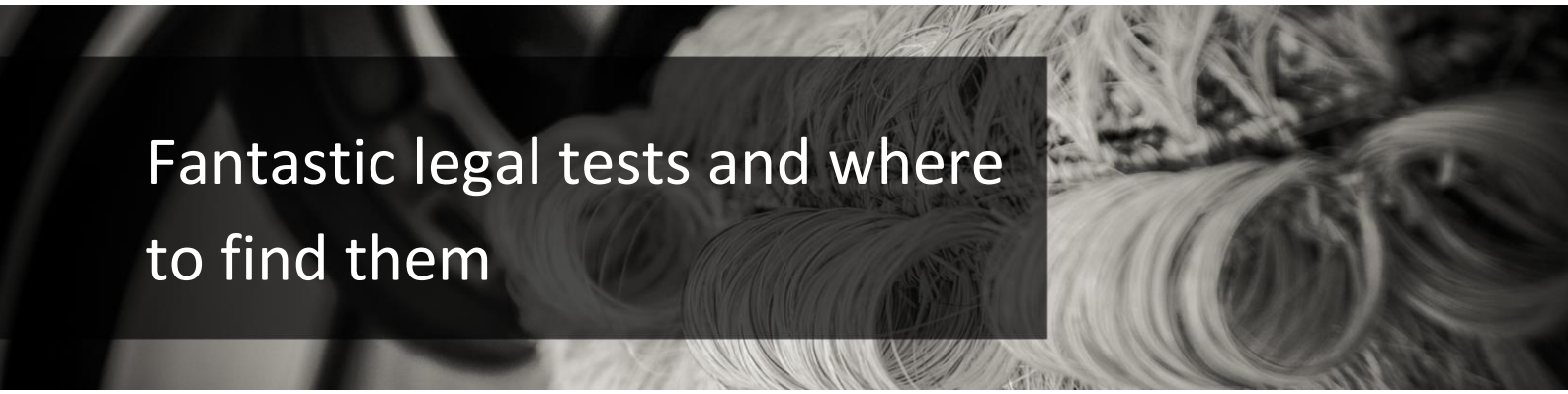

Fantastic legal tests and where to find them

Plausibility after *Warner-Lambert v Actavis*

By **Edward Cronan** (Pupil Barrister, Hogarth Chambers)

For a patent to be granted it has to fulfil a number of requirements. Two key requirements are sufficiency of disclosure and the need for an inventive step. The legal concept of 'plausibility' has grown to fill a legislative gap in the assessment of those criteria. The UK Supreme Court came to consider the concept of plausibility in a **decision** handed down on 14th November 2018.

The Supreme Court decision confronted criticisms of judicial activism in the development of the plausibility concept, and the Court failed to reach unanimous agreement on the law. The majority of the court ultimately backed a statement of the law of plausibility that raised concerns among the minority of the Court. The issue that worried the Judges was the potential knock-on effect of imposing an overly high standard of plausibility on the research and development of new drugs.

The minority of the Supreme Court voiced concerns that the majority's decision, set out in the speech of Lord Sumption, risked raising the standard of plausibility. If true, this could preclude patentability of innovative medicines at an appropriate stage in the R&D cycle, making further investment uneconomical. This article analyses Lord Sumption's speech by drawing out the key principles of the new test of plausibility. These principles are then applied to real scenarios from drug development and patent litigation.

Practical assessment of the Supreme Court's new test shows that the circumstances where clinical trial data are required to make an invention plausible should be very limited. The author suggests that the concerns

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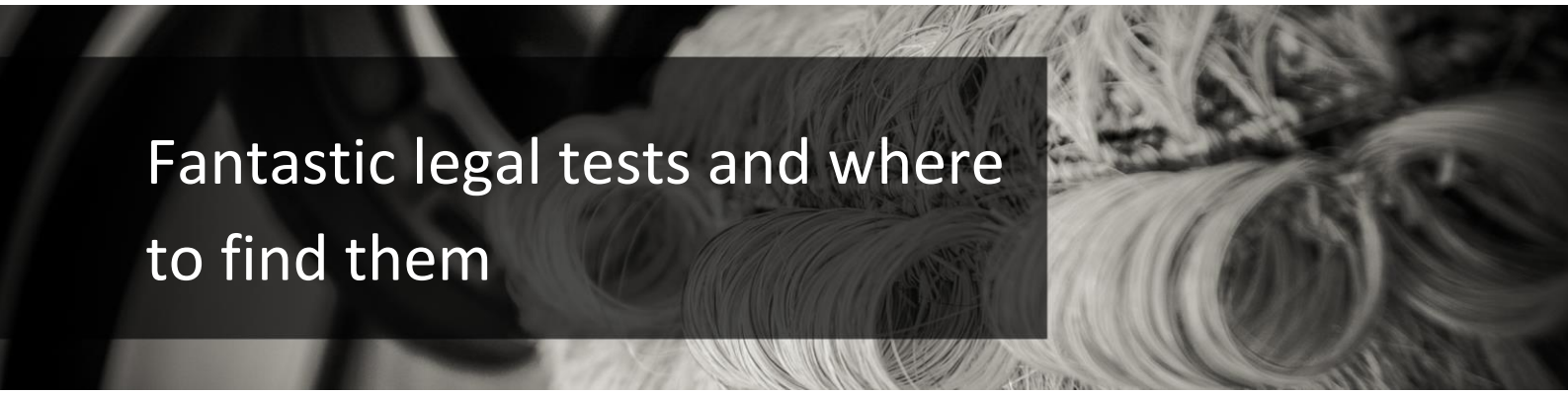

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expressed by the court's minority, that the new test required a "prima facie case of therapeutic efficacy", are unfounded. To the extent there is uncertainty regarding Lord Sumption's standard, it is perhaps because there has been an elision of the sufficiency and inventive step perspectives on plausibility in the supporting reasoning.

The full article was published in the **Journal of Intellectual Property Law & Practice** which can be accessed here

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