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Plausibility - always the first test for invalidity?

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Overview

1. **Where does plausibility come from?**
   - Origins in EPO inventive step
2. **The 'threshold test'**
   - UK cases
   - Where is the bar set?
   - Role of post-published data
3. **Plausibility under insufficiency**
   - Recent UK cases
4. **Conclusions for the UK**

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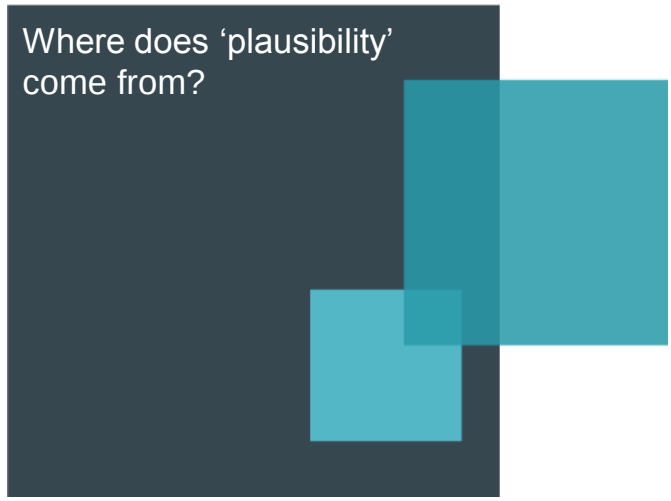
Where does ‘plausibility’ come from?



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The origins of plausibility

- Neither the EPC nor UK Patents Act 1977 mention plausibility (or the requirement for a technical contribution)
- Underlying principle
  - *The scope of the patent monopoly must be justified by the patentee’s contribution to the art*
- Arises out of ‘problem and solution’ approach i.e.:
  - The need to identify a technical contribution achieved by the claimed invention that is not found in the closest prior art
  - Then defining the technical problem to be solved as the achievement of these results
  - Question: is it credible that this technical problem has indeed been solved?

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Key EPO decisions (1) - *AgrEvo (T939/92)*

- Claim to a large class of compounds said to possess herbicidal activity
- *"It has long been a generally accepted legal principle that the extent of the patent monopoly should correspond to and be justified by the technical contribution to the art…the same legal principle also governs the decision that is required to be made under Art 56 EPC, for everything falling within a valid claim has to be inventive*"
- "*…in view of the underlying general legal principle…the selection of such compounds, in order to be patentable, must not be arbitrary but must be justified by a hitherto unknown technical effect which is caused by those structural features which distinguish the claimed compounds…[and] which can be fairly assumed to be produced by substantially all the selected compounds"*

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Key EPO decisions (2) – *Johns Hopkins (T1329/04)*

- GDF-9 had been identified as a putative member of the TGF-β superfamily (based on sequence homology – with no data in application as filed)
- The claim in question was to a DNA sequence encoding a protein having GDF-9 activity
- "*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, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve*"

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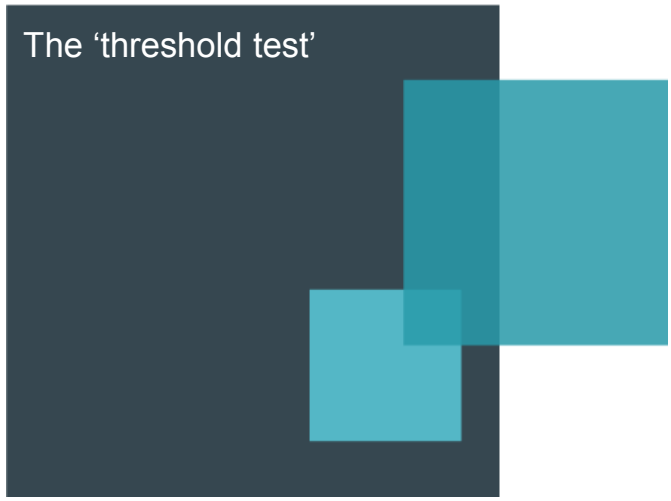
The 'threshold test'



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UK case - *Conor v Angiotech* [2008] HL

- Claim was for a coronary stent coated with taxol suitable for preventing restenosis
- Lord Hoffmann considered both *AgrEvo* and *Johns Hopkins* and approved the principle that a specification must:
  - "*pass the threshold test of disclosing enough to make the invention plausible*"
- Importantly, if the technical effect is plausible:
  - "*the question of obviousness should not be subject to a different test according to the amount of evidence which the patentee presents to justify a conclusion that his patent will work*".
- In other words:
  - The target to be hit by an obviousness attack is the claim itself
  - This should not be watered down based on the disclosure (or lack thereof) of the specification e.g. was it obvious to make a taxol coated stent to prevent restenosis; not was it obvious that it might do so.

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UK cases considering 'threshold'

- *Lilly v HGS [2011] SC* ✓
  - "*more than incredible*" / "*in some cases an educated guess may suffice*"
  - "*must be some real reason for supposing that the statement is true. The important point, however, is that the standard isn't any higher than that*"
- *Regeneron and Bayer v Genentech [2013] CA* ✓
  - 'principle of general application' to make it credible that VEGF antagonists could have therapeutic utility across full spectrum
- *Sandvik v Kennemetal [2011] Arnold J* ✗
  - No support in the specification or CGK for the claimed parameters having any technical significance
- *Prendergrast's Application [2000] Neuberger J* ✗
  - Mere assertion not enough
  - That said, "*relatively rudimentary tests would suffice*"

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So what data/disclosure is needed?

- Ascertained from the specification read in light of the CGK
- The standard to be satisfied will vary from case to case and in some cases no data at all is required (e.g. *Lilly v HGS [2011] SC*)
- *Ipsen (T578/06)* and *Arch (T1642/07)* - Recent EPO cases where plausibility was established in absence of any data
  - "*The board notes that the EPC requires no experimental proof for patentability*…" (*Ipsen*)
  - Burden of proof on EPO to establish doubts to discredit plausibility
  - Burden to establish plausibility only switches to applicant if EPO can '*substantiate doubts*' as to plausibility
- Nevertheless helpful to include data in application (especially where technical contribution will not speak for itself) and have fallback positions for compounds/uses of interest

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Role of post-published evidence

- "…*post-dated evidence may not be relied upon…to establish a technical effect which is not made plausible by the specification*" *Mylan v Yeda (Arnold J)*
- 'Confirmatory' role of post-published evidence unlikely to be material given policy reasons for plausibility test.
- Grey area around role of contemporaneous evidence not included in application:
  - "…*it seems to me that the problem is different in the case of evidence which is extrinsic to but contemporaneous with, the patent. Such evidence does not contravene the fundamental principle [that inventive step should be judged at the priority date]*" *Mylan v Yeda (Arnold J)*

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Is plausibility all you need? - NO

- 2nd STEP – 'classical' obviousness
  - Still go on to assess obviousness (clearest example is manner in which plausibility is used to formulate the PSA test at EPO)
  - If lack of plausibility rules out technical effects, risk ending up in 'minimalist' position where the only technical effect is providing an alternative (i.e. most vulnerable to obviousness/arbitrary).
- **AND** 3rd STEP - 'failure of promise'
  - Even if plausibility (and 'classical' obviousness) succeed, there can be a further assessment *Mylan v Yeda (Floyd LJ [2013])*

    "when it turns out that a technical property or effect made plausible by the specification turns out not to exist in fact."
  - No general principle that all evidence on obviousness must be available at priority date (e.g. commercial success and other 'secondary' evidence)

    "*I cannot see any principled objection to the admission of evidence as to the true nature of the advance made by the invention in connection with an objection of lack of inventive step*"

Conclusions so far (inventive step)

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- 1st of 3 steps
- Determined based on specification and common general knowledge
- Threshold set low – "*more than incredible*"
- Role of post-published evidence to establish plausibility is 'confirmatory' (but more readily used to attack validity)
- Lacuna between threshold test for plausibility and test for inventive step is the target for patentees i.e. plausible but not obvious (*Conor*)
  - Likely to be difficult to argue implausibility alongside 'classical' obviousness when no data in patent (as in *Conor*)
  - But can argue both – e.g. where claim covers a broad range of products and some of obvious and some are not effective.
- Commonly argued in UK; but rarely successful.

Limits of plausibility under inventive step?

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- Only for certain claims?
  - **NO** - ought to apply to all product claims
  - In *Sandvik v Kennemetal* the patentee argued that the attack that the patent did not make it plausible that the claimed features conferred any technical advantage was only legitimate for chemical compound selection patents. This was rejected.
- Only when the technical effect is <u>not</u> a feature of the claim?
  - **LIKELY** (as if the technical effect is a feature of the claim, all of the products have the technical effect).
- [*NOTE: Pharmacia v Merck [2002] CA* – patent invalidated for insufficiency on 'plausibility' grounds despite technical effect (anti-inflammatory activity with fewer side effects) not being part of claim
  - But may not be decided same way today (*Lilly v HGS (CA)*)]
- So what if the technical effect **<u>is</u>** a feature of the claim? – e.g. medical use – **<u>insufficiency…</u>**

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‘Plausibility’ under insufficiency

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Foundation again in the EPO – *Salk* T 0609/02

- *“Sufficiency of disclosure must be satisfied … on the basis of the information in the patent application together with the common general knowledge.”*
- *“… not requiring an absolute proof that the compound is approved as a drug…”.*
- *“…for a sufficient disclosure of a therapeutic application, it is not always necessary that results of applying the claimed composition in clinical trials, or at least to animals are reported.”*
- *“Yet, this does not mean that a simple verbal statement … is enough”*
- *“It is required that the patent provides some information in the form of, for example, experimental tests, to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se.”*
- *“Showing a pharmaceutical effect in vitro may be sufficient”.*
- *“Once this evidence is available from the patent application, then post-published (so-called) expert evidence (if any) may be taken into account, but only to back-up the findings in the patent application … and not to establish sufficiency of disclosure on their own.”*

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UK case - *Regeneron / Bayer v Genentech* [2013] (CA)

- "*The claimants also advance an obviousness case along the lines permitted by the decision of the Technical Board of Appeal in the* Agrevo *case: T 939/92. In substance they say that the claim that VEGF antagonists would be useful for preventing angiogenesis in the treatment of all non-neoplastic diseases was not plausible*." (*Floyd J, HC*)
- Similar pleading under insufficiency and only considered there. The CA appeal agreed:
  - *"It must therefore be possible to make a reasonable prediction the invention will work with substantially everything falling within the scope of the claim or, put another way, the assertion that the invention will work across the scope of the claim must be plausible or credible…*
  - *On the other hand, if it is not possible to make such a prediction or if it is shown the prediction is wrong and the invention does not work with substantially all the products or methods falling within the scope of the claim then the scope of the monopoly will exceed the technical contribution the patentee has made to the art and the claim will be insufficient. It may also be invalid for obviousness, there being no invention in simply providing a class of products or methods which have no technically useful properties or purpose."* (*Kitchin LJ, CA*)

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UK case - *Eli Lilly v JAI* [2013]

- Again, *Agrevo* issues not considered under obviousness – "*in my view Lilly's real objection is not one of obviousness, but of insufficiency, and I shall consider the matters relied on in that context*"
- Formulated a two-stage enquiry for insufficiency:

  1. Does the disclosure of the patent, read in light of the CGK, make it plausible that the invention will work across the scope of the claim; and

  2. If so, does the later evidence establish that the invention cannot be performed across the claim scope without undue burden i.e. scope of protection needs to be commensurate with technical contribution – may lead to an enquiry as to whether have established a principle of general application
- Arnold J:
  - *"Thus I conclude that the disclosure in the Patent does make it plausible that passive immunisation of a suitable antibody to Aβ will be effective to prevent and/or treat a disease characterised by amyloid deposit.*
  - *That is not the end of the enquiry, however. It remains to be considered whether the Patent makes it plausible that* ***any*** *antibody to Aβ (provided it is of IgG1 isotype) will be effective to prevent and/or treat a disease characterised by amyloid deposit*"

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UK case – *Hospira v Genentech* [2014]

- Birss J:
  - "*For these reasons the idea of "plausibility" as part of the law of sufficiency of disclosure has been developed both in the EPO (**T609/02 Salk Institute**) and the UK (**Regeneron**). The term "plausibility" has been coined to characterise what it is that a patent specification must provide in order to be sufficient, short of full clinical proof of efficacy*."
  - "*Putting this another way, the assertion that the invention will work across the scope of the claim must be plausible or credible. Therefore although proof that a medicine works for a particular therapeutic purpose is not required, the patent specification must show that the product has an effect on a disease process so as to make the claimed therapeutic effect plausible. The effect must be plausible to a person (or team) skilled in the art reading the patent with their common general knowledge*."
- Held that the squeeze was perfect – if the skilled team would not take the next obvious step from the prior art, they would not do so based on the patent.
- Squeeze was also applied to the enablement part of the test for priority:
  - T903/05 Gemvax in which the Technical Board of Appeal rejected the suggestion that to be entitled to priority it was necessary for the priority document to contain data which made it plausible that the claimed invention worked.
  - "*I find that in law the test for priority includes the requirement for plausibility in a case like this one.*"

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Conclusions on insufficiency

- 1st of 2 steps (parallel to 1st and 3rd steps under inventive step)
- Since the technical feature is part of the claim, then unlike with the plausibility assessment under inventive step, there seems to be limited ability to find a fall-back position (e.g. by arguing a different, lesser technical contribution)
- Again, determined based on specification and common general knowledge
- Again, threshold seems low (but less guidance under insufficiency)
  - "*A question for another day is the extent to which the standard for plausibility differs from the standard for obviousness. Given the way in which the case has been argued and the findings I have made, I do not have to address that question*" (*Birss J – Hospira*)
- Safer to include data in application rather than rely on rationale for plausibility based on CGK (for same reasons as for inventive step)
- Post-published data again only confirmatory for establishing plausibility but can be used more readily to invalidate claim

Conclusions on plausibility in the UK

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- Fundamental question: is there a real technical advance commensurate with the scope of the claim?
- Plausibility has become more prominent as a first step under insufficiency and inventive step
  - If technical advance is *not* part of claim – lack of inventive step if not plausible (*AgrEvo* and *Johns Hopkins* – *Conor / Dr Reddy's / Sandvik*)
  - If technical advance *is* part of claim – then it is insufficient if it is not plausible across scope of claim (*Salk – Regeneron / Eli Lilly / Hospira*)
  - Gives rise to squeeze arguments (*Hospira*)
- If in doubt, plead both (*Regeneron*)
- Threshold for plausibility seems to be low
- Post-published data can be used to attack the patent validity more readily than to uphold it
- Plausibility crops up under other headings too:
  - lack of industrial application (*Lilly v HGS*)
  - even finds its way into priority… (*Hospira*)

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Andrew Hutchinson

Young EPLAW
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