



YEARS

Review of Patent Cases

in the English Courts in 2025

25-year milestone edition

Bristows

Quotation of the Year

“Due to the present unfortunate conflict between this Court and Munich 1 and UPC Mannheim, I have previously commented that some de-escalation is desirable, otherwise we will be at risk that the grant of ASIs and AASIs becomes the norm, without advancing matters one way or the other.”

Mr Justice Mellor in *Acer Incorporated & Ors v Nokia Technologies OY* [2025] EWHC 3331 (Pat) at §436

The information contained in this document is intended for general guidance only. If you would like further information on any subject covered by this Review, please email 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 20 7400 8000.

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Foreword

It was 25 years ago, in this publication, that Bristows' first annual review of patents cases was written by a young Brian Cordery, produced at the kitchen table over his Christmas holidays. Highlights of that first edition, a mere 5½ pages, included a note that the Patents County Court had been revived – by **Michael Fysh QC** – and mention of “*the first interim injunction in a patent case for several years*”, referring to **Jacob J**'s landmark decision in the paroxetine case and the birth of “*clearing the way*”. So much has changed over the past quarter century, yet, stepping back, perhaps very little. The English courts and their judges remain the envy of the world. They continue to deliver high-quality, detailed, and well-reasoned decisions, albeit at a price, and they are written with such eloquence and clarity that they are accessible to non-specialists, thereby promoting open justice. That said, their output remains prolific, and hence our job remains as it always was - to be your companion and guide.

Welcome to our review of patent cases for the year 2025.

Introduction

In 2025 the English courts remained busy despite more choices of litigation forum than ever before and the growing trend for some competing courts to embrace long-arm jurisdiction. The English courts delivered a good number of decisions – 68 – similar to that seen in the last two years and not out of step with the longer term (66 in 2024, 68 in 2023, 75 in 2022, 66 in 2020, 86 in 2019 and 63 in 2018).

The year was notable for at least the following developments:

- Not one but **two formulation patents being held as valid** (Novartis' Xolair® and Regeneron's Eylea®) showing that positive data points in the field of pharmaceutical secondary patents do exist.
- Further clarification as to the circumstances where an **interim licence declaration in respect of Standard Essential Patents** will be granted, and the first **anti-anti-suit injunctions** granted by the UK protecting against anti-interim-licence injunctions granted by the UPC and German national courts.
- **A rare assessment of an account of profits** in *Lufthansa v Astronics*.
- **The return of Dr Thaler and DABUS** with a related divisional application and a declaration that AI wasn't the inventor after all (or was it?)

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**. Judges are referred to according to the office held at the time of their decision (not subsequent elevation). As ever, the authors have endeavoured to cover every important development that occurred during the year. However, as this is a condensed summary, not every decision is mentioned.

For last year's case law from the UPC system, please refer to our separate UPC Review of the Year (which for those reading on a screen, can be accessed via the hyperlink [here](#)¹).

- The UK's position on plausibility continuing to be somewhat tougher than elsewhere in Europe, leading to the demise of **AstraZeneca's dapagliflozin patent**.

¹ Alternatively, go to <https://www.bristows.com/viewpoint/publications/upc-review-of-the-year/>

Claim construction and infringement

Construction

In *Samsung Bioepis v Alexion*², Alexion's patent claimed the antibody eculizumab by way of a "consisting of" claim with defined heavy and light chain amino acid sequences. However, owing to an accident of history, the claimed light chain amino acid sequence contained, in addition to the eculizumab sequence, the 22 amino acid leader sequence which plays a part in the expression of light chain but is normally cleaved off in the final assembled antibody, meaning that on a literal basis, no biosimilar antibody would infringe. Sure enough, Samsung Bioepis and Amgen alleged that their biosimilar eculizumab products, without the leader sequence, did not infringe. Alexion argued that the biosimilar products infringed on a purposive construction.

Meade J preferred the claimants' interpretation and found that the claim was limited to antibodies including the 22 amino acid leader sequence. Of relevance was that the skilled person has an appreciation of the patent system and would expect the patentee to be claiming something new. Therefore, the skilled person would understand that the patentee is unlikely to have intended to cover prior art which is acknowledged in the specification (see *Virgin v Premium*³ and *Jushi v OCV*⁴). In this instance, the patent had disclosed "eculizumab" as being known in the art. It was unfortunate for the patentee, but irrelevant for the assessment, that owing to another error, the correct sequence of eculizumab had not, in fact been prior disclosed. The claim scope having been determined to include the leader sequence, the patent was effectively unenforceable. Nevertheless, as **Meade J** commented, "Patents do sometimes claim things which are suboptimal or whose purpose is not entirely evident. That is not a licence to rewrite the claims."

Prosecution history

The sceptical but not absolutist approach of the English courts to the use of the file wrapper when interpreting claims continues to be tested but still holds firm. In the eculizumab case⁵, the defendants sought to rely on the patent's history before the EPO, including the fact that the TBA had refused to allow an amendment to remove the leader sequence from the antibody claim on the basis that this would add matter. Likening this to *Actavis v Lilly*⁶, the Judge refused recourse to the file because it failed to meet either of the permitted exceptions of resolving ambiguity or being contrary to public interest. Here, Alexion was prevented from capturing territory refused in prosecution not because of the prosecution history, but because a narrow interpretation was determined to be the correct way to construe the claim.

Numerical Ranges

HHJ Hacon considered the interpretation of numerical ranges in *Celltrion v Genentech & Novartis*⁷ concerning Novartis and Genentech's jointly owned patent for a liquid formulation of omalizumab. When considering an integer in the claim to "about 150 g/L" of an omalizumab, Celltrion, seeking overlaps with the prior art, argued that conventional rounding convention would mean this encompass anything from 145.0 to 154.9 g/L, but that the use of "about" in the claim meant that it would stretch further and also encompassed 125 g/L. **HHJ Hacon** held that the flexibility to be given to a number in a patent claim will be fact dependant, but that if a number is proceeded by "about" some variation must be assumed. However, he dismissed Celltrion's argument about the lower end of the range, finding the skilled team would consider it encompassed between 145 and 155 g/L. This was in part because there was a technical significance of the concentration of drug in the formulation; higher concentrations mean lower injection volumes which are preferred for being more comfortable for patients. Celltrion made a similar point in relation to a further integer in the claim to "0.04% polysorbate 20", arguing that this should

² *Samsung Bioepis UK Limited & Amgen Limited v Alexion Pharmaceuticals* [2025] EWHC 1240 (Pat)

³ *Virgin Atlantic v Premium Aircraft* [2010] RPC 8

⁴ [2018] EWCA Civ 1416

⁵ *Samsung Bioepis v Alexion* [2025] EWHC 1240 (Pat)

⁶ [2017] UKSC 48

⁷ *Celltrion Inc. v Genentech, Inc. & Novartis AG* [2025] EWHC 174 (Pat)

extend to 0.02% polysorbate 20. **HHJ Hacon** disagreed again, but here on the basis that the skilled team would have assumed the patentee to have had good reasons to specify that particular figure and therefore, as a deliberate limitation, any flexibility would not have gone beyond normal rounding convention.

Infringement under the doctrine of equivalents

In *Formycon & Samsung Bioepis v Regeneron*⁸ the English High Court came to a different conclusion to the Munich Regional Court on infringement of Regeneron's patents for a liquid formulation of aflibercept (Eylea), finding that the biosimilars did not infringe. Regeneron relied only on a narrow claim to an ophthalmic formulation comprising specified amounts of aflibercept and certain excipients which they alleged Formycon and Samsung Bioepis infringed under the doctrine of equivalents. When considering the first *Actavis v Lilly*⁹ question (whether the variant achieved substantially the same result in substantially the same way as the invention), **Meade J** held that the comparison between the variant and the invention should be conducted at the same level of generality as the claims, ultimately finding no infringement as Formycon's and Samsung's products achieved stability in a different way to the invention. **Meade J** also held that even if he was wrong on that point, Regeneron would fail on the third *Actavis* question (whether the skilled reader would consider strict compliance with the literal meaning of the claims was an essential requirement of the invention), as the claim Regeneron relied upon was a dependent claim which had been drafted very narrowly to correspond with certain Examples in the patent in suit and would be understood as such.

An interesting issue arose in relation to the second *Actavis* question (knowing that the variant achieves substantially the same result as the invention, would it be obvious that it does so in substantially the same way): namely, whether experiments should be permitted to investigate how the variant works. It has long been recognized that an affirmative answer to the second question almost always follows

an affirmative answer to the first, and, as **Meade J** pointed out, the second question will really only ever avail a defendant when their product is a "black box", such that how it works is a mystery. The Judge declined to allow experiments on principle; the old law under *Improver*¹⁰ question 2 had not permitted them, and although *Actavis* marked a sea-change in which **Lord Neuberger** re-balanced this element of the test in favour of the patentee, allowing experiments to work out how the variant worked would effectively abolish the second question entirely and would put too great a burden on third parties.

The mere fact that a variant is disclosed in a patent specification does not mean that it necessarily embodies the inventive concept and will infringe by equivalents if not caught by the normal interpretation of the claim. In *Well Lead v CJ Medical*¹¹, a patent to a device for removing kidney stone fragments by suction via the urethra disclosed a number of diameters for the tube diameter but was held to claim only a size range within a manufacturing tolerance of 5%. Variants outside this range, although disclosed, were not found to infringe under normal interpretation owing to the fact that the patentee had made a deliberate selection and were not equivalent because *Actavis* question 3 (strict compliance) applied.

Indirect infringement

*Prevayl v Whoop*¹² concerned wearable smart technology in the form of a "smart bra" which measures biological data produced by the wearer. Prevayl alleged that Whoop indirectly infringed the patent through the supply of two separate products: a sports bra (the Whoop Bra) and a bio sensor device (the Whoop 4.0 sensor module) which could fit into a bra pocket. Multiple alternative sensors could fit and work with the Whoop Bra and the Whoop 4.0 sensor module could also be used in other contexts, for example as a wrist sensor.

Whoop accepted that supplying the Whoop Bra was indirect infringement but disputed that supplying the Whoop 4.0 sensor module would indirectly infringe the patent, concerned that damages calculated on the sales of the

⁸ *Formycon AG, Klinge Biopharma GmbH & Samsung Bioepis (UK) Limited v Regeneron Pharmaceuticals, Inc & Bayer Healthcare LLC* [2025] EWHC 2527 (Pat)

⁹ [2017] UKSC 48

¹⁰ *Improver Corp v Remington Consumer Products Ltd* [1990] FSR 181 [2025] EWHC 492 (IPEC)

¹² *Prevayl Innovations v Whoop* [2025] EWHC 399 (IPEC)

Whoop 4.0 sensor module would capture non-bra-related sales. **HHJ Hacon** considered these concerns “*of no practical substance*” since in a damages enquiry, Prevayl would only be entitled to claim damages for customers working the invention, i.e. for the instances of Whoop 4.0 sensor module use with a Whoop Bra.

Reviewing the law on indirect infringement in the *Nespresso* case¹³, the Judge considered the meaning of “*means relating to an essential element*” and formed a view that it was “*probably*” unnecessary that the means should contribute to the inventive concept provided the means made a contribution to implementing the technical teaching of the invention. A feature of completely subordinate importance to the technical teaching could be regarded as a non-essential element. Where the component in question is an essential means, it will be suitable for putting the invention into effect if an adaptation of such means, or its use together with other means, would put the invention into effect.

In this case, the Whoop 4.0 sensor module was not a completely subordinate part of the invention, and it was not disputed that its use in combination with the Whoop Bra would put the invention into effect. Accordingly, had the patent been valid, it would have been infringed either by sales of the bra or the sensor.

Validity

Novelty

The law on novelty in relation to prior art disclosing numerical ranges was fairly well settled in 2018 by the Court of Appeal’s decision in *Jushi v OCV*¹⁴. Essentially, where the prior art discloses a range of possibilities, to anticipate it must provide an individualised description of the invention as claimed, including the relevant value of the element in issue. Some ranges may be more susceptible to individualisation than others (e.g. a range of temperatures to be used in a process may carry with it an implicit

disclosure that the skilled person may choose any value within the range).

In *Celltrion v Genentech & Novartis*¹⁵ the novelty-only prior art disclosed a liquid formulation of omalizumab with polysorbate in a range between 0.01% to 0.1%. The patent in suit claimed 0.04% polysorbate 20. **HHJ Hacon** noted that whilst, arguably, the prior art range could be broken down into 10 individual disclosures, each 0.01% apart, the disclosure did not refer specifically to polysorbate 20. Taking into account the 5 types of polysorbate covered by the general reference, there was actually a potential total of 50 individual disclosures (or, in effect, a selection from 2 lists, one of 5 and the other of 10). Based on EPO case law, which failed to find anticipation by 6 or 10 disclosed alternatives, the novelty attack was rejected and the patent held valid. Ultimately, the question is whether the skilled person would clearly and unambiguously derive the subject-matter at issue from the document as a whole. In this case they would not.

The subject of novelty and selection from lists came before the Court of Appeal in *ModernaTX Inc v Pfizer & BioNTech*¹⁶, **Arnold LJ** giving the leading judgment. At first instance **Meade J** had found that Moderna’s patent relating to modified mRNA was novel and inventive, as well as infringed by Pfizer/BioNTech. The claim at issue required “*An mRNA wherein 100% of nucleotides comprising uracil in the mRNA are replaced with nucleotides comprising N1-methyl-pseudouridine.*” Pfizer/BioNTech argued that the twin features of N1-methyl-pseudouridine and 100% replacement were disclosed in a single prior art citation, albeit separately. They argued there was a clear pointer always to use 100% replacement as the teaching of the document as a whole was that 100% replacement is preferred because it confers improvements in both efficiency of translation and reduction in immunogenicity.

¹³ *Nestec SA v Dualit Ltd* [2013] EWHC 923 (Pat)
¹⁴ [2018] EWCA Civ 1416

¹⁵ [2025] EWHC 174 (Pat)
¹⁶ *ModernaTX Inc v Pfizer Limited/BioNTech Manufacturing GmbH and others* [2025] EWCA Civ 1032

Arnold LJ disagreed, deciding that there was “no pointer whatsoever” to a combination of N1-methyl-pseudouridine and 100% replacement. He concurred with **Meade J** that just because it would be obvious to make a 100% replacement does not mean that there was a clear and unambiguous disclosure of making that replacement.

Anticipation by equivalents

In *Celltrion v Genentech & Novartis*¹⁷ **HHJ Hacon** was faced with a pleading by Celltrion that there was anticipation by equivalents; in other words, that when broadened by the doctrine of equivalents, the claimed subject matter encompasses a variant that is already present in (anticipated by) the prior art. First flagged by **Arnold J** in *Generics v Yeda*¹⁸ in the immediate aftermath of *Actavis v Lilly*, this is a point that also caught the attention of **Meade J** in *Optis v Apple*¹⁹, who remarked “*This is an extremely important point for UK patent law. It seems certain to need the consideration of the Court of Appeal and very probably the Supreme Court.*” As readers will appreciate, in the meantime we have seen the development of the *Formstein*²⁰ defence, not in the Supreme Court but in the IPEC²¹, with subsequent approval of the principle by an appeal court judge sitting at first instance²². Against this background, **HHJ Hacon** noted that “*I think that now it would be more accurate to say that the *Formstein* defence has become part of English law subject to a ruling to the contrary by the Court of Appeal or the Supreme Court.*” The *Formstein* defence prevents a patentee from relying on the doctrine of equivalents where the extended claim scope would make the patent invalid and so prevents injustice. In the Judge’s view, this was the appropriate solution to the difficulty of anticipation by equivalents. He concluded: “*There may be some pedantic satisfaction to be had in making the scope of a claim identical*

from the perspective of both novelty and infringement, but this is outweighed by practical difficulties that would follow in the train of that view of the law. And there is no practical injustice inherent in the view that equivalents of the invention are irrelevant to an assessment of novelty.”

The identity of the skilled team

Meade J’s decision in *Formycon v Regeneron*²³ gave rise to a couple of interesting points relating to the identity of the skilled person or team. First, on whether the skilled team has a “*leader or boss*”, he noted that it was wrong to envisage a team in which one member is the head, directing all the others as if they were subordinates. Each team member is assumed to play their own part; the nature of each member’s role is fact-specific, as are the relationships between them. The team may have a leader if the facts make it appropriate, but not in the head/subordinate style and not so as to cut across each member playing their part. The second point was **Meade J**’s rejection of a “*reverse Schlumberger*”²⁴ attack, dismissing the Claimants’ argument that when it came to considering obviousness, the only relevant members of the skilled team were those who were required to put the invention in effect. The expertise required to put the patent into effect is only part of the picture and it was also relevant to consider the problem that the patent aims to solve.

Echoes of *Schlumberger* sounded in *Battlekart Europe SA v Chaos Karts*²⁵, where the patent concerned the application of virtual reality technology to go-karting. The problem being solved by the patent was in the field of real life go-karting experience, but the solution lay in the field of the immersive entertainment industry. The difficulty in such a situation is that it may be artificial and unfair to the patentee to elide two technically remote fields in one skilled person/team as this would unfairly broaden their common general knowledge for the

¹⁷ [2025] EWHC 174 (Pat)

¹⁸ *Generics (UK) Ltd v Yeda Research and Development Co Ltd* [2017] EWHC 2629 (Pat)

¹⁹ *Optis Cellular Technology LLC & Ors v Apple Retail UK Ltd & Ors* [2021] EWHC 1739 (Pat)

²⁰ Federal Supreme Court (*Bundesgerichtshof*) 29.04.1986 Case No. X ZR 28/85 “*Moulded Curbstone*”

²¹ *Technetix BV v Teleste Ltd* [2019] 126 (IPEC)

²² *Birss LJ in Facebook Ireland Ltd v Voxer IP LLC* [2021] EWHC 1377 (Pat)

²³ *Formycon AG, Klinge Biopharma GmbH & Samsung Bioepis (UK) Limited v Regeneron Pharmaceuticals, Inc & Bayer Healthcare LLC* [2025] EWHC 2527 (Pat)

²⁴ *Schlumberger v EMGS* [2010] EWCA Civ 819

²⁵ *Battlekart Europe SA v Chaos Karts 1 Ltd* [2025] EWHC 1936 (IPEC)

obviousness analysis. Combining the concepts in *Schlumberger* with those set out by **Birss J** in *Illumina*²⁶, **HHJ Hacon** held that the field of the problem that the patent seeks to address must come from a technical field known to have existed at the priority date. The question is then whether the skilled person/team in this field, having read cited prior art from another field would either have (a) come to the invention; or (b) decided that the prior art concept had a sufficient prospect of being used to warrant consulting an expert in the field of the prior art. In the event, neither side approached the issue of the skilled team from the *Schlumberger* perspective and both produced only one expert each. These experts specialised in different fields so it fell to **HHJ Hacon** to determine which of the experts was closer to the skilled team of the patent and could best speak to its common general knowledge.

Obviousness

Pharmaceutical formulation patents are not commonly found inventive by the English courts, although such things do happen, as readers familiar with *Teva v Leo*²⁷ will remember, the Court of Appeal reversing an obviousness finding by the trial judge in that case. Now, like buses, two positive data points have come at once.

First, in *Celltrion v Genentech*²⁸ **HHJ Hacon** found inventive the claim in the Xolair® formulation patent against the allegation that the claim was “*obvious to try with a reasonable expectation of success*”. Given that lawyers are so often asked by their clients for “prospects of success” in percentage terms, it is perhaps understandable that the question should arise of whether a numerical figure can also be applied to define a reasonable expectation of success: is this more or less than 50%? The Judge noted that although it is important to be precise about what, if anything, would have been obvious to try, when considering the relevant expectation of success it does not matter whether the expectation was

above or below 50%. The Judge noted that what amounts to a reasonable expectation of success is influenced by motivation: the higher the motivation, the lower is the expectation of success required for that expectation to be reasonable. In this case, the skilled person would not have tried a formulation with about 150g/L omalizumab or 0.04% polysorbate 20 as required by the narrow claim. It was therefore held to be inventive.

Secondly, **Meade J** upheld the validity of one of Regeneron’s Eylea formulation patents in *Formycon & Samsung Bioepis v Regeneron*²⁹. Anyone dealing with the validity of a formulation patent would find interesting **Meade J**’s remarks in the paragraphs that follow the title “*General obviousness considerations for formulations*”. Essentially, the Judge boils these down to “*two extreme propositions: that nothing is obvious in the formulation field because predictions can never be made for individual experiments, or that everything is obvious because the methods used are all routine.*” Announcing that both these propositions were wrong, he proceeded to give his judgment.

Meade J reiterated that obviousness is a multifactorial analysis where both the empirical nature of the field and the routine nature of the methods must be taken into account. Furthermore, the overall expectation of success of the project and the expectation of success of individual experiments were both relevant factors. While the high level of difficulty in a field is a factor to be taken into account, this may be matched by a high level of skill and should not be the overriding consideration. **Meade J** also noted that there was a difference in a perceived prejudice in the art being relevant to the analysis of the steps the skilled person would allegedly take to reach the claimed invention for the purpose of obviousness (e.g. the motivation to take a particular step), and relying on such a prejudice when the patent would otherwise be obvious but for the deterrent effect of the prejudice. For the latter to be relevant to the analysis of

²⁶ *Illumina Cambridge Limited v Latvia MGI Tech Sia* [2021] EWHC 1026 (Pat)

²⁷ *(1) Teva UK Ltd (2) Teva Pharmaceutical Industries Ltd v Leo Pharma A/S* [2015] EWCv Civ 779

²⁸ [2025] EWHC 174 (Pat)

²⁹ [2025] EWHC 2527 (Pat)

inventive step, the patent in suit must dispel the prejudice in order to make a relevant technical contribution. The obviousness case pleaded by the biosimilars related to a prior art citation that differed in dose/concentration, pH and excipients. The complexity of the overall picture, including some risks or pointers away from the formulation chosen by the patent led the Judge to dismiss the allegation of obviousness.

Just because the difference between the prior art and the patent is very small, does not mean that the difference is obvious. A good illustration of this is the case of *Accord v University of California and Astellas*³⁰ in which the Court of Appeal upheld **Mellor J**'s decision that Astellas' enzalutamide patent was inventive, notwithstanding that prior art created by Astellas itself differed in only a single substituent on a large molecule.

The appellant generics argued that the trial judge had worked too hard to frame the assessment of inventive step in a technical context and that a more general approach should be followed, focusing on the result to be achieved. **Arnold LJ** disagreed, finding that **Mellor J** was making the point that whether a molecular change is "trivial" is highly fact-dependent, and there is a real danger that triviality could be substituted for obviousness. It is not obvious that a change will have no material effect just because it is small.

Arnold LJ also dismissed an argument by the generics that it was unfair of the trial judge to find that their expert had been tainted by hindsight. **Mellor J** had been critical of the fact the generics' expert was pointed to the position on the molecule where the substituent lay and asked whether a change would lead to a material effect, rather than consider what would have been an obvious step forward from the closest prior art compound. "As with many quizzes, there was a clue to the answer in the phrasing of the question".

Following a first instance finding by **Mellor J** of obviousness against one of Abbott's patents for continuous glucose monitoring, Abbott settled its litigation case against Dexcom but wished to continue with an appeal against the first instance decision³¹. Therefore, as has become established practice following *Halliburton*³² and *Aerotel*³³, the Comptroller was requested by the Court to attend the appeal so that the judgment could be defended in an objective and non-partisan manner, thereby protecting the public interest.

Abbott based their appeal on the fact that the Judge had made a number of errors in his judgment, exacerbated by the delay in producing it. The Court of Appeal agreed that the Judge had fallen into error. On the one hand, when considering the meaning of the claim, he had decided that the needle coupled to the housing of the device required manual insertion where the force on, and movement of, the housing is the cause of the insertion of the needle. However, when making his findings on inventive step, the Judge had held that automatic insertion of the needle (as shown in the prior art) was sufficient to find the patent obvious. With no evidence from Dexcom to support obviousness of manual insertion, the Court of Appeal overturned the first instance decision.

As most UK practitioners know, a case against inventive step in the English courts is not well served by pleading a large number of prior art citations; if the patent is so obvious, why do none of the documents relied upon disclose the invention? Of course, there may be other reasons for pleading, and this was noted to be the case in *Salts v Pelican*³⁴, where Pelican cited four pieces of prior art for lack novelty and inventive step. Salts argued that this number meant that Pelican could not find one that worked. **Ian Karet OBE**, sitting as a Judge of the Chancery Division, disagreed, noting that

31 *Abbott Diabetes Care Inc and others v Dexcom Inc and others* [2025] EWCA Civ 1633

32 *Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2006] EWCA Civ 185

33 *Aerotel Ltd v Telco Holding Ltd* [2006] EWCA Civ 1371

34 [2025] EWHC 497 (Pat)

a number of the citations were relied on for inventive step and/or as part of an infringement squeeze, which seemed to be understandable.

Mosaicking

A point of distinction between the English courts and their continental cousins is the disinclination of the English courts to mosaic prior art citations; it is rare for an inventive step attack to succeed on this basis. In *Samsung Bioepis & Amgen v Alexion*³⁵, the biosimilars advanced an obviousness attack based on a combination of two pieces of prior art, arguing that the skilled person starting from the first piece of prior art would come across the second as a matter of routine, but the second piece of prior art was not common general knowledge. **Meade J** rejected this as illegitimate mosaicking of the prior art but also held that in any event the multistep obviousness attack would have failed as an impermissible stepwise approach following *Technograph*³⁶.

Similarly, in *Well Lead v CJ Medical*³⁷, **HHJ Hacon** rejected CJ Medical's attempt to mosaic prior art. CJ Medical had sought to rely on a prior art document (disclosing a sleeve placed over a flexible endoscope) in combination with a patent referred to therein (which disclosed a pressure-regulating mechanism). Whilst it is well established that in principle the content of a cross-referred document is available to supplement the cited disclosure, there is no unqualified assumption that it should do so in every case. Here, CJ Medical had not discharged its burden to show that the skilled person would have consulted the pleaded cross-referred document as opposed to any of the other documents to which the prior art citation referred. **HHJ Hacon** noted that he could not know whether the skilled person would have been more interested in the other referred documents since the other documents were neither in evidence nor shown to the experts.

Plausibility / Insufficiency

It remains the case that the English courts' approach to plausibility appears to be somewhat out of step with the approach adopted by other courts in Europe. The Supreme Court's decision in *Warner-Lambert*³⁸, decided before *G2/21*, remains binding and will continue to be so until the Supreme Court decides another case on the issue. Many practitioners thought that dapagliflozin³⁹ might end up being that case, but it was not to be, permission to appeal to the Supreme Court being refused. Nevertheless, the dapagliflozin litigation generated some important judgments from the Patents Court and Court of Appeal.

By the time of trial at first instance, the focus of the invalidity attacks against AstraZeneca's patent for its blockbuster SGLT-2 inhibitor, dapagliflozin, was on lack of plausibility. Did the patent specification "disclose some reason for supposing that the implied assertion of efficacy in the claim is true"? (per **Lord Sumption** in *Warner Lambert*⁴⁰). The main claim of the patent was to the dapagliflozin compound. Dapagliflozin was picked out (individualised) by the description and a synthesis was given. It was not clear from the description that it was tested for efficacy but an assay for testing was described in general terms. Academic publications mentioned in the patent made it plausible that SGLT-2 inhibitors worked as a class to treat diabetes. But there was no evidence in the specification to show that dapagliflozin itself was an SGLT-2 inhibitor. Although the patent said it was, the Judge, **Michael Tappin KC** sitting as Deputy, would not accept that this was effectively a verbal statement of an experimental result. Arguments made by the patentee that dapagliflozin bore structural similarities to another SGLT-2 inhibitor (phlorizin) were not convincing, there was no potency data in the patent and nor did the academic publications cross-referenced in the patent provide any data to show that dapagliflozin was an SGLT-2 inhibitor. It was

35 [2025] EWHC 1240 (Pat)

36 *Mills & Rockley (Electronics) Ltd v Technograph Printed Circuits Ltd* [1971] F.S.R. 188

37 [2025] EWHC 492 (IPEC)

38 *Warner-Lambert v Actavis* [2018] UKSC 56

39 *Generics UK and others v AstraZeneca AB* [2025] EWHC 1012 (Pat) and [2025] EWCA Civ 903

40 *Warner-Lambert Co LLC v Generics (UK) Ltd (t/a Mylan)* [2018] UKSC 56

a near-miss, but in the end the Judge felt compelled to decide that the patent did not make it plausible that dapagliflozin would treat diabetes, notwithstanding his reluctance to revoke a patent to what was clearly a breakthrough medicine.

On appeal, this finding was upheld. The Court of Appeal agreed that there was no statement that made it clear that dapagliflozin (or any other inhibitor encompassed by the patent) had been tested and there was no statement of results of the testing in the patent either. Further, even if the skilled person considered that dapagliflozin had been tested in the assay and some degree of SGLT2 inhibition found, they would not know the level of potency and whether that potency was sufficient to confer therapeutic utility in the treatment of diabetes.

The appeal presented an opportunity to consider the UK's approach to plausibility against the wider position in Europe. While it was undisputed that *Warner-Lambert* was binding on the Court of Appeal, AstraZeneca argued that in light of the decision in *G2/21* (and subsequent findings at the EPO and in national courts around Europe) the Court of Appeal should depart from statements made in its own decision in *Sandoz v BMS*⁴¹ that the *Warner-Lambert* standard of plausibility applied to product claims, and not only the medical use claims that were in issue in *Warner-Lambert*. However, **Arnold LJ** giving the leading judgment, did not consider *G2/21* a basis for departing from *Sandoz v BMS*. AstraZeneca's cause was not assisted by *G2/21* itself being unclear and therefore spawning a number of diverging decisions from the EPO's Boards of Appeal and national courts. However, **Arnold LJ** went on to hold that, even if the bar were to be lowered for a product claim such that the test for plausibility was whether the skilled team would have legitimate reason to doubt that dapagliflozin would be useful for the treatment of diabetes (i.e. *ab initio* implausibility) the patent would still lack plausibility.

Industrial application

It's been a while since the English courts entertained a case about perpetual motion machines (Arthur Pedrick is sorely missed). No doubt, therefore, **HHJ Hacon** was pleased to hear an appeal from the UKIPO's decision that the invention claimed in a patent application from a Mr Klemz defied the laws of physics and was therefore devoid of industrial application⁴².

The legal framework underpinning the appeal was **Floyd J's** judgment in *Blacklight Power Inc. v The Comptroller-General of Patents*⁴³, establishing the principle that where there is substantial doubt about an issue of fact which could lead to patentability, the patent should only be granted if there is a reasonable prospect that the invention will be found patentable if that issue of fact is fully investigated at a trial.

Mr Klemz' application was for “*an apparatus for generating a force*” and, more specifically, involved electromagnetic fields supposedly to create thrust without expelling mass. Mr Klemz considered that his invention would be applicable to spacecraft. **HHJ Hacon**, agreeing with the Hearing Officer, found the invention incompatible with the law of conservation of momentum and therefore incapable of industrial application, as well as insufficiently disclosed. Following the principles of *Blacklight*, and in what may or may not be a deliberate pun, he held that, even though there was a “*mass of doubts*” about a factual issue related to patentability, there was still no reasonable prospect that the invention would be shown to be patentable.

41 *Sandoz Ltd v Bristol-Myers Squibb Holdings Ireland Unlimited Co* [2023] EWCA Civ 472

42 *Klemz v Comptroller-General of Patents* [2025] EWHC 650 (Pat)
43 [2008] EWHC 2763 (Pat)

FRAND

2025 was a big year for developments in the (F)RAND⁴⁴ space, with a number of Court of Appeal decisions forming the basis for this continually evolving landscape, including: the decision in *Optis v Apple* overturning the first instance FRAND determination with a resulting 10x uplift to the FRAND rate; a 2:1 majority upholding Avanci's jurisdiction challenge in respect of Tesla's claim seeking to scrutinise the pool's rates; and a possible widening and then narrowing of the circumstances in which the UK court will order an interim licence declaration. First instance courts have also had plenty of issues to consider arising from the cross-jurisdictional nature of disputes in this area, from case management issues to jurisdiction challenges and anti-suit injunctions.

FRAND determination

The UK Court's third ever FRAND determination came in *Apple v Optis*⁴⁵ and was reviewed in 2025 by the Court of Appeal⁴⁶. The importance of the decision is underscored by the fact that permission has been granted by the Supreme Court to hear an appeal of the Court of Appeal decision. One of the key aspects of the decision was the appropriate methodology for deriving a FRAND rate. The first instance Judge, **Marcus Smith J**, had rejected the comparables approach adopted by both sides' experts and instead adopted his own approach of averaging lump sums from certain licences (almost all of which were licences entered into by Apple) and then deriving the amount payable to Optis based on Optis' share of the stack of relevant SEPs. **Birss LJ**, who gave the leading judgment on the aspects of the appeal relating to royalty terms, overturned the decision on the basis

that there was no justification for setting aside the common ground of the experts and instead held that the right approach was to adopt a comparables methodology.

The Court of Appeal considered it was able to determine a FRAND rate, based on the evidence submitted at first instance without needing to remit the matter. The Court calculated the FRAND rate using five licences it considered to be the most reliable comparables: one licence to Optis's portfolio (noting that a licence by the SEP holder of the same portfolio is likely to be the place to start to identify the best comparable) as well as four licences granted to Apple. The Court's methodology was to take the unpacked dollar per unit (DPU) rates from each licence, scaling the rates from the Apple licences to put the DPU rates on a common scale normalised by Optis' stack share and then to analyse the range of unpacked DPU rates to determine a FRAND rate, then using a top-down cross-check (noting that the evidence did not justify fine distinctions). The Court concluded that \$0.15 per Apple unit was FRAND for the Optis portfolio. To determine the lump sum payable by Apple, the Court applied the \$0.15 DPU to all of Apple's past sales and a 10% discount to projected future sales for 2021-2027, resulting in a total lump sum royalty of \$502 million (excluding interest). This was approximately 10 times higher than the lump sum determined at first instance (\$56.43M).

Arnold LJ gave the leading judgment on the non-royalty aspects of the appeal. He determined that interest was payable on all royalties for past sales until the date when Optis receives payment under the FRAND licence. The interest rate determined by the first instance court of 6% compounded with half-yearly rests, was not appealed so remained the applicable rate. **Arnold LJ** also held that certain terms imposed by **Marcus Smith J** were procedurally unfair - particularly a clause requiring Optis to withdraw or abandon all foreign proceedings.

⁴⁴ Depending on the relevant standards in question, the licensing obligation is sometimes by reference to 'fair reasonable and non-discriminatory' licences (**FRAND**), for example, under the standards governed by ETSI, such as the 3G, 4G and 5G standards used for telecommunications; or by reference to 'reasonable and non-discriminatory' licences (**RAND**), for example, under the standards governed by ITU-T, such as the video coding standards for digital streaming. The terms RAND and FRAND are used in this section to accord with the technology in each underlying dispute discussed

⁴⁵ [2024] EWHC 197 (Ch)

⁴⁶ [2025] EWCA Civ 552

Jurisdiction

Last year's review of jurisdiction challenges in the FRAND context may have suggested that the law was fairly settled in this area. Despite this, a further flurry of challenges were heard in 2025. In the context of a claim to determine FRAND rates for a pool licence, the Court of Appeal dismissed, albeit in a split decision, Tesla's appeal against Avanci's successful jurisdiction challenge⁴⁷. Tesla's claim included a request for a determination of FRAND rates to 5G SEPs in the patent pool administered by Avanci. In particular, Tesla sought declarations that Avanci's offered rate of \$32 per vehicle was not FRAND and asked the Patents Court to set FRAND terms for a global licence. The claim included InterDigital as a representative member of the pool. Although Tesla had in fact already negotiated one bilateral licence, Tesla argued that negotiating bilateral licences with the over 65 SEP owners in Avanci's pool was impractical and that commercial reality required a global platform licence. At first instance, **Fancourt J** had set aside service of Tesla's claim on Avanci and InterDigital, finding no serious issue to be tried. Tesla appealed on the basis that its claims engaged enforceable rights under ETSI's IPR Policy, which obliges SEP owners to license on FRAND terms. The majority of the Court of Appeal held that Tesla was attempting a "free-standing FRAND claim" untethered to any enforceable right. The case was thus indistinguishable from Vestel v Access Advance⁴⁸, where **Birss LJ** had held there was no jurisdiction because Vestel's claim was untethered to any legal standard. The Supreme Court will now decide whether it is to be settled law that FRAND determination claims against agents acting for SEP owners who have joined a patent pool will not be entertained by the English courts. The "commercial convenience" of obtaining a FRAND determination in respect of a pool of SEPs is not a reason for the court to find jurisdiction.

A more familiar type of FRAND proceedings was in play in MediaTek v Huawei⁴⁹, where MediaTek brought proceedings seeking declarations of infringement of UK SEPs, revocation of a Huawei patent, and determination of FRAND terms for a global cross-licence. Huawei challenged jurisdiction, arguing that China, where it had issued a rate-setting action in Shenzhen and an antitrust claim and where the majority of the parties' business activities occurred, was the proper forum. **Leech J** dismissed Huawei's applications. Rejecting Huawei's evidence that "the only activities which MediaTek suggested could infringe in the UK were the testing and verification activities and that these were a tiny proportion of its worldwide R&D", he held that MediaTek had a real prospect of proving UK acts of infringement and entitlement to damages. **Leech J** also rejected Huawei's argument that the Chinese claim would resolve the dispute, noting that the Shenzhen claim was limited to Chinese patents and would not determine global terms.

Huawei also requested a case management stay, based on a last-minute unconditional undertaking not to enforce its portfolio in the UK. **Leech J** described this issue as the one he found "most difficult to decide" but in his judgment "what Huawei's offer of an undertaking demonstrates is that Huawei appreciates that MediaTek is entitled to a FRAND licence of its UK SEPs" and that "as Huawei must be well aware, the offer of an undertaking is not sufficient to fulfil its obligation under clause 6.1 of the ETSI IPR Policy". With those points in mind, **Leech J** concluded that it would serve a useful purpose to make the licensing declarations which MediaTek sought through its claim and therefore refused the stays⁵⁰.

47 Tesla, Inc. and others v InterDigital Patent Holdings, Inc. and others [2025] EWCA Civ 193 delivered by **Phillips LJ** and **Whipple LJ**, with **Arnold LJ** dissenting

48 Vestel Elektronik Sanayi Ve Ticaret AS v Access Advance LLC (formerly HEVC Advance LLC) [2021] EWCA Civ 440

49 [2025] EWHC 649 (Pat)

50 MediaTek v Huawei [2025] EWHC 1689 (Pat)

An undertaking not to enforce UK patents was also considered in the context of a jurisdiction challenge in *Amazon v InterDigital*⁵¹. Amazon's claim was for the determination of RAND licence terms for video coding patents, including patents declared essential to International Telecommunication Union (ITU-T) standards, whose RAND declarations are governed by Swiss law. InterDigital challenged jurisdiction under CPR 11, contending that the claims were purely contractual and unrelated to UK patents. Following *Unwired Planet v Huawei*⁵² and multiple other examples of failed jurisdiction challenges in FRAND cases, **Meade J** dismissed the challenge, holding it to be established law that implementers can bring (F)RAND claims in this jurisdiction further to CPR 63.14 (a claim relating to a registered IP right) and the fact that InterDigital had given an undertaking not to enforce its relevant UK patents did not change the position. InterDigital also sought to distinguish the case from precedent by noting that it had offered international arbitration on favourable terms. **Meade J** disagreed and found that it would be wrong effectively to compel Amazon to submit to arbitration because arbitration should be a consensual process. Furthermore, Amazon could legitimately expect "open justice" in relation to its claim and arbitration would not provide this.

Another jurisdiction challenge concerning implementer initiated actions for the determination of RAND licence terms under the Swiss law-governed ITU-T regime, was considered in the decision handed down just one day earlier in *Acer v Nokia*⁵³, where Nokia was also relying on arbitration offers to support its challenge. Nokia argued that its "Adjustable Arbitration Offers" were RAND-compliant proposals, setting up (Nokia argued) the following dilemma for the Claimants: either they accept the Offers, in which case jurisdiction should be refused because the Claimants will be licensed under the terms resulting from the arbitration; or the Claimants

reject the Offers, in which case they would be unwilling licensees, and the court should refuse jurisdiction on the claim to RAND relief.

Mellor J dismissed this proposition, noting that it hinged upon a finding, which he was not prepared to make, that the Adjustable Arbitration Offers were RAND. Before concluding on these issues, however, **Mellor J** had to put aside the Claimants' "beguiling" suggestion that the ITU-T RAND regime could be treated the same as the ETSI-FRAND and conducted a fulsome analysis of the ITU-T RAND regime and the applicable principles of Swiss law. Having done this, the case is now key authority for the principle that – in relation to establishing jurisdiction at least – the ITU-T RAND and ETSI FRAND regimes do work in substantially the same way. **Mellor J** held that RAND terms are objectively determinable using established criteria (e.g. comparable licences and economic analysis), rejecting Nokia's argument that such an exercise involves discretion. Additionally, the ITU-T Licensing Declaration was found to impose a binding obligation to make RAND offers capable of acceptance and to grant licences, not merely negotiate. As such the court held the ITU-T Commitment forms a valid contract enforceable by third party beneficiaries. It naturally followed that the Claimants could establish jurisdiction for RAND claims in the same way as FRAND claims.

Nokia's arguments on *forum conveniens* necessitated the identification of another forum which has jurisdiction to determine the dispute. Nokia argued that this was an arbitration venue, but **Mellor J** held that "Arbitration, like mediation, is a form of alternative dispute resolution and not a forum at all". And even if it were a forum, it was not a more appropriate than England. Finally, Nokia's proposal for a case management stay was not entertained. **Mellor J** explained in no uncertain terms that he agreed "with the Claimants that it would be an egregious case management decision wholly at odds with the overriding objective..." particularly given there were no other RAND determining proceedings either on foot or mooted.

51 [2025] EWHC 3334 (Pat)

52 [2020] UKSC 37

53 *Acer Incorporated and Others v Nokia Technologies Oy* [2025] EWHC 3331 (Pat)

Interim licence declarations

The development of interim licence case law, which began in October 2024 with the Court of Appeal's decision in *Panasonic v Xiaomi*⁵⁴ continued apace in 2025. In *Alcatel v Amazon and Others*⁵⁵ the Court of Appeal reversed **Zacaroli J**'s decision⁵⁶ refusing Amazon permission to amend its pleadings to claim an interim licence to Nokia's SEPs. Unlike previous interim licence cases, *Alcatel* related to licence declarations governed by Swiss law RAND obligations. At first instance, **Zacaroli J** refused permission to amend since he considered Amazon's claim to an interim licence had no real prospect of success. This was because he did not think there was a sufficiently arguable case that the Swiss law principles could lead to the conclusion that Nokia is obliged to enter into an interim licence. **Zacaroli J** also refused permission on case management grounds: he did not think that an interim licence could be determined in a few days and thought it "would be a waste of the parties' and the court's resources to hold two RAND trials". However, during the permission to appeal hearing, the judge clarified that the case management issue was not part of his reasoning on the point of law.

The Court of Appeal reversed the judgment. **Arnold LJ** held that Amazon should have permission to amend because there was a real prospect that Amazon could show there were no material factual differences between this case and *Panasonic v Xiaomi*. Should Amazon do so, then *Panasonic v Xiaomi* would also be "legally indistinguishable" from the present case. Notwithstanding that the case management considerations did not appear to be determinative of the first instance decision, **Arnold LJ** also noted that the interim licence hearings in *Panasonic v Xiaomi* and *Lenovo v Ericsson*⁵⁷ only occupied the Patents Court for three days, and he expected an interim licence hearing in the present case (which benefitted from these precedent decisions and the appeal

decision in *Lenovo v Ericsson*) would take less time. This suggests that case management considerations will not be a powerful factor in deciding similar future cases.

In February 2025, the Court of Appeal gave judgment in *Lenovo v Ericsson*⁵⁸. At first instance, the absence of reciprocal undertakings to enter into licence terms ultimately decided by the English court was a decisive factor. Furthermore, the first instance court did not consider that Ericsson's litigation strategy was aimed at securing supra-FRAND rates. Indeed, **Richards J** was persuaded by Ericsson's evidence that it had made Lenovo an offer within the FRAND range and thus was not acting in bad faith and was not obliged to offer an interim licence. The decision was reversed on appeal. **Arnold LJ** noted features of the case that were different to *Panasonic v Xiaomi* but found none of them distinguished the case such that the precedent of *Panasonic* should not be followed. In particular, **Arnold LJ** found that evidence that Ericsson had made a FRAND offer was no answer to the fundamental question (mirroring *Panasonic*): "what is the point of Ericsson pursuing the Brazilian, Colombian and US proceedings, and attempting to exclude Lenovo's products from those commercially important markets, with all the massive attendant effort and expense for both parties?". **Arnold LJ** considered there were only two possible answers: either the US proceedings would achieve the same result as the determination by the English court, but do so more quickly, or, more likely, "Ericsson want to achieve a better outcome than a determination by the English courts would provide". He thus accepted Lenovo's submission that the conclusion reached in *Panasonic v Xiaomi* was equally applicable in the present case, and the interim licence declarations were granted.

54 [2024] EWCA Civ 1143

55 [2025] EWCA Civ 43

56 [2024] EWHC 1921 (Pat)

57 [2024] EWHC 2941 (Pat)

58 [2025] EWHC Civ 182

Again, *Panasonic* was followed in relation to calculation of the appropriate terms of an interim licence with the Court of Appeal holding that this should be the “*mid-point figure*” between the two parties’ offers. Notably, Ericsson submitted that the declaration should not be granted because and Ericsson would ignore it and so it could serve no useful purpose. Ericsson contrasted the position in *Panasonic* by stating that they have “*less reason to fear censure by this Court than Panasonic because they have not invoked the jurisdiction of the English court and have not undertaken to abide by their determination of FRAND terms*”. **Arnold LJ** was unmoved, concluding: “*I not only hope that Ericsson will see the error of their ways, but consider there is a real prospect of them doing so*”.

The first decision at first instance granting an interim licence declaration came in July with **Mellor J**’s judgment in *Samsung v ZTE*⁵⁹. However, as explained below and continuing a running theme of interim licence cases, this decision was overturned by the Court of Appeal. As with precedent cases, both parties had, almost simultaneously, launched a flurry of related actions in multiple jurisdictions, including Germany, China, the United States, and Brazil, each seeking to secure a favourable forum for the determination of FRAND terms. Indeed, ZTE argued that the global claims brought by both parties simply mirrored one another. Furthermore, both sides proposed interim licence offers before the hearing and essentially the main issue left for determination was forum: ZTE wanted any adjustment of the terms of the interim licence into a full licence to be done by the Chinese court, whereas Samsung favoured the UK.

Having carefully reviewed the background, **Mellor J** found a difference between the strategies each party had employed. The Judge noted that Samsung had commenced its English FRAND claim to obtain court-determined terms of a FRAND cross-licence and would only leverage injunctive relief in the UK to persuade ZTE to accept those terms.

Samsung had not sought injunctions from other jurisdictions at the time it had commenced its UK claim. However, ZTE “*went on the offensive*” after having begun the Chinese Proceedings and commenced a “*campaign of seeking injunctive relief in jurisdictions known to decide upon and grant injunctive relief relatively speedily*”. **Mellor J** asked himself what a willing licensor in the position of ZTE would have done after Samsung commenced the English claim and decided that the willing licensor would have “*proceeded as speedily as possible to the FRAND trial*” instead of escalating the dispute. He therefore found ZTE had engaged in bad faith and granted Samsung’s interim licence declarations. Recognising that a key factor in the decision was the fact that the English court was the court first-seised of the FRAND claim, the Judge noted that while this is not always “*a trump card*” it “*may be a tiebreaker in an appropriate case*”.

The Court of Appeal⁶⁰ saw things differently. As in previous cases, **Arnold LJ** gave the leading judgment noting that this “*case differs from the previous cases in that the parties agree that there should be an interim cross-licence, and even agree as to the terms of the interim cross-licence, and in particular how much should be paid for it*”. He then distinguished the case from *Panasonic* and *Lenovo* by noting that ZTE were not attempting to coerce Samsung, through injunctive relief, to agree to more favourable terms than would result from the UK FRAND determination. Instead, ZTE sought to force Samsung to agree to a FRAND determination in China. **Arnold LJ** found that “*unless there is a legitimate and substantiated objection to the forum in question, it does not constitute bad faith for a SEP owner to seek to force an implementer to accept determination of FRAND terms by the SEP holder’s preferred court rather than the implementer’s preferred court*.” Since Samsung had not raised a legitimate objection to a determination in the Chinese court, ZTE had not acted in bad faith and the interim licence declaration granted by the lower court should be set aside.

⁵⁹ *Samsung Electronics Co., Ltd & Anor v ZTE Corporation & Ors*. [2025] EWHC 1432 (Pat)

⁶⁰ [2025] EWCA Civ 1383

Finally, in December came **Mellor J**'s decision in *Acer v Nokia*⁶¹. The Judge had to consider three interim licence declarations sought by Acer. Broadly, these were (i) a declaration that, pending final determination of the terms of a RAND licence, a willing licensor and willing licensee would agree to enter into an interim licence on terms set by the Court; (ii) the terms of that interim licence; and (iii) a declaration that if Nokia refused to offer such a licence within seven days of the Court's order, it would be in breach of its RAND commitment and be considered an unwilling licensor.

Mellor J noted that following the Court of Appeal in *Samsung v ZTE*, it is not necessarily bad faith for an SEP owner to pursue infringement proceedings in other jurisdictions, provided there is no legitimate objection to an alternative forum for determining FRAND terms. However, he considered that Nokia's desire to arbitrate, instead of seek determination of FRAND terms in a foreign Court, distinguished the case from *Samsung v ZTE*. In particular, **Mellor J** found that Nokia's so-called "Adjustable Arbitration Offers" (an offer of a licence with terms adjustable following arbitration) were only offers of a process (arbitration). He therefore concluded that it was "not an offer of RAND terms capable of acceptance" and that "Nokia has adopted a position of conditional willingness, the condition being that the Claimants must consent to arbitration". **Mellor J** found this constituted bad faith on the part of Nokia.

Mellor J then considered whether granting the declarations would serve a useful purpose. In relation to declarations (i) and (ii) he accepted Acer's arguments that such declarations would clarify the parties' rights and obligations, assist in determining the sums payable under an interim licence, and potentially facilitate settlement. He was also satisfied that these declarations would not offend comity. In relation to declaration (iii), the Judge followed the precedent of declaring financial terms that were a "mid-point rate". However, following **Birss LJ**'s dicta in *Samsung v ZTE* that

a "graduated response" may be better and in many cases "a simple determination by a court of the appropriate financial terms to operate in the interim until the parties had signed a final agreement, is all that would be needed" his analysis on declaration (iii), that Nokia would be considered an unwilling licensor if it did not offer the interim licence, was different.

Noting, with approval, **Meade J**'s comments in the *Amazon v InterDigital*⁶² AASI judgment (discussed below), **Mellor J** pointed out that the "apparent perception, on the part of foreign courts, that the English Court, when granting an interim licence declaration, imposes a de facto prohibition on litigation brought to enforce the equivalent SEP rights in their jurisdictions" was incorrect and that "we consider that these interim licence declarations do not interfere in any foreign proceedings, so there is no comity issue". Nevertheless, and again following **Birss LJ**'s commentary, **Mellor J** considered it important to "de-escalate" the situation between the UK and foreign courts, and that this could be done "by being careful only to grant interim declarations that have a proper useful purpose in the UK". On the basis that declaration (iii) would not cause Nokia to "change course", and it therefore had no useful purpose in the UK, he declined to grant that declaration.

Anti-suit injunctions

Perhaps unsurprisingly, given the now developed case law on interim licence declarations, 2025 also saw the first so-called "anti-interim-licence injunctions" (AILIs) granted by the UPC and German national courts, although whether their scope is limited to interim licence declarations or extends also to cover final relief was not fully settled by the end of 2025. These were sought by InterDigital in the context of their dispute with Amazon over codec SEPs used in streaming technologies. The UPC and German national courts granted the AILIs with the effect that Amazon could not pursue its requests for interim licence declarations from the English Court.

Amazon's reaction in the UK was an application seeking anti-anti-suit relief to safeguard (i.e. prevent InterDigital from stopping) Amazon's claim for final RAND relief in the UK (**AASI**). InterDigital had initially stated to the English Court that final RAND relief was not blocked by the German and UPC AILs, just the interim licence declarations, but it subsequently adduced evidence in the context of Amazon's expedition application for the main proceedings which implied that expedited final English relief might interfere with the German and UPC proceedings. Against that backdrop, **Meade J** considered that InterDigital "*may well be intending to seek to ... block final RAND in this court*" and granted the AASI on an *ex parte* basis until the return date hearing when InterDigital would have the opportunity to make submissions. The Judge made it clear that the injunction was not intended to criticise or interfere with the AILs and was specifically directed to "*preserve the position from what ... would be an exceptionally disruptive application by InterDigital*".

At the return date hearing⁶³, after having heard InterDigital's submissions, **Meade J** ordered that the AASI be continued. He considered that InterDigital had the opportunity to put in evidence to clarify its intentions as to seeking an ASI against Amazon's pursuit for final relief but failed to do so. Further, InterDigital's proposed undertakings did not deal with the possibility that InterDigital would yet again change its stance and try to contend or contrive that the existing German and UPC ASIs prevented Amazon seeking final RAND relief in the UK. The Judge concluded that "*InterDigital would dearly like to prevent final RAND relief being sought in the UK and there is a very high likelihood that if not prevented by an AASI then it would seek to expand the ASI relief in Germany or the UPC*".

As to the scope of the AASI and potential issues of comity, the Judge clarified that the AASI did not have the effect of preventing InterDigital from bringing patent infringement proceedings or contesting the effect of any final RAND

licence determined by the UK court in any foreign jurisdiction. The Court also made clear that, while desirable not to have overlapping rate-setting proceedings, the English Court is not saying that it is the only court that can determine RAND and the AASI does not prevent other rate setting claims; it is for each court to decide within its own procedures whether or not to proceed with a global rate setting. All the AASI does is protect the Court's jurisdiction to determine final RAND relief.

Less than three weeks after the *ex parte* AASI was granted against *InterDigital*, the English Court granted another *ex parte* AASI, this time against Nokia upon an application by Warner Brothers⁶⁴. The backdrop of this decision was that Nokia had commenced proceedings against Warner Brothers in Brazil, Germany, the UPC and the US and on the same day Warner Brothers commenced UK proceedings, seeking amongst other things a RAND determination and interim licence. Warner Brothers argued that in view of the new landscape where the UPC and German courts have shown willingness to grant AILs, there is a "*real and immediate risk that other SEP holders, including Nokia, will adopt the same approach*" which would prevent Warner Brothers from commencing or pursuing their UK action. Whilst there was no precedent for Nokia having sought any such relief in its other recent cases where the implementers had sought a RAND determination from the English Court, **Mellor J** considered that the risk of Nokia seeking an anti-suit injunction (including an AILI) in respect of the UK proceedings was not "*negligible or so small as not to justify relief*" and so granted the AASI on an *ex parte* basis pending the return date hearing.

Against a similar fact pattern in *Paramount Skydance v Nokia*⁶⁵, **Meade J** made clear that anti-anti-suit relief is not automatic and remains "*a quite exceptional remedy*". On the specific facts which included that Nokia had in the meantime made a statement in the Warner Brothers proceedings that it had not applied for any anti-suit injunctions and did not intend

63 [2025] EWHC 3170 (Pat)

64 *Warner Bros Discovery Inc v Nokia Corp* [2025] EWHC 2888 (Pat)
65 [2025] EWHC 3083 (Pat)

to do so to prevent Warner Brothers from prosecuting any aspect of its UK claim, the Judge considered it was not appropriate to make an *ex parte* order.

Upon hearing Nokia at the return date hearing (which was a combined hearing for the Warner Brothers and Paramount actions)⁶⁶, the Court considered the AASI which was granted *ex parte* in favour of Warner Brothers should not continue on the basis of the contractual undertakings offered by Nokia. **Meade J** considered there was no need to require Nokia to make those undertakings to Court as it had not done anything to suggest it might break its contractual promise.

A common theme from a number of the AASI and interim licence declaration decisions is that of de-escalation – the UK courts’ desire to reduce international conflict and any perception that the UK courts are seeking to criticise or tread on the toes of foreign courts. Indeed, **Meade J** added at the end of his decision on the continuation of the AASI in *Amazon v InterDigital*⁶⁷, “one can only hope – I certainly hope – that de-escalation will be a cooperative effort internationally with flexibility in all directions”.

Evidence

Meade J’s decision in *Amazon v InterDigital*⁶⁸ brought with it a warning to practitioners to ensure evidence (even put forward in other proceedings) is objectively accurate. At a hearing convened of the Judge’s own motion, after InterDigital’s request for an *ex parte* AILI had been granted in Germany and the UPC, **Meade J** expressed his concerns over the submissions and evidence put forward by InterDigital before those courts. For example, **Meade J** noted that the statements about the speed at which an interim licence declaration being heard and granted in the UK, which suggested it would come on “very soon”, were “objectively speaking, obviously incorrect and unmaintainable”. In response, InterDigital’s lawyers had to provide witness statements

to the Judge to explain their evidence and apologise. The Judge maintained that he considered the evidence misleading but accepted, based on the explanation, that the individuals did not act with “calculated ill intent”.

Case management of FRAND cases

The trend for expediting UK FRAND trials continued in 2025, with varying degrees of expedition granted in *Samsung v ZTE*⁶⁹, *MediaTek v Huawei*⁷⁰ and *Amazon v InterDigital*⁷¹. The Court has consistently found that the risk of damaging injunctions in parallel proceedings and a danger that the implementer could be coerced into agreeing supra-FRAND rates to avoid such injunctions, are sufficiently good reasons to expedite the UK FRAND trial. Other factors also weighing in favour of expedition in *Samsung* and *MediaTek* included: protecting the integrity of the English proceedings and a desire to bring an end to wasteful worldwide litigation. The Court has also again endorsed hearing the FRAND trial ahead of any technical trials, rejecting Huawei’s request to have technical trials first to test the strength of MediaTek’s portfolio.

However, in terms of the degree of expedition granted, the court has been unwilling to expedite trials to the extent that this interferes with other court commitments or to the extent that the parties do not have sufficient time to prepare for trial, recognising that the resulting trial window may not be “perfect” in view of the possible timelines in parallel proceedings.

Supplementary protection certificates (SPCs)

To most originators in the field of life sciences, SPCs are very important. This is because the period of the SPC – which as readers will know, lasts up to 5½ years if a paediatric extension is obtained - usually comes when the product which is the subject of the SPC is at the peak of its sales. In this period, every day of extra legal

66 [2025] EWHC 3248 (Pat)

67 [2025] EWHC 3170 (Pat)

68 [2025] EWHC 2600 (Pat)

69 [2025] EWHC 705 (Pat)

70 [2025] EWHC 1016 (Pat)

71 [2025] EWHC 2921 (Pat)

exclusivity can be worth millions or even tens of millions of pounds.

Post-Brexit, the EU Regulation governing the SPC regime was ported over to UK national law⁷². Although the higher courts of the UK have power to depart from CJEU decisions, by and large, the Judges have, so far, tended to align with the decisions from Luxembourg on the issues they have considered. One area of alignment concerns SPCs for second or further medical uses for a product and the requirement in Art. 3(d) of the SPC Regulation that the Marketing Authorisation (**MA**) relied upon for the SPC should be the first MA to place the product on the market as an authorised product. As many readers will know, in the *Santen*⁷³ reference, the CJEU departed from its earlier *Neurim*⁷⁴ ruling and held that the SPC regime did not permit SPCs for further medical uses of previously authorised products. In the English Court, *Merck Serono*⁷⁵ sought an SPC relating to cladribine based on its patent to cladribine's use in the treatment of multiple sclerosis but, agreeing with the High Court and the UKIPO, the Court of Appeal refused to grant such an SPC. This was for two reasons. The first reason was that the Court of Appeal had already ruled in *Newron*⁷⁶ that SPCs could not be granted where the MA relied upon was not the first to place the product on the market. This ruling was binding on the Court. Secondly, the Court of Appeal held, *obiter*, that it would not have departed from the CJEU ruling in *Santen* even if had been free to do so. This was because of the need for balance, certainty and consistency in the interpretation of the law, even if these factors could sometimes come at the cost of a meritorious invention being denied extended protection. Interestingly, there are signs from Germany that Europe may not be of one mind on this point: at the end of 2025, the German Court made a reference to the CJEU as to whether Art. 3(d) precluded an SPC for a

veterinary product where the first MA was for human use.

An important exception to the legal exclusivity provided by SPCs for a given product was introduced into EU and UK law by the SPC manufacturing waiver, which allows a manufacturer of a generic or biosimilar version of a product protected by an SPC: (i) to manufacture it for export outside the EU/UK and/or (ii) to manufacture and stockpile it during the last six months of the SPC's lifetime for sale in the EU/UK on the first day after SPC expiry. In either case, the manufacturer must provide certain information in the form of a notice to the SPC holder (and the relevant national IPO) three months before the act of manufacture.

Litigation over the interpretation of the SPC manufacturing waiver was perhaps inevitable. The German Court on the one hand, and the Dutch and Belgian Courts on the other, have given conflicting views on the level of information that a generic/biosimilar manufacturer should provide within its notice⁷⁷. Litigation in the UK on this issue came in the second half of 2025 when Alvotech and Fisher gave notice (twice) to Regeneron and Bayer that they intended to manufacture a biosimilar version of the successful product aflibercept (sold as a medicine under the brand name Eylea®) in the last part of the SPC period⁷⁸. Regeneron and Bayer sued Alvotech and Fisher, alleging that both notices were defective as, *inter alia*, they did not contain the reference numbers for the MAs in Japan (the export destination).

Given the imminence of the SPC expiry on 22 November 2025, **Meade J** made an order for expedition following a hearing on 29 September and heard the trial on 24 November, announcing at the end of the hearing that in his judgment the biosimilars were correct and the notices were not deficient. Although there were many sub-issues, the Judge held that

⁷² Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products

⁷³ C-673/18

⁷⁴ C-130/11

⁷⁵ *Merck Serono SA v Comptroller-General of Patents, Designs and Trade Marks* [2023] EWHC 3240 (Ch); [2025] EWCA Civ 45

⁷⁶ *Newron Pharmaceuticals S.p.A v The Comptroller General of Patents, Trademarks and Designs* [2024] EWCA Civ 12

⁷⁷ *Janssen Biotech v. Formycon* 21 O 12030/23 (District Court Munich I); C/09/657817 / KG ZA 23-1039 (The Hague District Court); A-24-02113 (Brussels Enterprise Court)

⁷⁸ *Regeneron Pharmaceuticals, Inc. & Anor v Alvotech HF & Anor* [2025] EWHC 3050 (Pat)

the dispute boiled down to a short point of legislative interpretation: can a party seeking an SPC export waiver give a valid notification prior to having an MA (or the number of the MA) in the export country so long as they provide the MA number later, or is a notification without an MA number inherently invalid, which would have the effect that the three month period would not start until an MA was granted and the number publicly available? Agreeing with the Dutch and Belgian Courts, the Judge found for Alvotech and Fisher on this issue, holding that the lack of provision of the MA numbers for Japan did not make the waiver notice defective.

The Judge also confirmed that Art. 5 does not require the intended country of export to be completely free of IP rights in order for a SPC manufacturing waiver notification to be valid. In particular, waivers are not precluded for export countries where protection is open to serious challenge, or is obviously invalid, or does not cover the maker's product. In order to police compliance with the waiver conditions, the SPC holder is entitled to request information from the maker, including confidential information. The information to be provided in the notification cannot be expected to be enough on its own for the SPC holder to make a definite decision as to whether infringement is taking place in the third country.

It was hoped that during the course of 2025 progress would be made in the corridors of Brussels on the proposed new SPC Regulation. Unfortunately, the legislation appears to be stuck in the system for now. Nevertheless, at the end of 2025, the Commission published a proposal for a new Biotech Regulation which included the introduction of a 12-month extension to SPCs for medicinal products developed by means of biotech processes and for advanced therapy medicinal products (ATMPs).

The extension of the SPC would be reserved for products with an MA granted by the EU for a medicine developed by means of biotech processes or an ATMP provided that the following conditions are met:

1. the medicine contains a new active substance “*distinctly different*” from that of any authorised medicine in the EU.
2. the medicine has a “*distinctly different*” mechanism of action and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicine in the EU for the same disease;
3. the efficacy clinical trials supporting the marketing authorisation are conducted in more than two EU Member States: and
4. at least one manufacturing step, excluding packaging, quality testing and certification, is performed in the EU.

If the legislation is enacted as drafted, it seems inevitable that disputes will arise as to the meaning of “*distinctly different*”. Nonetheless, it seems that the proposal is receiving support from industry.

Procedural issues

Entitlement

Determination of the right to a patent after grant is governed by s. 37 of the Act, and by the Court where the Comptroller declines to deal, which often happens when the question of entitlement is bound up with a more complex contractual dispute. So it was in the case of *Dr Vanessa Hill v Touchlight Genetics*⁷⁹, where Dr Hill, a former Director and one of the founders of Touchlight, sought a declaration of entitlement to patents owned by the company relating to the production process for a particular type of close-ended DNA. In dispute was whether the invention had been devised before or after a service contract between

Touchlight and Dr Hill under which Dr Hill worked as Touchlight’s Chief Scientific Officer and whether the contract required Dr Hill to assign all IP rights to Touchlight during the term of the agreement.

Dr Hill’s case was that she had devised the invention before the service contract was entered into and that the contract was effective to transfer only certain rights, leaving her exclusivity to other rights and in particular those relating to aspects of the invention that allowed it to operate at low temperatures.

The Judge, **Michael Tappin KC**, sitting as Deputy, rejected Dr Hill’s claims and held that the entire invention had been assigned to Touchlight under the service agreement because it had been devised after that agreement became operative. This having been decided, Dr Hill’s case failed. Touchlight had pleaded contingency positions relating to contractual interpretation, estoppel and limitation but having won on the timing issue, no decision was necessary on those points.

Unjustified threats

A clear finding of unjustified threats of patent infringement was made by **Bacon J** as part of a wider action by Cabo against MGA⁸⁰. The subject matter of the dispute was small plastic toys in spherical packaging, MGA’s version of which – “*LOL Surprise!*” – was a sell-out success in the US and the number 2 best-selling toy in the UK. The claimant, Cabo, launched a similar-looking toy but never got its business off the ground, failing after a short time. In addition to the groundless threats claim, Cabo sued MGA for a number of allegedly unlawful acts under competition law including abuse of dominant position and entering unlawful agreements with retailers. Cabo claimed in excess of £50 million in damages.

The unjustified threats finding was robust and made in short order. MGA’s statements to Cabo’s customers clearly engaged the provisions of s. 70 of the Act and Cabo was without doubt a person aggrieved. It was of no

consequence that MGA had made the threats shortly after filing the patent, which had not yet published (and went on to be revoked 2 years after grant), notwithstanding that the application, being unpublished at the time would not have been visible. MGA had also accepted that threats made before grant can be construed as threats to bring proceedings upon grant (following *Brain v Ingledew*⁸¹). Ultimately, however, a declaration that MGA’s conduct constituted unjustified threats was all that Cabo obtained – its damages claim before the Judge failed for lack of evidence in the counterfactual case that it would have traded profitably.

Estoppel

In *Samsung Bioepis v Alexion*⁸², the biosimilars alleged that Alexion had taken different positions in other proceedings in relation to whether eculizumab was part of the state of the art by the priority date of the patent in suit. As a result, Samsung Bioepis argued that Alexion was prevented by judicial estoppel or by the doctrine against approbation and reprobation from denying that its antibody eculizumab was part of the prior art. Further, Samsung Bioepis and Amgen both argued that it would have been an abuse of process for Alexion to assert the patent in suit against them. Ultimately, **Meade J** declined to deal with these issues as he had found the patent in suit both not infringed and obvious. He noted that these were novel points of law and were not argued before him in sufficient detail to allow a decision. Creating what would essentially amount to a new judge-made route of revocation would be a major step which should not be taken without full arguments and unless necessary.

Strike-out

The Courts will usually bend over backwards to assist litigants in person. However, there are limits. In *Bin Ahmad v Comptroller-General of Patents*⁸³, Mr Ahmad brought an appeal to the High Court against the decision of the Comptroller-General of Patents refusing his

80 *Cabo Concepts Ltd v MGA Entertainment (UK) Ltd* [2025] EWHC 1451 (Ch)

81 *Brain v Ingledew Brown* [1996] FSR 341

82 [2025] EWHC 1240 (Pat)

83 *Othman Bin Ahmad v Comptroller-General of Patents* [2025] EWHC 936 (Pat)

application for a patent, alleging malice and corruption by the IPO. These allegations were swiftly rejected by **Mellor J**: “*Not only are they unsupported, none of these allegations should ever have been made. Mr Ahmad’s status as a litigant in person does not excuse the making of these utterly meritless allegations...*”.

The allegations surrounded the deemed refusal of one of Mr Bin Ahmad’s patent applications following Mr Ahmad’s failure to respond to a notice of final rejection. The Comptroller-General applied to strike out the claim, or, in the alternative, that the appeal be decided by summary judgment. In relation to the strike-out application, the Judge explained that the usual course is to assume that all of the facts set out by the Claimant are true. However, many of the assertions made – including those of corruption – were so fanciful that even if everything was assumed in Mr Ahmad’s favour, there was still no sustainable case that could possibly enjoy any prospect of success. **Mellor J** therefore had no hesitation in granting the application for strike-out. In the alternative, and for similar reasons, the Judge confirmed that had the strike-out application not been successful, he would have granted summary judgment.

Interim injunctions

Practitioners interested in interim injunction applications in pharma cases were treated to an epic saga during the course of 2025 in the dapagliflozin litigation between *AstraZeneca v Glenmark*⁸⁴. Various interesting themes emerged. Does the litigation system cause generics to lose patience and launch early? Should generics that have “invested” in litigation be treated differently from those that wait to launch after a patent has been found invalid? Does conduct that causes the timeframe for the injunction in question to be short bias the quantification of damages question against the originator?

In mid-February, Glenmark informed AstraZeneca that it intended to launch its generic dapagliflozin product on 17 March 2025 (right in the middle of the planned trial of the revocation action brought by Glenmark to clear the way). AstraZeneca responded by seeking an interim injunction and both sides adduced both commercial as well as expert evidence on the impact of generic entry. The application was heard by **Michael Tappin KC** sitting as a Deputy Judge. Applying the principles laid down in *American Cyanamid v Ethicon*⁸⁵, he found that “*damages are calculable to a reasonably high degree of accuracy*” for AstraZeneca, regardless of whether one or several generic medicines entered the market. In making this finding it was important that the length of time between potential launch and the form of order hearing following trial would be short and that during this time it was unlikely that AstraZeneca would reduce its price (Glenmark having argued that they would have retained a high price and had limited sales) or be forced to make any irreversible changes to e.g. its supply chain. For Glenmark, damages were held not to be an adequate remedy as the damages it would be suffer would be much more difficult to assess. For example, the sales Glenmark could make were unknown and would have been dictated by whether more than one generic entered the market. In addition, Glenmark would lose its first mover advantage. There were also some skinny label infringement matters which may make the assessment more difficult. The injunction was therefore refused, with Glenmark providing an undertaking to pay an estimate of profit per pack into a separate bank account for each pack sold between the injunction being refused and the form of order hearing following the validity trial.

Although the Deputy Judge refused AstraZeneca permission to appeal, the Court of Appeal granted it, and heard the appeal on an expedited timeline on 9 April 2025. In the meantime, Glenmark gave undertakings not to launch but was allowed to supply some material for wholesalers to hold pending launch.

84 *AstraZeneca AB & AstraZeneca UK Limited v Glenmark Pharmaceuticals Europe Limited* [2025] EWHC 748 (Pat) & [2025] EWCA Civ 480

85 *American Cyanamid Co v Ethicon Ltd* [1975] A.C. 396

In its decision⁸⁶ the Court of Appeal reversed the decision of the Deputy Judge, in part because a change in circumstances led to a finding that damages would not be an adequate remedy for AstraZeneca: in the time between the hearing before **Michael Tappin KC** and the hearing in the Court of Appeal, two other generic companies had informed AstraZeneca they were ready to launch. AstraZeneca argued that this would risk a decrease in the price of its Forxiga® product prior to the form of order hearing and serious difficulty in reinstating the price would follow. The Court of Appeal found that damages would not be an adequate remedy for either side, meaning the Court went on to consider the status quo. Here, Glenmark's conduct on timing went against it. **Arnold LJ**, giving the leading judgment, was very clear that Glenmark's failure to clear the path and attempt to “*jump the gun*” rather than awaiting the outcome of the main proceedings made it more difficult for the Court to do justice to all the parties. He stated “[c]learing the path involves taking the steps necessary to obtain a judgment before launch. If proceedings are not commenced sufficiently far in advance to achieve that without a degree of expedition of the trial, then it is incumbent on the party seeking to clear the path to apply for that degree of expedition”.

Following the grant of the preliminary injunction by the Court of Appeal, AstraZeneca's patent was held invalid at first instance so the parties found themselves in Court again to discuss the preliminary injunction in May as AstraZeneca sought to maintain the preliminary injunction until the appeal of the validity decision⁸⁷. This time the application was in relation to four generics (Glenmark, Viatrix, Teva and Sandoz) and a pharmacy chain (Bestway). One of the main points of this appeal was the question of whether, in light of the UK's Voluntary Scheme for Branded Medicines Pricing, Access and Growth (**VPAG**), AstraZeneca would be able to increase its prices following a temporary price reduction to compete with the generics. The Court received two letters from the

Department of Health and Social Care which related to this topic. While the Department did not submit any evidence, the correspondence made it clear that no NHS body would pursue a policy directed to deterring an originator drug company from restoring historic levels of actual selling or list prices following vindication of the originator's patent rights. As such, arguments on the impact of this scheme were of limited relevance. Nevertheless, hearing the application, **HHJ Hacon** found that AstraZeneca would reduce their prices, and would struggle to raise them again in the future. He also found that the likelihood of error in the calculations of potential loss to the generics created a risk of irreparable harm for the generics, too. Given that damages were not an adequate remedy for either side, **HHJ Hacon** held that the status quo should be maintained by granting the preliminary injunction. Glenmark, Viatrix and Teva argued that they should be given preferential status over Sandoz and Bestway, who had not proactively taken steps to clear the way and had sought to ride on their coattails by launching immediately after the first instance finding of invalidity, but this argument was rejected by **HHJ Hacon** and all were made subject to the preliminary injunction. Appeals of this decision were rejected by both **HHJ Hacon** and the Court of Appeal, and the injunction remained in place until the outcome of the main appeal on validity.

After the Court of Appeal dismissed the main appeal on the merits, upholding the lower court's finding of invalidity of AstraZeneca's patent, the Court heard an application from AstraZeneca for an interim injunction pending the outcome of any appeal to the Supreme Court or an application for permission to appeal to Supreme Court⁸⁸. The Court of Appeal considered that it should “*arrange matters that, [if and] when the appeal comes to be heard, the appellate court may be able to do justice between the parties*”.⁸⁹ Applying the American Cyanamid principles, the Court found that the application should be refused as neither

86 [2025] EWCA Civ 480
87 [2025] EWHC 1339 (Pat)

88 *AstraZeneca AB & AstraZeneca UK Limited v Generics UK and others* [2025] EWCA Civ 924

89 *Minnesota Mining and Manufacturing Co v Johnson & Johnson Ltd* [1976] RPC 671 at 676 (**Buckley LJ**, my interpolation)

an appeal nor an application for permission to appeal would have a reasonable prospect of success based on the findings of the Court of Appeal and the High Court on the merits of the case. However, in case the Court was wrong about that it held that the *status quo* should be maintained for a short period to allow the Supreme Court to determine an application for permission to appeal. The Court therefore granted an additional 14-day interim injunction, which was subsequently extended further by the Supreme Court pending determination of the application for permission to appeal. Ultimately, the Supreme Court refused permission to appeal and the injunction fell away.

Later in the year came a further important assessment of the law and grounds for an interim injunction in the proceedings between *Boehringer Ingelheim and Dr Reddy's*⁹⁰. In September 2025, more than a year before the scheduled trial date, and perhaps necessitated by the decision against the validity of the dapagliflozin patent causing generic entry in an overlapping market, Dr Reddy's gave 28 days' notice that it intended to commence sales of its empagliflozin products in the UK. As a result, Boehringer Ingelheim brought an application for an interim injunction which was heard by **Michael Tappin KC**, sitting as a Deputy Judge of the High Court. Again, the Deputy Judge applied the guidelines laid down in *American Cyanamid v Ethicon*⁹¹. While it was common ground that there was serious issue to be tried, a key issue to be considered was the assessment of damages and how the empagliflozin market may change over the period until trial in October 2026. There were a number of factors which made it very hard for the Deputy Judge to assess how the market for empagliflozin would evolve over the next 14-15 months, including entry of generic dapagliflozin medicines and the impact this may have on the empagliflozin market; the risk of further generic launches and a complicated patent infringement assessment in light of some skinny-labelling issues. This assessment led to

the Court holding that damages were not an adequate remedy for either side. The balance of convenience (injustice) was held to be in favour of maintaining the status quo and the injunction was granted. Dr Reddy's failure to take effective steps to clear the way before its launch was an important factor. The trial in the proceedings was fixed, by consent, at a time when the dapagliflozin litigation was advanced and Dr Reddy's did not adapt its litigation strategy to prepare for a change in market conditions, for example by seeking, expedition of the trial. It could not now rely on this failing to its advantage.

Practitioners involved in pharma interim injunction applications should take note of the Court's view that the witness evidence provided by the Department of Health and Social Care (an intervener) in the empagliflozin case was so helpful on matters relating to pricing/reimbursement and prescribing that it should be reviewed by any Court hearing an application for an interim injunction in future.

Inventorship

*"In 2023, the appeal of the UK IPO's refusal to grant two patents to an AI machine called DABUS reached the Supreme Court, and in one of the final judgments of the year, that Court, led by Lord Kitchin, unanimously dismissed the appeal of Dr Thaler (the owner of DABUS)*⁹². *The Supreme Court agreed with the findings of the UK IPO and all the lower courts on three issues.*

First, the Supreme Court held that DABUS could not be considered an inventor within the meaning of the Act. It was clear that an inventor must be a natural person. Secondly, Dr Thaler was not the owner of any invention made by DABUS and so was not entitled to apply for a patent. The Court again was clear that there is no invention because DABUS cannot be an inventor. Even if there were some invention, it could not be considered transferred by the doctrine of accession in the same way the owner of a tree owns the fruit of that tree – this only

⁹⁰ *Dr Reddy's Laboratories (UK) Limited v Boehringer Ingelheim International and others* [2025] EWHC 2834 (Pat)

⁹¹ [1975] A.C. 396

⁹² *Thaler v Comptroller-General of Patents, Designs and Trade Marks* [2023] UKSC 49

*applies to tangible property. Finally, the Hearing Officer was correct to hold that the applications would be taken to be withdrawn at the expiry of the sixteen-month period specified by r. 10(3) of the **Patent Rules 2007** by reason of Dr Thaler failing to satisfy either of the requirements in s. 13(2) of the Act: he did not identify any person(s) whom he believed to be the inventor or inventors of the inventions described in the applications and his ownership of DABUS did not provide a proper basis for entitlement. This is the end of the road for Dr Thaler in the UK.”*

Thus concluded our review of patent cases for the year 2023. Little did we know that Dr Thaler would be back.⁹³

In parallel to the UK patent applications that were the subject of the line of cases leading to the Supreme Court, Dr Thaler had filed an International Application claiming entitlement to the same priority documents. The parent application was prosecuted in parallel with the proceedings on the related patents which came before the Supreme Court. Following the Supreme Court decision, the prosecution was terminated – but three days earlier, Dr Thaler filed a divisional application. The original Form 7 for this application suffered from the same deficiencies as before but, wise from the Supreme Court decision, Dr Thaler now filed a further Form 7 in which he named himself as the inventor. The questions ultimately before the Judge, **Michael Tappin KC**, sitting as Deputy Judge, were (i) whether the divisional application was filed out of time; and (ii) whether the further Form 7 met the requirements of s. 13(2) of the Act.

On the first issue, the divisional could only be validly filed while the parent was still alive. The date of the parent’s termination was disputed. The IPO hearing officer took the view that the termination date was almost a year earlier than Dr Thaler said because the effect of a failure to comply with formalities (in this case providing a statement which complied with the requirements of s. 13(2)) applied *ex tunc*

to a date marking the end of the originally prescribed period for meeting those formalities. **Michael Tappin KC** agreed – this was a pure formalities rule. It did not require the IPO to make a decision on whether the content of the information provided was correct, only that it had been provided in time, which it hadn’t. Dr Thaler’s argument under s. 3 of the Human Rights Act that s. 13(2) must be read in such a way so as to not deprive him of his possessions was also rejected.

On the second issue considered by the Judge, the question was whether the revised Form 7 was “*obviously defective*”. Here, for the first time, Dr Thaler declared himself the inventor (not DABUS). Dr Thaler argued that although his belief had not changed (DABUS was the inventor), his declaration was not defective because his understanding of the law had changed following the judgment of the Supreme Court. The Judge considered whether, on the basis of the materials provided to the UKIPO, it was clear that his statement of inventorship was defective, ultimately determining that it was. Even the final Form 7, naming Dr Thaler as the inventor, included a statement to the effect that whilst Dr Thaler owned, built, trained and used DABUS, the invention was generated by DABUS. These statements clearly identify DABUS, not Dr Thaler as the “*actual deviser*” of the invention. The appeal was dismissed.

Pleading amendment

A complex, and potentially high value, inventor compensation claim is presently trundling slowly through the court system and has been doing so for many years, since 2022. At the time of **Meade J** giving his judgment on a case management application in *Parsons v Convatec*⁹⁴ in May 2025, a case management conference had yet to happen. The subject matter of the application before **Meade J** was a re-pleading point, Convatec seeking better particulars from Parsons in relation to the seven patent families in suit. The Judge upheld an earlier ruling that a “*claim-by-claim*” approach

93 [2025] EWHC 3072 (Ch)

94 [2025] EWHC 1225 (Pat)

to identifying an invention is inappropriate for employee compensation; instead, the invention must be identified from the specification as a whole. Furthermore, the Court provided a sharp reminder to defendants that they must properly engage with factual assertions in their defence, such as specific meetings where inventions were allegedly devised, rather than relying on bare denials or “*interpretational issues*” regarding the patent.

The question of whether to allow amendments to pleadings shortly before trial came before **Meade J** in *Lenovo v Ericsson*⁹⁵. This is a discretionary exercise and the Court will consider not only whether the amendments can be accommodated before trial but the degree of prejudice to the parties in allowing or denying the amendment. Here, unusually, the Judge was in difficulty when assessing whether a refusal would create prejudice because Lenovo had not provided *any* explanation for the lateness of its proposed amendment. In the circumstances, the Judge made his best attempt at working out what had happened, noting that Lenovo may have been under the mistaken notion that evidence could be put in, mismatching the current pleadings with a view to fixing them later. The Judge explained in no uncertain terms that such practice is “*unacceptable*” and would amount to a “*reckless disregard*” of the impact of such conduct. Ultimately the three late amendments were refused, albeit primarily on the basis that they were “*very late*” and could not be dealt with meaningfully ahead of trial.

Experts

As is well known, it is a mistake to conflate the roles of the expert witness and the person skilled in the art. The former is not a proxy for the latter but a teacher whose role is to educate the court - a maker of the mantle for the court to don⁹⁶. However, it is equally a mistake to divorce the two roles entirely. In *Modernatx Inc v Pfizer & BioNTech*⁹⁷, **Arnold LJ** set out in some detail the role of an expert and the

identification of the skilled person, which in this case were closely related. **Arnold LJ** explained that, in general, expert witnesses have 3 main roles: (1) to educate the court about the technology and to provide the court with the common general knowledge; (2) to give evidence on one or more contested issues in the case, in particular obviousness; and (3) in some instances, to interpret results. In order to be properly qualified, an expert witness must be in a position to speak to the common general knowledge of the skilled person at the relevant date. An expert witness who cannot do this cannot be said to be properly qualified, no matter how good a witness the person in question is. It may therefore be relevant in some cases to determine which of two expert witnesses more closely reflects the skills and experience of the skilled person as a such a witness is better placed “*all other things being equal, to assist the court to assess whether a particular step would be obvious to the skilled person than a witness whose expertise does not closely reflect that of the skilled person*”. Accordingly, it was held that the trial judge had been entirely correct to consider how closely the witnesses’ experience corresponded to that of the skilled person.

Explicitly instructing an expert to follow the *Pozzoli*⁹⁸ approach can create a risk of hindsight. Thus came the warning from **Arnold LJ** in *Accord v Astellas*⁹⁹ where the generics’ expert had been asked to follow *Pozzoli*. Just because the approach is commonly adopted by the courts, it does not follow that it is necessary to instruct the expert to do so. In the case at hand **Arnold LJ** considered that it would have been preferable had the expert been asked what compounds would have been obvious choices to investigate having read the prior art poster and with a desire to develop an alternative with similar therapeutic potential. However, he did note that he was not intending to be prescriptive about expert instruction, particularly in other kinds of cases.

⁹⁵ [2025] EWHC 613 (Pat)

⁹⁶ *Rockwater v Technip* [2004] EWCA Civ 381

⁹⁷ *Modernatx Inc v Pfizer Limited/BioNTech Manufacturing GmbH and others* [2025] EWCA Civ 1032

⁹⁸ *Pozzoli SpA v BDMO SA* [2007] EWCA Civ 588

⁹⁹ [2025] EWCA Civ 936 (Pat)

Confidentiality

The Court of Appeal considered the scope of confidentiality redactions in a FRAND judgment in *Optis v Apple*¹⁰⁰. As is now conventional, **Marcus Smith J**'s original rate-setting judgment resolving licensing terms between Optis and Apple¹⁰¹ was handed down in a redacted form, so that detailed financial data relating to licences involving non-parties such as InterDigital, Qualcomm, Nokia, Google, Huawei, and LG (the **Third Party Licensors**) could be kept from public view. **Marcus Smith J** was of the view, however, that a “less-redacted” version could be made public: one which maintained confidentiality for lump sums but disclosed unpacked per-unit rates and certain derived data; and he ordered the publication of the “less-redacted” judgment in February 2024¹⁰². The Third Party Licensors appealed, arguing that disclosure of unpacked rates and averages would harm their commercial interests and undermine confidentiality.

The central legal issue was whether **Marcus Smith J**, who had taken particular note of *JC Bamford v Manitou*¹⁰³ and the Trade Secrets (Enforcement, etc.) Regulations 2018, correctly applied the confidentiality test. The Court of Appeal ruled that **Marcus Smith J**'s conclusion that *JC Bamford* had created a new test was wrong. The Court found “*there is only one test. The question is whether in the circumstances the principle of open justice gives way to the interests of justice itself*”. The Court thus reinstated the balancing approach from *Unwired Planet v Huawei*¹⁰⁴ and *InterDigital v Lenovo*¹⁰⁵ and in applying this approach, found the High Court erred in distinguishing between lump sums and unpacked per-unit rates. Both types of data represent pricing information and disclosure would harm licensors. However, there was not sufficient evidence of harm in relation to non-financial licence terms (e.g., sub-licensing provisions) to justify their redaction.

¹⁰⁰ *Optis Cellular Technology LLC and Others v Apple Retail UK Ltd and Others* [2025] EWCA Civ 1263

¹⁰¹ [2023] EWHC 1095 (Ch)

¹⁰² [2024] EWHC 197 (Ch)

¹⁰³ [2023] EWCA Civ 840

¹⁰⁴ [2017] EWHC 3083 (Pat)

¹⁰⁵ [2023] EWHC 1577 (Pat)

Damages under cross-undertaking

The limits of compensation under a cross-undertaking were tested in *Sandoz v Bayer*¹⁰⁶. Following the revocation of Bayer's rivaroxaban patent, under which Sandoz suffered a preliminary injunction, Sandoz sought an account of profits, rather than standard compensatory damages, alleging that Bayer had acted dishonestly before the EPO to obtain the patent. **Michael Tappin KC** struck out this claim, clarifying that a cross-undertaking is the “price” paid for a preliminary injunction and is strictly compensatory in nature. The Court ruled that it does not permit a respondent to claim the patentee's profits, even in “*exceptional circumstances*”.

In a subsequent decision¹⁰⁷, Sandoz attempted to use the same allegations of wrongdoing to improve their award of damages. The Court also rejected this argument, finding no nexus between Bayer's alleged state of mind at the EPO and the evidential difficulties of constructing the counterfactual market. The Court reaffirmed that while damages are assessed liberally in any event, that is because the patentee is a “*wrongdoer*” in the context of a discharged injunction; it does not require a trial of the patentee's underlying conduct in obtaining the patent.

In *DSM v Mara Renewables*¹⁰⁸ **Mellor J** had deemed Mara the overall winner after two of the three patents in suit were invalidated. He rejected DSM's argument that they were the winners based on the large “cheque” they expected to receive for the one valid, infringed patent, noting that financial recovery on an inquiry is a separate matter from the outcome of a liability trial. The Court also refused DSM's request for customer identities via *Island Records*¹⁰⁹ disclosure, holding such highly confidential information was not necessary for DSM to make an informed election between damages or an account of profits.

¹⁰⁶ [2025] EWHC 2201 (Pat)

¹⁰⁷ [2025] EWHC 2533 (Pat)

¹⁰⁸ [2025] EWHC 1514 (Pat)

¹⁰⁹ *Island Records Ltd v Tring International Plc* [1996] 1 W.L.R. 1256

Account of profits

The prize for the longest judgment of the year, running to 382 pages, goes to **Mr Justice Leech** for his decision on Lufthansa’s claim for an account of profits¹¹⁰, following a successful liability trial in which Astronics, Safran and Panasonic were found to infringe Lufthansa’s patent covering an in-seat power supply system for aircraft passengers.

The infringing system was 10 times more commercially successful than Lufthansa’s own (sold via a licensee), so an account of profits was a natural choice of financial remedy, but there were a number of hurdles to clear along the way. First, it had to be established that the defendants did not have a viable non-infringing alternative, i.e. did they really have to rely on the patent to make sales? **Leech J**, after revisiting the liability question in respect of the defendants’ proposed alternative product in the counterfactual, decided that it was not a viable non-infringing alternative. The question then became: is Lufthansa entitled to all the defendants’ profits on the items sold or only a fraction of those profits attributable to the features of the patent? Lufthansa argued that the patent was inextricably linked to the regulatory framework for the product such that no sale was possible without using the patent. The Judge agreed the patent was essential in part but nevertheless found that the patented feature (concerning the supply of AC power to personal electronic devices) was only one element of the regulatory framework and incidental to the overall function of the defendants’ system. There were many other reasons why the defendants’ product was 10 times more commercially successful.

When considering apportionment, **Leech J** stated that “[w]here the infringer generated a pool of profits from a complex product by multiple causes, the closest approximation may be to decide how much the patentee would have agreed to accept for a licence to commit the infringing acts”. Ultimately, he used the

agreement between Lufthansa and its licensee as an example of an acceptable licence rate and accepted a figure put forward by the defendants’ expert that 13% of the infringing profits emanated from the infringing features. The Court ultimately ordered Astronics to pay US \$4.42 million, Panasonic US \$7.384 million and Safran US \$81,800 (subsequently increased to US \$567,800 at the consequential hearing the following month¹¹¹).

Costs

Perhaps unsurprisingly, given the complexity of the preliminary injunction proceedings in the dapagliflozin litigation mentioned above, identifying the successful party for the purpose of awarding costs was a key question in *AstraZeneca v Glenmark*¹¹². Following the revocation of the dapagliflozin patent, **HHJ Hacon** addressed whether costs reserved from earlier interim injunction hearings should follow the final result. He concluded that, although *AstraZeneca* had been provisionally successful in obtaining injunctions, the generic companies were the ultimate “winners” because the patent—the foundation of the relief—was held to be invalid. Consequently, AstraZeneca was ordered to pay the generic companies’ costs for those applications, as the “balance of convenience” at the interim stage did not insulate the patentee from the consequences of a final loss.

In relation to the first instance proceedings on the merits in dapagliflozin¹¹³, **Michael Tappin KC** applied a 10% deduction to the claimants’ costs because they had pursued a “classical obviousness” case until closing submissions before abandoning it. The Court held that while this issue was distinct and increased costs, it was not “unreasonable” to have run it, and thus the claimants were not required to pay AstraZeneca’s costs on that specific issue.

¹¹⁰ *Lufthansa v Astronics, Safran and Panasonic* [2025] EWHC 375 (Pat)

¹¹¹ [2025] EWHC 1034 (Pat)

¹¹² [2025] EWHC 2203 (Pat)

¹¹³ *Generics (UK) Ltd v AstraZeneca AB* [2025] EWHC 2203 (Pat)

Pfizer v GlaxoSmithKline, reported in our review of 2024's patent cases, spilled over into 2025 in that **Mellor J**'s decision on costs was handed down in January. The costs of the litigation were significant, and Pfizer's costs, at over £6 million, were almost double those of GSK. Both sides accepted that the Judge should make an issues-based order; the dispute was on the level of discount to be made to winning party Pfizer's costs. The Court determined an overall 30% deduction from Pfizer's costs was appropriate. This reflected Pfizer's loss on separate issues including priority, Belgian law and novelty, which **Mellor J** described as "technical points without merit".

Looking ahead to 2026

Last year was heavier on FRAND cases than we might have expected when the year began. Reading the runes for 2026, this trend may continue. For example, we might expect to see:

- A Supreme Court decision in *Tesla v InterDigital* on whether the English Courts have jurisdiction to determine FRAND terms at the request of an implementor where the licence is offered by an intermediary as part of a pool (hearing date: 27 April 2026).
- A Supreme Court decision in *Optis v Apple* on the correct approach for determining FRAND terms for SEPs and whether the Court of Appeal erred in its handling of the case (hearing dates: 29 June – 1 July 2026).
- Further FRAND determinations, with FRAND trials having been listed in *Samsung v ZTE, InterDigital v Amazon and MediaTek v Huawei*.

Elsewhere, we expect:

- In the *Entresto*® litigation, further deliberations in the Patents Court on the issue of plausibility.

- A decision from the Supreme Court in the *Emotional Perception* case on whether the statutory restriction on patenting a program for a "program for a computer... as such" applies to artificial neural networks (this judgment being given on 11 February 2026).

As ever, whatever the year may bring, we look forward to reporting on it next year.

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