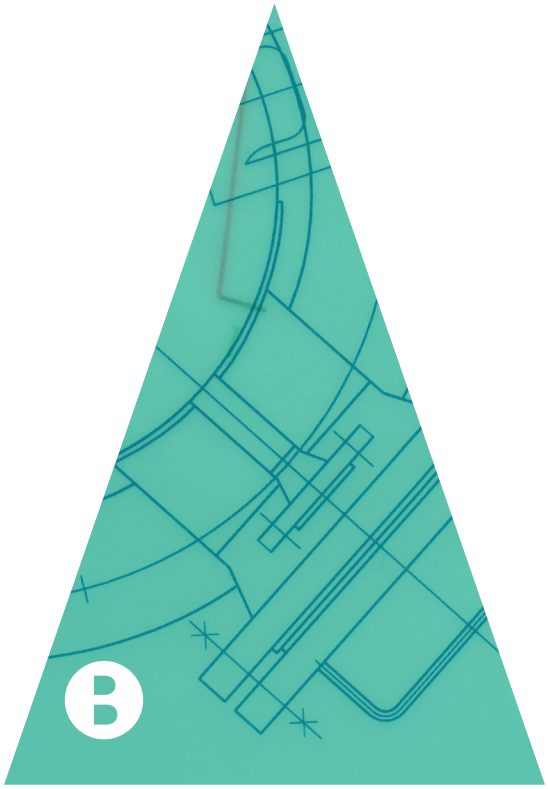
Review of Patent Cases in the English Courts in 2023



Bristows

Quotation of the Year

"... the standard of plausibility which should be applied is the standard adopted by the majority in Warner-Lambert ... It is fair to say that [this] corresponds to the 'ab initio plausibility' test identified in Sumitomo ... [T]he harmonised approach adopted by the Enlarged Board, while eschewing the language of 'ab initio plausibility' and 'ab initio implausibility', is as a matter of substance much closer to the former than to the latter."

Arnold LJ in *Sandoz and Teva v BMS* [2023] EWCA Civ 472 (4 May 2023)

"Hence, according to [the UK Court of Appeal in the apixaban case] the 'ab initio plausibility standard' has to be applied when examining effects in relation to inventive step of product claims. The board's interpretation of G 2/21 is different from this..."

The referring EPO Board of Appeal 3.3.02 in *Sumitomo* (28 July 2023)

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Introduction

For patent practitioners everywhere, 2023 was a significant year. Ten years after the signing of the international treaty governing its operation, and having overcome innumerable hurdles, including Brexit, the Unified Patent Court (**UPC**) finally opened its doors for business. As ever, we report in the final section of this review on what happened, and for the first time include some UPC cases in our annual summary. Closer to home, the English courts were busy, delivering a total of 68 judgments in patents cases, an output not out of step with previous years (75 in 2022, 66 in 2020, 86 in 2019 and 63 in 2018). The year was notable for at least the following developments:

- The retirement of **Lord Kitchin** from the Supreme Court. One of the finest lawyers of his generation, **Lord Kitchin** provided exceptional clarity of thought and analysis in many patent cases, including his last, *Thaler*[1], included in this review.
- The Court of Appeal in *Sandoz and Teva v BMS*[2] providing the first decision in Europe to take into account the EPO Enlarged Board of Appeal decision in *G2/21* (plausibility).
- Two major FRAND determinations in *InterDigital v Lenovo*[3] and *Optis v Apple*[4].
- **Sir Anthony Mann**'s decision in Emotional Perception AI's Application taking a permissive approach to the patenting of AI inventions in the UK and marking a shift in UK IPO practice.
- Guidance on the sequencing of trials in Standard Essential Patent (**SEP**) cases, putting priority on hearing the FRAND aspects of the case earlier in the proceedings.

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**", the European Patent Convention 2000 as the "**EPC**" and the UPC Agreement as the "**UPCA**". Judges are referred to according to the office held at the time of their decision (not subsequent elevation) and counsel who have taken silk are referred to as KC throughout. As ever, the authors have endeavoured to cover every important development that occurred during the course of the year. However, as this is a condensed summary, not every decision is mentioned.

Claim construction and infringement

Construction

To what extent must a feature relied upon for technical effect or technical contribution be written into the language of the claim? Readers may recall **HHJ Hacon**'s decision last year in *Teva v Novartis*[5], in which Novartis' patent for a film-coated tablet formulation of deferasirox was lost because the advantageous features of improved bioavailability and reduced food effect were not spelt out in the claims and so were held not to be part of the inventive concept for the purpose of the *Pozzoli* approach. As such, the claim was held to cover any sort of tablet and was therefore bad for obviousness.

Fast forward 12 months and contrast that with **Mellor J**'s decision in *Astellas v Teva and Sandoz*[6], also a pharmaceutical formulation case concerning the benefit of avoiding the food effect. The question was whether the claim required the modified release mirabegron formulation to possess a particular pharmacokinetic profile (a reduction in either Cmax or Cmax and AUC) which would lead to a reduced food effect, or whether the effect of the modified release was only

1 *Thaler v Comptroller-General of Patent, Designs and Trade Marks* [2023] UKSC 49
2 *Sandoz Ltd & Teva Pharmaceutical Industries Ltd v Bristol-Myers Squibb Holdings Ireland Unlimited Co* [2023] EWCA Civ 472
3 *Interdigital Technology Corp v Lenovo Group Ltd* [2023] EWHC 1578 (Pat)
4 *Optis Cellular Technology LLC v Apple Retail UK Ltd* [2023] EWHC 1095 (Ch)
5 [2022] EWHC 2847 (Pat)
6 [2023] EWHC 2571 (Pat)

relevant when considering the technical benefit of the claimed formulation. **Mellor J** held that the term "*a pharmaceutical composition for modified release*" had a special meaning in the claim because of definitions contained in the description, and therefore included the beneficial impact on the pharmacokinetic profile. As such, successful enforcement required a demonstration of this feature compared to conventional mirabegron formulations. While one defendant, Teva, had admitted infringement for their existing product (with a declaration of non-infringement (**DNI**) for a design-around product potentially to be heard at a later date), Sandoz had given no such admission and Astellas failed to meet their burden of proof at trial.

In principle, there is nothing to stop a party pursuing a claim construction on appeal different from that advanced at first instance, provided that no procedural unfairness results (e.g. if the other side were prejudiced by being deprived of the opportunity to adduce evidence they might otherwise have relied upon). There was a dispute about whether InterDigital had changed its position on appeal in the Trial B litigation between InterDigital and Lenovo[7]. However, **Arnold LJ** was not fazed: the correct interpretation of the claims of a patent is an issue of law for the court to determine and the court is not bound to accept either party's construction, either at first instance or upon appeal. As matters unfolded in the appeal, **Arnold LJ** took a slightly different construction to that adopted by **Mellor J**, below. Whilst this did not matter for essentiality/infringement, it was material to the consideration of novelty and had the effect of reversing **Mellor J**'s finding that the patent was anticipated by a marked-up version of a technical standard (3GPP TS 25.309 v6.2.0) called Filiatrault. As a result, InterDigital's appeal was allowed.

More than twenty years ago, the Court of Appeal decided in *Coflexip*[8] that when interpreting the wording of a product claim, the word "*for*" meant "*suitable for*", such that an accused product would infringe whether or not it was actually performing the ascribed purpose, otherwise the clear intention of the patentee to have a product claim would be defeated. The Court of Appeal in *Optis v Apple*[9] was fully cognisant of *Coflexip* when it decided the appeal in the context of Optis' patents for a physical uplink control channel. The claim at issue was a product claim – a mobile phone – which required the device both to spread and transmit signals, but not both at once. "*Spreading*" took place in accordance with a code multiplexing structure (**CMS**). **Birss LJ** noted that "*Coflexip is illustrative but cannot be taken too far. That is because in the end the issue is always and only a matter for the true construction of the patent in question*." However, given the nature of the claim, he followed *Coflexip* by upholding **Meade J**'s decision below[10] that the mobile device must be capable of operating with the relevant CMS when required to do so but is not limited to a situation in which that CMS is in fact in use. Thus oriented, **Birss LJ** also upheld **Meade J**'s findings on infringement and validity, thereby dismissing Apple's appeal completely.

Claim construction was the "*most difficult issue to decide*" when **Charlotte May KC** sat as a Deputy High Court Judge in *Ensygnia v Shell*[11]. The Deputy Judge's consideration of the issue began with deciding an apparently novel point of law: whether the description of embodiments said to be excluded from the scope of the claim should be excised from the specification when considering the meaning of the claim language, or whether the claims should be read in light of the whole description. The Deputy Judge preferred the latter approach, notwithstanding the lack of any helpful authority provided by the parties.

7 [2023] EWCA Civ 105

8 *Coflexip SA & Anor v Stolt Comex Seaway MS Ltd & Ors* [2000] EWCA Civ 242

9 [2023] EWCA Civ 758

10 [2022] EWHC 561 (Pat)

11 [2023] EWHC 1495 (Pat)

Proceeding to interpret the claim language, the Deputy Judge referred to the three key considerations identified by **Arnold LJ** earlier in the year in *InterDigital v Lenovo*[12]: (i) the wording of the relevant integer of the claim, (ii) the context provided by the specification and (iii) the inventor's purpose.

The main point in dispute was whether the printed QR codes affixed to petrol pumps on Shell's forecourts fulfilled the claim integer "*wherein the display is a sign*". The other words of the claim made it clear that the display was part of the computing apparatus. However, the only passage of the patent's description which dealt with the meaning of "*sign*" said that electronic displays were outside the scope of the claim, notwithstanding that the claim's features related to an electronic display. This conflicting teaching led the Deputy Judge to express her conclusion "*after anxious consideration and with some hesitation*" that a printed sign was within the claim, bearing in mind the inventor's purpose. Ultimately, the result of this finding was that the patent was invalid: the amendments which limited the meaning of "*sign*" to a non-electronic sign were not clearly and unambiguously disclosed in the application as filed and in addition for being bad for added matter under s. 72(1)(d), the claim also failed for having an extended scope of protection under s. 72(1)(e) of the Act.

In *Vernacare Limited v Moulded Fibre Products Limited*[13] in the Court of Appeal, **Sir Christopher Floyd** held that the Judge below had erred when determining the inventive concept of one of the claims by introducing an additional purpose-based element into the claim, with the result that the construction wrongly excluded a detergent resistant washbowl that was made for reasons other than achieving detergent resistance. When the inventive concept was properly formulated as a washbowl made from paper pulp containing a fluorocarbon (rather than a detergent-resistant washbowl so made), the claim was obvious over the cited prior art and an independent claim was also invalid in light of the expert evidence.

Infringement under the doctrine of equivalents

Where does purposive construction end and infringement by equivalents begin? As readers will remember, the original *Improver*[14] questions, designed to be a framework for purposive construction, included consideration of whether the variant has a material effect on the way the invention works (*Improver* question 1). *Actavis*[15] took that concept of "*immaterial variants*" and turned it into a series of three separate questions, thereby creating the doctrine of equivalents. So should the courts still consider the material effect of a variant under purposive construction?

If they do, perhaps unsurprisingly, there will be cases where the outcome of the application of purposive construction and the doctrine of equivalents is the same. In *Heraeus v First Light Lamps*[16], a case concerned with a sealing method for glass tubes, **Zacaroli J** considered that one of the factors used to construe the claim purposively included whether the variant would have a material effect on the way in which the invention worked. Indeed, the Judge noted that "*the parties were agreed that although the question raised by a case on infringement by equivalents is logically distinct from that raised when purposively construing a patent (Actavis, above, at §56), on the facts of this case there is no material difference*."

More often, infringement cases based on a normal construction and on the doctrine of equivalents will be entirely distinct. By way of example, in *Philip Morris Products v Nicoventures*[17], Nicoventures (**BAT**) had conceded that Philip Morris' IQOS ILUMA product did not infringe the patent in suit on a normal construction so the case turned on the application of the doctrine of equivalents.

12 [2023] EWCA Civ 105 at [81]
13 [2023] EWCA Civ 841
14 *Improver v Remington* [1990] FSR 181
15 *Actavis v Eli Lilly* [2017] UKSC 48
16 [2023] EWHC 1950 (Pat)
17 [2023] EWHC 2616 (Pat)

The decision on equivalents turned on the third *Actavis* question and in particular whether an embodiment disclosed but seemingly incompatible with the claim language meant not only that such an embodiment was outside the normal meaning of the claims but also that there was no infringement by equivalents. Here, **HHJ Hacon** found the inventive concept of BAT's patent to be "*An HNB [heat not burn] system in which (i) an article containing smokeable material is inserted into the heating zone of a heating apparatus, (ii) the smokable material is heated by inductive heating and (iii) the maximum temperature of the heater in the apparatus is exclusively determined by a Curie point of the heating material*". He construed "*exclusively determined*" to mean that there must at all times be a fixed relationship between a Curie point of the heater material and the maximum temperature of the heater.

The PMI product differed from the inventive concept in that (a) the heater is in the consumable and (b) the maximum temperature of the heater is not at all times fixed by reference to a Curie point of the heating material because it depends in part on whether the system is calibrating. The Judge considered these two differences collectively in determining whether PMI's product infringed as an equivalent (the approach he endorsed in *Regen v Estar*[18]) and had little difficulty in answering the first and second *Actavis* question in the affirmative: the way the Curie point is used in the IQOS ILUMA and the fact that its heater is in the consumable meant the same result was achieved in the same way as the inventive concept.

On the third question, the specification of BAT's patent disclosed and illustrated an HNB system in which the heater is in the consumable (as in the IQOS ILUMA). Applying the "*disclosed but not claimed*" principle, **HHJ Hacon** found that "*Without exception, the method, apparatus and system claims require the heater to be in the apparatus, not in the consumable*." As a matter of policy, he held that embodiments disclosed but not claimed must be available to the public to use freely: "*Where … the patentee says in the description that the technical effect identified can be achieved either by means A or B but goes on to claim only means B, this is a clear indication from the patentee that means A does not fall within the scope of the claims, whether as a matter of normal construction or equivalence. Any other approach to construction would sanction patents likely seriously to mislead the public*." The answer to the third *Actavis* question was therefore yes and there was no infringement by equivalents.

The *Formstein* defence - where infringement arguments that are based on equivalents cannot succeed because a piece of prior art would also infringe under the same analysis – is now established in English law. Having been mentioned in 2019 by **HHJ Hacon** in *Technetix v Teleste*[19], and blessed as a principle in 2021 by **Birss LJ** in *Facebook v Voxer*[20], it was applied for the first time as a successful defence in 2022 by **Mr Nicholas Caddick KC**, sitting as Deputy High Court Judge in *Vernacare Limited v Moulded Fibre Products Limited*[21]. The *Formstein* defence was one of the bases on which the Judge found one of two patents in suit valid and not infringed. Infringement of the second patent (also held valid) was admitted.

Unfortunately for practitioners interested in the *Formstein* defence, **Nicholas Caddick KC**'s findings on the first patent were not appealed when *Vernacare* came before the Court of Appeal[22]. However, as mentioned above, **Sir Christopher Floyd** reversed the Judge's findings on the second patent, having taken a different view on claim construction.

18 [2019] EWHC 63 (Pat)

19 [2019] EWHC 126 (IPEC)

20 [2021] EWHC 1377

21 [2022] EWHC 2197 (Pat)

22 [2023] EWCA Civ 841

Notwithstanding that it wasn't part of the appeal in *Vernacare*, the *Formstein* defence did get an outing in 2023, being held by **Bacon J** to be available to PCI-Pal in defending an infringement case brought by Sycurio in relation to its patent concerned with the processing of telephone calls within a call centre[23]. However, in this case, because the workings of PCI-Pal's system were considered confidential (and therefore redacted from the judgment) it is not clear exactly how the *Formstein* defence was dealt with.

De minimis

More often mentioned in limericks concerning a young lawyer called Rex than in patents court cases, the defence of *de minimis non curat lex* made a brief appearance in 2023 when it was argued that one example of an infringing item which fell outside the specified target manufacturing tolerances was sufficient evidence to justify a finding of infringement. This was put forward in *Heraeus v First Light Lamps*[24], Heraeus arguing that the number of infringing items was relevant only to the quantum of damages. **Zacaroli J** applied *Napp v Dr Reddy's*[25] and held that, even if the item had been infringing (which was not made out on the evidence), the patentee had failed to establish that infringement occurred on more than a de minimis number of occasions. It was not enough to suggest that "*mistakes do happen*" without providing any statistical basis for how often they might happen in practice.

Validity

The skilled person and their common general knowledge (CGK)

If a problem to be solved exists only briefly before a solution is found and patented, it can be difficult to establish the common general knowledge before the priority date. Was the problem established for long enough for knowledge surrounding it to be published?

This issue arose before **Meade J** in *Nokia v Oppo*[26] and as the Judge explained, the identification of CGK was difficult in this situation because it was not possible to rely on the "*classic way of proving CGK*" by using well-known textbooks. Instead, the Court was faced with using multiple documents within which lay the danger that focusing on any particular individual document could be misleading. Overall, the Judge concluded that "*What matters is information that became generally accepted; individual people in real life will have read different collations of documents from which they obtained the same information [which was CGK] … ideas specific to only one or two [documents] … were not*".

Novelty

When assessing novelty in *Nokia v Oppo*[27] the disclosure of a prior art citation known as Woo (a "*very unclear*" published European Patent Application), available for novelty only under s. 2(3)) of the Act, **Meade J** remarked on the limitations of expert evidence for novelty, noting that it is "*admissible where it elucidate[s] the technical considerations relevant to understanding [a] document and inadmissible where it descend[s] into mere analysis of words. Attributing meaning (or lack of it) once the technical context has been explained is the Court's function*". The Judge also dealt with the irregular situation whereby some parts of Woo claimed a priority date earlier than that of the patent in issue and other parts did not. Nokia argued that whilst only those parts of Woo with an earlier priority date could be relied upon for anticipation, the other parts of Woo (without priority) could be used to interpret the parts relied upon. **Meade J** thought that this was "*intuitively rather odd*" but in the end agreed with it since "*nothing in s. 2(3) … says that only part of [a document] must be read for the purposes of interpreting it, and to not read all of it might give its individual parts a meaning which was not (objectively) intended*". However,

23 *Sycurio Ltd (formerly Semafone Ltd) v PCI-Pal plc* [2023] EWHC 2361 (Pat)
24 [2023] EWHC 1950 (Pat)
25 [2016] EWHC 1517 (Pat)
26 [2023] EWHC 23 (Pat)
27 [2023] EWHC 23 (Pat)

the Judge also made clear that this nuance was not determinative of his conclusion that although it was arguable that Woo "*covered*" the method of the patent it did not "*disclose*" it and therefore did not anticipate it.

Obviousness

Continuing with *Nokia v Oppo*[28] in relation to obviousness, Oppo presented a stepwise analysis whereby the skilled person was assumed to seek to improve upon the cited prior art (**ZTE**) and find another document (**LGE**) which could be mosaicked with ZTE to render the patent obvious. **Meade J** noted upfront that, though a permitted approach[29], this presented acute dangers of hindsight following *Technograph*[30]. Specifically with respect to the mosaic of ZTE and LGE, **Meade J** reminded himself that the skilled person does not "*approach any particular citation with the expectation in advance that it will contain something useful*"[31]. This was important because there was no express cross-reference between ZTE and LGE so Oppo's case required the skilled person to read all of the relevant documents available to them (LGE was one of many) to improve the disclosure of ZTE. **Meade J** found that this amounted to an argument that all of the documents were CGK, which he rejected. He also rejected an argument that, since ZTE and LGE "*were of a broadly similar kind it would be obvious to connect the one to the other*". Furthermore, since each document presented a "*self-contained scheme*", **Meade J** concluded overall that "*the skilled person would not feel on solid ground cutting and pasting them*" together and, as such, Oppo's obviousness case failed.

A similar stepwise approach to obviousness based on a sequential reading of prior art documents was the subject of appeal in *Optis v Apple*[32], concerning Optis' patent for a method by which mobile phones access information from the network. An important part of the method involved a technique for generating a pseudo-random number. Pseudo-Random Numbers Generators (**RNGs**) are not truly random, such that different RNGs may be better or worse (i.e. exhibit more or less randomisation). Apple's argument at first instance was that the skilled person reading the prior art referred to as Ericsson would see a problem with the RNG it disclosed and seek to improve it. This would motivate them to look at a second prior art document (**NRC3**), which was CGK, and thence to a third document (**Knuth**), to which the second cross-referred, in which they would find the RNG used in the patented method.

The danger of hindsight in this analysis led to disagreement between **Arnold LJ** and **Birss LJ** over how **Meade J** had treated the expert evidence at first instance. NRC3 warned against using the type of RNGs described in Knuth but the Judge relied on evidence from Apple's expert that the skilled person would not heed these warnings since the level of randomisation necessary for the problem considered by the patent was lower than that required in other technical fields. **Arnold LJ** did not consider this to be a conclusion open to the Judge since there was no sufficient reason in evidence for the skilled person to ignore the warnings in NRC3 and the skilled person would have to have reasons for ignoring the warnings based on their common general knowledge. **Birss LJ** dissented. Expert evidence on what a skilled person might think in light of a document is admissible and hindsight need not be the only explanation for taking a certain position. To explain this, **Birss LJ** used a culinary metaphor: a modern recipe book might look back with scorn on a 1970s recipe for making spaghetti carbonara with cream cheese, yet an expert would be entitled to explain that the modern book was aimed at the gourmet and those with less refined tastes

28 [2023] EWHC 23 (Pat)

29 See *Actavis v ICOS* [2019] UKSC 15

30 *Mills & Rockley (Electronics) Ltd v Technograph Printed Circuits Ltd* [1972] RPC 346

31 See *Inhale Therapeutic Systems v Quadrant Healthcare* [2002] RPC 41

32 [2023] EWCA Civ 438

operating in a hurry might actually value the cream cheese method. Therefore, to arrive at a recipe using cream cheese might not necessarily involve hindsight. Accordingly, he did not believe **Meade J** had erred when finding it obvious to proceed from NRC3 to Knuth. However, **Nugee LJ** agreed with **Arnold LJ** and the appeal was allowed with the effect that Optis' patent was held valid.

The risk of invalidation by old or obscure prior art may seem harsh (see **Floyd LJ** in *Hozelock*[33]), but examples of very old art killing a patent are relatively rare, not least because the age of a piece of prior art can be a factor that influences the skilled person. An almost 50-year old citation was almost successful in *EnOcean v Far Eastern Manufacturing*[34]. However, whilst **Nicholas Caddick KC** (sitting as a Deputy) decided its age would not be off-putting (the skilled person must read any piece of prior art with interest and the question is whether the skilled person perceives in it something of relevance to the problem facing them) he also decided it would not have been obvious to change the workable solution presented in the prior art to something more complicated even though the concepts needed for the skilled person to arrive at the invention were part of the CGK.

The patent in *Teva & Sandoz v Astellas*[35], claiming mirabegron for the treatment of overactive bladder (**OAB**), had been held valid by **Meade J** at first instance in 2022, the obviousness attack having failed. The prior art disclosed the drug and some uses, but not the patented indication. In the context of a wider Markush formula, other members of the class were explained to be selective, and therefore useful in treatment, but uncertainty existed over the degree of selectivity and potency.

On appeal[36], this "*uncertainty*" aspect gave rise to an interesting consideration of the extent to which the patent must demonstrate that it has arrived at a solution. In this case, the specification presented the results of experiments in rats but said nothing about success in humans. However, the appellants accepted it was plausible that the invention would work. That being the case, **Arnold LJ** pointed to *Conor v Angiotech*[37] as making it clear that the question of obviousness does not depend on the amount of evidence presented in the patent. He also dismissed an argument that the patent made no technical contribution, having neither identified a new human ß3-AR agonist (mirabegron having been disclosed as such in the prior art) nor identified a new use for ß3-AR agonists (their potential for the treatment of OAB being common general knowledge). **Arnold LJ** agreed with **Meade J** that the technical contribution lay in teaching the use of mirabegron in treating OAB, and giving specific, concrete results in identified assays, albeit not in humans or human tissue. Accordingly, there was no basis for interfering with **Meade J**'s judgment and the appeal was dismissed.

Another reminder that first instance decisions on obviousness are hard to appeal came with the upholding of **Mr Campbell Forsyth**'s decision in *Advanced Bionics v Med-El*[38] that Med-El's patent was obvious. In giving judgment, **Arnold LJ** was firm in his view that **Mr Forsyth** had been entitled to find as he did and no errors of principle or law were committed. On the evidence before the Deputy Judge, the patent was bad, notwithstanding that it was later upheld by the Technical Board of Appeal (**TBA**) of the EPO. Different tribunals faced with different evidence are entitled to come to different decisions. This was also a case where the appellant patentee sought to rely on secondary evidence concerning long felt want: all the major companies in the field were said to have been aware of the prior art relied upon for many years yet not developed it. However, the evidence, a concession from the other side's expert, fell short of proving that the citation was well known and in

33 *Emson v Hozelock* [2020] EWCA Civ 871
34 [2023] EWHC 2615 (IPEC)
35 [2022] EWHC 1316 (Pat)
36 [2023] EWCA Civ 880
37 [2008] UKHL 49
38 [2023] EWCA 637

any event, even if it had been stronger, the evidence would have been secondary and not enough in this case to assist the patentee.

Plausibility

One of the year's most eagerly anticipated judgments was from the Court of Appeal in the apixaban litigation, which dealt with plausibility in the weeks following the EPO Enlarged Board of Appeal (**EBA**) decision in *G2/21*. **Arnold LJ** was the first Judge in Europe to address his understanding of the decision in a judgment.

Readers will recall that in 2022, **Meade J** invalidated BMS' compound patent for its blockbuster blood thinner apixaban (marketed as Eliquis®) for lack of plausibility[39]. In upholding that decision on appeal[40], **Arnold LJ** rejected BMS' contention that in the case of a claim to a single chemical compound there is no requirement that the specification makes it plausible that the compound is useful. In doing so, **Arnold LJ** was clear that the Supreme Court decision in *Warner-Lambert*[41] was binding upon him and applies equally to compound claims as it does to second medical use claims. There is no lower standard for compound claims. He also rejected BMS' proposition that a patent providing encouragement to test a particular compound in simple tests should be plausible, following the comments of **Sumption SCJ** in *Warner-Lambert*.

In *G2/21*, the EBA was asked to choose between two apparently conflicting lines of case law on whether to allow a patentee to rely on post-filed evidence to support a technical effect, referred to as *ab initio* plausibility and *ab initio* implausibility. The EBA considered the two lines of case law to be reconcilable under a unifying concept: "*A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention*". **Arnold LJ** disagreed that the two lines of case law were reconcilable; in *Warner-Lambert* the majority favoured *ab initio* plausibility and found the relevant claim invalid, whilst the minority favoured *ab initio* implausibility and found it valid. Furthermore, he considered the test set out by the EBA to be closer to *ab initio* plausibility than *ab initio* implausibility. However, given that he was bound by *Warner-Lambert*, this is commentary rather than law.

BMS appealed this decision to the Supreme Court, but permission was refused on the basis that the appeal raised no arguable point of law. At the time of this refusal, the Supreme Court was set to hear the appeal of the Court of Appeal's decision in *FibroGen v Akebia*[42] in March 2024, which, although concerned with slightly different issues to *Sandoz*, would have still presented the Supreme Court with an opportunity to comment on *G2/21*. However, *FibroGen* has now settled and so practitioners must await another opportunity for resolution of the apparent divergence between the English court (and the *Warner-Lambert* standard of *ab initio* plausibility) and the TBA, French and Dutch courts, which have since concluded that the EBA's decision is far closer to the lower standard of *ab initio* implausibility. Patience may be required.

Insufficiency

Bookending the EBA's decision in *G2/21* and the Court of Appeal's decision in *Sandoz and Teva v BMS*[43] (above), were two detailed considerations of plausibility in the context of insufficiency: first, **Meade J**'s decision in *Gilead v Nucana*[44] and then **Mellor J**'s decision in *Astellas v Teva and Sandoz*[45].

39 *Sandoz & Teva v Bristol-Myers Squibb* [2022] EWHC 822 (Pat)
40 *Sandoz & Teva v Bristol-Myers Squibb* [2023] EWCA Civ 472
41 [2018] UKSC 56
42 [2021] EWCA Civ 1279
43 [2023] EWCA Civ 472
44 [2023] EWHC 611 (Pat)
45 [2023] EWHC 2571 (Pat)

Nucana's two patents included product claims defined by a Markush formula. Both lack of industrial applicability and lack of plausibility were in issue, although ultimately the requirement for industrial applicability was relied upon to ensure that the technical contribution should not be set too low. **Meade J** rejected the "*potential to be used in the treatment of cancer*" as an acceptable target: "*It seemed to me to amount to saying that the specification just has to render it plausible that the effect might or might not exist, which is meaningless*". Likewise, the patent did not provide enough information about the mechanism of action of the compounds for them to be useful as research tools. The Judge did, however, apply his observation in *Sandoz and Teva v BMS*[46] that a patentee does not have to rely on the most ambitious technical contribution the specification discloses, hence cytotoxicity (without demonstrable effect as a treatment of cancer) was a feasible contribution. Notwithstanding this finding, the Judge decided that the skilled person would be unable to predict which compounds within Nucana's Markush formula would exhibit meaningful cytotoxic effects. As a result, and hedging his bets on the outcome of the EBA decision in *G2/21* (published 2 days later), he held the patents to be invalid on both the *ab initio* plausibility test and on the *ab initio* implausibility test.

Lack of plausibility was not the only defect in Nucana's patents – they were also manifestly insufficient on the classical basis (undue burden). In fact, *Gilead v Nucana* was closely similar in substance to *Idenix v Gilead*[47] ten years ago, in which **Arnold J** held Idenix' patent invalid on this basis. The broad Markush formula of the claims in that case covered billions of compounds and **Arnold J** held that the patent was "*setting the skilled team a substantial research project to select, synthesise and test the claimed compounds relying upon their own common general knowledge and claiming the results if they are successful*". Gilead's pleadings advanced essentially the same case. Once again, the Court found there to be an undue burden for the skilled person to produce certain precursors for making some compounds covered by the claims. To hammer home the undue burden argument, Gilead relied extensively on secondary evidence comprising real work done in the field at the relevant time (so much so that the weight of material required a separate legal team to process). **Meade J** cautioned against excessive focus on secondary evidence but found that it confirmed his view based on the primary evidence that Nucana's patent was invalid.

As mentioned above, the *Astellas v Teva and Sandoz*[48] case concerned a modified release formulation containing mirabegron, said to reduce food effect. **Mellor J**'s decision provided an application of the framework established by the Court of Appeal in *FibroGen*[49] to deal with the question of whether it is possible to make a "*reasonable prediction*" that the invention will work with substantially everything falling within the scope of the claim. As readers will recall, **Birss LJ** did this by adding two antecedent questions or steps: (i) what falls within the scope of the claimed class?; and (ii) what does it mean to say the invention works? Once these have been determined, the reasonable prediction question (step (iii)) can be assessed more effectively. **Mellor J** applied **Birss LJ**'s categorisation of structural and functional features from *FibroGen*, finding that the dissolution profile claimed was a functional feature that was part of the definition of the claimed class (step (i)), while the functional feature of reducing food effect was relevant to determining what it means to say the invention works (step (ii)). He found it was plausible

46 [2022] EWHC 822 (Pat)

47 [2014] EWHC 3916 (Pat) as upheld on appeal [2016] EWCA Civ 1089

48 [2023] EWHC 2571 (Pat)

49 *FibroGen Inc v Akebia Therapeutics Inc* [2021] EWCA Civ 1279

that compositions falling within the class would be capable of reducing the food effect. Even though the upper end of the limit for dissolution rate appeared to be arbitrary, that did not render the claims insufficient because products beneath that limit would work.

The *FibroGen* questions also featured in **Meade J**'s decision in *Teva Pharmaceutical Industries Ltd v Grünenthal GmbH*[50] in which Teva sought to clear the way of Grünenthal's formulation patent relating to formulations of a solution for intramuscular injection of the steroid testosterone undecanoate. Grünenthal had sought to amend the claims of the patent in suit both conditionally and unconditionally but in each case the amended claim included ranges of components within the intramuscular injection solution. The description contained examples with one particular formulation. Noting that the debate before him was really about *FibroGen* step (iii) (reasonable prediction), **Meade J** concluded that in the circumstances of the case and on the evidence before him, the degree of predictability about the behaviour of the intramuscular formulation as claimed was "*simply extremely low, verging on nil for significant changes to relevant parameters*" and, as such, all the claims of the patent as proposed to be amended either conditionally or unconditionally were insufficient for lack of plausibility across their scope and therefore invalid. In reaching this conclusion, **Meade J** was clear that he was not ruling that patentees were not permitted to generalise from preferred embodiments but rather that the extent of permitted generalisation was dependent on the subject matter of the patent.

Excluded subject matter

Practitioners who find this area of law difficult will be unsurprised by **Meade J**'s comments in *Nokia v Oppo*[51] that the "*case law is very important in this area, and has a complicated history*". In relation to step 2 of *Aerotel*[52] ("*identify the actual contribution*" of the claim), Oppo pointed to *HTC*[53] where **Floyd J** had said that the baseline against which the contribution of the patent would be assessed included "*any item of prior art for a novelty attack*". Accordingly, in attacking the patent, Oppo sought to rely on Woo (prior art available for novelty only under s. 2(3) of the Act). However, **Floyd J**'s judgment also suggests (obiter) that novelty-only prior art should not be included because, being unpublished at the priority date, it was not part of the "*real state of the art*". **Meade J** considered that "*this is not a straightforward point*" but in the end thought that Woo could be relied upon for the purposes of establishing the contribution of the patent. In making the point that novelty can lie purely in excluded matter, the Judge gave an example of "*a piece of novelty-only art that disclosed all the claimed features of a patent claim except for a claim feature that the product be painted blue (an aesthetic choice clearly excluded by Art. 52(2)(b))*". Notwithstanding this finding (which **Meade J** recognised could be said to be in disagreement with **Floyd J** in *HTC*) the contribution of Nokia's patent was not found to be excluded subject matter and the validity of the patent was thus upheld.

Sir Anthony Mann's decision in *Emotional Perception AI's Application*[54] is welcome news for those seeking to patent AI inventions in the UK and may mark a major shift in UK IPO practice. Sitting in retirement, **Sir Anthony** found that the UK IPO had erred in finding[55] a novel artificial neural network (**ANN**) implementing a recommendation system and characterised by its training method as being

50 [2023] EWHC 1836 (Pat)

51 *Nokia v Oppo* [2023] EWHC 23 (Pat)

52 *Aerotel v Telco* [2006] EWCA Civ 1371

53 *HTC v Apple* [2012] EWHC 1789 (Pat)

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

55 BL/O/542/22

excluded from patentability as a "*program for a computer... as such*" under s. 1(2)(c) of the Act. The hearing officer had considered that the emulated ANN could not be decoupled from the software platform that supports it. The applicant appealed on the grounds that: (1) there is no computer program; and (2) if there is a computer program, the exclusion does not apply because the claim reveals a technical contribution.

In relation to the first point, the Judge accepted the patentee's submissions that an ANN is not a program for a computer and should, in effect, be treated as a piece of hardware, irrespective of whether it was directly implemented as hardware or as an "*emulated ANN*". Accordingly, he found that the subject-matter exclusion did not capture this feature at all. Secondly, and in any event, he found that the claimed system demonstrated a technical effect outside the ANN that would be substantial enough to avoid the subject-matter exclusion. He found that the selection underlying the recommendation was based on "*technical criteria which the system has worked out for itself*" and that the output thereby constituted a technical effect outside the computer, thus escaping the subject-matter exclusion (if it had applied). Following this decision, the UK IPO has suspended its guidance on the examination of AI inventions and stated that "*patent examiners should not object to inventions involving ANNs under the "program for a computer" exclusion*." However, that is unlikely to be the last word: on 15 December 2023, the UK IPO confirmed that it had been given leave to appeal.

Added matter

If there is a risk that claims to a Markush formula might be overly broad, amending to narrower claims is not necessarily straightforward. Although the accepted wisdom is that the UK Courts are less likely than the EPO to find that amendments add matter, that did not prove to be the case in *Gilead v Nucana*[56]. Nucana had put forward unconditional amendments to narrow the possible substituents at X and Y of the Markush formula from H, F, Cl, Br, I, OH and Me to only one option for Y and only four options for X. What was at issue, therefore, was deletion or selection from multiple lists, a problem with the amendments which the TBA had identified in its preliminary opinion in the ongoing opposition proceedings. The Judge reviewed the principles of added matter, emphasising the goal of preventing an unwarranted advantage to the patentee and preserving legal certainty for third parties. To accord the original filing date of an application to a selection-type invention which was not disclosed in the application (because in reality it was only made at a later date) would give an unfair advantage to the applicant. In **Meade J**'s view, the EPO authorities supported the position that it was relevant to ask whether the amended claim presents a different invention with a new technical contribution. This did not replace the gold standard test but could be a "*likely symptom of there being added matter*". Overall, on the facts, the new class defined by the amendments was significantly different from that originally claimed and Nucana's position that every possible combination was disclosed was rejected.

Added matter by intermediate generalisation is a difficult ground on which to succeed. It was raised without success in *Ensygnia v Shell*[57], in *Nicoventures v Philip Morris*[58] and in *Abbott v Dexcom*[59]. In the latter, Dexcom argued that the PCT application only disclosed the use of a "*biased retention feature*" that interacted with a "*detent*" in the applicator housing. Claim 1 of the patent included integers involving biased retention features that did not interact with a detent. Dexcom's reasoning was, in part,

56 [2023] EWHC 611 (Pat)
57 [2023] EWHC 1495 (Pat)
58 [2023] EWHC 854 (Pat)
59 [2023] EWHC 2591 (Pat)

that there was a clear functional or structural relationship between the snap and detent feature disclosed in the PCT application and the amendment to refer only to a biased retention feature added matter. The Judge held that the amendment, whilst a generalisation of the snap and detent feature, in fact taught the skilled person nothing new. The added matter attack therefore failed.

FRAND

Perhaps the only thing that FRAND determinations and buses have in common is that after a very long wait (six years since **Birss J**'s decision in *Unwired Planet*[60]) two have come along at once: *InterDigital v Lenovo*[61] and *Optis v Apple*[62].

Mellor J delivered the 958-paragraph judgment in *InterDigital*. He found that Lenovo would need to pay a rate of US $0.175 per device, resulting in a lump sum payment of $138.7 million for a FRAND licence until the end of 2023. He emphasised that comparable licences remain the most important basis for establishing a FRAND rate, and considered that, unlike in *Unwired Planet*, top-down cross checks are of limited use.

The Judge considered how to select and deal with the comparable licences. Here (unlike in *Optis v Apple*) only licences to InterDigital's portfolio were considered. Factors considered in identifying relevant comparable licences included sales volumes, the location of those sales, and product mix across the different cellular standards. InterDigital sought to rely on 20 licences, often with smaller players, where InterDigital had achieved relatively high royalty rates, but **Mellor J** did not consider these were appropriate comparables. Instead, the Judge relied on one of Lenovo's preferred comparable licences - a licence between InterDigital and LG concluded in 2017. **Mellor J** '*unpacked*' this licence to determine the per unit royalty rate. The Judge considered the unpacking process should be as objective as possible. He took into account adjustments for the time value of money (i.e. due to an advance lump sum payment) and emerging markets (i.e. applying a discount in respect of sales in territories considered to be emerging markets).

In applying the derived per unit royalty rate to determine the lump sum payable by Lenovo, **Mellor J** decided that limitation periods played no role in FRAND determinations between a willing licensor and licensee. He therefore applied the rate to all of Lenovo's past sales. Whether Lenovo had to pay interest on these historic royalties was held over to the consequentials hearing[63]. There, he found that it was FRAND for a licensor to be awarded interest to compensate it for money not paid earlier, in this case at a rate of 4%, compounded quarterly. Despite this award of interest, **Mellor J** found Lenovo to be the overall "*winner*" of the FRAND trial when it came to awarding costs. This was because he had rejected the set of comparables relied on by InterDigital, and arrived at a per unit rate "*very close*" to that contended for by Lenovo; the fact that Lenovo was writing a substantial cheque was irrelevant. One further indicative factor was that the party mounting a substantive appeal against the judgment, was InterDigital not Lenovo.

As well as determining the FRAND rate, **Mellor J** also addressed the issue of whether the parties had been an unwilling licensor and licensee, respectively. The Judge's analysis of willingness in the context of the conduct of the negotiations turned on the offers made and/or rejected by the parties. The Judge considered InterDigital was unwilling by offering rates above what was found to be FRAND. Similarly, whilst the Judge concluded that "*Lenovo did drag their heels on occasion and to that extent, did not act as a willing licensee*", he considered Lenovo was justified in not accepting

60 [2017] EWHC 711 (Pat)

61 [2023] EWHC 1583 (Pat) (final public version) and [2023] EWHC 539 (Pat) (initial public version)

62 [2023] EWHC 1095 (Ch)

63 [2023] EWHC 1578 (Pat)

InterDigital's supra-FRAND rates and as a consequence found that, for the most part, Lenovo did conduct itself as a willing licensee. In terms of its subsequent conduct, the Judge considered that Lenovo did not act as a willing licensee when it failed to undertake a FRAND licence after liability for patent infringement had been established; indeed, **Mellor J** noted that, with the benefit of hindsight, he regretted not having granted a FRAND injunction immediately following the first technical trial.

As a postscript, **Mellor J** made a number of suggestions for case management of future FRAND proceedings, including encouraging: the agreement of the data sources to be used by the experts, early disclosure of potentially comparable licences under an appropriate confidentiality regime, and tighter case management with the parties focusing only on the issues which really matter.

Mellor J's *InterDigital* judgment was quickly followed by **Marcus Smith J**'s 285-page *Optis v Apple*[64] judgment in May 2023. The Judge determined that the total amount payable by Apple should be US$ 56.43m plus compound interest on past sales at 5% per annum, for a FRAND licence running until the expiry of all patents within the relevant portfolio and including a release for six years of past infringement[65]. **Marcus Smith J** took a different approach to comparable licences from **Mellor J** in *InterDigital*. Rather than relying on the licences to Optis' portfolio (branded "*worse than useless*"), **Marcus Smith J** relied on licences that Apple had entered into with other SEP holders. The Judge applied several different factors in order to select averages which he then used to derive the price payable by Apple for the Optis share of all SEPs. The Judge emphasised that the rate he computed was specific to Apple.

Similar to **Mellor J**'s approach in *InterDigital*, **Marcus Smith J** gave short shrift to the parties' allegations relating to the conduct of their negotiations, criticising them for "*wasting valuable time and money*" on these issues, and concluded in respect of the parties' conduct that Optis had not abused a dominant position (nor was it dominant), and that Apple had negotiated in good faith.

While both judgments contain a wealth of further judicial commentary on FRAND issues, to some extent they will be confined to the particular facts at issue in those proceedings. **Marcus Smith J** was clear in *Optis v Apple* that no findings of fact (including for example, an unpacked licence rate) from *Unwired Planet* could be binding or even simply adopted in another case at the risk of abdicating judicial responsibility[66].

2023 also saw a number of other FRAND developments. In April 2023, the Supreme Court granted permission to appeal in the *Optis v Apple* Trial F case. The Court of Appeal[67] had upheld **Meade J**'s finding[68] that a patentee is entitled to an injunction on a valid and infringed SEP unless and until the implementer undertakes to take a licence on the terms subsequently determined by the court to be FRAND (rather than the alternative condition of the implementer taking a licence on terms which have already been determined to be FRAND, as contended for by Apple). A hearing is anticipated in 2024. The Court of Appeal also considered the issue of in-house counsel access to confidential licences, ruling on the appropriate form of undertakings[69].

In July 2023, **Meade J** ruled[70] on various declarations sought by Oppo to protect itself from injunctive relief after an earlier ruling that one of Nokia's SEPs was valid and infringed by Oppo. Faced with competing interpretations of Clause 6.1 of the ETSI IPR Policy, he held that Nokia was required to make a FRAND offer

64 [2023] EWHC 1095 (Ch)

65 Calculated from the date the SEPs were first asserted, rather than from the date of first use of the patented technology as in *InterDigital*

66 [2023] EWHC 1095 (Ch) paragraph 364 (iii)

67 [2022] EWCA Civ 1411

68 [2021] EWHC 2564 (Pat)

69 *InterDigital Technology Corporation & Ors v OnePlus Technology (Shenzhen) Co & Ors* [2022] EWCA Civ 166

70 [2023] EWHC 1912 (Pat)

capable of acceptance by Oppo. Clause 6.1 did not have the effect of meaning Oppo was already licensed. He also decided that Oppo's undertaking to accept a FRAND licence from the Chongqing court in China (rather than the English court) was not sufficient to make it a beneficiary of Clause 6.1.

Meade J decided that as a matter of principle, an implementer found by the English court to infringe should not be permitted to remain on the market unlicensed on the basis that it has opted for a FRAND assessment in a foreign jurisdiction. Should two courts provide alternative FRAND terms, the choice of which FRAND licence to offer would be at the election of the patentee, not the implementer. Accordingly, **Meade J** considered Oppo to be an unwilling licensee: it had undertaken only to take a licence on the terms set in Chongqing. However, **Meade J** did note that the English courts would try hard to prevent FRAND rate-setting in respect of identical or overlapping geographical territories being conducted at the same time in the UK and in another jurisdiction purely by the patentee's own election.

Following two form of order hearings[71] which took place after the substantive trial, **Meade J** also granted Oppo qualified permission to appeal (certifying a leapfrog appeal to the Supreme Court in light of the extant *Optis v Apple* Trial F appeal), granted Nokia a stayed injunction against Oppo, and adjourned the upcoming FRAND trial. The case has since settled.

Supplementary protection certificates ("SPCs")

It is widely recognised and accepted, perhaps even with a degree of resignation, that the **SPC Regulation**[72] is an imperfect instrument of legislation. Most readers will be aware that there have been numerous references to the CJEU in this area for the last 15 years or so and, regrettably, the often Delphic pronouncements of the Court have led to further confusion and debate.

In late April 2023, the European Commission introduced a draft proposal which, if implemented, may resolve some (but certainly not all) of the major outstanding questions in the law. In particular, for many years now, it has been a matter of debate whether it is possible for a patentee to obtain an SPC based on its own patent but a third party's marketing authorisation (**MA**). The proposal seeks to amend Art. 6 of the SPC Regulation to make it clear that a patentee cannot obtain an SPC based on a third party's MA without the consent of that party. Further, for a long time it has been clear that it is possible to obtain two SPCs for the same product based on different patents held by different parties and a practice has emerged whereby two companies in the same group hold SPCs for the same product. The Commission's proposal provides an additional provision in Art. 3 that forbids companies holding an SPC on the same product if they are "*economically linked*". If implemented, there is no doubt that both provisions would spawn further debate in the SPC community and possibly further references to the CJEU.

Potentially more game-changing than the proposed clarification of certain aspects of the SPC Regulation is the Commission's proposal to introduce a centralised application process for SPCs to be handled by experienced national examiners working within the EU IPO. It has been observed by the Commission that the harmonised approach contemplated for the examination of SPCs by national IPOs has not been achieved: some IPOs thoroughly examine applications for SPCs, others carry out the most cursory of checks; some carry out examination straight

71 [2023] EWHC 2249 (Pat) and [2023] EWHC 2250 (Pat)

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

away, others wait until close to expiry of the basic patent. The proposed centralised system would in some respects resemble the process for obtaining European patents at the EPO, including the ability to file third party observations. However the system would have several notable differences, including a process for pre-grant opposition. Further, at the end of the process, the EU IPO would issue an opinion which, if positive, would be transmitted to the national IPOs of each country in which an SPC was sought. The Commission's proposal also provides for a unitary SPC system based on European patents with unitary effect. This would be similar to the regime described above but, at the end of the process, the EU IPO would grant a uSPC. Combined national and uSPC applications are contemplated.

Feedback on the proposals from stakeholders was published in October 2023. By and large, there is support for the centralised system although concerns were raised about whether the EU IPO was the right body to be assigned responsibility for this task and whether the prosecution/opposition system set out could be potentially used by SPC applicants and opponents alike to cause delay and uncertainty.

The Commission's proposals were trailed by its advocate at a CJEU hearing on 8 March 2023 concerning combined references from the Finnish and Irish courts in relation to validity challenges to SPCs obtained by Merck for the combination of sitagliptin and metformin. The references concerned Art. 3(a) and Art. 3(c) of the SPC Regulation and whether: (i) the combination was protected by Merck's patent (which was principally directed to sitagliptin but mentioned the possibility of combining this drug with other known medications) and (ii) a prior SPC to sitagliptin meant that Merck could not have a second SPC based on the same patent to a combination including sitagliptin. Frustratingly, the Advocate General's Opinion which was due to be issued in July 2023 was postponed first until December 2023 and then until April 2024.

Back in the UK, there were two SPC decisions of interest from the English Patents Court in 2023. The first concerned an application by Newron for an SPC for a combination of safinamide, levodopa and a peripheral decarboxylase inhibitor (**PDI**)[73]. The basic patent relied upon for the SPC was held to protect this combination and so it was common ground that Art. 3(a) was satisfied. The problem, however, lay with compliance with Art. 3(b) and the requirement for there to be an MA to place the product on the market as a medicinal product. The medicinal product relied upon by Newron was Xadago®, which lists safinamide as the sole active ingredient but makes reference to the medicine being used to treat Parkinson's disease as an add-on therapy to a stable dose of levodopa alone or with PDIs. Having reviewed the CJEU case law including most notably *Yeda*[74], **Recorder Douglas Campbell KC** held that it was clear that the therapeutic use of a product could not be imported into the definition of the product and therefore that the MA was not directed to the combination product.

In December 2023, **Michael Tappin KC**, sitting as a Deputy Judge, dismissed an appeal by Merck against a decision of the UK IPO to refuse an application for an SPC for cladribine based on a basic patent entitled "*cladribine for treating multiple sclerosis*"[75]. The UK IPO had refused the application for lack of compliance with Art. 3(d) of the SPC Regulation which requires that the MA relied upon for the SPC is the first MA to place the product on the market as a medicinal product in the EU. This was because there were earlier MAs for cladribine as a treatment for hairy cell leukaemia. Following the decisions of the CJEU in *Abraxis*[76] and *Santen*[77], it has been clear that

73 *Newron Pharmaceuticals SpA v Comptroller-General of Patents, Trade Marks and Designs* [2023] EWHC 1471 (Ch)

74 *Yeda Research & Development Co Ltd v Comptroller General of Patents* [2010] EWHC 1733 (Pat)

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

76 C-443/17 - *Abraxis Bioscience*

77 C-673/18 - *Santen*

the ruling in *Neurim*[78] which first permitted SPCs for second medical uses is no longer good law in the EU and the hearing officer accordingly refused the application. On appeal to the High Court, Merck raised 3 points: (i) that *Santen* is wrong and that the UK should follow its own trajectory in the case-law; (ii) that the facts of the case were distinguishable from *Santen* and (iii) that *Santen* had *ex nunc* rather than *ex tunc* effect such that Merck had a legitimate expectation that it would be granted an SPC in accordance with the law as stated in *Neurim*. Ultimately, the Judge found against Merck on points (ii) and (iii) and it was agreed that the High Court did not have the power to depart from CJEU case law. At the time of writing, it is understood that Merck has been given permission to appeal. This could provide the Court of Appeal with the opportunity to choose between following the CJEU case law and not permitting second medical use SPCs or following a different path. Given that *Neurim* was a reference from the English Court of Appeal[79] (on appeal from a decision of **Arnold J**) in which **Jacob LJ** stated: "*In short, if Neurim are wrong [and an SPC should not be granted], then the Regulation will not have achieved its key objects for large areas of pharmaceutical research: it will not be fit for purpose*", it will be interesting to see what happens.

Finally, 2023 bore witness to the first substantive decision on the so-called manufacturing waiver which allows third parties, amongst other things, to manufacture in the EU during the SPC term for export outside the EU and to prepare for day 1 post-expiry launch within the EU[80]. It came from the Munich District Court in a dispute between *Janssen and Formycon* following Formycon's wish to produce a biosimilar to Janssen's Stelara® medicine. Formycon notified Janssen and the German PTO of its intention to manufacture for export although it did not include a marketing authorisation number or confirmation of the third country to which export was intended to be made. Janssen was granted a preliminary injunction as the Court held that it was a requirement of the Regulation to provide the authorisation number for at least one country and that this country should be identified. Although this appears to be slightly at odds with the language of the Regulation, it seems that the Court held that the purpose of the manufacturing waiver, and in particular the 3-month notice period, is to enable the SPC holder to check whether an MA has been granted in the third country to which export is intended and that the information that Formycon had provided did not enable Janssen to carry out that analysis.

Separately, Medicines for Europe reported in June 2023 on the findings of a survey about the fitness for purpose of the manufacturing waiver. Overall, it was reported that most generics/biosimilar companies were making use of the waiver but many members were continuing to manufacture outside the EU owing to the present legal uncertainty as well as, among other things, the requirement to disclose confidential information to third parties.

Procedural issues

Territorial scope of the Act

We reported last year on the judgment of **Bacon J** in *Anan Kasei v Neo*[81], where the Judge found that Anan Kasei could not recover damages from Neo for its supply of catalytic converter materials outside of the UK. Neo had supplied a small amount of test product in the UK and the parties agreed an £85,000 damages payment for this. This test product allowed Neo to secure further orders, for which Rhodia sought over €24 million. Rhodia's problem was that these materials were manufactured in China, where the patent had

78 C-130/11 - *Neurim Pharmaceuticals (1991)*

79 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents* [2011] EWCA Civ 228

80 21 O 12030-23

81 [2022] EWHC 708 (Ch)

been invalidated, and supplied in territories without patent protection. **Bacon J** held that although damages are not in principle barred by virtue of the acts taking place abroad, on the facts there were multiple intervening contingencies and Rhodia had failed to prove that the foreign sales were caused by the English acts. Just nine months later, **Arnold LJ** delivered the leading judgment in the Court of Appeal[82]. Drawing upon the verdict of the US Supreme Court in *WesternGeco v Ion Geophysical*[83] he agreed with **Bacon J** that extra-territorial damages are, in principle, available but that on the facts of this case there was no causation due to the multiple intervening contingencies. Permission to appeal to the Supreme Court has been refused.

Preliminary issues

Readers will remember the pemetrexed litigation which ran throughout much of the 2010s. The settlement agreement with Eli Lilly required Teva to respect the patent in Europe and was governed by English law. Therefore, when there was an alleged breach of this agreement in Germany, the case came before **His Honour Judge David Hodge KC** for a case management hearing to determine Lilly's application for the court to make a determination on two preliminary issues[84]: whether the losses to be assessed were those of the claimant group as a whole or only the German subsidiary and whether damages could be claimed under German law only. The Judge refused the application on the basis these issues were not suitable for disposal on a preliminary basis: further disclosure and evidence would be needed and a preliminary issue hearing would delay the main trial. The Judge was also uneasy about dealing with the applicability of German law on the basis of assumed facts.

Arrow relief

In the years following its rise to prominence, *Arrow*[85] relief was pleaded widely. The idea of getting freedom to operate against an entire patent family via a declaration that an accused product was old or obvious is highly attractive. However, in recent years it has become clear that such declarations will not be given unless they serve a useful purpose (a requirement for any declaration granted by the English Courts). In fact, to this day, only two *Arrow* declarations have ever been granted in the UK[86]. A further refusal was added to the tally by **HHJ Hacon** in *Philip Morris v Nicoventures*[87]. PMI sought *Arrow* declarations in respect of two families of patent applications pending before the EPO. BAT's arguments against the grant of *Arrow* relief were that: (1) the declaration sought was unclear; (2) PMI had sought to expand the scope of the declaration relating to lack of novelty such that it stretched beyond the bounds of the disclosure in the prior art; and (3) the declaration lacked a useful purpose. Again, the Judge having disagreed on the first two points, the case turned on "*useful purpose*".

Having reviewed the case law on useful purpose, the Judge identified fourteen principles, the latter two of which were his own additions:

- An *Arrow* declaration is likely to serve a useful purpose if the applicant can show that (a) the respondent's portfolio of patent applications and/or patents creates real doubt, likely to continue for a significant[88] period, as to whether technical subject-matter which the applicant wishes to exploit can lawfully be used, (b) the applicant's reasonable intention to exploit that subject-matter would be of significant commercial advantage to it and (c) the declaration sought would, if granted, eliminate or significantly reduce the delay.

82 [2023] EWCA Civ 11

83 138 S Ct 2129 (2018)

84 *Eli Lilly & Co v Teva Pharmaceutical Industries Ltd* [2023] EWHC 68 (Ch)

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

86 *Fujifilm Kyowa Kirin Biologics Company Ltd v AbbVie Biotechnology Ltd* [2017] EWHC 395 (Pat) and *Glaxo Group Ltd & Ors v Vectura Ltd* [2018] EWHC 3414 (Pat)

87 [2023] EWHC 2616 (Pat)

88 In this context "*significant*" means cumulatively sufficient to warrant the intervention of the court

- The court will more readily find that there is a useful purpose where the respondent's behaviour has been consistent with an intent to prolong the doubt.

However, the Judge was also clear that he would be reluctant to discourage parties from consenting to revocation of patents where to do so will save costs and avoid unnecessary use of court time. On the facts of this case, BAT's conduct in the prosecution of the relevant patent families was not found to weigh in favour of granting *Arrow* relief. PMI also had not made out sufficiently in its evidence that the relief would have a material impact on its commercial plans. The *Arrow* declaration was therefore refused.

Licensing

The interpretation of royalty provisions in a sub-licence granted to Tesaro of patents held by the University of Sheffield and the Institute of Cancer Research was the focus of a dispute which came before **Richards J** in *AstraZeneca v Tesaro*[89]. AstraZeneca was the head licensee of the patents and the sub-licence granted to Tesaro contained obligations to pay royalties to AstraZeneca for sales of Tesaro's anti-cancer drug Zejula (niraparib).

The licensed patents were second medical use patents and the issue in dispute was whether Tesaro was required by the agreement to pay royalties on all sales of Zejula (i.e. a total sales royalty) or only on sales found to be infringing. Although the sub-licence was governed by English law, the United States doctrine of patent misuse was of some relevance to its interpretation because the United States was a major market for both AstraZeneca and Tesaro. The doctrine of patent misuse is intended to prevent patentees using agreements to extend the scope of a patent beyond that which the law allows. One of the practices that may be prevented by the doctrine is the charge of royalties on products which do not infringe the licensed patents. Tesaro argued that there was at least a significant risk that the total sales royalty would fall foul of this doctrine and therefore the court should not impute to the parties an intention to agree a total sales royalty.

The Judge concluded that the risk of patent misuse was relatively low in this case and that the parties' intentions should be taken from the language of the agreement, which pointed towards a total sales royalty structure. Although the agreement referred to use which "*may be claimed or covered*" by the licensed patents, this was found to relate to the fact that there were, or might be, patents relating to niraparib that AstraZeneca did not have the power to license. Royalties were therefore payable on all sales of Zejula, regardless of whether they related to an infringing use.

Inventorship

In 2023, the appeal of the UK IPO's refusal to grant two patents to an AI machine called DABUS reached the Supreme Court, and in one of the final judgments of the year, that Court, led by **Lord Kitchin**, unanimously dismissed the appeal of Dr Thaler (the owner of DABUS)[90]. The Supreme Court agreed with the findings of the UK IPO and all the lower courts on three issues.

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

89 [2023] EWHC 803 (Ch)

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

fruit of that tree – this only applies to tangible property. Finally, the Hearing Officer was correct to hold that the applications would be taken to be withdrawn at the expiry of the sixteen-month period specified by r. 10(3) of the **Patent Rules 2007** by reason of Dr Thaler failing to satisfy either of the requirements in s. 13(2) of the Act: he did not identify any person(s) whom he believed to be the inventor or inventors of the inventions described in the applications and his ownership of DABUS did not provide a proper basis for entitlement. This is the end of the road for Dr Thaler in the UK but cases have been heard relating to DABUS and equivalent patents in many other jurisdictions around the world, several of which have reached the same conclusion as the UK but certain jurisdictions (South Africa and Saudi Arabia) currently have patents in force listing DABUS as the inventor. The Supreme Court made it clear that it was deciding this case on the basis of interpreting the legislation as it is and not as it should be, bearing in mind the rapid development of AI technology. That would be a policy position requiring a change in legislation.

Inventor compensation

The attention commanded by a Supreme Court case can be influential. And so it may not be surprising that after Professor Shanks' successful inventor compensation claim in the Supreme Court in 2019 comes another case for inventor compensation in *Parsons v Convatec*[91]. Dr David Parsons, an analytical chemist, worked for Convatec from 1991 to 2022 during which time various inventions, mostly concerned with silver in antimicrobial products, were patented, primarily in Convatec's name. In September 2022, Dr Parsons brought an action against Convatec seeking compensation under s. 40 of the Act on the basis that he was the inventor and the inventions were of "*outstanding benefit*" to the company and therefore eligible for compensation. Convatec sought to strike out parts of Dr Parsons' claim in respect of five patent families, arguing that some patents weren't initially granted to Convatec, Dr Parsons wasn't named as an inventor in others, and that his claims under certain patents were time barred.

Zacaroli J heard Convatec's strike out application. Only the time bar point gained any traction, and on this, having considered the prescribed period for making the compensation claim under s. 40(1) of the Act (beginning on the date of the grant of the patent and ending 1 year after the patent has ceased to have effect) he agreed with Convatec that Dr Parsons was too late in respect of two patents. Although the Court has a discretion to extend the period, the Judge declined to do so, mainly because the extensions required would be many years in length, the patents were on a public register and Dr Parsons was still working in the field at the time their term ended. It did not matter that the term ended prematurely by revocation and Dr Parsons said he wanted to wait in order to bring all his claims at once. Hence, Convatec succeeded in striking out parts of Dr Parsons's claim. The rest of the case will proceed to trial.

Listing

Recorder Douglas Campbell KC's case management decision in February 2023 to hear the FRAND trial before the technical trials (i.e. trials on the issues of infringement and validity) in *Kigen v Thales*[92] is significant. This approach aims to resolve the broader commercial issues first which could influence the outcome of the technical trials.

In July 2023, in a passage of his judgment in *Nokia v Oppo*[93] entitled "*Reflections*", **Meade J** endorsed this approach: "*There have now been multiple FRAND/SEP litigations in the UK where the FRAND trial has been scheduled to take*

91 [2023] EWHC 1535 (Pat)

92 *Kigen (UK) Ltd v Thales Dis France SA* [2023] EWHC 313 (Pat)

93 [2023] EWHC 1912 (Pat)

place only after a number of technical trials, up to 2 years or longer after the litigation has been initiated. … It is becoming ever clearer that technical trials are not about what is really in issue in these disputes. What is really in issue is FRAND terms. … I do not see why it should not be possible to prioritise the FRAND issues more than has been the case to date, and, for example, to schedule at the start of a case such as this a single trial, or two trials which are simultaneous or very close in time, covering technical issues and FRAND. If the patentee failed to show that there was a SEP that was valid and essential then the FRAND terms could not be imposed on the implementer by putting it to its election. There would be consequences in terms of costs and use of resources if no patent was found valid and essential but that can happen in any action where the establishment of a cause of action and the consequences of its breach are tried together."

Putting this into practice, in November 2023, **Meade J** decided in *Panasonic v Xiaomi*[94] that he would expedite the listing of a FRAND trial as well as placing it ahead of the technical trials in the same matter. Xiaomi had applied for an expedited listing of the FRAND trial in part because Panasonic had launched parallel proceedings in other jurisdictions, including Germany, and Xiaomi had expressed a concern that, as a result of the parallel proceedings, "*it might be forced either to agree to supra-FRAND rates or even to leave the market in some or other jurisdictions*" before the High Court had given judgment on the FRAND trial. **Meade J** decided expedition was appropriate given that Panasonic did not wish to be prevented from enforcing any injunction that might be granted outside the UK in the meantime.

Confidentiality regimes

The Court has always sought to balance the competing interests of the parties when deciding what confidentiality regime is appropriate in any given situation. Whilst forming an early confidentiality club is now more or less standard practice in FRAND disputes, the terms of that club continue to be debated. In *InterDigital v OnePlus*[95] the Court of Appeal endorsed the guidance given in *Mitsubishi v OnePlus*[96] on the appropriate terms. The appeal concerned the restriction on licensing activities for the individual at OnePlus who had sight of InterDigital's licences. At first instance[97], **Mellor J** ordered a 'wide' restriction, so that the OnePlus employee could not be involved in any licensing negotiations with any counterparty during the litigation and for two years afterwards. OnePlus appealed, arguing that the restriction on licensing activities should only apply to negotiations with the specific counterparty to the InterDigital licence that was disclosed. **Birss LJ**, delivering the leading judgment, found that knowledge of any SEP licence can still present a competitive advantage when negotiating with any counterparty. Therefore, **Mellor J**'s "*wide*" restriction was upheld.

Confidential information

The influence of foreign law on the question of whether a disclosure was made available to the public was dramatically illustrated in *AutoStore v Ocado*[98] with catastrophic consequences for AutoStore and its patents. Unusually, the proceedings were conducted as a split trial where the prior disclosure issues came on first. The key question **HHJ Hacon** had to answer was whether or not the prior disclosures of AutoStore's systems (which AutoStore had admitted were enabling disclosures of the patents in issue) were confidential. The disclosures in question were made in

94 *Panasonic v Xiaomi* [2023] EWHC 2871 & [2023] EWHC 2872

95 *InterDigital Technology Co v OnePlus Technology (Shenzhen) Co* [2023] EWCA Civ 166

96 [2020] EWCA Civ 1562

97 [2022] EWHC 2121 (Pat)

98 *Autostore v Ocado* [2023] EWHC 716 (Pat)

Russia while pitching for a contract, but this fact did not matter: **HHJ Hacon** noted that the criterion of being "*made available to the public*" in s. 2(2) of the Act "*is not affected by the place where the disclosure of any matter occurs, or by the domicile or location of either the discloser or recipient of the disclosure*". What did matter was the applicable law governing the parties' dealings. The parties were in dispute about this – indeed, they even disputed which law should be applied in order to decide the applicable law. AutoStore argued that Art. 12(1) of **Rome II**[99] applied, such that Norwegian law was applicable to the confidentiality issue since this was the law "*that would have been applicable to [the contract] had it been entered into*." The Judge disagreed and applied the provisions of **Rome II** governing any unfair competition (Art. 6(1)) or damage (Art. 12(2)) that would have occurred had any obligations of confidence been breached. In both instances, Russia was the relevant country and so Russian law applied. This, in turn, had the result that obligations of confidence could only have been established if the relevant parties entered an express contract of confidentiality, which had not happened. Accordingly, the disclosures were available as prior art and the patents were held invalid. Somewhat adding insult to injury, **HHJ Hacon** commented that he would have found that an equitable obligation of confidence arose had English law applied to the disclosures.

As students of patent law know, a public disclosure may take place where a skilled person can deduce by observation the operation of an invention even if the inner workings are inside a locked box[100]. However, if reverse engineering of a publicly visible apparatus is necessary to elucidate such information, the situation becomes more complicated. In *JCB v Manitou*[101] the information concerning a particular configuration (Configuration C) used on the majority of Manitou's publicly operated telehandlers was said to be confidential, notwithstanding that it could be obtained by reverse engineering. In addition, certain information in Manitou's Product and Process Description (**PPD**) was also said to be confidential, its value lying in its ability to act as a short cut to reverse engineer Configuration C. **HHJ Hacon** held that information relating to Configuration C was confidential but that it was in the interests of open justice to include the information from Manitou's PPD in the public version of the confidential annex to his judgment. Both sides were given permission to appeal this decision.

On appeal, **Arnold LJ** analysed the case law[102] and decided in Manitou's favour that the information was confidential and that there would be a breach of confidence if a short cut had been taken. **Arnold LJ** noted that the practice of the English courts is that open justice should give way to the protection of trade secrets only when, and strictly to the extent, necessary. However, where it is necessary, open justice must give way to a greater principle, which is justice itself. **Arnold LJ** also reviewed *sua sponte* the position under the **Trade Secrets Directive**[103], Art. 9(2)(c) of which gives the court the power to publish non-confidential versions of judgments from which passages containing trade secrets have been removed or redacted. Practitioners engaged in a confidentiality dispute will benefit from a review of the judgment and its summary of the law in full.

Experiments

An order for *Mayne Pharma*[104] disclosure (of work up experiments) was made by **Mr Campbell Forsyth** sitting as a Deputy Judge in *Safestand Ltd v Weston Homes Plc*[105]. Weston Homes conducted experiments to support their position that their Kwik Kage System did not infringe Safestand's patents for support trestles used on building sites

99 Regulation (EC) no 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations

100 *Lux Traffic Controls Ltd v Pike Signals Ltd* [1993] RPC 107

101 [2023] EWHC 408 (Pat)

102 *Force India Formula One Team Limited v 1 Malaysia Racing Team Sdn Bhd* [2012] RPC 29 and *Mars UK Limited v Teknowledge Limited* [2000] FSR 138

103 Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure

104 *Mayne Pharma Pty Ltd v Debiopharm SA* [2006] EWHC 164 (Pat)

105 [2023] EWHC 1098 (Pat)

and applied for permission to rely on the results in an amended Notice of Experiments. Safestand were successful in their application for *Mayne Pharma* disclosure to avoid the risk that the results being relied upon were partial or selective, particularly bearing in mind the complexity of parameters relevant to the claims such as longitudinal stability.

Experts

This section in last year's review concluded with the remark that "*As matters now stand, the extent to which interaction between a party's own experts is desirable or even required is unclear and further clarification from the Court is awaited with interest*." Some clarity emerged in 2023. Whilst writing his decision in the *Teva v Grünenthal*[106] case, **Meade J** took the opportunity to endorse the comments made last year by **Mellor J** in *Alcon v AMO*[107] that caution against keeping experts in silos. Three points can be derived from **Meade J**'s judgment on this issue: (1) it is important that experts have a genuine opportunity to consider their colleagues' draft reports to raise queries and concerns and to modify their own evidence if required; (2) how this is achieved will depend on the case – sometimes the exchange of draft reports will be sufficient; in other cases a meeting may be necessary, whether face to face or otherwise; and (3) mere rubber-stamping of one another's evidence is not enough.

In the same vein, in *Astellas v Teva and Sandoz*[108], **Mellor J** found cause to criticise how the instructing solicitors had handled the interaction between the experts dealing with different aspects of the evidence, and also questioned whether the experts had been provided with the most helpful instructions and background information. If an expert raises a question that can be answered by data held by the client or by having a discussion with another expert, then solicitors must reflect carefully about how to respond to such a question.

The *Sycurio*[109] case provides a reminder of the importance of selecting an appropriate expert. In her judgment, **Bacon J** went so far as to disregard almost entirely the evidence given by Sycurio's witness because it fell outside the witness' core area of expertise. Sycurio had sued PCI-Pal on its GB patent for a method of reducing fraud in call centres by blocking the telephone tones which contain sensitive information (e.g. payment card details) and which could otherwise be "*decoded*" by nefarious call centre agents. **Bacon J** decided that the invention related to a specific technical problem within the area of telephone payment systems and not, as Sycurio and its expert witness contended, a more general concept of payment card security systems. **Bacon J**, in explaining the role of an expert witness, referred to **CPR 35** and emphasised that an expert witness must give evidence on matters "*within their expertise*". The Judge continued by commenting that an expert "*should not ... give evidence on the basis that they have sought to read in and educate themselves in the relevant field for the purposes of the case in question*". Again, and unsurprisingly, **Bacon J** noted that it is the solicitors that bear the responsibility.

Fact evidence

Cook v Boston Scientific[110] settled after trial but before judgment was completed. **Mr Campbell Forsyth** (sitting as a Deputy High Court Judge) nevertheless took the opportunity to comment on an issue arising at trial over whether the trial witness evidence complied with **CPR PD 57AC**. Cook had made an application to vary the certificate of compliance required by paragraph 4.4 of **CPR PD 57AC** by reason of it not being possible to comply with the

106 [2023] EWHC 1836 (Pat)
107 [2022] EWHC 955 (Pat)
108 [2023] EWHC 2571 (Pat)
109 *Sycurio v PCI-PAL* [2023] EWHC 2361 (Pat)
110 [2023] EWHC 2163 (Pat)

relevant requirements during the preparation of the evidence. The application was made without notice so Boston did not receive the application notice or supporting evidence. No doubt curious as to why compliance was initially impossible, Boston wanted to receive a copy of the application notice and supporting evidence and pointed to **CPR 23.9** as a basis for being entitled to do so. Cook denied that **CPR 23.9** was triggered because the application to vary the certificate was not "against" Boston. The Deputy Judge disagreed – the effect of Cook's successful application to vary the certificate was that Cook was then permitted to rely on evidence which is prepared outside the requirements of **CPR PD 57AC** and the Statement of Best Practice, which clearly had an impact on Boston. Therefore, in future, parties applying to vary their certificate of compliance under paragraph 4.4 of **CPR PD 57AC** should be prepared to hand over the supporting evidence regarding their earlier failure to do so.

Damages

Roughly half of the Court of Appeal's forty-page judgment in *Warner-Lambert v Dr Reddy's*[111] was taken up with covering the complex procedural history behind the application, which concerned amendments to Warner-Lambert's pleadings as part of the damages inquiry in the pregabalin litigation. Readers may recall that the damages inquiry in question is for the purpose of determining the amount of compensation owing to Dr Reddy's under Warner-Lambert's cross-undertakings given in relation to various interim orders and also to compensate loss suffered by reason of Warner-Lambert's unjustifiable threats of patent infringement proceedings. The underlying point of law was whether, given the claims covering pregabalin to treat inflammatory pain had been held valid, Dr Reddy's damages should be reduced to account for sales of pregabalin products that would ultimately have been used to treat inflammatory pain, even if no infringement was made out. Warner-Lambert suggested this should be the case as its monopoly in relation to inflammatory pain made it unjust for damages to be payable. **Arnold LJ**, giving the leading judgment, firmly rejected this idea and the other Lord Justices of Appeal agreed. **Males LJ** put the point succinctly: "*If, by obtaining an interim injunction, a patentee prevents competitors from engaging in non-infringing activity and thereby causes them loss, there is nothing unjust or inequitable in requiring the patentee to compensate them for such loss*."

In relation to Warner-Lambert's second proposed amendment that would have introduced a new allegation of infringement (supply by pharmacists of Dr Reddy's product for treatment of the patented inflammatory pain indication), it was not necessary for the Court to decide whether there was any reasonable prospect of success (although **Arnold LJ** certainly expressed his doubts) because in any event such late amendment application constituted an abuse of process, coming as it did after the liability phase of the proceedings had concluded.

Costs

Following GE's successful defence to Siemens' infringement action against its Haliade X wind turbines being installed in Dogger Bank[112], the parties argued the costs consequences of that decision[113]. The first issue was the meaning of "*costs of and occasioned by*". Siemens had originally asserted two patents, one of which was subsequently dropped before trial. Before Siemens made that decision, GE had replaced one piece of prior art with another. When the patent was dropped, an order was made that Siemens pay GE's costs associated with that

111 [2023] EWCA Civ 73

112 *Siemens Gamesa Renewable Energy A/S v GE Energy (UK) Ltd* [2022] EWHC 3034 (Pat)

113 *Siemens Gamesa Renewable Energy A/S v GE Energy (UK) Ltd* [2023] EWHC 254 (Pat)

part of the proceedings save for the "*costs of and occasioned by*" GE's amendment which changed the prior art. Siemens argued that GE should pay the historical costs of the dropped prior art, as Siemens had incurred costs in dealing with that prior art that were wasted. **Meade J** disagreed. The ordinary meaning of "*costs of and occasioned by*" only refers to costs arising after any amendment, and there was nothing in the circumstances to displace that ordinary meaning. If parties wish for costs to be retrospective in a similar situation, the appropriate wording in the order is "*costs thrown away*".

The parties also debated the appropriate way to calculate the split of costs where there are separate issues on which the overall 'loser' has prevailed. The traditional method, and that adopted by Siemens, is for the parties to count paragraphs in evidence and/or skeletons and apportion costs accordingly. Instead, GE did its calculation via a review of the billing narratives, arguing that paragraph counting over-emphasises the importance of the issues at trial, rather than how they had developed over the entirety of the case. Siemens submitted that such an approach lacked transparency and was subject to perception bias. **Meade J** disagreed that the billing narrative approach was any more prone to perception bias than paragraph counting, but did accept, in principle, a lack of transparency given he had not seen any of the actual billing narratives. However, given the solicitors' familiarity with the proceedings, and the fact that the method had withstood Siemens' challenges, **Meade J** proceeded with GE's calculations (subject to the usual high margin of error). Separately, GE resisted any apportionment of counsel's brief and refresher fees on the basis that they would have been the same whether the relevant issues were in the case or not. This was rejected, with **Meade J** finding it undesirable for counsels' fees to not be subject to any review and that had the parties known that certain issues would not be in the case when trial length and brief fees were arranged, then they would have been shorter and smaller, respectively.

In *Oxford University Innovation Ltd v Oxford Nanoimaging Ltd*[114], costs had been managed under cost budgets. OUI claimed for indemnity costs from ONI but failed – the Court found no exceptional behaviour from ONI to justify penalising them. OUI also made a request for a summary cost assessment which was also denied. The Judge favoured a detailed assessment due to the substantial sums involved. ONI was ordered to make an interim payment of £925,000 to OUI, being the total amount of budgeted costs (c.£687K) and 60-65% of the unbudgeted costs (c.£379K).

Unitary Patent/Unified Patent Court

After more than a decade in the making, the Unified Patent Court (**UPC**) finally opened its doors on 1 June 2023. Alongside it, the unitary patent (**UP**) was also introduced: a new European patent right with effect across all countries participating in the UPC at the time of grant. There are currently 17 participating states (Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia and Sweden), most of which are hosting a Local or Regional Division (which will generally hear infringement actions, actions for provisional measures and injunctions). Bulgaria, Malta and Luxembourg are not hosting Local Divisions but Germany has made up for that by hosting four, in Düsseldorf, Hamburg, Mannheim and Munich. Ireland will hold a UPC referendum in June 2024 which, if the Irish population returns a '*yes*' vote, will allow Ireland to ratify the UPCA and become a participating state, at which point it has expressed an intention to introduce a Local Division in Dublin.

114 [2023] EWHC 138 (Pat)

Shortly after the UPC start date, Milan was finally confirmed as the third seat of the Central Division (which will generally hear revocation actions and actions for declarations of non-infringement). From June 2024, Milan will have responsibility for human necessities patents (excluding SPCs), while the Munich seat will be responsible for mechanical engineering, lighting, heating, weapons, blasting, chemistry and metallurgy (excluding SPCs) and the Paris seat will be responsible for all other International Patent Classifications plus SPCs. Until the Milan seat becomes functional, its cases are being split between the Munich and Paris seats.

A summary of the highs and lows of the first seven months of the UPC and some of the early decisions now follows.

- **Early statistics (as at year end)** – Almost 600,000 UPC opt-outs were filed in the first seven months, representing at least a third of all European patents (**EPs**) that would otherwise fall under the jurisdiction of the UPC, and most likely more, given the possibility to file bulk opt-outs covering multiple EPs. Over a thousand of those opt-outs had already been withdrawn by the end of 2023 and some of the patents for which the opt-out was withdrawn were asserted within the UPC shortly thereafter. There was also significant uptake of the new UP (which must be litigated within the UPC and cannot be opted out), with over 15,000 requests for UPs filed. A total of 67 infringement actions and 24 revocation actions were filed in 2023, with the Munich Local Division proving most popular for infringement actions, 34% of all infringement actions being filed in that Division.

  English was the dominant language of revocation actions (85%), which must be filed in the language of the patent. German was the most popular language for infringement actions (59%), followed by English (30%), although it will be interesting to see how this evolves over time, particularly given that all Local Divisions and the Nordic-Baltic Regional Division (the only Regional Division so far) have confirmed that they will accept English as the language of proceedings (a detail that was confirmed only shortly before the UPC start date). The language of proceedings was switched to English after filing in a number of actions (*Plant-e Knowledge v Arkyne Technologies*[115] and *Amgen v Sanofi*[116]), although a change from German to English was refused by the Mannheim Local Division in *Panasonic v Oppo*[117] (currently under appeal).

- **IT** – Unfortunately, the early days of the UPC were beset with IT issues as the UPC case management system (**CMS**) struggled to cope with the influx of last-minute opt-out requests before the UPC start date. This led to the first UPC cases being filed by hand following a number of last-minute dashes to various UPC registries. It also led to one of the first procedural UPC decisions in the proceedings between Sanofi and Amgen[118]. On day one of the UPC, Amgen filed an infringement action against Sanofi and Regeneron before the Munich Local Division and, in parallel, Sanofi filed a revocation action against Amgen in relation to the same patent before the Munich Central Division. However, with the CMS being down, both actions were filed by hand at different registries: Sanofi's revocation action was filed in Luxembourg and Amgen's infringement action was filed in Munich.

115 Case number: UPC_CFI_239/2023; order reference: ORD_581189/2023 (main proceedings: ACT_549536/2023; application number: ACT_574494/2023)

116 Case number: UPC_CFI_14/2024; order reference: ORD_584907/2023 (main proceedings: ACT_459916/2023)

117 Case number: UPC_CFI_222/2023 and CoA_472/2023 (main proceedings: ACT_578710/2023)

118 Case number UPC_CFI_1/2023; order reference: ORD_560432/2023 (main proceedings: ACT_459505/2023)

Amgen objected that Sanofi's revocation action was inadmissible on the basis that Amgen had filed their infringement action first, so Sanofi was blocked from filing a revocation action by Art. 33(4) of the UPCA, which required them to bring their revocation action in the same Division as the existing infringement action. Amgen also argued that, even if the revocation action was not blocked by Art. 33(4), the Luxembourg registry was the wrong place for the revocation action to be filed and that it should have been filed in the sub-registry of the Munich Central Division instead. However, the UPC Judge (András Kupecz, sitting in the Munich Central Division) sided with Sanofi, finding that Sanofi had filed their revocation action 20 minutes before Amgen's infringement action and that the Luxembourg registry was an appropriate location to file proceedings under Rule 4.2 of the Rules of Procedure (**RoP**), which allow parties to file at any registry when the CMS is non-functional.

The result is bifurcated proceedings, with the Munich Central Division hearing Sanofi's revocation claim and the Munich Local Division hearing Amgen's infringement claim. To add further complexity, the Munich Local Division is also hearing a counterclaim for revocation by Regeneron (the second defendant in the infringement action, which, unlike Sanofi, did not file a separate revocation action).

- **Preliminary Injunctions (PI)** – Although it will be many months before the first main action decisions are available (the first trials are not expected to take place until summer of 2024) there have been a number of early PI decisions. In *myStromer v Revolt*[119] (Düsseldorf Local Division), a PI was granted against Revolt on 22 June 2023, only 3 weeks into the new system, after Revolt's e-bike was displayed at a trade fair in Frankfurt. One point of interest is that the PI was issued on an *ex parte* basis despite Revolt filing a protective letter, with the decision noting that the court did not find the arguments in the protective letter convincing. This leads to some uncertainty regarding the utility of filing protective letters in the new system and it will be interesting to see whether other decisions follow the same approach.

  The first *inter partes* PI decision was issued in *CUP&CINO v Alpina*[120] in the Vienna Local Division, which related to milk frothing technology. The case is notable for one of CUP&CINO's patent attorneys mistakenly opting the patent out of the UPC after the PI action had been filed. However, the patent attorney in question was able to breathe a sigh of relief when the judges confirmed that it is not in fact possible for an opt out to be filed after an action has been commenced. Unfortunately for CUP&CINO, having heard the parties' arguments and seen Alpina's milk frother in action at the hearing, the Court was not convinced of infringement and denied the PI.

  Up next were the 10x *Genomics v NanoString*[121] proceedings in the Munich Local Division. 10x Genomics sought PIs against NanoString in respect of two of its patents relating to RNA and protein analyte detection. The Munich Local Division granted a PI in relation to the first patent in a decision running to over 100 pages, which included a detailed analysis of patent validity and harm to the patentee. Notably, the PI was issued without any requirement for 10x Genomics to provide any security. NanoString appealed the decision, leading to the first UPC Court of Appeal hearing in December[122].

119 Case number: UPC_CFI_177/2023; order reference: ORD_557761/2023 (main proceedings: ACT_552758/2023)

120 Case number: UPC_CFI_182/2023 (main proceedings: ACT_ 528738/2023)

121 Case numbers: UPC_CFI_2/2023 (main proceedings: ACT_459746/2023) and UPC_CFI_17/2023 (main proceedings: ACT_459996/2023)

122 At the time of writing, the outcome of that appeal is still pending

10x Genomics was less successful in relation to the second patent: the Munich Local Division rejected the PI application on the basis that infringement had not been established. However, luckily for 10x Genomics, it already had an injunction in place in Germany under the same patent, although this raises the question of how the Munich Local Division had jurisdiction to consider the request in the first place in light of the *lis pendens* rule in the Brussels Regulation (a point that is not addressed in the decision).

AIM v Supponor[123] involved another unsuccessful PI request. AIM had initially opted its patent out of the UPC but sought to withdraw that opt-out shortly before filing the PI request (a common UPC strategy which protects the patent from a centralised revocation action before an infringement action is filed). Unfortunately, AIM's strategy backfired as the Helsinki Local Division held that the patent's opt-out could not be withdrawn, since the patent had been subject to German infringement and nullity proceedings in 2022, still pending on appeal, and therefore Art. 83(4) of the UPCA applied to block the opt-out withdrawal.

The final PI decision of 2023, issued on 20 December, was in *SES-imagotag v Hanshow*[124]. The Munich Local Division dismissed SES-imagotag's PI request, finding that SES-imagotag's patent to electronic price tags was not infringed. In so doing, the Court followed Hanshow's argument that claim amendments made during patent prosecution are relevant for interpretation of the claims and that the original claims should be used as a guide to claim interpretation, an approach that is out of step with both the EPO and many national courts of UPC states. It will be interesting to see whether the Court of Appeal provides any clarity on this point.

- **Seizure and inspection orders** – The UPC demonstrated its ability to act quickly and decisively in a number of early seizure and inspection orders. In *Oerlikon v Himson* and *Oerlikon v Bhagat*[125], the Milan Local Division issued *ex parte* seizure orders for a trade fair within a day of Oerlikon filing the applications in June 2023. In *Jozef Frans Nelissen v OrthoApnea*[126], the Brussels Local Division also flexed its muscles, granting a request for an ex parte inspection at a symposium in Belgium in September 2023, within a day of the application being filed.
- **Access to documents** – One of the most controversial aspects of the new system concerns transparency and, in particular, public access to documents on the register. Rule 262.1 of the RoP distinguishes between public access to (a) decisions and orders and (b) written pleadings and evidence, the former being available as of right and the latter requiring a "*reasoned request*". The distinction between the two sets of documents, apparently to address GDPR concerns, was introduced to the RoP in July 2022 and changed the previous draft of the rules. Practitioners were reassured at the time that the threshold for granting document access requests would be low but unfortunately this does not appear to have been the case so far in practice. Requests by interested parties for access to written pleadings and evidence were denied in the *Sanofi v Amgen*[127] and *Astellas v Osaka*[128] proceedings (Munich Central Division), *Oerlikon v Himson*[129] proceedings (Milan Local Division), *10x Genomics v Nanostring*[130] proceedings (Munich Local Division) and *NJOY Netherlands v VMR*[131] proceedings (Paris Central Division). The sole case in which a request for access under Rule 262.1(b) was granted was in *Ocado v Autostore*[132] (now resolved by a global settlement), in which a request for access to the statement of claim was granted by the

123 Case number: UPC_CFI_214/2023 (main proceedings: ACT_545571/2023

124 Case number: UPC_CFI_292/2023 (main proceedings: ACT_567009; order reference: ORD_596193/2023)

125 Case numbers: UPC_CFI_240/2023 (main proceedings: ACT_549550/2023) and UPC_CFI_241/2023 (main proceedings: ACT_549585/2023; order reference: ORD_552793_2023)

126 Case number: UPC_CFI_329/2023 (main proceedings: ACT_574133/2023; order reference: ORD_575902/2023)

127 App_546231/2023

128 App_545443/2023

129 App_562298/2023

130 App_583953/2023

131 App_587276/2023 and App_587328/2023

132 App_543819/2023

Nordic-Baltic Regional Division, although access to the orders made in parallel cases between Ocado and Autostore in the Düsseldorf and Milan Local Divisions was denied on the basis of lack of jurisdiction. That order was subsequently appealed and the order stayed pending the Court of Appeal's decision.

Further requests for documents were filed in other proceedings but remained outstanding at the end of 2023, including *AIM v Supponor*[133] (Helsinki Local Division), *Joseph Franz Nelissen v OrthoApnea*[134] (Brussels Local Division), *NJOY Netherlands v Juul*[135] (Paris Central Division), *Plant-e v Arkyne*[136] (Hague Local Division) and a new request in *Astellas v Osaka*[137] (Munich Central Division). It is hoped that the Court of Appeal and/or the Divisions considering the outstanding requests for documents will take a more generous approach to reasoned requests in 2024 to ensure transparency and open justice within UPC decision-making.

2024 will be another exciting year for the UPC, with the first main action decisions expected in the second half of the year and opportunities for the Court of Appeal to clarify the approaches to be taken in relation to important substantive legal issues including infringement analysis and jurisdiction and a whole host of interesting and no less important procedural issues. Depending on the outcome of the Irish referendum in June, it may also be the year that we see Ireland joining the list of participating states and steps being taken to set up a new Local Division in Dublin.

Looking ahead to 2024

So 2023 was a good year, perhaps even a vintage year when taken in the round and bearing in mind the commencement of the UPC. Can we expect more of the same in 2024? Highlights to which practitioners can look forward include:

- The Supreme Court hearing the appeal in *Apple v Optis*, perhaps providing more clarification on FRAND issues in the UK. The Patents Court is also due to hear at least two more FRAND determinations.
- Staying with FRAND, the Patents Court will examine whether the rack rates set out on the Avanci website are supra-FRAND in *Tesla v Avanci*.
- Further clarity from the High Court on plausibility in the case of *Teva v AstraZeneca* relating to dapagliflozin. It remains to be seen how the English court will continue to diverge from the decision in *G2/21*.
- And finally, we look forward to seeing whether the Court of Appeal will take a different course from the CJEU case law when determining whether second medical use SPCs can be granted in Merck's appeal against the UK IPO decision regarding its SPC application for cladribine.

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

133 App_583849/2023 and App_583845/2023
134 App_585674/2023
135 App_587265/2023
136 App_597352/2023
137 App_588681/2023

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