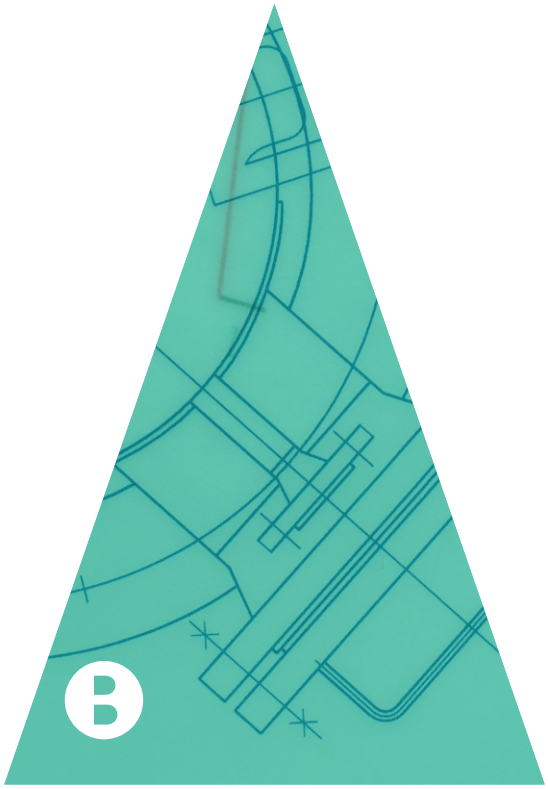
Review of Patent Cases in the English Courts in 2024



Bristows

Quotation of the Year

"I will begin with the secondary evidence because I find it compelling."

His Honour Judge Hacon in *Pfizer Inc v UniQure Biopharma BV*[1]

1 *Pfizer Inc. v UniQure Biopharma B.V. UniQure Biopharma B.V., CSL Behring LLC v Pfizer Inc., Pfizer Limited* [2024] EWHC 2672 (Pat)

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Introduction

2024 was the first full year in which the English courts ran in parallel with the UPC. A sense of separation anxiety may have crept into the minds of some practitioners, if not a palpable feeling of FOMO, but any fears that the UK as a jurisdiction would founder as litigants flocked to the new court have been happily dispelled. The English courts delivered a good number of decisions – 68 – in line with the years before that (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:

- The prevalence of patent cases on vaccines, not just in relation to the Covid-19 wars.
- The Court of Appeal reviewing the UK's second global determination of FRAND licence terms in *InterDigital v Lenovo*[2].
- A number of cases examining the role of motivation in the assessment of obviousness, including, in *Samsung v Janssen*[3] and *Sandoz v Bayer*[4], the impact on the *"obvious to try"* question of published information on clinical trials.
- The Court of Appeal curbing the enthusiasm over artificial neural networks by allowing the Comptroller's appeal in *Emotional Perception AI's Application*[5] and deciding that the application was excluded from patentability after all.
- The procedural *"crunch"* in the rivaroxaban litigation, where the parties ran out of road, necessitating multiple interim injunction applications and a sub-5-week substantive appeal.
- The return of the *Arrow*[6] declaration, successfully granted in *Pfizer v GSK*[7].

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 course of the year. However, as this is a condensed summary, not every decision is mentioned.

This year, for the first time in twenty years, the review does not include a section on the Unified Patent Court (or "Community Patent / EPLA" as the section heading read in the earlier editions). With the UPC system now established and busy generating its own case law, we have created a separate annual review of UPC cases, contained in a different publication, our UPC Review, which can be found here.

Claim construction and infringement

Construction

When interpreting patent claims, it is important to be pragmatic. Devising hypothetical examples that would make a nonsense of the proposed interpretation is not a useful exercise unless they are grounded in the specification or the common general knowledge (**CGK**). In April, **Birss LJ** gave the leading judgment of the Court of Appeal in *Supponor Ltd v AIM Sport Development AG*[8]. The defendant, Supponor had appealed the High Court's findings that AIM's patent was valid and infringed. In particular, the defendant's appeal on claim construction advanced a number of hypothetical examples that were covered by the High Court's claim construction, but nevertheless impractical. No evidence was provided by the defendant

2 *Interdigital Technology Corporation, Interdigital Patent Holdings, Inc., Interdigital, Inc., Interdigital Holdings, Inc. v Lenovo Group Limited, Lenovo (United States) Inc., Lenovo Technology (United Kingdom) Limited, Motorola Mobility LLC, Motorola Mobility Uk Limited* [2024] EWCA Civ 743

3 *Samsung BioEpis UK Limited v Janssen Biotech, Inc.* [2024] EWHC 1984 (Pat)

4 *Sandoz AG, Sandoz Limited, Accord Healthcare Limited, Teva Pharmaceutical Industries Limited, Cipla Limited, Amarox Limited, Hetero Labs Limited, Generics (UK) Limited, Viatris (UK) Healthcare Limited, Stada Arzneimittel AG v Bayer Intellectual Property GmbH v Teva (UK) Limited, Cipla (EU) Limited, Thornton & Ross Limited, Genus Pharmaceuticals Limited* [2024] EWHC 796 (Pat)

5 *Comptroller-General of Patents, Designs and Trade Marks v Emotional Perception AI Ltd* [2024] EWCA Civ 825

6 *Arrow Generics Ltd v Merck & Co Inc* [2007] EWHC 1900 (Pat)

7 *Pfizer Limited v GlaxoSmithKline Biologicals S.A and Id Biomedical Corporation of Quebec* [2024] EWHC 2523 (Pat)

8 [2024] EWCA Civ 396

to show that these hypothetical examples were part of the CGK. **Birss LJ** indicated that this was not the correct approach to patent construction. Patents are construed through the eyes of the person skilled in the art, imbued with the CGK. If matter is not set out in the patent and is not part of the CGK, then it is not relevant to construction. **Birss LJ** also reminded the parties that limitations not present in the claim language are not to be read in by reference to examples which appear in the specification, even where those examples are consistently more limited than the broad language of the claims.

Interestingly, the case also deals with the role of the inventive concept in the interpretation of patent claims. The defendant had submitted that the Judge, at first instance, erred in arriving at a construction which was inconsistent with the inventive concept disclosed in the patent. However, **Birss LJ** explained that the defendant had this the wrong way round. Identifying the inventive concept may be useful when considering obviousness or equivalence; however, it is something which can only be done properly *after* construing the claims. Therefore, it is the inventive concept which ought to be consistent with, and follow from, the properly construed claims (not the other way around).

A few months later, construction issues were again before the Court of Appeal in *Sycurio v PCI-PAL*[9], illustrating the importance of having regard to claim language that is clear on its face, even if broad. In this case, the patent related to the secure processing of payments by telephone to a call centre, seeking to prevent fraud by blocking from the call centre agents the dual-tone multi-frequency (**DTMF**) data produced when the customer enters sensitive details using the telephone keypad. The point on appeal was whether the integer of independent claim 9, requiring transmission of *"said request via a data interface to an external entity"*, required the request to be sent directly to the external entity without entering the call centre's data processing environment. **Arnold LJ**, giving the lead judgment, upheld **Bacon J's** first instance decision finding that the claim was drafted in broad and general terms and was not limited to covering a situation where the call processing system lies outside the boundary of the call centre environment. He observed that all that is required was transmission *"via a data interface to an external entity"*. As such, the language on its face covered both direct and indirect routes of transmission. Furthermore, given that the specification disclosed a variety of possible embodiments, including some where sensitive data is processed within the call centre environment, there was nothing to support the idea that the claims embraced some embodiments and not others.

However, clear and seemingly unambiguous claim language is not necessarily unyielding when applying the purposive approach to claim construction. Remember *Catnic*[10], and the word *"vertical"*? In *Advanced Cell Diagnostics Inc v Molecular Instruments Inc*[11], the issue was whether claim language requiring *"non-overlapping"* regions of nucleic acid hybridisation (in the context of an invention to in situ nucleic acid detection by capture probes) was infringed by products which hybridized to *overlapping* regions. Acknowledging that this required *"a more than usual degree of mental gymnastics"*, **Meade J** held that the claim did not mean *"completely non-overlapping"* (and referred to *Catnic* by analogy). This, and two further points of construction, turned on the basis that the language of the patent was *"broad and inclusive"* whereas Molecular Instruments had advanced an *"excessively literal and linguistic"* approach. As such, had the patents been valid, he would have found infringement under normal/purposive construction.

9 [2024] EWCA Civ 606

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

11 *Advanced Cell Diagnostics Inc v Molecular Instruments Inc* [2024] EWHC 898 (Pat)

It's hard to use purposive interpretation to effectively delete a word from within the claim language, as might happen when the claim uses the indefinite article "a" to denote the singular and the argument is advanced that the claim should also cover the plural. Exactly this situation arose in *Pfizer v GSK*[12] in which **Mellor J** considered the validity and infringement of two of GSK's patents relating to its RSV vaccine. Under a normal construction the issue of infringement hinged on the claim wording *"a soluble F protein polypeptide comprising an F2 domain and an F1 domain"*. The description of both patents in issue contained a definition of a polypeptide, namely *"a polymer in which the monomers are amino acid residues joined together through amide bonds"*. Pfizer and its expert took the view that Pfizer's RSV vaccine was comprised of two polypeptides. The Judge agreed and as such there was no infringement of either patent under normal construction.

Infringement under the doctrine of equivalents

The specificity of the claim language in *Pfizer v GSK*[13], mentioned above, meant that as well as there being no infringement under the normal interpretation of the claims, there was no infringement under the doctrine of equivalents: the definition of "polypeptide" led **Mellor J** to find that the patentee had probably intended strict compliance with the claims under the third *Actavis*[14] question, which put an end to the matter.

The determination of inventive concept is key to the doctrine of equivalents. The extent to which a party may modify its case on inventive concept after a judgment has already been rendered on the point was an issue before **HHJ Hacon** in *Safestand v Weston*[15], concerning a declaration of non-infringement (**DNI**) on Weston's products, modified in light of an earlier infringement ruling. Refusing to strike out the infringement allegations under Safestand's modified inventive concept, the case was allowed to proceed to trial on the basis that Safestand was not making a binding choice (following *Express Newspapers*[16]) and therefore did not fall foul of the doctrine against approbation or reprobation (a rule against taking inconsistent positions in litigation). The Judge explained that Safestand was required to argue its infringement case by reference to the findings in the earlier decision on the patents, but whether its new case on inventive concept is consistent with that is an arguable matter for trial rather than something that was capable of being decided on an interlocutory basis.

On the other hand, Weston's *Formstein* defence was struck out. This defence was based on prior art which had been raised at the first trial. One of the prior art citations was considered and the patent found inventive over that citation. **HHJ Hacon** considered that an argument relying on that same prior art as a *Formstein* defence would require the Court to consider the same issue it had already decided and as such would give rise to an estoppel following *Virgin v Zodiac*[17]. An alternative citation (a prior use) was also raised on the first day of the substantive trial and was not permitted into the case. **HHJ Hacon** considered it would not be in conformity with the rule in *Henderson v Henderson*[18] to permit a *Formstein* defence to be run using this prior use citation given the finding that Weston *"could and should have pleaded that case in good time for it to be argued at the substantive trial"*.

Unusually, in *Cloud Cycle Ltd v Verifi LLC*[19] validity was not challenged and infringement was only argued on the basis of equivalents. The central question before the Judge, **Recorder Douglas Campbell KC**, was the inventive concept of claim 1, relating to the measurement of *"slump"* in concrete mixing trucks through the use of sensors. In finding no infringement, the Judge rejected the

12 *Pfizer Limited v GlaxoSmithKline Biologicals S.A and Id Biomedical Corporation of Quebec* [2024] EWHC 2523 (Pat)
13 [2024] EWHC 2523 (Pat)
14 *Actavis Group PTC EHF v ICOS Corp* [2019] UKSC 15
15 [2024] EWHC 2807 (Pat)
16 *Express Newspapers Plc. v News (U.K.) Ltd. and Others* [1990] F.S.R. 359
17 *Virgin Atlantic Airways Limited v Zodiac Seats UK Limited* [2013] UKSC 46
18 [1843] 3 Hare 100
19 [2024] EWHC 2001 (Ch)

arguments of both parties and used his own formulation of the inventive concept. He comforted himself by performing a cross-check under the Protocol on the Interpretation of Art. 69 of the EPC, as **Arnold LJ** had done in *FibroGen*[20].

Territoriality

When a step in a process claim is conducted abroad, where does that leave the issue of infringement in the UK? A new case on this point, extending the *Menashe*[21] and *Illumina*[22] line of jurisprudence, came before **Mellor J** in *Sandoz v Biogen*[23]. The proceedings related to Biogen's patent for a method of assessing a patient's risk of developing progressive multifocal leukoencephalopathy (**PML**) based on an index value reflecting the patient's anti-JCV antibody titre. According to the method of the claim, a patient would be determined to be at high risk of PML above a specified index value.

Sandoz had developed an anti-JCV antibody test that would be offered to clinicians in the UK. The assay of the patient's serum or plasma sample – including the generation of the index value – would take place abroad. All other steps, including the taking of blood and the review of the index value by the clinician in their assessment of PML risk, would take place in the UK.

Biogen alleged that Sandoz would infringe the patent in suit as it threatened and intended, in the UK, to use the method of the claims and/or offer the method of the claims for use. The Judge considered the principles laid down in *Illumina*[24]. In *Illumina* it was held that the substance of the method claims was used in the UK and only the automated aspects were conducted offshore. Sandoz argued that in this case, conversely, the substance of the method would be carried out outside the UK.

Mellor J agreed that there was no doubt that the main elements of the method were conducted outside the UK. While Biogen submitted that the clinician in the UK would use the method, the Judge held that once the index value was received, there would be no exercise of clinical judgment and so the core of the method would be used outside the UK. The fact that the clinician and the patient in the UK would benefit from the results of the method did not mean that the method was being used in the UK.

Joint tortfeasance

As part of the *Advanced Cell Diagnostics Inc v Molecular Instruments* case mentioned above[25] in which **Meade J** considered infringement of patents owned by Advanced Cell Diagnostics (**ACD**) by Molecular Instruments (**MI**) in relation MI's nucleic acid hybridization products, a territoriality question arose in relation to importation. MI denied infringement on the basis that title had passed to its UK customers in the US and as such, it did not commit any infringing act in the UK. However, infringement by MI was also alleged on the basis of joint tortfeasance with its customers, which became the focus of the decision on infringing acts in relation to the method claims in one of the patents.

Applying the Supreme Court's principles from *Fish & Fish v Sea Shepherd*[26], **Meade J** held that MI was indeed a joint tortfeasor with some of its customers by providing troubleshooting assistance, which led to the requirements of the method claims being fulfilled in the UK. Regarding such customers, MI knew the exact parameters being used, would steer and recommend the choice of parameters and would provide such assistance in a common design. It did not matter that it was the customers who initiated the troubleshooting process or that MI was not contractually

20 *FibroGen Inc v Akebia Therapeutics Inc* [2020] EWHC 866 (Pat)

21 *Menashe Business Mercantile Ltd v William Hill Organization Ltd* [2002] EWCA Civ 1702

22 *Illumina Inc v Premaitha Health Plc* [2017] EWHC 2930 (Pat)

23 *Sandoz AG and others v Biogen MA* [2024] EWHC 2567 (Pat)

24 [2017] EWHC 2930 (Pat)

25 [2024] EWHC 898 (Pat)

26 [2015] UKSC 10

obligated to provide it. In contrast, for customers to whom MI just provided its products with standard instructions, no such joint liability arose. Therefore, had the patents been valid, MI would have been jointly liable for infringement of the method patent. The product patents, however, were held not to be infringed since the claims concerned kits with a permeabilising agent, which was not included in MI's kits on import.

In a dispute between *Insulet v Menarini Diagnostics*[27], **Richards J** dismissed an application to set aside an Order allowing service outside the jurisdiction on the basis that Insulet had a realistic prospect of success in showing that EOFlow (the overseas defendant) on whom service was sought would be held at trial to be acting in a common design with the other defendants in relation to infringement of a patent relating to an insulin pump. On the facts of the case at hand, EOFlow had entered a distribution and service agreement with the other defendants. The Judge considered that on the basis of certain clauses of the agreement and a press release issued when the agreement was signed, it was at least realistically arguable that there was a common design between the defendants, including EOFlow.

EOFlow had argued that there was no pleading of communication, evidenced or inferred, that constituted inducement or persuasion in relation to dealing in the UK. **Richards J** held that he did not consider *"communication"* an essential matter of the law on common design and referred to the leading case of *Lifestyle Equities*[28]. He accepted there would usually be a communication but at this stage of the proceedings it was realistic to consider that there were discussions on the nature of the arrangement between all the defendants, including EOFlow. An application to appeal the decision was refused, the Judge considering that this case was not setting a precedent for any overseas defendant in a distribution and supply agreement to become a party to a UK infringement case as a multifactorial assessment was needed.

Waiver

The prelude to the mRNA vaccine patent wars came in October 2020 when Moderna made a statement that it would not enforce its COVID-19 patents against those making vaccines intended to combat the pandemic, for so long as the pandemic continued. Then, in March 2022, it *"updated"* its pledge to apply only to companies manufacturing in or for low- and middle-income countries. In *Pfizer and BioNTech v ModernaTX*[29], Pfizer argued that Moderna's pledge precluded it from being able to enforce its patents against Pfizer until May 2023 when the Emergency Committee advised the WHO that COVID-19 no longer constituted a public health emergency of international concern and as such, the pandemic ended.

However, **Richards J** held that the 2020 statement was not a promise or guarantee, but a *"forward-looking statement"*. Indeed, it included a sentence that the document was neither a promise nor guarantee and readers should not place undue reliance on it. It was a statement of Moderna's contemporaneous intention, which Moderna reserved its right to change. As such, no binding unilateral contract arose. **Richards J** further held that Moderna had not waived its patent rights under US federal law. At most, the 2020 statement constituted a temporary forbearance to sue, but this was not an express waiver of patent rights. Even if it was an express waiver, it was validly retracted via the 2022 statement. However, **Richards J** did agree with Pfizer to the extent he found that it had received non-contractual consent to do otherwise infringing acts in the period between the two statements.

27 *Insulet Corporation v Menarini Diagnostics Limited and others* [2024] EWHC 3086 (Pat)

28 *Lifestyle Equities v Ahmed* [2024] UKSC 17

29 *Pfizer Ltd, BioNTech SE v ModernaTX Inc* [2024] EWHC 1648 (Pat)

Validity

The skilled person and their common general knowledge (CGK)

When considering the identity of the skilled person or team, an early question to consider is whether the person or team is the same for inventive step and sufficiency. In *Schlumberger*[30] type cases where there is a difference, the test set out by **Birss J** in *Illumina v Latvia*[31] should be used to define the skilled person or team. In fact, in *Pfizer v GSK*[32], **Mellor J** indicated that the Illumina questions were universally useful, even where there is no difference in the skilled team for assessing obviousness and insufficiency. They guard against a hindsight approach in which a team is assembled based on the solution in the patent and not the problem in the established field. **Mellor J** noted that another way of guarding against a hindsight approach is to address at the outset what an undisputed member of the skilled team would do having read a cited piece of prior art. In this case, the issue was whether or not a structural biologist would be on the team in addition to a vaccinologist. Both approaches confirmed that a structural biologist would also be on the team.

In addition to providing helpful guidance on how to assess the composition of a skilled team, the case also serves as a reminder to practitioners preparing expert evidence that it is now expected that experts reflecting different members of the skilled team should communicate. Whilst GSK, the patentee, had prepared evidence from both team members, it had failed to facilitate communication between the experts and thus faced criticism for taking a siloed approach and for its vaccinologist evidence on CGK being too narrow. In particular, GSK's skilled vaccinologist had considered it would not be CGK for a vaccinologist looking to make an RSV vaccine to look at other, structurally related vaccines. Ultimately, GSK's patents were found to lack inventive step.

Novelty

If asked to explain the concept of mosaicking in relation to prior art, most UK practitioners would probably say that combining prior art citations is only acceptable in relation to inventive step and only where obvious to do so, such as where there is a clear cross-reference in one of two documents to the other, allowing both to be read together. Take note, therefore that, in *ACD v MI*[33] **Meade J** explained that there is no absolute rule against mosaicking in relation to novelty. However, he noted it is only possible where the pointer from one document to another is clear and unmistakeable. A general cross-reference is not good enough. In the prior art document in question, there were two footnote citations to the second prior art document. **Meade J** held these were pointers to the skilled person that there was relevant and interesting information on the subject matter in the second document, but did not disclose what that information was or how to use it. Thus, on the facts there was no anticipation as the cross-reference was too general and the disclosure of the referred-to piece of prior art was not sufficiently clear.

The idea of a clear and unmistakeable pointer arose in a different context – that of making a selection from a list – in *ModernaTX v Pfizer*[34]. Here, Moderna asserted two patents against Pfizer in respect of the latter's SARS-CoV-2 vaccine, *"Comirnaty"*. The first related to modified mRNA wherein the uracil bases are replaced with N1-methyl-pseudouridine. **Meade J** rejected Pfizer's novelty attack on this patent, finding that the references in the key piece of prior art to N1-methyl-pseudouridine did not amount to an individualised disclosure. Even if it was individualised, choosing it from the long list

30 *Schlumberger Holdings Limited v Electromagnetic Geoservices AS* [2010] EWCA Civ 819

31 [2021] EWHC 57 (Pat)

32 [2024] EWHC 2523 (Pat)

33 [2024] EWHC 898 (Pat)

34 [2024] EWHC 1695 (Pat)

in which it was found would be a selection without a clear and unmistakeable pointer to do so. He held the prior art disclosure was extremely tentative and open ended, and the extent of what it was proposing and its reasons for doing so were both woolly. Interestingly, in a parallel Dutch case, the Court had found the Dutch patent to be anticipated by the same prior art. **Meade J** acknowledged that an opposite finding from such a court was reason for him to stop and check his result. However, he concluded that this judicial divergence stemmed from differing evidence before the courts and was affected by the fact that the Dutch Court did not consider obviousness.

In relation to a second patent, concerning a beta coronavirus mRNA vaccine formulated in a lipid nanoparticle, anticipation was argued as a squeeze with added matter: if all the features were disclosed by the application as filed so as to avoid added matter then, applying the same standard in a consistent way, they must be disclosed by the prior art in question. The argument was complicated by one claim feature (the treatment effect) being functional in nature, which led the Judge to consider but not conclude whether the feature was plausible across the scope of the claims. A conclusion on this point was, ultimately, not necessary because he found that the physical features of the claim were not adequately disclosed by the prior art or the application as filed. Whilst the lack of novelty argument failed because it required combining various disclosures from the prior art without any teaching to do so, the added matter argument therefore succeeded for the same reason.

In *Samsung BioEpis UK Limited v Janssen Biotech, Inc*[35], Samsung sought to revoke Janssen's patent to ustekinumab for use in the treatment of ulcerative colitis. Anticipation was alleged over a poster said to have been presented at a conference in Washington before the priority date. Samsung prevailed in a dispute over the publication date of the poster, largely thanks to a *"selfie"* taken by the poster author at the conference in question to show his wife that included some (but not all) of the poster content. However, **Meade J** held that the poster did not anticipate the patent. Although it referred to a study of the claimed antibody in the claimed use, it was a retrospective study of a small number of ulcerative colitis patients from an unblinded single-centre study with no control group or placebo. The Judge held that it did not demonstrate efficacy in the claimed therapeutic area.

Obviousness

Mindset and motivation are key components of obviousness, both involved in the question of whether the skilled person "would" (rather than merely "could") conduct a particular approach leading to the invention. One of the more interesting areas emerging from the case law in this area is the role played by clinical trials in life sciences cases. Where a clinical trial protocol is devised that ultimately leads to an invention, and the trial is at the expensive Phase III stage, is it the case that a skilled person reading the published protocol would regard it as obvious to do the work on the basis that something potentially useful is bound to result?

In *Samsung v Janssen*[36], the notorious "selfie" poster prior art not only failed to anticipate Janssen's invention but failed to make it obvious, **Meade J** deciding that it only provided a hope of success rather than the required "reasonable expectation". However, Samsung had also pleaded obviousness based on a set of slides containing positive phase III clinical trial results, which it argued would give the skilled person a high degree of confidence that the claimed antibody would work in the treatment of the claimed indication. **Meade J** agreed, but took care to limit the decision to its

35 [2024] EWHC 1984 (Pat)

36 [2024] EWHC 1984 (Pat)

facts. Janssen had filed the priority application before the publication of the slides, which only became prior art because entitlement to the claimed priority date for the relevant claims was lost. The Judge nevertheless sounded a warning note: *"Patentees can have limited room for manoeuvre when it comes to when they have to file for clinical approval, making trial protocols public, and filing a patent application. It would be a concern if the system made it hard for patentees in general to conduct clinical trials and at least have the chance to try to obtain a valid patent over a second medical use."*

Meade J was referred in argument to case law of the EPO Boards of Appeal (*T96/20* and *T239/16*) to the effect that publication of a detailed safety and efficacy clinical trial protocol creates a presumption that there is an expectation of success, rebuttable only if there is evidence to the contrary in the prior art. He declined to adopt this position, noting that: *"I do not think this can be a presumption that is applicable in all circumstances or a general rule to be applied blindly. It depends on the facts. It may be relevant in an individual case that there is a clinical trial ongoing, especially if it is a major one, in phase III. The skilled person would be likely to assume that those sponsoring and undertaking the trial had reasons based on earlier work, or analysis of the mechanisms at work, for having an expectation of success. However, I think that greater importance would usually be attached by the skilled person to the concrete evidence about prospects of success that they could understand and analyse themselves."*

Availability to the public need only be short-lived if a disclosure is to become part of the state of the art, even if no longer available at the priority date. In *Sandoz v Bayer*[37], **HHJ Hacon** confirmed that prior art posters that were not available to the skilled person on the priority date of the patent, but which had been made available to the public by being presented at an earlier conference, could be mosaicked. Based on that mosaic, he concluded that the claimed use of rivaroxaban for the treatment of a thromboembolic disorder by means of once daily administration would be obvious[38].

In the context of motivation provided by clinical trials, the reasoning for the finding of obviousness in that case is particularly interesting. The two prior art posters comprised Phase I (safety) clinical trial results. On the basis of this information, the Judge ruled that the skilled team would have thought that it was worth applying to the ethics committee for permission to conduct a Phase II (efficacy) trial which included a once-daily dosing arm, and that it was likely that permission would be granted. **HHJ Hacon** held that this amounted to the same thing as a reasonable expectation on the part of the skilled team that a once-daily dose would be both safe and effective. His finding of obviousness was made in the face of evidence that the Board of Appeal of the European Patent Office had maintained the Patent as granted, that first instance courts in Australia, Belgium, the Netherlands (twice), Norway and Sweden had held that the claimed invention did not lack an inventive step and that the preliminary opinion of the German Federal Patent Court came to the same conclusion. As usual when validity decisions across EPC member states differ, the Judge was careful to point out that the evidence before him was also different.

When it came to the inevitable appeal,[39] this *"different evidence"* point became significant in itself. Bayer complained that HHJ Hacon had been influenced by its decision not to adduce in the UK the *"invention story"*, which had been told in other jurisdictions and explained

37 *Sandoz AG v Bayer Intellectual Property GmbH* [2024] EWHC 796 (Pat)

38 The authors are grateful to Claire Phipps-Jones in her assistance with the summary of the *Sandoz v Bayer* judgments

39 *Sandoz AG v Bayer Intellectual Property GmbH* [2024] EWCA Civ 562

that persuasion was necessary before the ethics committee because dose ranging with rivaroxaban, an anticoagulant, in trials for the first time in sick patients was risky: too much rivaroxaban and there was a risk of death by bleeding, too little and there was a risk of death by clotting.

The Court of Appeal disagreed and held that the Judge's finding of obviousness did not turn on this basis and was instead based on the correct legal criteria of whether the skilled team would have had a reasonable expectation that a once-daily dose would be safe and effective. Giving the leading judgment, **Arnold LJ** explained that it was common ground between the parties that the skilled team having read the two prior art posters would have carried out a Phase II trial of rivaroxaban. Bayer did not challenge **HHJ Hacon's** finding that rapid-release rivaroxaban would have been used for such a trial, and it was common ground that, if the skilled team decided to include once daily administration of rivaroxaban in the trial, it would have been used as specified in claim 1 of the Patent. There was also no dispute that the skilled team would have considered whether to include once daily administration as a regimen in the Phase II trial. The only issue was whether the skilled team would have had a reasonable expectation of success with respect to once daily administration. Whilst Bayer complained that the Judge had mischaracterized the case as one in which the skilled team was concerned with approval by an ethics committee, and not with the technical question of whether the claimed once-daily administration would be safe and effective, **Arnold LJ** noted that elsewhere in his decision the Judge had applied and answered correctly the correct legal question. As such, the Court of Appeal dismissed the appeal, upholding the invalidity finding based on obviousness.

Testing obviousness by using the approach set out in *Pozzoli*[40] remains standard procedure in the UK. In *Pfizer v GSK*[41], one of the grounds on which obviousness was pleaded relied on materials (an abstract together with the associated slides and oral disclosure) made available to the public at a conference. Applying the *Pozzoli* test, **Mellor J** found that the difference between these materials and the patents was the identity of the virus whose F protein was stabilised in accordance with the invention. Given the Judge's findings on who was in the skilled team and matter which should be considered CGK, it was held that the skilled team would have been aware of the analogy between two viruses (PIV (parainfluenza) in the prior art and RSV as claimed in the patent) and would consider it obvious that they could make a stabilised form of the pre-fusion conformation of the F protein of RSV.

There are, however, cases in which the *Pozzoli* approach does not necessarily form the most useful framework for assessing obviousness. For example, it was not used by the parties in *ModernaTX v Pfizer*[42] in respect of either of the two patents in suit. In the case of one patent, it was accepted that the differences between the prior art and the claimed invention would be obvious if key decisions were made about looking for and identifying other modified nucleotides. In the case of the other patent, the issue was not the physical differences between the embodiment taught in a specific example from the prior art and the claimed invention, but whether the skilled person would have decided to proceed with an mRNA vaccine for MERS-CoV starting from that example. One patent was upheld, the other revoked.

Very occasionally, a case settles but proceedings continue. So it was in the litigation between JCB and Manitou concerning telehandlers, which yielded a first instance

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

41 [2024] EWHC 2523 (Pat)

42 *ModernaTX, Inc. v Pfizer Limited, Pfizer Manufacturing Belgium NV, Pfizer Inc., BioNTech Manufacturing GMBH, BioNTech SE* [2024] EWHC 1695 (Pat)

decision from **HHJ Hacon** in 2022[43]. Permission to appeal was given and although settlement followed, the terms of the settlement allowed JCB to appeal the invalidity finding against one of its patents (three were found invalid at first instance) without Manitou's involvement. As is established practice, following the Court of Appeal decision in *Halliburton*[44] and CPR PD 52D 14.1(6)(b), the UK IPO was informed of the appeal and made representations to the Court. Giving the leading judgment, **Birss LJ** overturned the finding of obviousness from the court below. It is unusual for the Court of Appeal to interfere with the findings of the judge below on matters relating to the evidence. However, here, **Birss LJ** explained that **HHJ Hacon** had been under a mistaken assumption about the disclosure of a given method in the prior art, attributable to confusing submissions by JCB. This only became apparent following submissions filed after the appeal hearing, at the request of the bench, in relation to the closing arguments made at first instance.

Coming full circle to where we began on obviousness, the issue of motivation came closely under the microscope before **Mellor J** in the context of a patent licensed to Astellas for the small molecule enzalutamide[45]. As readers familiar with life sciences cases will know, challenges to patents claiming the basic molecule for a pharmaceutical product are rare, and successful challenges even more so, the fallen apixaban patent[46] being the only UK example in recent times. Unlike the outcome of the apixaban litigation, here the patent was upheld as valid, illustrating the difficulty in toppling such monolithic rights.

The obviousness case centred around two prior art citations – a poster and a set of slides – which originated from the inventors' work. The slides and poster both disclosed what was agreed to be the closest prior art compound, RD162, which differed from the claimed compound, RD162' (enzalutamide), by a single alternative substituent at *"Position X"*.

Broadly speaking, the generics challenging the patent put forward a case that it was obvious for the skilled team to investigate the structure-activity relationship, assisted by computer modelling, as part of the drug discovery process and that the change in substituent was a small one which would have been found as a matter of routine. Astellas disagreed and raised secondary evidence illustrating that in real life the course of action adopted to modify the molecule was different from the obviousness case proposed. **Mellor J** noted a particular difficulty with obviousness assessments in cases such as this, which is whether the skilled team would be motivated to move away from the prior art molecule (rather than be content with it, given its good efficacy and other useful properties). This is because they would realise it would be proprietary to the authors of the prior art document and very likely already patented, and hence beyond reach. Indeed, the Judge noted that: *"This case raises, in an acute form, the issue as to the extent to which competitive and patenting considerations should influence an obviousness analysis"*.

In relation to the slides cited as prior art, the Judge noted the case was finely balanced and he had changed his mind more than once. The Judge ultimately favoured the patentee's expert evidence and made three points that are useful to bear in mind for any case on obviousness. First, if steps are obvious, it should be possible to explain this clearly and in the evidence in chief. Second, in litigation there is intense focus and much analysis of the route(s) to obviousness and obstacles. Third, it is unsurprising that, with skilful cross-examination driven by an intense focus on the target, obviousness arguments may appear to

43 [2022] EWHC 1724 (Pat)

44 [2006] EWCA Civ 1715

45 *Accord Healthcare and others v (1) Regents of the University of California; and (2) Astellas Pharma Europe Ltd* [2024] EWHC 2524 (Pat)

46 *Sandoz Ltd & Ors v Bristol-Myers Squibb Holdings Ireland Unlimited Co.* [2023] EWCA Civ 472

have force. Although **Mellor J** noted that, as a matter of principle, this did not mean that an obviousness case could not be proved through cross examination of a patentee's experts, in the specific circumstances of this case, he did not consider he had sufficient primary evidence to establish a finding of obviousness and the validity of the patent was upheld.

Secondary evidence

Obviousness cases are so multifaceted that sometimes secondary evidence is adduced in support of a party's argument, this being any evidence other than the primary evidence comprising the opinions of the expert witnesses in the case. Often it is factual evidence, such as a contemporaneous account of what actually happened in the real world. As mentioned above, in *Accord v Astellas*[47], Astellas raised some points of secondary evidence to demonstrate that the skilled team in real life took a route different from the route proposed by the patent challengers as being obvious for the hypothetical skilled team. Illustrating that it is almost always less preferred than the primary evidence, **Mellor J** placed no weight on any of it.

The impact of secondary evidence was also considered by **Meade J** in in the *Pfizer v GSK*[48] case. As with the *Accord v Astellas* case, nothing turned on the secondary evidence - the Judge found he had compelling primary evidence of obviousness and further held that the secondary evidence was not complete or persuasive enough to displace that. Nevertheless, **Meade J** made a number of practical observations which practitioners might find useful as to how a secondary evidence case should be run. The overarching observation is that cases of secondary evidence should be fully pleaded so as to allow responsive pleadings, appropriate case management directions and consideration in both written and oral evidence before the Court: *"In future, ... if a party does not plead its case on secondary evidence, it will run the risk of an objection to it being upheld and/or the Court refusing to take it into account. The rules of pleading apply just as much to Patent cases as any other type of case"*.

Against this background, none of which is controversial, the case of *Pfizer v UniQure*[49] stands out as being unusual. Here, **HHJ Hacon**, sitting as a Judge of the Patents Court, was faced with a case where obviousness was pleaded in relation to a single prior art citation against UniQure's patent concerned with nucleic acid for use in gene therapy treatment of haemophilia B. The only difference between the protein of the prior art and that encoded by the nucleic acid of the patent was a single amino acid at a position that was acknowledged to be of no inventive significance. The arguments on the multifactorial question of inventive step were framed around expectation of success in an *"obvious to try"* analysis.

The Judge noted that *"on certain facts, obviousness could turn on just one factor. In such an instance, inevitably the evidence and argument will largely, or even wholly, concern that factor"*. This led him to consider the secondary evidence first – before the primary evidence of the experts in the case – seemingly on the basis that he found it so compelling. Here, the facts before the Court were that when the protein of the invention was discovered in real life, it happened by serendipity, was met with *"considerable surprise and was regarded as a breakthrough, a game changer in the long pursuit of an effective means to treat haemophilia B"*. Consequently, the Judge formed the view that these facts *"strongly point towards an inventive step"*.

47 [2024] EWHC 2524 (Pat)
48 [2024] EWHC 2523 (Pat)
49 [2024] EWHC 2672 (Pat)

Of course, the Judge did go on to consider the expert evidence and considered that here *"the primary evidence explains the secondary evidence"*. In this regard, it was problematic for Pfizer that little weight was given to their expert evidence on gene therapy (for reasons explained later in this review), leaving the Judge to prefer the evidence of UniQure's expert, supporting the patent's validity, who opined that the shortlist of amino acid options disclosed by the prior art patent specification would have been dismissed by the skilled team as being devoid of technical significance and merely *"as a scientifically meaningless bit of patent drafting"*. Accordingly, **HHJ Hacon** concluded that: *"It was not obvious to try using a gene encoding R338L-FIX for gene therapy in the treatment of haemophilia B with any reasonable expectation of success. In fact, there would have been a reasonable expectation of no success"*.

Extension of scope and added matter

Readers will recall the 2023 decision of **Charlotte May KC**, sitting as a Deputy High Court Judge in *Ensygnia v Shell*[50] in which Ensygnia's patent was found to be invalid for extension of scope, added matter and obviousness. **Arnold LJ** had granted Ensygnia permission to appeal all of the invalidity findings (expressing some doubt over the obviousness appeal) whilst Shell was granted permission to appeal the Deputy Judge's finding on construction. In giving the leading judgment, **Birss LJ** upheld the High Court's findings.

At first instance, the Deputy Judge held that claims should be read in light of the whole description, notwithstanding that embodiments in the description were said to be excised from the scope of the claim. This approach led to the Deputy Judge finding that the skilled person would understand the *"sign"* of claim 1 to be a non-electronic static sign such as a piece of paper. This was upheld by the Court of Appeal. They noted that reading such specific limitations into general words in patent claims is not usually conducive to reasonable certainty for third parties but in this case it was the only way to make sense of the amended specification. The Deputy Judge's findings on invalidity by reason of added matter and extension of scope were also upheld: the claim of the post-grant amended specification did cover a non-electronic static sign, whereas the claim of the patent as granted did not.

Plausibility / Insufficiency

Billed as making *"a major contribution to one of the most important challenges which faced the medical use of mRNA at the priority date"*, CureVac's patents provided yet more material for the courts in their adjudication of the vaccine wars. The central issue in *BioNTech v CureVac*[51], was the plausibility or sufficiency of the patents, characterised by CureVac as providing *"... a novel class of mRNA molecules as defined in claim 1, all or substantially all of which provide for improved expression of an antigen derived from a viral pathogen associated with an infectious disease, such improved expression resulting from the mRNA having the Poly(A) sequence identified in the claim"*.

In deciding the attack of insufficiency, made on a claim scope basis, **Meade J** was required to assess whether (1) the technical effect was disclosed in the patent, (2) if yes, whether it was plausible across the scope of the claims, and (3) whether it was possessed by substantially all mRNAs covered by the claims. On (1), **Meade J** noted that the law allows the patentee some flexibility in identifying the technical contribution (thereby allowing the patentee to reframe it to some extent, e.g. to meet a new piece of prior art). CureVac argued the technical effect was the introduction of a

50 *Ensygnia IP Ltd v Shell UK Oil Products Ltd* [2024] EWCA Civ 1490

51 *BioNTech SE, Pfizer Inc., v CureVac SE & ors* [2024] EWHC 2538 (Pat)

linker to produce an mRNA with a split poly(A) tail, which improves protein expression. The Judge held this was not disclosed at all, either by the specification generally nor, in particular, in view of the data in the patent (in relation to which certain CGK theories could have explained the improved expression).

On (2), applying *Warner-Lambert*[52], **Meade J** held the effect was not plausible in any event in view of the general doubt and uncertainty in the CGK regarding degradation pathways. Interestingly, the Judge commented that it still must be possible to have a plausible patent which presents a brand-new idea for the first time, which the skilled person would understand would work purely from the CGK. However, he considered this would be more likely in the mechanical field than second medical use life sciences cases, which he noted is what the Supreme Court was considering in *Warner-Lambert* when it held essentially that one cannot base plausibility on the CGK without support from the patent application itself.

Finally on (3), the number of mRNAs covered by the claims was *"colossal"*, yet the experimental evidence before the court was in the order of 100 sequences and so did not *"even being to scratch the surface of the claims"*. Unsurprisingly, the Judge held that the technical effect was not demonstrated across substantially the whole of the claim and accordingly the patents were invalid.

The case of *Sandoz v Biogen*[53] addressed many issues but sufficiency was one of the most notable. As mentioned above, Sandoz challenged the validity of Biogen's patent for a method of assessing a patient's risk of developing progressive multifocal leukoencephalopathy (**PML**) by scoring the patient's anti-JCV antibody titre. For the patent in suit to be sufficient on the Judge's preferred construction, the skilled team needed to be able to produce a test that identifies an individual as being at high risk of developing PML at an index value of 1.5 that is the same anti-JCV antibody titre as in the test disclosed in the patent. **Mellor J** held that the skilled team would be unable to do so (classical insufficiency), and that even if by chance they had, they would not have known this (uncertainty insufficiency). A key point was that the index value was calculated by reference to a claimed but undisclosed cut-off calibrator. **Mellor J** held that although it may be difficult for a patentee to describe a calibrator in words, which does not excuse them from the requirement to make an enabling disclosure. Although Biogen described them as burdensome, there were options available to meet the disclosure requirement such as depositing a calibrator and making it available on request.

Sandoz also made use of secondary evidence to support its case on insufficiency. Notably Sandoz had only been able to develop its own anti-JCV antibody test because it had access to post-priority samples and results that had been tested using Biogen's commercial test (which would not have been available to the skilled person at the priority date). Even then, it took Sandoz 18 months to develop their own test and the index value output from the Sandoz test did not correspond exactly with the output from the Biogen test.

Excluded subject matter

Sir Anthony Mann's decision in *Emotional Perception AI's Application*[54] in last year's review was celebrated for taking a permissive approach to the patenting of AI inventions in the UK and marking a shift in UK IPO practice. Readers may recall the appeal to the High Court had reversed the Hearing Officer's decision, with the High Court holding that an artificial neural network (**ANN**) was not excluded from patentability under s. 1(2) of

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

53 *Sandoz AG v Biogen MA Inc* [2024] EWHC 2567 (Pat)

54 *Emotional Perception AI Ltd v Comptroller-General of Patents, Designs and Trade Marks* [2023] EWHC 2948 (Ch)

the Act. The invention in question was an ANN-based system for providing media file recommendations to a user, such as might be received from a digital music facility.

2024 saw the further appeal of the case to the Court of Appeal and a further reversal of fortune for Emotional Perception: **Birss LJ** gave the leading judgment in the Court of Appeal[55] (with **Arnold LJ** and **Nicola Davies** LJ agreeing) and allowed the Comptroller's appeal, ruling that an ANN is a computer and the weights and biases, which are acquired through training and applied by the ANN to the input, are a computer program. Accordingly, the exclusion from patentability under s. 1(2) of the Act was engaged.

In deciding whether the claimed invention nevertheless involved a substantive technical contribution that meant that it was patentable, **Birss LJ** agreed with the Hearing Officer that the functionality of providing improved file recommendations was *"subjective and cognitive"* in nature and hence the subject matter of the application remained excluded.

Although perceived by some as a setback to the UK's promotion of AI technology, it is worth noting that the approach taken by the Court of Appeal is consistent with the view on ANNs taken by the Technical Boards of Appeal at the EPO. However, permission has been granted for an appeal to the Supreme Court so the Court of Appeal judgment is unlikely to be the last word on the matter.

FRAND[56]

The English courts were kept very busy with FRAND issues in 2024. Highlights were:

- the Court of Appeal reviewing the second global determination of FRAND licence terms by the English Court in *InterDigital v Lenovo*;
- the Patents Court had the opportunity to consider how to deal with a claim against a patent pool and the relevance of FRAND to non-essential patents; and
- the courts also considered issues arising from parallel SEP/FRAND proceedings, manifested in the form of applications for interim relief (including novel *"interim licence"* declarations), jurisdiction challenges, and case management issues.

Determination of FRAND licence terms

The Court of Appeal clarified the approach to determining FRAND licence terms in *InterDigital v Lenovo*[57], considering the FRAND rate, methodology and principles applied by **Mellor J** at first instance.

The Court of Appeal overturned **Mellor J's** determination of the FRAND rate. Both **Birss LJ** and **Arnold LJ** found that the first instance judge's reasoning was internally inconsistent: on the one hand, finding that heavy discounting for past sales was not FRAND and that Lenovo should not benefit from non-FRAND factors; yet, on the other hand, making no correction to eliminate this non-FRAND feature when determining the FRAND rate implied by the comparable licences. **Arnold LJ** considered that the market rate established by the comparables at first instance was sub-FRAND as InterDigital had been affected by a degree of hold-out in those deals (demonstrated by being forced to give heavy discounts for past use). **Nugee LJ** expressed his doubts that the appeal should be allowed, on the basis that **Mellor J** was alive to the relevant issues, but did not go as far as to formally dissent.

The difficulty for the Court of Appeal was how to correct the FRAND rate derived at first instance as both parties were seeking their *"jackpot"* cases on appeal rather than putting

55 *Comptroller-General of Patents, Designs and Trade Marks v Emotional Perception AI Ltd* [2024] EWCA Civ 825

56 For those readers not accustomed to the world of standard-essential patents (**SEPs**), **Birss J** provided helpful guidance in *TQ Delta v ZyXEL* [2019] EWHC 1089 (Pat) on the distinction between fair, reasonable and non-discriminatory licence terms: **FRAND** and **RAND**: *"This action concerns standard essential patents which relate to the ITU-T standard concerned with DSL. The obligation which the standard essential patent holders have relation to this standard setting environment is to give licences on a RAND basis. The obligation is RAND rather than FRAND. I will almost certainly use the expression FRAND by force of habit but it makes no difference whatsoever."*

57 [2024] EWCA Civ 743

forward any middle ground to seek to quantify the distortion alone. The Court of Appeal therefore *estimated* the revised FRAND rate as $0.225 per unit (previously, $0.175) when taking into account a modified adjustment ratio and accordingly arrived at a lump sum figure of $178.3m (previously, $138.7m).

As to the top-down cross-check analysis contended for by InterDigital on appeal, the Court of Appeal agreed with **Mellor J** that the comparables analysis provided a much more reliable basis for estimating FRAND, but noted that its corrected rate of $0.225 was, in any event, less inconsistent with the top-down analysis than the first instance rate.

InterDigital's final ground of appeal was that the finding at first instance, that it had acted as an *"unwilling licensor"*, was wrong and it should now be granted a declaration that it was a willing licensor. The Court of Appeal did not reach a conclusion on whether InterDigital was or was not a willing licensor because it held that the declaration sought would not serve a useful purpose. However, it made clear that an SEP holder's conduct or willingness is unlikely to impact the FRAND licence terms determined by an English court, unless it is egregious, in which case this may affect the award of interest or the position on costs.

As to Lenovo's cross-appeal, both grounds were rejected. First, the Court of Appeal held that limitation periods do not apply to FRAND terms, noting that the context and purpose of a FRAND determination is quite different to a damages claim. The Court held that a willing licensee would agree to pay for its use from the day when it first implemented the relevant standard; as such, Lenovo should pay royalties in respect of all of their past sales. Second, it held that the Court has the power to award interest and this was payable on the sum held to be FRAND at a rate that reflects the time value of money – here, 4% compounded quarterly.

Applications for interim relief

Conventional wisdom dictates that applications for preliminary injunctions (**PIs**) in the UK will fail in any case where damages are an adequate remedy. The complexities of calculating monetary compensation in SEP cases does not change this dynamic. In *Motorola Mobility v Ericsson*[58], the claimants (Lenovo) were unsuccessful in obtaining a PI both at first instance and on appeal. The cases confirm the applicability of the *American Cyanamid*[59] test for a PI in the SEP context and highlight that the court will not look favourably on an application which may be characterised as *"anti-suit relief by the back door"*. In this case, Lenovo and the defendant, Ericsson, are in a multi-jurisdictional conflict over the global licensing of their respective SEP portfolios. Ericsson had already obtained a PI against Lenovo in Brazil and then Colombia and, in response, Lenovo sought a PI from the Patents Court. The relief sought was on *"unusual terms"* since Ericsson could avoid the injunction by agreeing to enter either a global FRAND cross-licence, an interim cross-licence, or another agreed mutual regime. Each alternative was aimed at nullifying the injunctions Ericsson had obtained in other jurisdictions. Lenovo argued that the relief was justified since it had been put at *"an illegitimate and unconscionable disadvantage in its licence negotiations with Ericsson by the terms of the Brazilian and Colombian interim injunctions"*.

The *American Cyanamid* question of irreparable harm was key, complicated by the fact that Lenovo sought to support its application on the basis of the harm it suffered in Brazil and Colombia. Lenovo also argued it would be damaged if it was forced to accept a cross-licence on supra-FRAND terms due to the *"coercive pressure of Ericssons actions"*. The Court disagreed, stating: *"the possibility that Lenovo might decide to accept the rates*

58 *Motorola Mobility LLC & Anor v Ericsson Ltd & Anor* [2024] EWHC 1267 (Pat) and [2024] EWCA Civ 1100

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

demanded by Ericsson rather than pursue this claim to trial does not establish that Lenovo will not be adequately compensated by royalties/ damages if the injunction sought is not granted". Additionally, the Court found there was a disconnect between the relief sought by Lenovo and the harm alleged. The relief was therefore not granted.

However, this is not the end of the story in respect of the award of interim relief in FRAND cases. The Court of Appeal's decision in *Panasonic v Xiaomi*[60] has established the authority of the English courts to grant declarations relating to an interim licence. The background facts are important: soon after proceedings were served, Xiaomi committed to take a FRAND licence on terms determined by the English Court which was reciprocated in the form of a mutual undertaking from Panasonic to offer such a licence. Citing the injunction risk it faced, Xiaomi made an application to expedite the FRAND trial to have it heard before parallel proceedings in Germany and the UPC. The trial was expedited but, for practical reasons, an injunction risk from the parallel proceedings remained which led Xiaomi to make its application for a declaration that a willing licensor in the position of Panasonic would agree to enter into, and would enter into, an interim licence to Panasonic's SEPs pending the determination by the English Court of FRAND terms for a final licence.

Leech J, at first instance[61], refused to grant the declaration Xiaomi sought but, by split decision, this was overturned by the Court of Appeal, which granted the declarations sought, subject to some modification of the terms of the interim licence. **Arnold LJ**'s judgment began by emphasising that *"the FRAND obligation extends to the process by which the parties negotiate for a licence"*. He then set out two preliminary points: (i) SEPs are not property rights of the same status as other patents, the SEP regime is a liability regime in which the SEP holder's remedy is a financial one and the *"only role"* for an injunction is to enforce the SEP holder's entitlement to that financial remedy; and (ii) the implementer is entitled to a licence from the first day it implements the standard provided it is willing to take a licence on FRAND terms. On the basis of these building blocks, **Arnold LJ** asked whether it was consistent with FRAND *"for Panasonic to try to force Xiaomi to agree to terms more favourable to Panasonic than the English courts would order by pursuing proceedings elsewhere with all the attendant cost and expense for both parties"*. He decided it was not and was therefore prepared to grant the declaration Xiaomi sought.

In contrast, in *Lenovo v Ericsson*[62] the request for an interim licence was rejected. Although Lenovo had committed to taking a licence determined by the English Court, Ericsson was not and instead had initiated a rate setting action in the Eastern District of North Carolina (**EDNC**). This difference was a crucial factor behind **Richards J**'s decision to deny Lenovo's application since, without mutual undertakings, the Court could not compel the parties to enter into the licence that the English Court would, in due course, determine. Furthermore, evidence was presented that Ericsson had already made a FRAND-compliant offer in October 2023. These factors influenced **Richards J**'s conclusion that while *"Ericsson's litigation strategy is certainly robust; I have no high degree of assurance that it is designed to secure supra-FRAND rates."* This supported the Judge's conclusion that Ericsson was not acting in bad faith by pursuing litigation elsewhere and was not obliged to offer an interim licence.

In *Alcatel v Amazon*[63], Amazon sought to amend its pleadings to include a claim for an interim licence to Nokia's SEPs. Unlike the other interim licence cases considered

60 *Panasonic Holdings Corp v Xiaomi Technology UK Ltd* [2024] EWCA Civ 1143
61 [2024] EWHC 1733 (Pat)
62 *Lenovo Group Ltd v Telefonaktiebolaget LM Ericsson* [2024] EWHC 2941 (Pat)
63 *Alcatel Lucent SAS v Amazon Digital UK Ltd* [2024] EWHC 1921 (Pat)

above, these patents were not subject to the ETSI[64] regime. Instead they were governed by an obligation under Swiss law which Amazon argued required Nokia *"(1) to enter into negotiations in good faith for a RAND licence and (2) to refrain from seeking to enjoin Amazon in the meantime"*. **Zacaroli J** decided that, under (1) above, all Nokia was obliged to do was *"to enter into a licence on RAND terms"*; this did not require it to enter a licence at an early stage pending resolution of the terms of the final licence. Additionally, the Judge thought that (2) would, if true, *"logically provide Amazon with a direct defence to injunction proceedings commenced in any jurisdiction"* but could not provide *"a positive obligation"* to enter into a licence before the RAND licence was concluded. As such, there was no sufficiently arguable case that Nokia was obliged to enter an interim licence and the amendment was refused. **Zacaroli J** also noted he would have refused to give directions to resolve the interim licence terms. He considered it *"wholly unrealistic"* that such an exercise could be completed in a few days and that it would be *"a waste of the parties' and the court's resources to hold two RAND trials"*[65].

Jurisdiction challenges

In *Lenovo v Ericsson*[66], Ericsson brought a jurisdiction challenge against Lenovo's claim for patent infringement and a declaration of FRAND terms for a global cross-licence between the parties, arguing that the English Court should decline jurisdiction in favour of Ericsson's rate setting action in the EDNC. The Court dismissed the application. **Richards J** held that the claim was, in form and in substance, about the vindication of patent rights and it was not possible at that stage to conclude that Ericsson would necessarily be a net recipient under any global cross-licence, such that the claim to a FRAND injunction would fail the merits test. Additionally, whilst the issue of FRAND terms was already before the EDNC, there was a possibility that those proceedings would not determine a FRAND rate for a global cross-licence and that action was unlikely to result in an earlier resolution of the dispute.

Likewise, the request by InterDigital to stay English proceedings pending the outcome of parallel German proceedings in *Lenovo v InterDigital*[67] failed, as **Richards J** considered there were no proceedings pending in Germany that would result in a court determining FRAND terms before the conclusion of the English proceedings.

However, a jurisdiction challenge was successful in *Tesla v Avanci and InterDigital*[68]. Tesla's claim included a request for a determination of FRAND rates to 5G SEPs in the patent pool administered by Avanci (the **Avanci Licence**), alleging that the terms offered by Avanci for such licence were not FRAND. The claim also included InterDigital as a representative member of the pool. **Fancourt J** held that InterDigital could not properly defend the licensing claim because the Court would need to assess the value of all the other 5G SEP-holders who have patents in the Avanci pool in order to determine a FRAND rate and InterDigital alone would not be able to provide that information. Accordingly, the claim against InterDigital was struck out. Further, the Judge held that there was no independent basis for the claim against Avanci (who had not made a FRAND Commitment) and that a potential remedial claim against Avanci in respect of loss following a failure by the pool patentees to grant a FRAND licence (on the basis that Avanci, as an appointed agent, was jointly liable for that failure) was too remote. **Fancourt J** also suggested that Tesla would have failed to show that England and Wales was clearly and distinctly the most appropriate forum to hear the dispute, bearing in mind that the parties were Delaware companies, the Avanci Licence is administered

64 European Telecommunications Standards Institute

65 This decision was, however, overturned by the Court of Appeal in January 2025, who gave permission for Amazon to advance its claim for an interim licence

66 [2024] EWHC 846 (Ch)

67 [2024] EWHC 596 (Ch)

68 [2024] EWHC 1815 (Ch)

and regulated in the US, only 7% of the 5G SEPs are UK designations and crucially, there was no indication that Tesla would not receive justice in the US.

The Court also considered how to deal with claims for licences extending to non-essential patents in 2024. InterDigital raised a jurisdiction challenge in *Lenovo v InterDigital*[69] after Lenovo had been permitted, by **Mellor J**, to serve its claim out of the jurisdiction. Critically, Lenovo's claim included a request that the court settle FRAND terms of a global licence to InterDigital's patents declared essential to ETSI cellular standards (referred to as **Cellular SEPs**) as well as patents which are declared essential to other standards (**Other SEPs**) and non-essential patents (**NEPs**). Although InterDigital accepted that the English Court had jurisdiction to settle terms of a licence for Cellular SEPs, they disputed that this was also the case for the Other SEPs and NEPs, relying on the principle in *Donohue v Armoco Inc*[70] that a single permissible claim could not be used as a Trojan horse to bring in other claims that were not themselves permissible. InterDigital argued that Lenovo's claim could never succeed since, in earlier proceedings between the parties, **Mellor J** had already decided that InterDigital was only obliged to offer a licence to the Cellular SEPs. Furthermore, it was InterDigital's option as to which of the FRAND licences it offered. **Richards J** was unpersuaded by this argument noting the evolving nature of the jurisprudence on the *"right to choose"* and stating that Lenovo might still legitimately want a declaration as to whether a licence including the Other SEPs and NEPs was FRAND, notwithstanding that InterDigital may not offer it. Therefore, **Richards J** considered Lenovo's claim did pass the merits test and as such the jurisdiction challenge failed.

Similarly, **Zacaroli J** considered there was an arguable case that Nokia's RAND commitment required it to grant a licence to Amazon that included an option to use NEPs belonging to a company in the same corporate group, Alcatel (albeit that Alcatel itself was not bound to grant a licence to its NEPs as it had not given a RAND commitment to ITU-T)[71].

Case management and preliminary issues

Readers will recall that in 2023 we reported a change to the practice for ordering trials in SEP litigation – with FRAND trials listed to be heard first, ahead of technical trials. This trend continued in 2024, with a number of FRAND trials also being expedited. In *Lenovo v Ericsson*[72] **Richards J** considered that the ordering of trials is a matter of discretion under the Court's case management powers and directed that the FRAND trial be heard first to help the parties focus on the core issue between them (the terms of a global FRAND licence).

In each of *Lenovo v Ericsson*[73], *Lenovo v InterDigital*[74], and *Alcatel v Amazon*[75] the Court considered there was good reason for expedition of the FRAND trial on the basis of commercial pressure exerted on the implementer by parallel proceedings where injunctions were being sought.

The Court has also shown itself willing to decide a preliminary issue so as to provide clarity on a term of an existing licence which would affect the scope of the main trial. In *Motorola v Ericsson*[76], Motorola claimed that 354 of its products were already licensed on the true construction of clause 2.4A of a 2011 licence agreed by the parties and applied for an order that the construction of clause 2.4A be determined as a preliminary issue. **Zacaroli J** granted the order sought, following the guidance of **Neuberger J** in *Steele v Steele*[77], that although the preliminary issue

69 *Lenovo Group Ltd & Ors v Interdigital Technology Corporation & Ors* [2024] EWHC 1036 (Pat)
70 [2001] UKHL 64
71 [2024] EWHC 1921 (Pat)
72 [2024] EWHC 1734 (Pat)
73 [2024] EWHC 1734 (Pat)
74 [2024] EWHC 1922 (Pat)
75 [2024] EWHC 1921 (Pat)
76 [2024] EWHC 2027 (Pat)
77 [2001] CP Rep 106

would not dispose of the case entirely it would *"dispose of a very significant part of the action, or provide clarity that a detailed investigation of the 354 products is required"*. Additionally, there was a chance that determination of the preliminary issue would *"significantly cut down the cost and time involved in pre-trial preparation or at the trial itself"*.

Confidentiality

Unsurprisingly, the determination of FRAND disputes entails examination of commercial information on royalty rates of a most sensitive nature. Disputes inevitably arise about how much of this information should be kept confidential, meaning its inclusion in judgments should be redacted, against the interests of the public in open justice. 2024 provided an indication that the courts are toughening up in this area by allowing even less into the public domain. Following his FRAND judgment, which was initially provided in a redacted form (the **Redacted Judgment**), **Marcus Smith J** handed down a judgment on consequential matters in the *Optis v Apple*[78] dispute, including as to which redactions to the FRAND judgment should be maintained, and which should be lifted. The Judge first noted that the *"main (but not the only) driver of assertions of confidentiality was the lump sum rates contained in the comparable licences"*.

In assessing whether to maintain redactions, the Judge noted that there was now a *"new test"* to be employed when considering the protection of confidential information (following *JC Bamford v. Manitou*[79]). Strictly, the test from this case related to the protection of trade secrets but the Judge held it to apply more generally (based on the definition of trade secrets in the Trade Secrets (Enforcement, etc) Regulations 2018). This superseded the *"old test"* used by **Birss J** in *Unwired Planet v. Huawei*[80]. Under the old test the court would balance the parties' interests in maintaining confidential information as against the public interest in open justice. **Marcus Smith J** indicated that he would have been minded to remove many of the redactions relating to the terms of the comparable licences and the workings that used figures from the licences. However, in the Judge's view the new test made it clear that *"open justice takes second place"* to the protection of trade secrets and so the Judge maintained many of the redactions.

Supplementary protection certificates (SPCs)

Even the most pessimistic of IP practitioners would have been loathe to suggest that fourteen years after the CJEU decision in *Medeva*[81], and seven years after it was reinterpreted by the Grand Chamber in *Gilead*[82], there would still be a live debate about the interpretation of Art. 3(a) of the **SPC Regulation**[83]. And yet here we are.

How can this have happened? Playing the blame game isn't usually constructive but it seems that the CJEU must bear a lot of responsibility. Space does not permit a review of all the missteps taken by the CJEU in the past decade in this area but, since it provides the backdrop for arguably the most important SPC decision of 2024, it is worth re-stating that in *Gilead* it was held that:

"Article 3(a) of [the SPC Regulation] must be interpreted as meaning that a product composed of several active ingredients with a combined effect is 'protected by a basic patent in force' within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination.

78 [2024] EWHC 197 (Ch)

79 *JC Bamford Excavators Ltd v. Manitou UK Ltd* [2023] EWCA Civ 840

80 *Unwired Planet International Ltd v. Huawei Technologies Ltd* [2017] EWHC 3083 (Pat)

81 C-322/10

82 C-121/17

83 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.

For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent: the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent." (emphasis added)

One obvious question which this statement of the law doesn't answer is the situation where a combination product is expressly mentioned in the claims of the basic patent but is not understood to form part of the invention disclosed. This glaring ambiguity was the subject of co-joined references from the Finnish and Irish Courts in cases involving Merck[84]. These references also contained questions on the definition of "product" for the purposes of the Regulation and on the scope of Art. 3(c) of the SPC Regulation which requires that the product of the SPC must not have previously been the subject of a certificate.

Each of the *Merck* references related to a patent primarily directed to a new compound to treat a disease (ezetimibe for cholesterol and sitagliptin for diabetes, respectively). Each patent also referred to the possibility of using the new active ingredient with certain well-established drugs for that disease (simvastatin for cholesterol and metformin for diabetes) and had claims expressly covering such combinations although there was no specific teaching to the combination or data in the patents. The question was therefore whether the SPC applications for ezetimibe + simvastatin on the one hand and sitagliptin + metformin on the other, based on marketing authorisations (**MAs**) to the respective combinations, satisfied the requirements of Art. 3(a) and/or 3(c). Fifteen months after the hearing in March 2023, the Advocate General (**AG**)'s opinion was published in June 2024[85]. Six months later, the ruling of the Court largely followed the AG in holding that to satisfy Art. 3(a), expressly mentioning the product was not enough: both stages of the *Gilead* test needed to be satisfied. In relation to Art. 3(c), the CJEU did not expressly overturn the earlier rulings in the two *Actavis*[86] cases which had given a teleological interpretation to the provision. However, it is clear that the Court has taken a different approach, such that the existence of an earlier SPC for A will not, in principle, preclude an SPC being granted for A+B.

The approach to Art. 3(a) and (c) in the *Merck* references is more aligned with the wording of the Regulation and, in that respect, is to be welcomed. However, less satisfactorily, it again leaves some questions unanswered. In particular, whilst the operative part of the ruling states that a combination of A+B will be protected for the purposes of Art. 3(a) *"provided that the combination of those two active ingredients necessarily falls under the invention covered by the same patent"*, the text of the judgment states *"If the basic patent discloses that A+B has a combined effect going beyond the mere addition of the effects of those two active ingredients and which contributes to the solution of the technical problem, it may be concluded that the combination of those two active ingredients necessarily falls under the invention covered by that patent."*

Does this mean that some form of synergy is required for a combination SPC to be valid? Or is this only one way in which the potentially broader *"necessarily falls under the invention"* test may be satisfied? Surely the question of whether a combination falls under the invention of a patent is a matter for the national court to determine? How this is to be resolved is unclear but, disappointingly, it seems inevitable that further CJEU references will follow.

84 C-119/22 & C-149/22

85 C 119/22 and C 149/22

86 C-442/12 and C-557/13

It remains open, of course, for the higher courts of the UK to take a different approach to the interpretation of the SPC Regulation (as implemented in UK law) in this post-Brexit era. However, the appetite for so doing may not be strong, especially as the new test for Art. 3(a) appears to have moved closer to **Arnold LJ**'s *"core inventive advance"* test[87].

Another area of SPC law where the applicant is urging the English Court to depart from earlier CJEU case law is in relation to Art. 3(d) and the issue of SPCs for further medical uses of known products. This was one of Merck Serono's grounds of appeal in its application for an SPC for cladribine to treat a form of multiple sclerosis (**MS**), where the drug had already been authorised to treat hairy cell leukaemia. SPC enthusiasts will recall that for a period of some 8 years, following the ruling in *Neurim*[88], and prior to *Santen*[89], SPCs were permitted to be granted in respect of further medical uses despite the wording of Art. 3(d) of the Regulation. In the appeal[90] against the rejection of Merck's SPC application, it was agreed that the High Court could not depart from *Santen*, which closed the door on such SPCs. Whilst keeping this option alive for a further appeal, Merck ran two further arguments. The first, that *Santen* did not apply to further medical uses, was given short shrift by **Michael Tappin KC**, sitting as a Deputy Judge. Merck's second argument was more creative: they argued that post-*Neurim*, they had ploughed considerable resources into the development of cladribine to treat MS with a legitimate expectation that they would receive an SPC for this indication and that it would be unjust to deny an SPC in the circumstances. This argument was also rejected. The Court ruled that *Santen* applied *ex tunc*. No legitimate expectation had been created and the usual position was that the law was the law, as interpreted by the Courts, both in the UK and the EU. An appeal of this decision was heard in December 2024 and the decision will be reported in next year's review[91].

There were two other SPC decisions of interest from the English courts in 2024. The first was an appeal by Halozyme against the rejection by the UK IPO of its application for SPCs for (i) trastuzumab in combination with recombinant human hyaluronidase (**RHH**) and (ii) rituximab with RHH. The question which **Meade J** had to consider was whether the hearing officer had erred in principle in finding that RHH did not have a pharmacological, immunological or therapeutic effect in relation to the therapeutic indications of the relevant MA. Having found that it was reasonably open to the hearing officer to reach the conclusion that RHH did not have such an effect, the appeal was dismissed[92] and the Judge did not need to decide the extent to which it is permissible to stray outside the four corners of the product label to determine whether a component of a medicine should be regarded as an active ingredient.

The need for the product protected by a patent to match the relevant MA was considered by the Court of Appeal in Newron's SPC application[93]. Relying on *Yeda*[94], it was held that where a patent claimed a combination (e.g. A+B) and the MA was for a single product (e.g. A), an SPC could not be granted. Moreover, the fact that A was commonly prescribed to be taken with B was not enough, even if such co-administration was referenced in the SmPC for the single medicine. According to the Court of Appeal, the matter needed to be kept simple: **Birss LJ** noted that *"it ought not require minute analysis of the lengthy detailed annex to a marketing authorisation to answer the relevant question"*. In keeping with this, an application to introduce expert evidence examining the MA was rejected. While the application failed for its lateness, **Birss LJ** also took the opportunity to clarify that, given the need for simplicity, expert evidence on the MA should not be required.

87 *Teva v Gilead* [2019] EWCA Civ 2272

88 C-130/11

89 C-673/18

90 *Merck Serono SA v Comptroller-General of Patents, Designs and Trade Marks* [2023] EWHC 3240 (Ch)

91 This decision was handed down in February 2025.

92 *Halozyme Inc v Comptroller-General of Patents, Designs and Trade Marks* [2024] EWHC 3202 (Pat)

93 *Newron Pharmaceuticals S.p.A v The Comptroller General of Patents, Trademarks and Designs* [2024] EWCA Civ 128

94 C-518/10

We could not finish the section on SPCs without an update on the legislative reform of the SPC regime in the EU, on which we reported in last year's review. Less progress than initially expected took place in 2024, although the European Parliament adopted its position on the proposals for EU Regulations on the recast of the SPC regime and the unitary SPC on 28 February 2024. The legislative proposals are currently awaiting discussions at the level of the European Council. At the time of writing, there is no indication as to when this might happen.

Procedural issues

Strike out

It was a difficult day in Court for the claimants in *Remfry v GKN*[95] as **Bacon J** granted the defendants' strike-out application in relation to two aspects of the claimants' infringement case, noting that summary judgment would have been granted had strike-out not been. First, the claimants had alleged contributory infringement of a patent relating to a refuelling system for armoured combat vehicles. The defendants were both involved in the provision of armoured combat vehicles to the Ministry of Defence (**MOD**) which in their unmodified state were agreed not to infringe. Summarising the law on contributory infringement under s. 60(2) of the Act, the Judge deemed the relevant question to be whether it is *probable* that the defendants' product would be modified into an infringing product, such that the intention to do so would or should have been known to the defendants. However, the claimants failed to provide evidence that modification was likely and, in fact, the MOD, as the end customer, confirmed it was not going to modify the armoured combat vehicles.

Second, the defendants succeeded in striking out the second claimant's claim for a period during which it was struck-off the register of companies. The second claimant attempted to argue what was deemed by the Judge as an *"implausible"* unpleaded case that contradicted its previous written evidence that, following termination of a pre-existing exclusive licence upon being struck-off the register, an oral unwritten licence had been granted by the licensor. The Judge did not believe that a fuller investigation at trial would provide further evidence altering her conclusion so, this portion of the claim was also struck-out.

Interim injunctions

The timing of the hotly contested Xarelto® (rivaroxaban, a blockbuster anticoagulant drug) saga before the English courts was such that it became necessary for the patentee, Bayer, to seek an interim injunction after trial but before judgment on the basis that a gap existed between the end of the SPC term for the drug (1 April 2024) and the date on which the court indicated it would hand down judgment in early April. The trial had taken place in January 2024 and the injunction requests were made in March/April.

At the hearing of the first of the injunction requests[96], **HHJ Hacon** confirmed that his judgment was a mere 9-10 days away (*"probably on 9 April"*). He indicated his position to be that no great deal of irreparable harm would occur to either party during that period and that Bayer's loss would be fairly easy to calculate. Despite that seemingly positive finding for the generics on the *American Cyanamid*[97] principles, he applied *Neurim v Generics (UK)*[98] on the importance of maintaining the *status quo* and granted a short injunction pending hand down of his decision in the main action. Teva pointed out that there were 17 other generics with product approvals, waiting to launch upon SPC expiry on 1 April. To injunct only the defendants to the application (Teva and five other generics)

95 *Remfry & Anor v GKN Aerospace Services Ltd & Anor* [2024] EWHC 1691 (Ch)

96 *Bayer Intellectual Property GmbH v Aspire Pharma Ltd* [2024] EWHC 711 (Pat)

97 [1975] A.C. 396

98 [2022] EWCA Civ 370

would not be fair. The Judge was unpersuaded, noting that in the circumstances Bayer would inevitably seek *ex parte* interim injunctions against any of the other 17 who might attempt market entry, notwithstanding the associated delay.

As to why the Court hadn't issued its judgment in advance of the cliff-edge of SPC expiry, the Judge deals with this in several paragraphs under the heading *"Communication with the court"*, noting that he did not appreciate the consequences of SPC expiry, nor the importance of the case until he was *"taken aback"* by the scale of the parties' attendance at the hearing, which was only five-and-a-half weeks before the date of SPC expiry. He concluded:

"The point is that in circumstances such as this parties should keep the court informed. It may or may not be possible for a preferred deadline for the handing down of a judgment to be met, this is always a matter of giving priority to commitments. But if the court is properly informed, such as by a jointly agreed brief summary of reasons and possible consequences filed at the trial or subsequently, the court will be in a better position to give the matter appropriate priority. The parties may for their part be given an update of the likely date of the judgment, which in the present case may have affected their willingness to spend large sums on the application. In short, better communication with the court is desirable."

At the consequentials hearing[99] following judgment (which was handed down on 12 April), despite refusing permission to appeal, **HHJ Hacon** granted a further 16-day injunction limited to sale/supply (and not other infringing acts) on the basis of *Skatteforvaltningen v Solo Capital*[100], placing the Court of Appeal in the position that best allowed it to do justice between the parties. The Court of Appeal itself gave permission to appeal (and also granted expedition and a further short intervening injunction on the papers to maintain the *status quo* pending determination of the appeal) and heard the merits appeal on 16 May – an impressive feat that shows how quickly expedition can accelerate English proceedings when necessary.

As noted earlier in this review, the Court of Appeal upheld the Judge's findings on obviousness[101], which brought an end to the matter and terminated the injunctions. Of course, the damages suffered by the injuncted generics will now be the subject of a separate damages inquiry that will be reported upon in a future edition of this review if it does not settle. In a postscript to the appeal judgment, **Arnold LJ** reiterated **HHJ Hacon's** message that the trial judge should have been sufficiently warned of the potential consequences if he failed to deliver a judgment by 1 April 2024. He also made an interesting observation on the timing of the litigation that is relevant to future actions seeking to "clear the way":

"From that date the Respondents knew that they had two and a half years in which to obtain an order for revocation of the Patent if they wished to clear the way for marketing rivaroxaban for once daily administration after 1 April 2024. The first claim form seeking revocation of the Patent was filed by three of the Respondents a full year later in October 2022. Other claim forms followed later still. The claims were joined and progressed without any expedition. ...

This situation could and should have been avoided by the Respondents bringing proceedings earlier than they did, or at least keeping the Patents Court properly and timeously informed..."

99 [2024] EWHC 852 (Pat)

100 *Skatteforvaltningen v Solo Capital Partners LLP* [2021] EWHC 1683 (Com) 7216

101 *Sandoz AG v Bayer Intellectual Property GmbH* [2024] EWCA Civ 562

102 *Cloud Cycle Ltd v Verifi LLC* [2024 EWHC 233 (IPEC)

There were two interim injunction applications in the IPEC in 2024. In the first of these, *Cloud Cycle v Verifi*[102], the parties were poles apart: **HHJ Hacon** considered an application from Verifi for an interim injunction alongside an application from Cloud Cycle Ltd (**CCL**) to determine its claim for a declaration of non-infringement on a summary judgment basis. The summary judgment application was taken first, the Judge noting that the threshold test of whether there was a serious issue to be tried was the same for the purposes of both applications and, accordingly, if Verifi had a serious prospect of showing CCL infringed the patent, then the summary judgment application must fail. Verifi succeeded on the basis of the doctrine of equivalents, albeit *"subject of course to a clearer PPD and to expert evidence"*. This then led to the subsequent stages of the *American Cyanamid* test for the interim injunction. **HHJ Hacon** ultimately concluded that there was a risk of harm to Verifi in view of price depression if the injunction was not granted but the *"risk to CCL if an injunction is granted is by contrast more likely to be an existential threat, raising the possibility of seriously affecting CCL's ability to trade at a vulnerable stage in its development."* On the basis of the balance of convenience, the injunction application therefore also failed.

The second IPEC application came before **Charlotte May KC** (sitting as a Deputy Judge of the High Court)[103] in the context of a medical device case relating to a patent for ureteral access sheaths used to remove kidney stones. The injunction request was dismissed. Of note, the Deputy Judge held that damages would be an adequate remedy for any lost sales the claimant suffered (its arguments, which involved non-financial considerations such as the deterrent effect of an injunction on third parties and the assertion that an injunction would silence the defendant from making derogatory comments where rejected). Interestingly, in this regard, the Court decided on the evidence that the claimant would be able to restore its prices (if depressed) if it prevailed at trial, noting that the *"NHS is a sophisticated purchaser who understands the impact that patents have on pricing (up or down)"*. Another nail in the claimant's coffin was the *status quo* in favour of the defendant. By the time the claimant had filed the injunction request the defendant had been dealing in its competing product for several months including advertising the product at medical conferences and making sales.

Arrow[104] relief

Having come this far in the review, readers will already appreciate that **Mellor J's** decision in the *Pfizer v GSK*[105] case touches upon almost every aspect of patent law. *Arrow* declarations are no exception, and – spoiler alert – against a backdrop of recent failures in other cases, the case is notable for the *Arrow* declaration being granted. The declaration sought by Pfizer against GSK's patent family (two members of which were in suit and others pending) was that at the priority date/filing date it was obvious to make an RSV antigen which *inter alia* resembled the prefusion conformation and to the use that antigen in the treatment or prevention of RSV-associated diseases. The decision on the *Arrow* declaration is brief, given over 12 paragraphs at the end of a very long judgment (845 paragraphs). GSK resisted the declaration based on the non-obviousness arguments discussed above and also on the basis it would not serve a useful purpose. The useful purpose was said to be a public health interest because while GSK said it would not seek an injunction in respect of maternal use of its RSV vaccine, it would do so in relation to the older adult population for which Pfizer's vaccine would also be available. The existence of GSK's divisional applications was also raised. Having succeeded in its revocation claim against the two patents in suit for obviousness, the declaration gave Pfizer certainty over its ability to supply the UK market.

103 *Well Lead Medical Co Limited v CJ Medical Limited* [2024] EWHC 951 (IPEC)

104 [2007] EWHC 1900 (Pat)

105 [2024] EWHC 2523 (Pat)

106 [2024] EWHC 2567 (Pat)

In *Sandoz v Biogen*[106] Sandoz sought an *Arrow*-type declaration on a different basis. Not on novelty or obviousness based on the accused product belonging to the state of the art (or an obvious modification of it) but on the basis of insufficiency in relation to Biogen's family of patents, which were said to be intrinsically bad because the initial PCT application did not disclose a JCV test clearly and completely enough for the skilled person to be able to determine a patient to be at high risk of developing PML at an index value of 1.5 or any other index value disclosed. As such, anything born from that family was bound to be insufficient. The justification for requesting the declaration was that Biogen intended to assert a pending divisional if or when it granted.

In analysing the case law on *Arrow* relief, **Mellor J** referred to the following point from **Kitchin J** in the *Arrow* case: *"For the court to start anticipating the examination process would be to usurp the function of the EPO and this is inconsistent with the framework of the EPC and the Act"*. The Judge found that even if Sandoz was correct that the PCT application cannot give rise to a valid patent at any point in the future, an English court could not make a finding of insufficiency unless and until any divisional patent was granted. Until then, it is for the EPO to determine. As such, the request for an *Arrow* declaration was refused.

Exclusive licences

Few cases are as messy as that of *Flitcraft v Price*, involving patents relating to timber building products. Readers may recall that an earlier case in the same litigation involved committal proceedings against Mr Price for contempt of court[107]. By the time the litigation reached the Court of Appeal, things had scarcely improved and an exasperated Master of the Rolls was moved to add a few paragraphs to the judgment *"just in case the heinous nature of what Mr Price and Mr Middleton have done is lost in the meticulous detail of the two main judgments above"*[108].

This statement was directed at what the Master of the Rolls called *"an intolerable deception"*: bringing false claims and supporting them with false evidence. The deception concerned the true ownership of the patents, said to be owned by Price and exclusively licensed to Supawall. However, Price had been declared bankrupt, such that the Official Receiver (**OR**) owned the patents. Price's deception related to his insistence that he had assigned the patents to a friend just before bankruptcy, and then taken them back, once discharged.

The effect of the OR owning the patents was two-fold: Price had no standing to bring an infringement claim, and the claim by Supawall as exclusive licensee was defective because the true proprietor had not been joined under s. 67 (3) of the Act (requirement to make the proprietor a party to proceedings brought by an exclusive licensee). The Judge in the Court below had allowed Supawall's claim to proceed by curing the defect through allowing the OR to be added as a party (it was common ground that the Court has the power to add a party to proceedings, even after judgment).

The addition of the OR as a party and the award of litigation costs against Price on the indemnity basis, bearing in mind his conduct, were the subject of the appeal by Flitcraft. The appeal was rejected on both counts and in considering the exercise of the first instance Judge's discretion on the joinder point, **Sir Christopher Floyd** noted that the purpose of s. 67(3) was firstly so that both proprietor and licensee were before the court at the same time in order to deal with the apportionment of any financial relief and also so that the defendant is not exposed to a subsequent infringement action by the proprietor. Where those objectives can still be achieved, even,

107 [2019] EWHC 2476 (Pat)

108 *Flitcraft Limited, Garry Flitcroft v Philip Price* [2024] EWCA Civ 136

as here, after judgment, the Court should allow the joinder. On the facts, the OR had communicated that it was aware of the earlier judgment and had no intention of bringing any further proceedings or in seeking to alter or vary the judgment.

Employee compensation

Deputy Judge Pat Treacy (sitting as a Judge of the Chancery Division) heard an application to amend pleadings in a claim brought by Dr Parsons[109], a chemist and former employee of the defendant, Convatec, under s. 40(1) of the Act for employee compensation. The application to amend centred on the interpretation of *"invention"* and the appropriate approach to identifying inventions in such cases. It was necessary for the Judge to consider whether a claim-by-claim approach to identifying an invention was necessary, as argued by the defendant, or whether a broader interpretation, as suggested by the claimant, was appropriate. The Court ultimately held that a claim-by-claim approach to identifying an invention was not appropriate in cases under s. 40(1), favouring a broader interpretation, focusing on the *"Eureka moment"* that led to the invention. The Judge also commented that early mediation is strongly encouraged in disputes of this nature.

Expedition

As we have already mentioned, even the fastest of the world's rocket dockets would be put in the shade by the speed at which the Court of Appeal handled the merits appeal in the rivaroxaban litigation: from first instance judgment to appeal hearing in less than 5 weeks, with no shortage of substance. The need for expedition was not even questioned. Often, however, expedition applications follow a less certain path.

The desire to influence foreign proceedings in Germany was not considered a good enough reason in *Dish v Aylo*[110], where Aylo sought expedition in order to obtain an English decision before the German courts would consider validity in a parallel case in December 2024. **Meade J** concluded that there was no guarantee that the German court would pay sufficient heed to an English decision and that under the legal framework, expedition is only justified in cases of real commercial urgency. The Judge also considered the Practice Statement[111], paragraph 3 of which states *"Where it will enable a case to be tried within 12 months, or shortly thereafter, the Court may list a trial up to one month earlier than the applicable Trial Window without the need for any application for expedition."* In this case, the ordinary listing trial window was to be in early January 2025. **Meade J** also concluded that there was also no need for acceleration under the Practice Statement as the difference in timing would not have a significant impact.

On the other hand, in *Texas Instruments v Network System Technologies*[112], **Meade J** considered there would be grounds for expedition of the UK revocation action so that it could be heard before the infringement hearing in parallel proceedings in the UPC. In this case an injunction was being sought in the Munich Local Division against Texas Instruments (**TI**) and its customers, Audi and Volkswagen, who manufacture cars containing the TI chips which were alleged to infringe the patents in the UPC. Whilst the Judge noted that use of a UK judgment to influence the outcome of a case in the UPC was a *"very weak factor"* for obtaining expedition in light of the low risk of an injunction gap at the UPC, the wider commercial context gave rise to a potential need for expedition. In particular, some of the cars manufactured by Audi and Volkswagen in Germany are imported into the UK. The defendant had offered undertakings not to assert the UK patents but these lacked clarity on the question of whether they would bite on imported cars manufactured in Germany. The Judge recognised the need for early commercial certainty and ordered

109 [2024] EWHC 2111 (Pat)

110 *Dish Technologies LLC v Aylo Premium Ltd* [2024] EWHC 1310 (Pat)

111 Meade J's Practice Statement of 1st February 2022

112 *Texas Instruments Incorporated v Network System Technologies LLC* [2024] EWHC 1066 (Pat)

expedition, to take effect unless clearer undertakings were offered by the defendant.

Meade J found himself with a similar application before him in June. In this instance, the claimant, Samsung BioEpis, sought to expedite the trial to December 2024, or as early as possible[113]. They argued that Alexion's communication of its patent rights to national authorities and individual prescribers had created a *"chilling effect"* in the market, potentially inhibiting the prescription of Samsung's biosimilar product. The Judge considered the factors for expedition set out in *Gore v Geox*[114] and concluded that a party must demonstrate an objective need for urgency before other factors are considered. While a specific *"cliff edge"* date (e.g., product launch or expiry of an IP right) can create urgency, it is not the only way to demonstrate a need for expedition. Continuing harm that can be brought to an end by a trial would also suffice. The Court contemplated that the existence of parallel UPC proceedings in this case could be a factor in considering expedition, but, again, it would not be a primary factor, especially in the absence of an injunction gap. **Meade J** held that there was a need for expedition due to the potential chilling effect on the market and the trial was listed for mid-February 2025.

Listing

It has been a feature of some recent cases in the pharmaceuticals field that a great many generics companies can be involved as co-defendants. The rivaroxaban litigation is one such example. Such cases often throw up disputes about trial listing, usually because the generics want a trial at the earliest possible opportunity and may seek listing before the case management conference (**CMC**) has taken place. **Meade J** had to grapple with such an application in *Generics v AstraZeneca*[115]. Ultimately, due to the lack of urgency, the need for greater cooperation among the generics companies, and the unavailability of AstraZeneca's counsel, **Meade J** declined to order a trial listing and reserved the issue to the CMC Judge. On the overall timing, the Judge commented that while the court aims to bring cases to trial within 12 months, this is not an inflexible rule and there is discretion to deviate from this timeline depending on the specific circumstances of the case.

In July, trial listing was considered again in a dispute between *Fujikura v Sterlite Technologies*[116]. The claimants, Fujikura, wanted to bring forward the trial date from October to July because they believed the defendant's claim that their client representatives were unavailable in July was inaccurate. **Sir Anthony Mann** dismissed the claimants' application, stating that the Listing Officer had made their decision based on the information provided at the time, and that further investigation was not appropriate. The Judge emphasised that the listing process should not be subject to tactical manoeuvring and that parties are expected to be genuine and honest about their availability. He also highlighted the importance of respecting the Listing Officers' decisions and avoiding unnecessary challenges to the listing process – challenges to their decisions should be reserved for situations where something went clearly wrong, there is manifest unfairness, or bad faith is evident.

Disclosure

In *Salts Healthcare v Pelican Healthcare*[117], the Court faced an application from the claimant seeking disclosure on the issue of infringement on the basis that the defendant's product and process description (**PPD**) was deficient. Salts Healthcare's primary position was that the defendant had already had one attempt at redrafting its PPD, and that having failed to get it right the second time, it ought to give documentary disclosure. **David Stone** (sitting as a Deputy High Court Judge) disagreed. Citing comments made by Meade J at the CMC of the action, he held that documentary

113 [2024] EWHC 1407 (Pat)
114 *WL Gore & Associates GmbH v Geox SPA* [2008] EWCA Civ 622
115 [2024] EWHC 137 (Pat)
116 *Fujikura Ltd & Anor v Sterline Technologies Ltd* [2024] EWHC 2138 (Pat)
117 *Salts Healthcare Ltd v Pelican Healthcare Ltd* [2024] EWHC 1539 (Pat)

disclosure should always be a last resort in such situations and the better course is always to try to fix the PPD. Accordingly, he specified with greater particularity exactly what would be needed in the third version of the PPD.

Pleading amendment

Patent litigation practitioners may sometimes be complacent when it comes to the late amendment of pleadings. Such is life when the expert evidence is produced late in the timetable and the case needs to be adjusted. However, a reality check came in the context of **Leech J's** refusal of a pleading amendment in the long-running damages inquiry in the proceedings between Lufthansa and Astronics[118]. The application to amend came 11 weeks before trial and was billed as uncontroversial, but the Judge saw it as an attempt to advance a *"substantial new case"*. The amendments would have caused the claimant prejudice owing to the significant amount of extra work required and pressure on the legal team. Furthermore, the availability and proportionality of evidence required to prove the allegations in the amendments was unclear and it appeared as though many disclosure searches would have to be repeated in light of the expanded scope of the defendants' case.

Experts

After some years of debate, it is now becoming established practice that in cases involving multiple experts per party, the experts ought to communicate, or at least have sight of one another's draft reports. In *Pfizer v GSK*[119], **Mellor J** criticised GSK, the patentee for failing to facilitate communication between the members of the skilled team and for taking a siloed approach. In particular, its vaccinologist evidence on CGK was too narrow: GSK's skilled vaccinologist had considered it would not be CGK for a vaccinologist looking to make an RSV vaccine to look at other, structurally related vaccines. Ultimately, GSK's patents were found to lack inventive step.

In *Abbott v Dexcom*[120], Abbott levelled a number of criticisms at the manner in which Dexcom's evidence had been put together, arguing that the two reports from Dexcom had been put together in a vacuum and did not consider what other members of the skilled team would say. Abbott noted that neither of Dexcom's experts had seen the other's written report or considered the impacts of that report on the skilled team. In his judgment, **Mellor J** considered there were shortcomings in the expert evidence of both sides. In relation to the arguments made by Abbott, the Judge agreed that in cases involving a skilled team *"it is better if the experts in different disciplines at least see what the other is saying"*. He went on to state that in some cases it is necessary for such experts to confer (making note of the decision in *Alcon v AMO*[121]). However, in instances where evidence has been produced in a silo, the Judge did not consider the evidence was automatically of no merit. It was necessary to consider whether the manner in which the evidence was prepared impacts on the force of reasoning.

The practice known as *"sequential unmasking"* (the expert considering the CGK, then the prior art, then the patent, separately and in sequence) is also desirable standard practice but, again, something towards which the courts will not take an absolutist approach. In *ACD v MI*[122], **Meade J** acknowledged that sequential unmasking is indeed an ideal which parties are well-advised to follow when possible. However, he accepted that it is sometimes not possible for various reasons. In those cases, the court has to assess whether hindsight has crept in. In this instance, on the facts, he held it had not.

118 *Lufthansa Technik AG v Astronics Advanced Electronic Systems & Anor* [2024] EWHC 1918 (Pat)

119 [2024] EWHC 2523 (Pat)

120 *Abbott Diabetes Care Inc v Dexcom Inc* [2024] EWHC 1664 (Pat) (Trial B)

121 [2022] EWHC 955

122 [2024] EWHC 898 (Pat)

There was an interesting question during a CMC in *Dr Vanessa Hill v Touchlight Genetics Limited*[123] should the parties be permitted to appoint experts or should a scientific adviser be appointed to best assist the court in understanding the scientific issues in the case (relating to manufacture of synthetic DNA vectors). **Mellor J** noted that the issue he had to decide had not previously arisen in the context of entitlement proceedings, although similar issues had been addressed in patent validity and infringement proceedings. The Judge held that although both experts and scientific advisors have an educational role, there was a clear difference, in that a scientific adviser is not to address technical disputes. Given that it was not clear that there would be no technical issues in dispute, the Judge ordered technical expert evidence be permitted with certain restrictions on its scope.

Finally, it is a fact of life that when choosing an expert, one's options might be limited. Nevertheless, using a *"hired gun"* in the English courts, or even an expert that has given evidence in the same litigation elsewhere, carries its risks. **HHJ Hacon**, sitting as a Judge of the High Court, made this plain in *Pfizer v UniQure*[124] when criticising Pfizer's expert: *"It would seem that since retirement she has spent quite a lot of her time, presumably lucrative time, as an expert for Pfizer in relation to subject matter with which this litigation is concerned... My impression was that at some point during the preparation and delivery of evidence in the US and elsewhere [Pfizer's expert] has developed the understanding that the primary duty of an expert witness is not to say anything that may damage Pfizer's case if it can be avoided... Also, [she] was cross-examined on the written evidence she has given in the Netherlands. It emerged that in some of that evidence [she] had omitted relevant material, providing at best an incomplete picture... In the end this did not work in Pfizer's favour. [Pfizer's expert's] apparent anxiety to toe the party line left me with the view that although I would consider her evidence as carefully as the evidence from other witnesses, I should treat it with some caution."*

Fact witnesses

Pat Treacy, sitting as a Deputy Judge, dealt in one hearing with a series of applications relating to trial witness evidence. The case[125] (relating to lobster aquaculture) was assigned to the IPEC and, as such, the Deputy Judge said complex interim hearings should be a rarity and that witness evidence should only be adduced in relation to an identified issue where it passes the cost benefit test. The Deputy Judge gave the parties a stern warning about spending disproportionate time dealing with marginal points or failing to engage meaningfully with issues before an application was made. The defendants were refused permission to adduce further evidence in relation to paragraphs of the claimants' evidence dealing with *"background contextual material"*, and certain paragraphs of the defendants' evidence were struck out for irrelevance. Other paragraphs survived on the basis that a certain amount of *"scene-setting"* was unavoidable.

Skeleton arguments

Dealing with a significant application to amend pleadings in *Hill v Touchlight*[126], **Joanna Smith J** noted that there was a disconnect between the provisions of the Patents Court Guide and the overarching Chancery Guide on the timing of skeleton arguments. Paragraph 14.7(a) of the Patents Court Guide provides for service of skeleton arguments by 10:30 AM on the working day before the hearing, whereas paragraph 14.57 of the Chancery Guide provides that skeleton arguments in a heavy application should be served by midday two clear days before the hearing. Noting that the Patents Court Guide trumps the Chancery Guide, the Judge proposed that the Patents

123 **[2024] EWHC 553 (Pat)**
124 *Pfizer Inc v UniQure Biopharma BV* [2024] EWHC 2672 (Pat)
125 *Ocean on Land Technology (UK) Ltd v Land* [2024] EWHC 396 (IPEC)
126 [2024] EWHC 1913 (Pat)

Court Guide should be amended on this point, and made the following recommendation: *"parties to heavy applications in the Patents Court, where there have been no directions for exchange of skeletons in advance, would be well-advised to liaise over the exchange of skeleton arguments with a view to ensuring that reasonable time to read and digest those skeleton arguments is provided in advance of the hearing date"*.

Looking ahead to 2025

Last year was heavier on the FRAND cases than we might have expected when the year began. Reading the runes for 2025, this trend may continue. For example, we might expect to see:

- the appeal of Marcus Smith J's decision in *Optis v Apple*[127], the third UK FRAND determination;
- an appeal on the interim licence issue in *Lenovo v Ericsson*[128]; and
- most likely an appeal on the jurisdiction question in *Tesla v Avanci*[129].

Outside the world of FRAND, there may be more to come on artificial neural networks given that permission to appeal to the Supreme Court has been given in *Emotional Perception v Comptroller of Patents*[130]. And in the life sciences field, we can expect to see a number of interesting cases involving both small molecules and biologic drugs. At the time of writing the Patents Court Diary indicates that:

- the trial in the eculizumab litigation between Samsung BioEpis and Alexion will begin on 17 March;
- the dapagliflozin action between Glenmark & others and AstraZeneca will come before the court on 10 March and should offer the Judge a good opportunity to review the law on plausibility; and
- the litigation between Formycon and Regeneron concerning aflibercept will go to trial on 9 June.

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

127 [2023] EWHC 1095 (Ch)
128 [2024] EWHC 2941 (Pat)
129 [2024] EWHC 1815 (Ch)
130 [2024] EWCA Civ 825

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