

BRISTOWS

Review of Patent Cases in the English Courts in 2017

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Quotation of the Year

"Indeed, in my view, to characterise the issue [of claim construction] as a single question of interpretation is wrong in principle, and unsurprisingly, therefore, can lead to error."

Per **Lord Neuberger** in *Actavis v Eli Lilly* [2017] UKSC 48, at para 55.

The information contained in this document is intended for general guidance only. If you would like further information on any subject covered by this Bulletin, please e-mail Brian Cordery (brian.cordery@bristows.com), Dominic Adair (dominic.adair@bristows.com) or the Bristows lawyer with whom you normally deal. Alternatively, telephone on + 44 (0) 20 7400 8000.

Index

Quotation of the year	Inside front cover
Introduction	2
Claim construction and infringement	2
Use of prosecution history as an aid to construction	5
Indirect infringement	6
FRAND and competition defences	6
Validity	7
Patentable subject matter	7
Novelty	7
Entitlement to priority and enablement	8
Obviousness	9
Insufficiency	10
Added matter	10
<i>Arrow</i> declarations	10
Supplementary protection certificates (SPCs)	12
Damages	13
Account of profits	13
Employee compensation	13
Tort of unlawful interference	13
Costs	14
Indemnity basis	14
Procedural issues	14
Jurisdiction	14
Disclosure	15
Interim injunctions	15
Stays	16
Expedition	16
Shorter Trials Scheme	16
Public interest	16
Issues from the IPEC	17
Unitary patent / Unified Patent Court	17
Looking ahead to 2018	19
The authors	20

Introduction

As the reality of Brexit sunk in and the UK marched towards splendid isolation or trudged towards a financial cliff edge, depending on one's point of view, 2017 will be remembered by UK patent practitioners as the year in which the law on construction and infringement changed dramatically. The authors make no apology for devoting a considerable part of this review to an analysis of the Supreme Court's decision in *Actavis v Eli Lilly*¹ and the handful of first instance and appeal judgments that have subsequently applied various aspects of this decision.

Preparations for the Unified Patent Court (the "UPC") continued in 2017, notwithstanding the uncertainty delivered by the Brexit vote in 2016. Just when it seemed that there couldn't be any more surprises, it was the turn of the Germans to deliver a curveball: a challenge to the legality of the UPC regime brought in the German constitutional court by local IP practitioner Dr Ingve Stjerna. Our UPC author, Alan Johnson, provides his personal reflections on this and other UPC issues in the final section of this review.

Although *Actavis* dominated the patent landscape in 2017, there were several other interesting decisions both on procedure and on substantive law, including:

- The granting of the first *Arrow* declaration by the English courts following a decision of the Court of Appeal opining that such declarations are possible in principle.
- The first judgment on FRAND royalty rates and a later FRAND injunction decision.
- Long-awaited analysis of the principles laid down in *Mayne Pharma*² as to the obligations of disclosure on a party seeking to rely on experiments in litigation.
- Further references to the CJEU in relation to the **SPC Regulation**.³ Will the question of the meaning of "protected by a basic patent in force"⁴ ever be resolved?

In terms of the number of decisions, 2017 was a little quieter than 2016, with several larger cases settling just ahead of trial. There were 62 substantive decisions in 2017, compared with 82 in 2016, and 78 in 2015.

As with previous years, this review attempts to summarise the most important decisions on a topic-by-topic basis. The **UK Patents Act 1977** is referred to as the "**Act**" and the **European Patent Convention 2000** as the "**EPC**".

As ever, the authors have endeavoured to cover every important development that occurred during the course of the year. However, as this is a condensed summary, not every decision is mentioned.

Claim construction and infringement

For a dozen years, the authors of this review have repeatedly stated that the law of construction of patent claims in the UK is governed by the single, "bedrock" question derived from the decision of the House of Lords in *Kirin-Amgen*, namely: what would the skilled person have understood the patentee to be using the language of the claim to mean?⁵ Furthermore, it was generally understood that this is all that needs to be assessed when considering infringement. Year after year we noted that, although they had never been formally disapproved or abandoned, the *Improver*/*Protocol*⁷ questions belonged to a different era, and had, like the office fax machine, by and large fallen into disuse.

In what was clearly the most important UK patent case of the year by a country mile, 2017 witnessed the renaissance of the *Improver*/*Protocol* questions, albeit in a modified form, in the decision of the Supreme Court in *Actavis v Eli Lilly*⁸ concerning pemetrexed. The facts of the case are well known. Put shortly, Lilly owned a patent claiming the use of pemetrexed disodium in combination with vitamin B₁₂ to treat cancer. The background to the invention was that pemetrexed had been found to be an effective treatment for certain types of cancer but with significant side effects. The patent taught that administering pemetrexed together with vitamin B₁₂ caused a noticeable reduction of those side effects. Actavis did not challenge the validity of the patent but sought a declaration of non-infringement (DNI) in respect of various other salts of pemetrexed, including pemetrexed dipotassium which will be used as the exemplar here. Actavis contended that the skilled person would understand very well the meaning of pemetrexed disodium and that, in contrast to terms such as "vertically", the word on which *Catnic*⁹ turned, a clearly defined chemical substance did not allow for variance in interpretation. Actavis also sought a DNI in respect of certain other European designations of the patent. To the surprise of many practitioners, **Arnold J** chose to assess the issue of the construction and infringement using the *Improver*/*Protocol* questions¹⁰ and, having done so, found that there was no infringement, direct or indirect.¹¹

¹ [2017] UKSC 48.

² *Mayne Pharma v Debiopharm* [2006] EWHC 164 (Pat).

³ Regulation (EC) No. 469/2000 concerning the supplementary protection certificate for medicinal products.

⁴ As required by Article 3(a) of the SPC Regulation.

⁵ *Kirin-Amgen v Hoechst Marion Russel* [2004] UKHL 46, at para 32.

⁶ *Improver v Remington* [1990] F.S.R. 181, at para 189.

⁷ The Court of Appeal rebranded the *Improver* questions after the Protocol on the Interpretation of Article 69 of the EPC, which they sought to implement in *Whitely v Driffield* [2001] R.P.C. 7.

⁸ See footnote 1, ante.

⁹ *Catnic Components v Hill & Smith* [1982] R.P.C. 183.

¹⁰ Digressing for a moment, in the authors' view, it may have been this extra-territorial element of the dispute that prompted Arnold J at first instance to consider the issue of construction/infringement using the unfashionable *Improver*/*Protocol* questions, as he was aware that variations of these questions are used in many continental jurisdictions. Ironically, it may have been this element of the case that ultimately led to consideration of the issues by the Supreme Court and the ensuing reshaping of the law.

¹¹ *Actavis v Eli Lilly* [2014] EWHC 1511 (Pat).

On appeal, **Floyd LJ**, with whom the other judges agreed, held that there could be no direct infringement.¹² Although he also used the *Improver* questions, **Floyd LJ** held that Lilly failed on questions 2 and 3 on the basis that, until he or she tested the dipotassium salt, the skilled person would not know if the salts worked in the same way and, besides, the skilled person would have understood that strict compliance with the term was an essential element of the invention. However, disagreeing with the trial judge, **Floyd LJ** held that sales of pemetrexed dipotassium would indirectly infringe the patent as the user was directed to reconstitute the lyophilised formulation in saline solution, which would inevitably lead to the presence of pemetrexed ions and sodium ions in solution.

The Supreme Court hearing took place in early April 2017 and, like most Supreme Court hearings, was shown live on television. Although it may have failed to topple *Strictly Come Dancing* from the top of the ratings table, it was nonetheless interesting to observe, and evident from the debate, that change was afoot. The team of five judges, led by **Lord Neuberger**, was not going to deliver a judgment which simply stated that the current approach adopted by the lower courts was appropriate.

The judgment was handed down on 12 July 2017. The immediate reaction of the profession was not unlike the 10-second silence that accompanied the largest explosion of 2017's other big drama: *Star Wars: The Last Jedi*. Momentary shock and then mild disbelief. The Supreme Court had held that **Lord Hoffmann's** approach to construction, as encapsulated in the bedrock question set out above, was out of step with **Article 69 EPC**.¹³

Reflecting on the bedrock question, the Supreme Court held that, instead, a problem of infringement should be determined by addressing two issues through the eyes of the skilled person:

1. Does the product or process in question ("the variant") fall within any of the claims as a matter of normal interpretation, i.e. applying the normal principles of interpretation of documents?
2. If not, does the variant vary from the invention in a way or ways which is or are immaterial? That raises a question that normally would have to be answered by reference to the facts and expert evidence.

When addressing the second question, i.e. whether the variation is immaterial, the Supreme Court held that

one should ordinarily ask three questions:

- i. Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent?
- ii. If yes, would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?
- iii. If yes, would a reader of the patent have concluded that the patentee nevertheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

The significant change with this formulation is that it introduces hindsight into the determination of the second question, as the skilled person is now deemed to know that the variant achieves substantially the same result as the invention and the patentee is not required to demonstrate this based on a disclosure in the patent or the relevant common general knowledge (CGK). This adjustment had a significant impact on the outcome of the case, as the trial judge had found as a fact that the skilled person would not know which other pemetrexed salts would have acceptable properties for use in the formulation.

The *Actavis* decision has raised as many questions as it has answered. What does "normal" mean in the context of the first question? What does "literal" mean in the context of the second question? Does the decision have any impact on validity? What about numerical ranges? What about the situation where the patentee exemplifies several solutions in the specification but claims only one of them? We have now had several decisions from the lower courts which have examined the Supreme Court decision, and the following judicial observations have been made:

- *Generics (UK) v Yeda Research*¹⁴ – **Arnold J** opined that the phrase "as a matter of normal interpretation" referred to purposive construction, albeit that the Supreme Court did not use those words: "I do not consider that **Lord Neuberger** can have meant anything different, even though he appears to have eschewed the expression "purposive construction" when describing the correct approach."¹⁵ The Judge also briefly touched upon the impact of the Supreme Court

¹² *Actavis v Eli Lilly* [2015] EWCA Civ 555.

¹³ To put it in Lord Neuberger's words, "to characterise the issue as a single question of interpretation is wrong in principle, and unsurprisingly, therefore, can lead to error", see *Actavis v Eli Lilly* [2017] UKSC 48, at para 55.

¹⁴ [2017] EWHC 2629 (Pat).

¹⁵ *Ibid* at para 138.