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# *Where are we now with plausibility?*

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## What's the big deal with plausibility?

For the first time since the first edition in 1884, the 18th edition of *Terrell on the Law of Patents* (2016), the leading text book for UK patent practitioners, included a reference to "plausibility"

Foreword by Birss J: "The emergence of that concept [plausibility] (or rather arguments about an alleged lack of it) in relation to each of inventive step, sufficiency and industrial applicability represents a significant recent legal development in the life sciences."

"Chapter 13 of the last edition ("Invalidity Due to Insufficiency") contained no reference to the objection of want of plausibility … most cases of invalidity before the Patents Court now contain an allegation that the teaching of the patent is not plausible. This represents a significant change in law and practice."

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# Why the need for plausibility?

- At the grant stage – EPO as gatekeeper of European patent system
- **To prevent speculative claiming.** Prendergast's Applications [2000]:

  "…[otherwise] it would be possible to make valid Swiss-type applications in relation to **all sorts of speculative uses** for established drugs and other chemicals **without a shred of evidence as to whether they would work, let alone as to whether they do work**. That seems to me to be potentially embarrassing in terms of overwork for the Patents Office … It appears to me to risk giving an uncovenanted benefit to a substantial or rich organisation which might seek to register a remarkable number **of wholly speculative patents**…"
- **A check on overbreadth.** Regeneron v Bayer [2013]:

  "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**. The products and methods are then tied together by **a unifying characteristic or common principle**. If it is possible to make such a prediction it cannot be said the claim is insufficient because the patentee has not demonstrated the invention works in every case."
- **Objective is to distinguish those applications which solve a technical problem from those which merely pose a further problem for the skilled person**

LT:1780155.2




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# What can we draw out from EPO case law?

- A **mere assertion** that compound X is suitable for treating disease Y is **not sufficient** without any more to render the invention plausible
- The disclosure of the patent specification does not have to be definitely predictive of the efficacy of the invention: ***in vitro* tests** which may well not be reproducible in humans or animals **may suffice**
- An **example** of adequate support to amount to a plausible disclosure would be **experimental tests**, showing that the claimed compound has a **direct effect on a metabolic mechanism specifically involved in the disease**
- **Later published data are not admissible** if they alone render the invention plausible
- Ultimately the purpose of the requirement of sufficiency is to place the reader in possession of the invention **without imposing undue burden** on him by way of further investigation or research

LT:1780155.2

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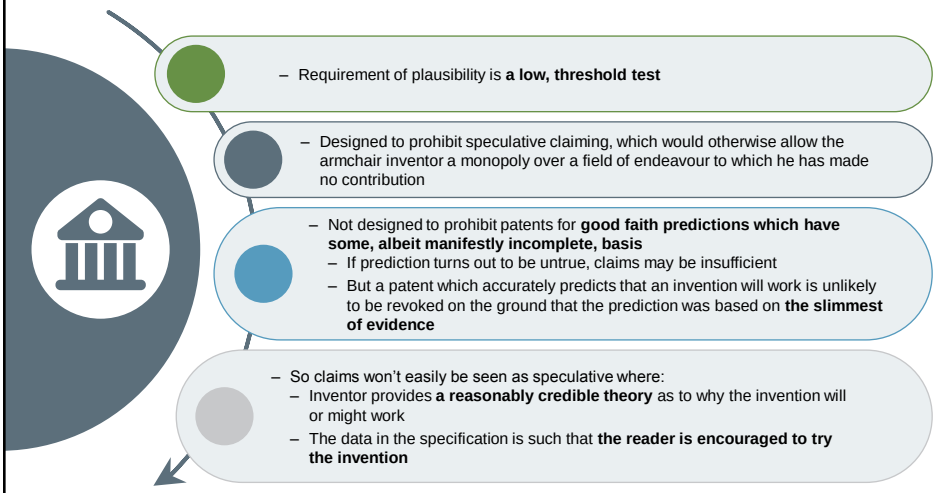
# Warner-Lambert v Generics [2016] (Court of Appeal)





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# But test for plausibility (re sufficiency) is not the same as "reasonable expectation of success" for obviousness

**Warner-Lambert v Generics [2016]**

- Argument re whether the invention is only to be treated as plausible if the reader of specification would be encouraged to try invention with a reasonable prospect of success
- No reason to align the tests
- A test designed to prevent speculative claiming **need go no further than requiring the patentee to show that the claim is not speculative: the specification does not need to provide the reader with any greater degree of confidence in the patentee's prediction than that**

**Actavis v Eli Lilly [2015]**

- Policy considerations are different
- For obviousness, a fair expectation of success is required because, in an empirical art, many routes may be obvious to try, without any real idea of whether they will work
- The denial of patent protection based upon the "obvious to try" criterion alone would provide insufficient incentive for R&D, and would lead to the conclusion that a research program of uncertain outcome would deprive a patent of inventive step
- **Requirement of plausibility is different - it is to exclude speculative patents, based on mere assertion, where there is no real reason to suppose that the assertion is true**

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# Two recent patents that survived in the UK

**Merck v Ono [2015]**

- The use of anti-PD-1 antibodies for treating "cancer"
- Data in the patent made it plausible that PD-1 receptors can manipulate the immune system and treat cancers in general
- Fact that anti PD-1 monotherapy does not treat some cancers was not fatal, because at the date of application describing the invention as a treatment "for cancer" was a "fair level of generality" – the law "did not require perfection"

**Actavis v Eli Lilly [2015]**

- The use of tomoxetine for the manufacture of a medicament for treating ADHD
- The skilled clinician would have considered it a reasonable hypothesis that TCA efficacy in treating ADHD was as a result of selective NE re-uptake inhibition
- He would have considered the position in relation to ADHD would be more complex than depression but this does not detract from the conclusion that the skilled team would consider the invention to be credible





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# So how much is enough to meet the low plausibility threshold?

| | | |
|---|---|---|
| 01 Comprehensive proof! | 05 A reasonably credible theory: Warner-Lambert v Generics | 09 Enough to encourage the reader to try the invention: Warner-Lambert v Generics |
| 02 Some evidence that it might work | 06 A reasonable hypothesis: Actavis v Eli Lilly | 10 A claim? (too close to a mere assertion?) |
| 03 The slimmest of evidence: Warner-Lambert v Generics | 07 Some real reason for supposing that the statement is true: HGS v Eli Lilly | 11 Something that suggests a line of enquiry might be worthwhile? |
| 04 A reasonable or good faith prediction: Regeneron v Bayer; Warner-Lambert v Generics | 08 An educated guess: HGS v Eli Lilly | 12 **When does it cross the line of being more than just mere speculation?** |

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# Some policy considerations…

1. If an invention satisfies the statutory test for sufficiency (and is in fact enabled across the full scope of the claim), should there be room for a separate objection of plausibility to arise?
2. Should plausibility play a role at all in the statutory test for sufficiency?
3. Is plausibility inconsistent with the requirements of TRIPS and the EPC?
4. Where a claim has been held to be plausible across some but not all of its breadth, why should reliance on post-published evidence not be permitted to fill the gap?
5. Does plausibility place undue pressure on the patentee to file its new use patent ASAP when it cannot know if a drug will treat every sub-condition until clinical trials are completed?
6. Could a strict approach to plausibility stifle innovation and R&D in the life sciences?





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# Questions?

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