

- In PSA, when formulating problem, only "reasonably predictable", "fairly assumed", "credible" effects can be taken into account

Schering (T 1045/98) – 2001

- First time use of term "plausible" in context PSA

Johns Hopkins (T 1329/04) - 2005

- Post-published evidence may only be taken into account when application makes effect plausible

"The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one"

→ Plausibility is part of PSA

- Keeps speculative patents out
- Technical effect can be taken into account only when it has been made plausible by application
- A lack of plausibility by itself does not deprive a patent from patentability (so not a "requirement")

Plausibility: origin and development at EPO

Art. 83 EPC: Sufficiency

Deprenyl (T 0210/02) – 2004

- Plausibility has "has nothing to do with the sufficiency of the disclosure"

Salk (T 609/02) – 2004

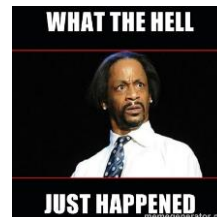
- Ref to G 5/83: "attaining the claimed therapeutic effect is a functional technical feature of the claim"
- "Sufficiency of disclosure must be satisfied at the effective date of the patent"
- Post-published evidence admissible only when application makes effect plausible (cf. Johns Hopkins)

→ By means of the law of evidence "plausibility" becomes an aspect of the law on sufficiency

- Salk effectively introduces a plausibility requirement for patents in which effect is part of claim
- If effect would be there, but patent does not say so, patent could still be held insufficient
 - Note that when "plausibility" hurdle is taken, patent may still be held insufficient if it does not work

Questions that pop to mind

- Can you then still argue Agrevo obviousness when effect is part of claim?
 - **Yes**, see e.g. T 1045/98, T 0893/02, T 0210/02, T 0715/03, T 0710/05, T 0716/08, T 1545/08
- Burden of proof post grant? How to argue "serious doubts, substantiated by verifiable facts" if patent works?



Plausibility: origin and development at EPO

Novelty, priority and industrial applicability

Novelty (art. 54 EPC)

- T 158/96: Prior art disclosed wording of claim, but it was plausibly contradicted → not novelty destroying
- T 1593/05 and T 1437/07
 - Art. 83 EPC requirements are the same for prior art → "**Salk**" **also applicable** → plausibility applies
 - Questionable whether that conclusion can be drawn

Priority (art. 87 - 89 EPC)

- T 0903/05 (Gemvax)

"Beyond the issue of enablement, the Board sees no legal basis for imposing additional criteria such as the presence of experimental data in the priority document which make plausible that the invention would work."

Industrial applicability (art. 57 EPC)

- T 898/05: application must make industrial applicability "plausible"

Plausibility: the Netherlands

Inventive step, novelty, industrial applicability

Inventive step

- Dutch courts apply the PSA and thus (also) follow Agrevo / Johns Hopkins
 - See e.g. Court of Appeal, 25-10-2016 (**Teva / Synthon**) which notes
 - It is established case-law at EPO and Dutch courts
 - It is a low threshold test
 - This qualification is probably inspired by UK courts (EPO has never said so)

Novelty

- District Court, 29-6-2016 (**MSD / Ono**)
 - First Dutch decision on role of plausibility with respect to novelty / prior art
 - When it concerns medical use claims, prior art is novelty destroying only when effect is made plausible
 - DC states that it follows the EPO (but did not investigate whether Dutch law is similar in this respect)
- Also see District Court, 27-7-2016 (**Astrazeneca / Sandoz**)

Industrial applicability

- No Dutch case law

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Plausibility: the Netherlands

Sufficiency (and priority)

Sufficiency (and priority)

- District Court, 24-4-2014 (**Merck / Mylan**)
 - Swiss type claim → effect in claim
 - It may remain unanswered whether a lack of plausibility would lead to a lack of sufficiency
- Court of Appeal, 27-1-2015 (**Novartis / Sun**)

"The claimed invention needs to be disclosed in an enabling manner in the priority document, in the sense that it needs to be credible that the claimed invention works, or to put it differently: solves the problem"

- CoA did not explain why Dutch law would differ from EPO case law (**Gemvax**)
- Supreme Court upheld this decision (14-4-2017)
 - It was put forward that the test applied by the CoA for claiming priority was wrong, but no objection was made to the above part of the test applied by the CoA

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Plausibility: the Netherlands

Sufficiency (and priority)

Sufficiency

- Court of Appeal, 26-4-2016 (**Ajinimoto / GBT**)
 - Both lack of inventive step and lack of sufficiency were argued based on a lack of effect,
 - Argument: application contains data for 2 amino acids only and no data that others would also work
 - CA starts by saying that burden of proof that patent would not work is on claimant. It then considers:

"Now that it is undisputed that the patent (reproducibly) works for at least 2 amino acids [...] it is not immediately implausible that the patent actually works (reproducibly) for other amino acids"
 - So CoA does not apply a plausibility "threshold" test
 - As to the admissibility of (post-published / post priority) evidence, CoA considers:
 - In national invalidation proceedings Dutch law of evidence applies in full
 - No reason to not consider post-published evidence when examining the enablement of a patent
 - *i.a.* based on post-published evidence CA refutes insufficiency argument

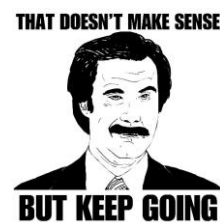


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Concluding remarks

Time to adopt a more holistic approach

- Court of Appeal contradicts itself re plausibility and sufficiency in Novartis / Sun and Ajinimoto / GBT
 - In Sun / Novartis, Salk is (implicitly) applied
 - Ajinimoto / GBT is not in line with Salk
- EPO applies plausibility in context of novelty as it continues on the same line as Salk
- So if Dutch Courts do the same, they should first make up their mind re Salk
 - Does Dutch law of evidence contain same restrictions re the admissibility of evidence as Salk?



More importantly:

1. **Do we really need plausibility to infect all legal concepts within patent law?**
 - For keeping "speculative" patents out, it seems sufficient apply a plausibility test within PSA only
2. **Is it really a "low" threshold test? That is not what plausible means (in Dutch)**
 - Should the hurdle not be higher than a "reasonable expectation of success"?

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Concluding remarks

"Plausibility" as a low threshold test vs. "reasonable expectation of success" in applying the PSA

Prior art: active substance X with salt **A** for treatment of Y
 Application: active substance X with salt **B** for treatment of Y



Type of salt is an almost irrelevant technical feature, without much of an influence
 → Expectation of skilled person that prior art or application will work does not change: **20%**

- Plausibility is a low threshold test, so expectation of success of **15%** sufficient
- Reasonable expectation of success requires "fair expectation", so threshold **40%** expectation of success

→ Application will be granted!

- Plausibility hurdle will be taken by application (>15%)
- Prior art does not render application obvious as there is no "reasonable expectation of success" (<40%)

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