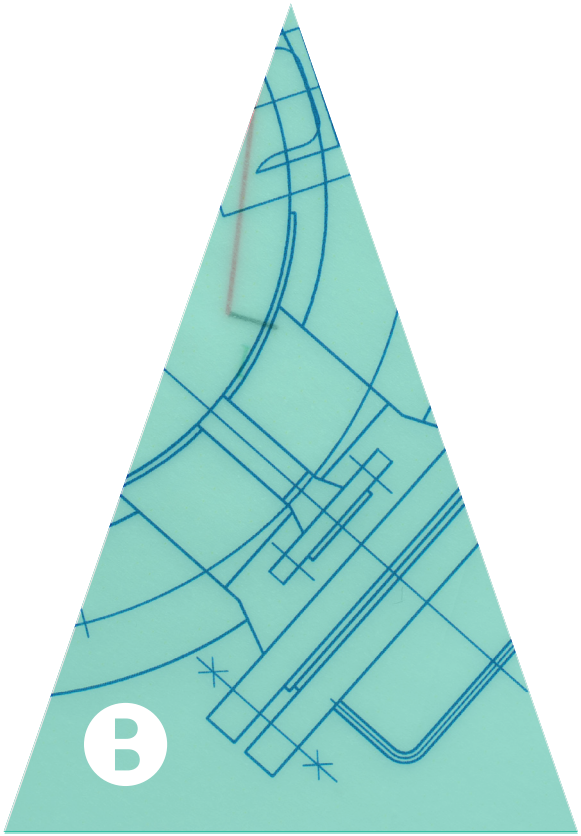
Review of Patent Cases in the English Courts in 2018



Bristows

Quotation of the Year:

"On the subject of direct infringement under section 60(1)(c), the other members of the court are however equally divided [...] I am the "swing" voice, and it is with some unwillingness that I pronounce on the issue at all. All our remarks on it will be obiter, and it is often better to leave a truly contentious and difficult issue to a case where it matters. I also confess that my own view has swung between the two sides."

Per **Lord Mance** in *Warner-Lambert v Generics (UK)* [2018] UKSC 56, at para 198.

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Introduction

2017 witnessed the upheaval of the English law of the construction and infringement of patents by the decision of the UK Supreme Court in *Actavis*.[1] 2018 saw another Supreme Court patent decision, albeit on more selective issues, in *Warner-Lambert v Generics (UK)*,[2] a dispute involving a second medical use patent for the use of pregabalin for the treatment of pain. As will be discussed below, it is hard to distil any real points of principle from the decision. Opinion is divided amongst practitioners, not just in the UK, about the suitability of non-specialist courts of final instance deciding patent cases. On the one hand, it is refreshing and often insightful to have senior judges from different traditions challenging the established orthodoxy of patent law. On the other hand, the established orthodoxy is the established orthodoxy for a reason – usually as the result of several decades, and sometimes more than a century, of jurisprudence. It seems to the authors that perhaps the optimal combination for a Supreme Court panel is a blend of judges without specialist patent law experience combined with one or more judges with a background in the field. Happily, the autumn of 2018 saw the promotion to the Supreme Court of **Lord Kitchin**, and there is no doubt that he will flourish in that arena.

As for the Unified Patent Court ("UPC"), 2018 was spent mostly in a holding pattern as the decision of the Bundesverfassungsgericht ("BVerfG", the German Federal Constitutional Court) on the constitutionality challenge brought by Dr Stjerna was awaited, and the shape of Brexit continued to be debated, though not resolved, in the UK Parliament. There was some good news for proponents of the system when the UK lodged its instruments of ratification in Brussels on World IP Day.[3] Further analysis of UPC developments is provided by Alan Johnson towards the end of this review.

Although the *Warner-Lambert* decision was the only patents decision from the Supreme Court in 2018, it was probably not the most important decision of the year. Contenders for that accolade include:

- The decision of a strong Court of Appeal in *Unwired Planet*,[4] holding that **Birss J** had been right in principle to impose a global licence, as well as to hold that the 'ND' part of FRAND is a 'general' non-discrimination obligation. The Court of Appeal also held that the framework established by the CJEU in *Huawei v ZTE*[5] does not present a set of prescriptive rules.
- The further refinement of the principles governing the granting of *Arrow* declarations, particularly in the Court of Appeal's decision in *Vectura*.[6] It is now clear that, where justice will be done and a useful purpose will be served, the courts may well consider whether to make a declaration that a given product or process formed part of the state of the art or an obvious modification thereof at a given date.
- The principles laid down by the Supreme Court in *Actavis* have begun to bed down in English law. The *Icescape*[7] decision, in particular, provides a useful summary of these principles and confirms that the English courts continue to take a sceptical attitude to file-wrapper estoppel.

There were yet further decisions and references on the interpretation of the **SPC Regulation**.[8] Opinion is divided among practitioners as to whether the CJEU decision in *Gilead*[9] has clarified the meaning of **Article 3(a)** or just added to the confusion.

In terms of the number of decisions, 2018 was the quietest year for a decade. As with 2017, several larger disputes settled just ahead of trial. There were 56 substantive patent decisions in 2018, compared with 62 in 2017 and 82 in 2016.

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

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

Claim construction / interpretation and infringement

It is an old adage of patent law that the Court must construe the patent as if the defendant had never been born. This is a matter of fairness and avoids the Court having too close an eye on the infringement when evaluating the issue of construction. However, construction seldom makes sense in the abstract: the relevant word or phrase has to be construed in context. As **Jacob LJ** said in *Technip*: "*most sensible discussions of the meaning of language run on the general lines 'does it mean this, or that, or the other?', rather than the*

1 *Actavis v Eli Lilly* [2017] UKSC 48.
2 [2018] UKSC 56.
3 26 April 2018, coincidentally also the birthday of Sir Robin Jacob.
4 *Unwired Planet v Huawei* [2018] EWCA Civ 2344.
5 C-170/13.
6 *GlaxoSmithKline v Vectura* [2018] EWCA Civ 1496.
7 *Icescape v Ice-World* [2018] EWCA Civ 2219.
8 Regulation (EC) No. 469/2000 concerning the supplementary protection certificate for medicinal products.
9 *Teva v Gilead* C-121/17.

open-ended 'what does it mean?'" [10]

In *Regeneron v Kymab*,[11] the Court of Appeal revisited **Henry Carr J**'s construction of the words "in situ replacement" in the context of the engineering of gene loci in transgenic mice. The Court rejected Kymab's criticism that the Judge had erred by having too close an eye on Kymab's process when construing the claim. Perhaps toughening the test somewhat, **Kitchin LJ** (as he then was) noted that what the court must not do is permit itself to be inspired by the acts of the infringer to cause the language to have a meaning "it will not sensibly bear".[12] Eschewing the framework for deciding the issues of construction put forward by the parties, **Kitchin LJ** simplified the issues to a binary choice on the meaning of "*in situ* replacement" between insertion and displacement, i.e. "positional displacement" and "insertion and deletion". Preferring the former, he maintained the Judge's construction and hence the finding of infringement against Kymab. It is a notable feature of the infringement case on appeal that Regeneron argued infringement under the doctrine of equivalents for the first time, the Supreme Court decision in *Actavis*[13] having been given in the period between first instance and appeal. Having already considered the first *Actavis* question of whether as a matter of normal interpretation the Kymab mice infringe, and having found that they did, **Kitchin LJ** noted that it was not necessary to consider the second question of equivalents. Had that been necessary, the Court said it would have remitted the case to **Henry Carr J**.

However, later in the year, the Court of Appeal did get an opportunity to consider the doctrine of equivalents in circumstances where the first instance decision had been given before *Actavis*: *Icescape v Ice-World*.[14] Although the findings on infringement were *obiter*, the decision is still extremely useful to practitioners as a guide to the approach that English courts will take to the issue of the construction and infringement of patents going forward. **Lord Kitchin**, giving the leading judgment (his last at the Court of Appeal, given shortly after his appointment to the Supreme Court), dispelled any doubt that *Actavis* had resulted in a sea-change in approach: "*[i]t is, in my view, clear that [the approach in Actavis] is markedly different from that which the courts in this country have adopted since Catnic*".[15] The salient facts of the case concerning the issue of infringement could have been dreamed up for the purposes of an exam question on the topic: the claims were directed to coolant pipes for mobile ice-rinks arranged in series, whereas in the apparatus alleged to infringe the coolant pipes were arranged in parallel.

Lord Kitchin went through the test prescribed by *Actavis*. To the first question – whether the claim was infringed as a matter of normal interpretation – he confirmed that this meant "purposive" interpretation and answered the question in the negative. This led on to the second question – whether the variant nonetheless infringed because it varied from the invention in a way or ways which was or were immaterial. He went through the reformulated *Improver* questions[16] and found: (i) the Icescape system did achieve the same result in the same way as Ice-World's claim because it possessed the flexible joint member that was the inventive core of the patent; (ii) this would have been "*entirely obvious*" to the person skilled in the art; and (iii) the skilled person would not have concluded that Ice-World intended strict compliance with the wording of the claim – again, because the inventive core was the flexible joint member and not the array of the pipes themselves (the array being described in the final integers of the main claim). Accordingly, and arriving at a different conclusion to the judge below, **Lord Kitchin** concluded that, had the patent been valid, Icescape would have infringed.

One of the three issues considered by the Supreme Court in the *Warner-Lambert*[17] case was the correct approach to the construction and infringement of patents with Swiss-type claims (to the use of a drug in the manufacture / preparation of a medicament to treat a given disease). As many readers will know, Swiss-type claims arose as a result of the decision of the EPO in the *Eisai* case in the mid-1980s.[18] Since the turn of this decade, patent applications with these type of claims have no longer been permitted but granted patents and SPCs based on such patents with Swiss-type claims will be in play until the early 2030s and so remain important. The findings of the Supreme Court in *Warner-Lambert* regarding Swiss-type claims are obiter in light of the decision that the patent was insufficient. Moreover, although it was common ground that Swiss-type claims are purpose-limited process claims, there was a divergence of views among the five Supreme Court judges as to the correct approach, with three different views being expressed on the issue. **Lord Sumption** (with whom **Lord Reed** agreed) suggested that the intention of the manufacturer of the medicine should only be assessable by reference to the printed material contained within the packaging of the medicine – the so-called "outward presentation" test, as he called it. **Lord Briggs** and **Lord Hodge** took the view that the

10 *Rockwater v Technip* [2004] EWCA Civ 381, at para 42.
11 [2018] EWCA Civ 671.
12 *Ibid*, at para 72.
13 See footnote 1, *ante*.
14 See footnote 7, *ante*.
15 [2018] EWCA Civ 2219, at para 59. Reference to *Catnic Components v Hill & Smith* [1982] RPC 183.
16 From *Improver v Remington* [1990] FSR 181.
17 See footnote 2, *ante*.
18 *EISAI/Second Medical Indication* G 5/83.

manufacturer's subjective intention was crucial. **Lord Mance** expressed considerable reluctance to offer an opinion but eventually followed the approach of **Lord Sumption** and **Lord Reed**, adding an important caveat that the circumstances of the supply of the medicine could suggest infringement, even if the medicine itself was not outwardly presented for the patented indication. It remains to be seen what the lower courts will make of this ruling and what applicability (if any) the decision will have in relation to so-called EPC 2000 claims, which are purpose-limited product claims.

L'Oréal v RN Ventures[19] concerned RN Ventures' alleged infringement of L'Oréal's patent for a mechanical device for the treatment of acne through the removal of sebum plugs from skin pores. The patent claimed two main embodiments – a shear mode of action (up and down), and a tension / compression mode of action (in and out). The issue was whether the main claim should be interpreted such that it included the shear mode, which was the mode used by RN Ventures' products. **Henry Carr J** concluded that, as a matter of normal interpretation, the shear mode of action (and therefore RN Ventures' products) fell within the scope of the claim. He pointed to the fact that the specification: (i) indicated a preference towards the shear mode; and (ii) described the shear mode as causing tension and compression. However, despite finding infringement under a normal interpretation of the claims, **Henry Carr J** noted that RN Ventures' products would not infringe under the doctrine of equivalents. He explained that this was because the skilled person would have understood the patentee to have considered the implementation adopted by RN Ventures' products at length, and would have understood the patentee to have chosen not to include that implementation. Interestingly, this is consistent with the position of the German Federal Court of Justice in *Okklusionsvorrichtung*.[20] However, **Henry Carr J** expressly stated that he was not deciding whether there should be a general principle of "deliberate selection" (i.e. there is no patent infringement by equivalents if the description discloses several possibilities as to how a technical effect can be achieved but only one of those possibilities is included within the claims) when considering equivalents under English law.

The Court of Appeal (with **Lewison LJ** giving the leading judgment) gave a reminder of its reluctance to interfere with fact-based judgments in *AP Racing v Alcon Components*.[21] At trial, **HHJ Hacon** found that AP Racing's patent for structurally-improved disc brake calipers via the use of peripheral stiffening bands was infringed by one (of the seven in issue) of Alcon's disc brake calipers. AP Racing appealed based on HHJ Hacon's allegedly incorrect application of the construction of a key feature of the main claim and submitted that a further two of Alcon's disc brake calipers infringed its patent. However, the Court of Appeal dismissed the appeal. It applied both *Fine & Country v Okotoks*[22] and *Henderson v Foxworth Investments*[23] and, respectively, found that: (i) the application of the trial judge's construction was an evaluative judgment with which the Court of Appeal had to be especially cautious about interfering; and (ii) the trial judge had not reached an unreasonable conclusion.

Use of the prosecution history

As readers will be aware, in *Actavis*,[24] **Lord Neuberger** made it clear that use of the prosecution history is only appropriate in two instances: (i) where an issue is "*truly unclear*" on the reading of the patent and the prosecution history "*unambiguously resolve[s]*" the point; and (ii) where it would be contrary to the public interest for the prosecution history to be ignored.[25] However, in *L'Oréal v RN Ventures*,[26] RN Ventures tried its luck in arguing that during prosecution L'Oréal had limited its main claim for a mechanical device for the treatment of acne through the removal of sebum plugs from skin pores to a tension / compression mode of action to support inventive step (and in so doing had excluded a shear mode of action). Further, the Examiner had noted the distinction between the two modes and required that the subsidiary claims to the shear mode be deleted. It argued that this indicated that the Examiner was under the impression that L'Oréal was choosing to exclude the shear mode, and that L'Oréal had approved this. However, **Henry Carr J** maintained the courts' strict approach on this issue and found that neither of the instances set out in *Actavis* applied. His reasoning was that: (i) there was no statement in the prosecution history that amounted to a clear disclaimer of the shear mode; (ii) the amendments were concerned with the effect of the mode of action on the skin rather than the mode itself; and (iii) not all claims directed to the shear mode were deleted. He further noted that L'Oréal was not under a duty to correct any misunderstanding on the part of the Examiner on the scope of the claims, and strongly emphasised that "*reference to the prosecution history is the exception, and not the rule", and that "[p] arties should think carefully in future before incurring additional costs in arguing about [it]*".[27]

In *Icescape v Ice-World*,[28] the Court of Appeal briefly

[19] [2018] EWHC 173 (Pat).
[20] *Okklusionsvorrichtung* X ZR 16/09.
[21] [2018] EWCA Civ 1420.
[22] [2013] EWCA Civ 672.
[23] [2014] UKSC 41.
[24] See footnote 1, *ante*.
[25] *Ibid*, at para 88.
[26] See footnote 19, *ante*.
[27] *Ibid*, at para 77.
[28] See footnote 7, *ante*.

considered the prosecution history of Ice-World's patent for a mobile ice rink. Although an argument was advanced that the file showed that the array of pipes (series / parallel) was an essential feature of the claims, **Lord Kitchin** was forceful in his conclusion that this argument had no merit, fell well below the threshold set by *Actavis*, and was *"a very good illustration of why it is generally so unprofitable to explore the prosecution history"*.[29]

In summary, the UK continues to adopt a sceptical approach to the use of the prosecution history as an aid to the interpretation of the claim.

Manufacture versus repair

Back in 2013, in *Schütz v Werit*,[30] **Lord Neuberger** set out eight general principles with which to conduct the analysis on the *"somewhat slippery"* meaning of the word "makes", which is of course one of the acts of infringement listed in **section 60(1)(a)** of the **Act**. In so doing, **Lord Neuberger** considered that the distinction between "manufacture" on the one hand and "repair" on the other would inevitably be a matter of fact and degree. This issue cropped up again in 2018 in relation to a rather unusual set of facts regarding a ship incorporating a pneumatic cement discharge system which was the subject of a patent.[31] The vessel had run aground in 2008 and flooded extensively. The owner had made a claim via its insurers. Ownership of the vessel was subsequently transferred to other undertakings and acquired by the claimant in 2012. The claimant and previous owners undertook significant work on the ship to enable the pneumatic cement discharge system to function, and contended that it was no more than repair. The defendant argued that the work undertaken amounted to the installation of a new patented system, and thus amounted to an act of manufacture. Despite the extensive nature of the repairs, and their high cost, **Arnold J** considered that the acts fell on the repair side of the line. One factor in his analysis was that none of the components related to the key inventive concept of the patent. The Judge also held that, by selling the vessel, the defendant had realised the economic value in the ship and thereby exhausted its rights in the patent in the EEA. An alternative implied licence argument run by the claimant was unsuccessful.

FRAND and competition defences

In 2017, **Birss J** handed down his decision in *Unwired Planet v Huawei*,[32] the first UK decision as to what constitutes a fair, reasonable, and non-discriminatory ("FRAND") royalty rate under a patent licence. FRAND is an important issue for standard essential patents ("SEPs") because the *quid pro quo* for declaring patents as essential to a telecommunications standard, meaning that anyone wishing to implement that standard will need a licence to those patents, is that the SEP owners must be prepared to grant licences of their SEPs on FRAND terms. Therefore, it is hardly surprising that the first UK decision dealing with such issues was subject to an appeal. However, the Court of Appeal unanimously upheld[33] **Birss J**'s decision and dealt with three main points.

First, was the question as to whether, in the circumstances, a FRAND licence would be of global scope, or whether it could be limited to the UK only. The Court of Appeal considered **Birss J** was entitled to find as he did: a patentee's decision to license its patents only on a global basis can in principle be FRAND (based on the facts of the case) and, if such a licence is refused by an implementer, the SEP holder should be entitled to the usual relief available for patent infringement, including an injunction. On the facts, the Court of Appeal considered (agreeing with **Birss J**) that a licensor and licensee in the parties' position, acting willingly and reasonably, would regard country by country licensing as "*madness*".[34]

However, as part of its decision, the Court of Appeal explained that it disagreed with **Birss J**'s finding that there was only a single set of FRAND terms in any given scenario; the Court considered that in reality a number of sets of terms may all be fair and reasonable. Significantly for patentees, the decision notes that where patentee and licensee both propose terms within this FRAND range, the patentee holds the trump card. Once it has made a FRAND offer, it has discharged its obligation and, if that is not accepted by an implementer, the latter may be injuncted, notwithstanding any FRAND counter-offer it might have made.

The second main point on appeal was whether the 'ND' (non-discriminatory) limb of the FRAND obligation required that an SEP holder must offer a given licensee the same rates as those charged to any other licensee in a similar position. Or whether the obligation was instead to have a general justifiable rate offered to all licensees, but which could be lowered in a particular case (e.g. where a licensee has taken an early licence without prolonged negotiation) without then needing to be lowered for all. The Court of Appeal agreed with **Birss J** that the 'ND' obligation is a general one, and that "a *benchmark rate for what was a fair and*

[29] *Ibid*, at para 79.
[30] [2013] UKSC 16.
[31] *Parainen Pearl Shipping v Kristian Gerhard Jebsen Skipsrederi* [2018] EWHC 2628 (Pat).
[32] [2017] EWHC 705 (Pat).
[33] See footnote 4, *ante*.
[34] *Ibid*, at para 110.

reasonable valuation of the patents, provided that it was on offer to all potential licensees seeking the same kind of licence without reference to their size or any other characteristic, was 'itself non-discriminatory'".[35] Further, it considered an SEP holder should not be prevented from charging less than the licence is worth if it chooses to do so. Therefore, given that the offer to Huawei was found to be at the fair and reasonable benchmark rate, the Court of Appeal concluded it was on non-discriminatory terms regardless of the lower rate agreed with Samsung.

Finally, the Court of Appeal had to consider the extent to which the framework set out in the CJEU's decision of *Huawei v ZTE*[36] provided a set of mandatory conditions with which an SEP holder must comply before starting an action seeking injunctive relief. Here, the Court of Appeal agreed with **Birss J** that only one part of that framework is mandatory: the obligation on the SEP owner to contact and notify the implementer before starting litigation. It considered the remaining points of the framework were not mandatory conditions but instead provide a "*safe harbour*" for the SEP holder "*by ensuring that the commencement of the proceedings does not, in and of itself, amount to an abuse [of dominance]*".[37] If the SEP holder strayed outside the framework, it still faced the risk of falling foul of **Article 102** of the **Treaty on the Functioning of the European Union** and being unable to obtain an injunction, but this assessment would depend on the facts rather than being a *fait accompli*.

Huawei is seeking to appeal this decision to the Supreme Court, so there may be yet more to come on this case.

FRAND devotees may also recall the comment made by **Henry Carr J** in *TQ Delta v Zyxel*,[38] reported last year, as to the sequencing of FRAND and SEP technical trials and whether it may now be time to consider having the FRAND trial first. The judicial winds have, however, turned against that idea throughout the course of the year. In *Koninklijke Philips v Asustek*, a FRAND trial is due to be heard in early 2020 following the decisions[39] that two of the three patents litigated this year were valid and essential. Further, in *Conversant v Huawei*,[40] **Henry Carr J** ordered that the two technical trials be heard first, followed by a FRAND trial to potentially save costs on the basis that, if Conversant were unsuccessful in both trials, it would be very unlikely a FRAND hearing would proceed. **Birss J** also appeared to agree with such approach in his comments in *TQ Delta v Zyxel*.[41]

Validity

Skilled person and common general knowledge

One of the starting points in patent cases is to identify the owner of the eyes through which the invention and prior art should be considered. The identity of the skilled person or team is often the subject of considerable debate between the parties as it is particularly relevant for setting the level of common general knowledge ("CGK").

The issue came up in the first of the *Koninklijke Philips v Asustek* SEP trials.[42] In that case the question was whether the skilled person would be limited (as argued by the defendants) to being a regular attendee of the standardisation meetings for the relevant technology; or whether the skilled person could also be someone who occasionally attended such meetings, or someone who was working behind the scenes to support standards delegates (as argued by the patentee). **Arnold J** explained that, where a patent does not cover more than one field of activity, it is addressed to a single kind of skilled person, but "*the skilled person to whom it is addressed is not restricted to those who are most skilled in the field (i.e. the standards delegates)*".[43] He therefore held that the skilled person may be either a standards delegate, an occasional attendee, or a worker behind the scenes; and thus that the CGK was that common to all three groups of people.

Some CGK principles also came up in the second and third *Koninklijke Philips*[44] trials. In trial B, **Arnold J** emphasised the well-trodden principle of case law that a piece of information that would not be regarded as a sufficiently reliable foundation for further work could not be within the CGK. In trial C, **Arnold J** explained that, for information to be CGK in the UK, it must be generally known to the relevant class of persons in the UK. However, the skilled person in the UK could, in principle, be working on designing and building a product for a foreign market (in that case a mobile phone, compliant with standards in place in that other market).

Entitlement to priority

The jurisprudence of the EPO and the English courts is clear that, when considering whether the priority document provides an enabling disclosure of the claimed invention, it is important to use CGK only as a guide to interpret the priority document's disclosure. It is not to be used as a supplement to fill any gaps, even if those gaps were obvious to fill and could lead

35 *Ibid*, at para 177.
36 See footnote 5, *ante*.
37 *Unwired Planet v Huawei* [2018] EWCA Civ 2344, at para 268.
38 [2017] EWHC 3305 (Pat).
39 [2018] EWHC 1826 (Pat); [2018] EWHC 1732 (Pat); and [2018] EWHC 1224 (Pat).
40 [2018] EWHC 1216 (Ch).
41 [2018] EWHC 2577 (Pat).
42 [2018] EWHC 1224 (Pat).
43 *Ibid*, at para 150.
44 [2018] EWHC 1732 (Pat); [2018] EWHC 1826 (Pat).

the skilled person to work the invention starting from the priority document without difficulty. The skilled person must be able to derive the subject matter of the claim directly and unambiguously from the disclosure of the priority document.

A good illustration of the correct approach to priority was provided by the Court of Appeal's decision in *Icescape v Ice-World*,[45] upholding the first instance decision on this point. The claim at issue, to a coupling member for coolant pipes in mobile ice rinks which allowed the piping to fold back upon itself for ease of transportation and assembly, was not fully disclosed by the priority document. Although all bar one element of the main claim was CGK and the one element that was not CGK was disclosed in the priority document, that did not assist. The Court could not read into the priority document aspects of the CGK which it did not disclose. Even though the element disclosed was, in essence, the core of the invention, the test did not discriminate between essential and non-essential features of the invention; that door was closed by the EPO Enlarged Board of Appeal in its decision in G 2/98.[46]

Novelty

The novelty of claims with numerical ranges overlapping with those in the prior art is no different from novelty in any other circumstances. **Floyd LJ** had reasoned as much, obiter, in *Lundbeck*,[47] and had a chance to affirm it in a non-*obiter* ruling in *Jushi v OCV Intellectual Capital*.[48] At first instance, **HHJ Hacon** had opted to follow the EPO's approach that an overlapping range would be novelty destroying only where the skilled person would seriously contemplate applying the teaching of the prior art document in the range of overlap.[49] **Floyd LJ** had found this approach difficult to follow in *Lundbeck*, and cautioned against relaxing the rigour of the general law of novelty. Such an approach would only be sound as a way of distinguishing between matter properly disclosed in the prior art and matter so hidden or submerged in it as not to be available. However, the Judge preferred the statement of the law in *Synthon*[50] and *Dr Reddy's*,[51] and elected to take these cases as the relevant yardstick. Nevertheless, the Court of Appeal arrived at the same conclusion as the first instance judge, dismissing Jushi's argument that the prior art disclosed each and every possible combination of values within its numerical ranges as not sitting well with the decision in *Dr Reddy's* in the context of Markush formulae.

In *Bose v Freebit*,[52] **Roger Wyand QC**, sitting as a Deputy Judge, confirmed the principle that, in order to anticipate the claims of a patent, it did not matter whether all implementations of the prior art fall within the scope of the claim – if the prior art taught a use which fell within the scope of the claim, the claim would be anticipated. The case also considered the question of what needs to be shown in order to claim anticipation by prior use. The question is whether the product relied upon had the features of the claim and was made available before the priority date of the patent. If the details of the product relied upon were unclear, the Court had to determine, based on the evidence before it, whether it considered, on the balance of probabilities, that the product relied on had the features of the claim.

Obviousness

The primary evidence in relation to an allegation of inventive step will comprise the evidence of suitably qualified expert witnesses who will prepare reports on issues such as the CGK, the mindset of the skilled person, what the skilled person would do having read prior art citations and so on. This primary evidence can be, and often is, supplemented by so-called "secondary evidence" which may consist of, among other things, contemporaneous matter surrounding the invention. In *Schlumberger v Electromagnetic Geoservices*, **Jacob LJ** held that such secondary evidence "can, and often does, play an important role".[53] In last year's review, we noted that **HHJ Hacon** had taken into consideration the fact that the challenger to a patent had not introduced a particular patented feature until after the patent was published in finding that the feature was not obvious. In 2018, **HHJ Hacon** again found that secondary evidence relating to an allegation of obviousness was persuasive in a case relating to a colonoscope cuff. In particular, the Judge considered that, if the invention was obvious, the idea would have occurred to the other major players in the field. He also took into account the invention history, and that trials with a prototype to the patented design called "Bog Brush 1" had yielded unexpectedly beneficial results in terms of visualisation of colonic folds during withdrawal.

Secondary evidence also played a small role in some other cases this year and, notably, was considered by **Arnold J** in the three trials between Koninklijke Philips and Asustek. In the first of these,[54] when considering whether the invention in the relevant SEP was obvious, after coming to a conclusion on the primary evidence, the Judge looked to secondary evidence as to whether other pre-priority work (in particular the

45 See footnote 7, *ante*.
46 *Requirement for claiming priority of the "same invention"* G 2/98.
47 *Lundbeck v Norpharma* [2011] EWHC 907 (Pat).
48 [2018] EWCA Civ 1416.
49 See e.g. *TOSHIBA/Thickness of Magnetic Layer* T 26/85, and *UNILEVER/Washing Composition* T 666/89.
50 *Synthon v SmithKline Beecham* [2005] UKHL 59.
51 *Dr Reddy's Laboratories v Eli Lilly* [2009] EWCA Civ 1362.
52 [2018] EWHC 889 (Pat).
53 [2010] EWCA Civ 819, at para 77.
54 See footnote 42, *ante*.

standards contributions) was more consistent with the obviousness or non-obviousness arguments. He also considered the post-priority developments relied upon by the parties. In the other two SEP trials,[55] he also used the secondary evidence to reinforce the conclusion he said he would reach if the primary evidence stood alone.

Insufficiency

Readers seeking a detailed exposition of the law on insufficiency, including so-called *Biogen*[56] (or breadth of claim) insufficiency, need look no further than the Court of Appeal's decision in *Regeneron v Kymab*.[57] Set out over 17 pages and including EPO jurisprudence as well as UK cases, **Kitchin LJ** used it to set the scene for a reversal of **Henry Carr J**'s finding that Regeneron's patents for transgenic mice were insufficient. One of the key difficulties for the patentee was the fact that, on any view, one of the examples in the specification was too ambitious and could not be performed as drafted. To overcome what appeared to be a classic case of undue burden, the Court of Appeal had to do something unusual: they returned to the first instance evidence and assessed anew a point mentioned by the patentee (so not a new argument as such), but not taken up by the first instance judge. Regeneron's failure to mention **Henry Carr J**'s omission upon receiving his draft judgment was heavily criticised given its later reliance upon the argument on appeal. The point in question concerned the ability of the skilled person to take from the CGK the concept of a "minigene", which could be used to perform the teaching of the ambitious example by another route. The Court of Appeal was also persuaded that, alternatively, further obvious steps could be taken in sequence to arrive at the invention, with the skilled person's motivation for pursuing the sequence deriving from the fact that, as drafted, the example was simply too difficult.

In addition to deciding that there was no undue burden in performing the teaching of the patent, the Court of Appeal also found that the invention in the patent (the reverse chimeric locus) was a principle of general application, deserving of broad protection, and commensurate with the major technical advance it contributed: mice so transformed by the genetic engineering were not immunologically sick. Being a principle of general application meant simply that an element of the claim was stated in general terms. It is sufficiently enabled if the skilled person can reasonably expect the invention to work with anything falling within the general term and the patent is not rendered insufficient just because a particular form of the invention may be an inventive improvement; a claim may embrace variants which may be provided or invented in the future. The Court of Appeal in its handling of the case, and perhaps its generosity to the patentee in allowing evidence from first instance to be developed before it for the first time, was clearly swayed by the importance of the invention in the arena of biotechnology. In his review of the jurisprudence, **Kitchin LJ** noted cases which emphasised the need to be sensitive to the nature of the invention and the contribution it has made to the art in assessing the sufficiency of disclosure, and that without "dominant patents" there existed a risk in the field of biotechnology that patent protection would become illusory. He referred to the unchallenged testimony of the inventors of the patent at first instance, and concluded that "*the invention in the reverse chimeric locus was accordingly, a striking, radical and highly original departure in the art*".[58]

Insufficiency by ambiguity is a rare beast. One reason for this is because, as **Birss J** concluded in *Unwired Planet*[59] (agreeing with **Arnold J** in *Generics (UK) v Yeda*[60]), cases of true ambiguity must be differentiated from cases where the claim is merely difficult to construe on account of having a fuzzy boundary or a puzzle at the edge of the claim. True ambiguity requires a failure by the specification to teach the skilled person enough to know whether they are within the claim or not. Sometimes this is associated with the failure to specify a technical test. 2018 brought with it a new example of insufficiency by ambiguity in the case of *GlaxoSmithKline v Vectura*.[61] Vectura's patents claimed a drug formulation for dry powder inhalation comprising composite active particles in which additive particles were adhered to or smeared over the active particles so as to form a coating. The problem for Vectura was differentiating a particle with which the coating was structurally combined by being fused or smeared over from one on which the coating was merely present but without any structural association. This led not only to problems with Vectura's experiments, which the Judge concluded were not capable of discerning infringement by reason of not having been validated against the patents' examples, but also more generally to a failure of the specification to teach the skilled person how to determine whether or not a process or product is within the claims, either at all or across the breadth of the claims, without requiring undue effort. Although Vectura had put forward certain techniques said to be capable of resolving the infringement question, the Judge found that these techniques were not mentioned in the

55 [2018] EWHC 1732 (Pat); and [2018] EWHC 1826 (Pat).
56 After *Biogen v Medeva* [1996] UKHL 18.
57 See footnote 11, *ante*.
58 *Ibid*, at para 39.
59 *Unwired Planet v Huawei* [2016] EWHC 576 (Pat).
60 [2012] EWHC 1848 (Pat).
61 [2018] EWHC 3414 (Pat).

specification and were not part of the skilled person's CGK.

Insufficiency also arose several times in *Anan Kasei v Molycorp*.[62] The main claim in Anan Kasei's patent was to "*an oxide consisting essentially of ceric oxide*" with a large surface area after being heated to a certain temperature for a certain amount of time. Ceric oxide is commonly used in catalytic converters to purify vehicle exhaust gas. One of the most interesting points to arise was an insufficiency by ambiguity argument that the meaning of "*consisting essentially of*" was unclear such that the skilled person would be unable to implement the invention or determine whether he was working the same without undue effort or at all. On this point, **Roger Wyand QC**, sitting as a Deputy Judge, accepted Anan Kasei's submission, which relied on a line of case law from the Boards of Appeal of the EPO, that "*consisting essentially of*" meant that no other components may be present which materially affect the essential characteristics of the composition. He also found that, although this interpretation still has a "*fuzzy boundary*", it does not lead to a finding of insufficiency as "*[t]here is often a limit at the edge of a claim where the precise limit is difficult to ascertain*".[63]

Molycorp made a further interesting *Biogen* insufficiency argument that the breadth of the main claim was greater than the technical contribution, as there was no upper limit on the surface area in the claim and yet the specification did not teach infinitely high surface area. However, the Judge again agreed with Anan Kasei and found the patent was not insufficient on this basis as the skilled person would be able to identify the upper limit enabled by the teaching of the patent via routine trial and error.

The ratio of *Warner-Lambert*[64] is confined to insufficiency. The relevant question before the Supreme Court related to the amount of teaching in the application as filed or priority document which was necessary to render it plausible that the invention had been made. As with the issues of construction and infringement, there was a divergence of opinion between the Supreme Court judges, albeit on this occasion there was a clear majority in favour of the view expressed by **Lord Sumption**. In summary, this view was that the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim was true. This was categorised by the Judge as a slightly stricter test than the test put forward by the Court of Appeal, which **Lord Sumption** considered amounted to "*little more than a test of good faith*".[65] Reading **Lord Sumption**'s analysis in isolation, most experienced practitioners would reach the view that little, if anything, had changed from previous statements on the subject matter. However, the views expressed by the two judges who dissented from the views of **Lord Sumption** perhaps suggest that the bar for plausibility has been raised a little. **Lord Hodge** in particular considered that, in his view, the EPO case law did not suggest that the patentee was required to demonstrate within its patent a prima facie case of therapeutic efficacy. Overall the authors conclude that the decision of the Supreme Court does not represent a major departure from the existing law. It is also clear that post-filed data can be relied upon to substantiate the teaching of the patent but that such data alone cannot form the basis of the invention taught in the patent.

Added matter

The English courts continue to follow the approach for assessing added matter, as set out in *Bonzel v Intervention*,[66] that the patentee should not be able to gain an unwarranted advantage by circumventing the "first-to-file" rule or gain a different monopoly to that which the originally filed subject-matter justified. This was explained again in *Bose v Freebit*,[67] relying on the jurisprudence of the EPO enlarged board of appeal in G 1/93[68] and *Vector v Glatt*.[69] The Judge in *Bose* also emphasised the point made by **Kitchin J** in *European Central Bank v Document Security Systems* as to the importance of considering the question of added matter without hindsight: "*care must be taken to consider the disclosure of the application through the eyes of the skilled person who has not seen the amended specification and consequently does not know what he is looking for*".[70]

Arrow declarations

Readers will recall that 2017 was the year in which the English courts first granted an *Arrow* declaration:[71] a new remedy which renders a patent family toothless against a defendant's product by declaring the product to be old or obvious in light of the state of the art at the priority date of that family, thus utilising the *Gillette*[72] squeeze that any person merely working the prior art cannot infringe a patent. Those readers with a keen interest in this area may also recall that, as matters stood at the end of the calendar year in 2017, one *Arrow* declaration had been granted (by **Henry Carr J** in *Fujifilm v AbbVie*[73]) and one had been refused (by **Arnold J** in *Generics (UK) v Yeda*[74]). During the course of the *Fujifilm* litigation, the Court of Appeal

62 [2018] EWHC 843 (Pat).
63 *Ibid*, at para 69.
64 See footnote 2, *ante*.
65 *Ibid*, at para 36.
66 [1991] RPC 553.
67 See footnote 52, *ante*.
68 *ADVANCED SEMICONDUCTOR PRODUCTS/Limiting feature* G 1/93.
69 [2007] EWCA Civ 805.
70 [2007] EWHC 600 (Pat), at para 102.
71 Named after the interim decision of Kitchin J in *Arrow v Merck & Co.* [2007] EWHC 1900 (Pat).
72 From *Gillette v Anglo-American Trading* (1913) 30 RPC 465, in particular Lord Moulton's speech at paras 480-481.
73 [2017] EWHC 395 (Pat).
74 [2017] EWHC 2629 (Pat).

had approved the remedy in principle[75] but noted two reservations: (i) in order not to offend against **section 74** of the **Act** (revocation), a claim for an Arrow declaration must be combined with a claim for revocation in circumstances where a granted member exists within the patent family concerned; and (ii) the mere existence of a pending patent application is not, of itself, reason enough to apply for an Arrow declaration.

The second point came into issue early in 2018 in *GlaxoSmithKline v Vectura*.[76] So clear seemed the Court of Appeal's judgment on this point that **HHJ Hacon**, sitting in the Patents Court, acceded to Vectura's request to strike out GSK's claim for an *Arrow* declaration in respect of Vectura's family of patents concerned with formulations for dry powder inhalers. It appeared to the Judge that there was really nothing more to GSK's case than this: subsequent patents may emerge from Vectura's applications which may threaten GSK's business in respiratory products. There was a suggestion that Vectura was in the habit of splitting out divisional patents very late in the day, but the Judge held firm that this did not alter the basic legal point that a pending application alone is not enough for an *Arrow* declaration. With this part of the claim struck out, it appeared, as many practitioners had thought, that the *Arrow* declaration was a remedy reserved for special cases.

However, later in the year the Court of Appeal reversed **HHJ Hacon**'s decision.[77] In a judgment that brought further clarity to the jurisdictional test for granting an *Arrow* declaration, **Floyd LJ** explained that the Court of Appeal's previous caution that the mere existence of a pending patent application is not, of itself, reason enough to apply for an *Arrow* declaration, needs to be read together with the subsequent point made in the same judgment: whether a sufficient case can be made for the exercise of the court's discretion. It should also be kept in mind whether the statutory remedy of revocation (if the patent application proceeded to grant) would deliver the relief that the claimant needs. **Floyd LJ**, with whom **Birss J** (sitting as a Court of Appeal judge) agreed, emphasised that the focus should be on whether the declaration would serve a useful purpose. In the case at hand, the Court was persuaded that GSK had a credible argument that they would not gain commercial certainty if they succeeded in revoking the granted patents in suit because Vectura had the potential to reformulate the inventive concept using applications still on file, which essentially amounted to the existence of a moving target, and that Vectura's past form in its filing behaviour supported this. As a practical matter, to avoid any danger that the breadth of the declaration sought, relating to a complex process for drug formulation, would present it with the unmanageable task of deciding whether every aspect was old or obvious, the Court recommended that GSK serve a schedule identifying which features were not already dealt with by the pleaded prior art, together with arguments why those features were obvious.

The trial of the action was heard before **Arnold J** at the end of November 2018, with judgment delivered less than a month later.[78] As mentioned elsewhere in this review, the Judge found Vectura's patents not infringed and invalid for insufficiency. Notwithstanding these findings, **Arnold J** proceeded to grant the *Arrow* declaration sought. Having found that GSK's process was an obvious modification of the prior art cited in the case, he granted the Arrow declaration for three reasons. First, although the patents in suit suffered from the failing that the skilled person did not know whether they were within the scope of the claims or not, future patents may grant with better drafted claims. Secondly, **Arnold J** had not found the patents in suit to lack inventive step. Therefore, this was not a *Generics (UK) v Yeda*[79] situation in which the validity of future patents could be judged summarily on an issue estoppel basis should the claims be sufficiently similar. Finally, **Arnold J** disliked that Vectura had resisted extending an already-proffered undertaking not to assert further patents from the families that were in suit to encompass a patent outside those families. Calling this "*an unusual combination of circumstances*",[80] **Arnold J** granted the declaration on the basis that the required useful purpose it would serve was that of formalising and emphasising the conclusions reached with respect to GSK's process and products, thereby avoiding the risk that such conclusions might be interpreted as mere *obiter dicta*. Perhaps surprisingly, given its prevalence in the Court of Appeal judgment on the strike-out reversal, and the apparent basis for GSK's credible argument in support of a declaration, there was no mention of any "bad behaviour" by Vectura in dividing-out new filings from long-standing applications many years after the priority date. The form of declaration granted was the narrower one of two alternatives sought by GSK, made with reference to a product and process description, on the basis that this risked the least uncertainty as to its scope.

As we enter 2019, it is clear that, as with many other areas of patent law, the English courts are prepared to take a flexible and creative approach in the interests of

[75] [2017] EWCA Civ 1.
[76] [2018] EWHC 375 (Pat).
[77] See footnote 6, *ante*.
[78] See footnote 61, *ante*.
[79] See footnote 74, *ante*.
[80] [2018] EWHC 3414 (Pat), at para 257.

furthering justice.

Supplementary Protection Certificates (SPCs)

2018 witnessed the 25th anniversary of the introduction of the **SPC Regulation** in Europe. Unfortunately, despite the passage of two and a half decades, the scope of the legislation remains remarkably unclear, despite the attempts of many leading European patent judges to resolve the issues.

Many practitioners were hopeful that the ruling of the CJEU in the *Gilead* reference made by the English Court might have represented the final say on the meaning of "protected by a basic patent in force" for the purposes of **Article 3(a)** of the **SPC Regulation**. However, it seems that such optimism may have been misplaced. As many readers will recall, this was a referral made by **Arnold J** in early 2017[81] on the issue of whether a combination of tenofovir disoproxil and emtricitabine was protected by a patent with a claim essentially to tenofovir disoproxil and "*optionally other therapeutic ingredients*". Following a rather confusing Opinion from **Advocate General ("AG") Wathelet**,[82] the Court handed down its decision on 25 July 2018.[83] The CJEU held that **Article 3(a)** should be interpreted as meaning that a product composed of several active ingredients is protected by a basic patent in force, even if the combination was not expressly mentioned in the claims where the claims relate necessarily and specifically to that combination. And for that purpose the skilled person, on the basis of the prior art [sic] at the priority date must find that: (i) the combination must necessarily, in light of the description and drawings, fall under the invention covered by the patent; and (ii) each of those active ingredients must be specifically identifiable in light of all the information disclosed in the patent.

The initial reaction from many commentators was reasonably favourable. However, as the dust settled, various questions started to emerge: how does it relate to functional claims, and what about claims which do as a matter of fact expressly mention a given combination but where the combination does not represent the core teaching of the patent?

As is regrettably so often the case with CJEU judgments, when the matter came back to the national court, both sides contended that the CJEU ruling supported their interpretation. The generics companies applied to have final judgment in their favour and Gilead sought permission to adduce further evidence and for directions towards a second trial. In a judgment given in September 2018,[84] **Arnold J** considered that the CJEU's ruling clearly favoured the generics, and that there was no basis in the patent for the skilled person to assume that emtricitabine embodied the technical contribution of the invention. Emtricitabine was also not specifically identifiable in light of all the information disclosed in the patent.

As we enter 2019, there are two pending references on **Article 3(a)** which may help provide further clarity. The first was submitted by the Court of Appeal in January 2018, relating to darunavir and the question of whether a patent which identifies a compound by reference to a Markush formula is sufficient to protect that compound for the purposes of the **SPC Regulation**.[85] The Court of Appeal saw it convenient to make a reference on this point despite **Arnold J** having considered that the issue was clearly in favour of the patentee. The second reference comes from the German Federal Patent Court[86] and relates to claims with functional definitions – the SPC in question relating to sitagliptin, a molecule which falls within the functional definition of the claim in the patent but which was developed by a licensee after the filing date. It remains to be seen whether the CJEU will decide either or both of these references by way of a reasoned order or whether it will require oral hearings.

Readers will recall that, back in 2012, in a positive development for patentees, the CJEU in *Neurim*[87] held that, for the purposes of **Article 3(d)** of the **SPC Regulation**, an earlier marketing authorisation ("MA") for an active ingredient could be ignored if the medicinal product to which that MA was attached fell outside the scope of the later basic patent relied on. In essence, this ruling paved the way for SPCs for second medical uses. However, the extent of the application of this ruling was unclear and, in the *Abraxis*[88] case, **Arnold J** made a reference as to whether the Neurim ruling extended to new and inventive formulations. The Opinion of **AG Saugmandsgaard Øe** was handed down on 13 December 2018[89] and was met with a certain degree of horror by many practitioners. In essence, the AG proposed to abandon the test in *Neurim* and to return to a literal interpretation of **Article 3(d)**, precluding the grant of a new SPC even in a situation where the MA relied upon was the first to cover the formulation protected by the basic patent. Given that the AG Opinion may well not be followed, we will not comment further in this review.[90]

81 *Teva v Gilead* [2017] EWHC 13 (Pat).
82 *Teva v Gilead* C-121/17, AG Opinion of 25 April 2018.
83 *Teva v Gilead* C-121/17, CJEU decision of 25 July 2018.
84 *Teva v Gilead* [2018] EWHC 2416 (Pat).
85 *Sandoz* C-114/18.
86 *Royalty Pharma* C-650/17.
87 C-130/11.
88 C-443/17.
89 *Abraxis* C-443/17, AG Opinion of 13 December 2018.
90 A further reference on this was made by the Paris Court of Appeal in Santen C-673/18.

One issue which remains ripe for consideration is whether it is permissible for a patentee to obtain an SPC based on a third party's MA. Ever since the *Biogen* case in 1999[91] there have been occasional allusions to the issue but no direct ruling. This issue of SPC "piggy-backing", or "squatting" to use a more pejorative term, is set to be considered by the English Court in early 2019 in the *Eli Lilly v Genentech*[92] case concerning IL-17 antibodies.

Although uncertainty remains over many aspects of the **SPC Regulation**, a 2018 ruling from the CJEU has clarified that SPCs are not available for hybrid medical devices / medicinal products.[93] Thus if, as many originators would hope, SPCs should be permitted for such products, a new Regulation will be required. Whilst mentioning reform, it should be mentioned that a study on the legal aspects of SPCs in the EU by the Max Planck Institute was published in the middle of 2018.[94] Extending to almost 700 pages, only serious enthusiasts will have read it cover to cover. The report nevertheless provides food for thought in this crucial area of law for life sciences companies. In the meantime, a proposal to introduce an export manufacturing exemption from SPC infringement is under active consideration by the European Parliament.

Damages

It is well-known that a successful patentee cannot achieve double-recovery when it comes to financial compensation for infringement. **Section 61(2)** of the **Act** explicitly prevents this. However, is there anything to prevent a damages inquiry and proceedings for an account of profits running in parallel, provided only one (presumably the higher) award is taken at the end? This was the question for **HHJ Hacon** (sitting as a High Court Judge) to decide in *Edwards Lifesciences v Boston Scientific*.[95] Whilst, in principle, the Judge accepted parallel proceedings were possible, he declined to make an order that they should proceed in the case at hand. Boston, having succeeded in its infringement claim against Edwards,[96] was concerned that intra-group movement of money within Edwards might be used to diminish any compensation if it elected for an account, arguing that the validity of any such deductions was an undetermined point of law. However, the Judge noted that Boston had received *Island Records* disclosure[97] to assist in deciding between damages and an account of profits and, whilst the point of uncertainty was a valid one, no successful patentee ever had complete certainty as to which was the better course. To run both in parallel would significantly increase the cost of the exercise and Boston instead ought to consult its advisors, assess their advice and make a proper election in the normal way. As is recorded in a subsequent judgment in the litigation,[98] Boston eventually elected to pursue an account of profits.

Costs

Henry Carr J reinforced the costs consequences of failing to register an exclusive licence within six months of its grant in *L'Oréal v RN Ventures*.[99] Earlier that month, **Henry Carr J** had found that RN Ventures' products infringed L'Oréal's valid patent for a mechanical device for the treatment of acne.[100] Many years before the proceedings were brought, on 1 July 2008, L'Oréal SA granted an exclusive licence to the patent in suit to L'Oréal UK. A relevant addendum was also later entered into on 1 August 2012. However, the licence was not registered at the UK Intellectual Property Office until 9 December 2016. It was common ground between the parties that **section 68** of the **Act** prevented L'Oréal UK from recovering the costs of the infringement claim but not L'Oréal SA. Citing **Lord Neuberger** in *Schütz v Werit*,[101] the Judge found that the purpose of **section 68** is to incentivise registration by an appropriate date, and that to allow L'Oréal SA to recover those costs which L'Oréal UK could not would leave the section with "*very little bite*". Therefore, he exercised his discretion to deprive both L'Oréal entities of 17.5% of their costs. This accounted for the registered design right claim that ran alongside the patent infringement claim, the invalidity claim and also the infringement that took place after registration of the licence. However, **Henry Carr J** granted both parties leave to appeal, stating that it was appropriate for it to be reviewed by the Court of Appeal as it was an unusual case, both in respect of the principles that he applied and the way the costs were apportioned.

In *Conversant v ZTE*,[102] the Court had to determine the issue of costs in relation to an application for an anti-suit injunction which had been compromised by the parties. Following *Brawley v Marczynski (No 1)*,[103] there is no court-ordered convention that, where litigation has been settled, there should be no order as to costs. Rather, "*where it was obvious which party would have won had the substantive issues been fought to a conclusion it would be appropriate to award costs to that party*".[104] **Henry Carr J** thus considered he first

91 C-181/95.
92 Pending at the time of publication.
93 *Boston Scientific* C-527/17.
94 Romandini, R. et al., 'Study on the Legal Aspects of Supplementary Protection Certificates in the EU', Ares(2018)2748080.
95 [2018] EWHC 664 (Pat).
96 [2017] EWHC 405 (Pat).
97 After *Island Records v Tring International* [1996] 1 WLR 1256.
98 [2018] EWHC 1256 (Pat).
99 [2018] EWHC 391 (Ch).
100 See footnote 19, *ante*.
101 See footnote 30, *ante*.
102 [2018] EWHC 2549 (Ch).
103 [2002] EWCA Civ 1453.
104 *Ibid*, as reported in [2003] 1 WLR 813.

needed to determine whether it was obvious how he would have decided the anti-suit injunction application had it not been compromised. The anti-suit injunction was applied for by Conversant against Chinese proceedings brought by ZTE which related to a FRAND dispute which the English Court had previously held it had jurisdiction to hear.[105] The Judge considered it was obvious that Conversant would have succeeded on its application had a compromise not been reached. He explained that he would have required ZTE to amend its complaint in the Chinese proceedings (as it had agreed in its compromise), failing which he would have granted the anti-suit injunction. The Judge's rationale for this was that the aspects of the complaint which had been agreed to be deleted or amended were "*vexatious, in that they sought to obstruct, or could have had the effect of obstructing, pending proceedings before the English court; or of undermining or frustrating the performance of a judgment given by the English court*".[106] He therefore decided that ZTE should pay Conversant's costs of the application.

Procedural issues

Jurisdiction

Readers may remember that in 2017 **Henry Carr J** had dismissed an application by UCB to strike out on jurisdictional grounds a claim by Chugai for a declaration from the English Court that no royalties were owing under a US patent.[107] The parties had agreed under the licence agreement that the English courts should have exclusive jurisdiction over the disputes, and **Henry Carr J** rejected the argument that deciding the question on the scope of the patent's claims would inevitably involve considerations of its validity and therefore run counter to the rule in *Moçambique*[108] that a dispute concerning the validity of a foreign patent was not justiciable in the English courts. The merits of the case were heard by **Birss J** early in 2018,[109] who construed the patent claims in Chugai's favour, having been persuaded on the "extrinsic" evidence from the state of the art, rather than the "intrinsic" evidence from the specification and its file-wrapper, which was evenly balanced. Although not exercised, the Judge noted that US law permitted him a "tie-breaker" whereby, should the claim remain ambiguous after applying all the available tools of claim construction, it should be construed so as to preserve validity.

The question of jurisdiction also arose in the context of SEP litigation where a FRAND determination was in issue. In *Conversant v Huawei*,[110] **Henry Carr J** held that the English Court has jurisdiction to determine global FRAND terms even in circumstances where the vast majority of infringing acts were taking place in another jurisdiction.[111] ZTE and Huawei argued that, in circumstances where some 70% of alleged infringing acts were taking place in China and less than 1% in the UK, it seemed a little odd for the English Court to feel it was best placed to settle the main commercial dispute between the parties as to what was a FRAND rate. The Judge concluded, however, that as acts of UK patent infringement were being alleged against the defendants (particularly where each had a UK subsidiary), only the English Court could hear both infringement and validity aspects of those claims. Once jurisdiction was established on that basis, the FRAND issue was a question of relief that it would also need to address. That conclusion, though, requires patentees to make good on a claim of patent infringement before FRAND can be considered.

Mirroring the jurisdictional issues raised in *Conversant*, **Morgan J**'s decision in *Apple v Qualcomm*[112] showed the difficulties an implementer may face in trying to get the English Court to accept jurisdiction of multinational FRAND (and competition) issues. Without a UK patent issue to particularly point to, Apple's case was largely struck out on jurisdictional grounds.

Disclosure

In *TQ Delta v Zyxel*,[113] **Birss J** reiterated that standard disclosure is no longer the default option in any civil case. He also made some comments on the approach to carrying out disclosure, explaining that the correct approach is to carry out a search in accordance with the scope of disclosure ordered and, only once that search has been conducted, consider whether the documents found are relevant and whether they should be disclosed.

The disclosure of documents regarded as confidential by a party to the proceedings and a third party is never a trivial matter, but such considerations may be overridden by the need to resolve a dispute proportionately to the costs. That was the case in *The Big Bus*,[114] where the Patents Court ordered pre-action disclosure of comparable licences so as to determine the value of the dispute, to allow the parties to make an informed assessment of whether the claim was worth litigating, and to promote settlement. A similar application for specific disclosure of a licence was made in *Smart Reamer v NOV*.[115] Resisting disclosure,

[105] *Conversant v Huawei* [2018] EWHC 808 (Pat).
[106] *Conversant v Huawei* [2018] EWHC 2549 (Ch), at para 24.
[107] See footnote 40, *ante*.
[108] *British South Africa v Companhia de Moçambique* [1893] AC 602 is authority for the rule that an English court has no jurisdiction to hear an action concerning the determination of the title to, or possession of, immovable property situated out of England, or the recovery of damages for its trespass.
[109] [2018] EWHC 2264 (Pat).
[110] See footnote 105, *ante*.
[111] This Court of Appeal upheld Henry Carr J's decision at the start of 2019 in *Conversant v Huawei* [2019] EWCA Civ 38.
[112] [2018] EWHC 1188 (Pat).
[113] See footnote 41, *ante*.
[114] The *Big Bus v Ticketogo* [2015] EWHC 1094 (Pat).
[115] [2018] EWHC 1265 (IPEC).

Smart Reamer noted the many differences between the two cases. The claimant was not in the patent licensing business and was likely to seek an injunction, the licence NOV sought disclosure of was not of comparable geographical scope, and NOV had shown no interest in settling this litigation by taking up a licence. Nevertheless, **HHJ Hacon** decided to order disclosure on the basis that the potential damage to Smart Reamer was "*fairly tenuous*", and that "*anything that is likely to promote settlement is an end to be desired*".[116]

As we enter 2019, patent litigation practitioners are watching carefully for guidance on the implementation of the Disclosure Pilot Scheme introduced by **CPR Practice Direction 51U**. Can it be that this will broaden the scope of disclosure in patent cases? It seems unlikely, but only time will tell.

Confidentiality

It is common practice in patent litigation proceedings in England for the parties to agree a confidentiality club whereby access to confidential documents in the proceedings is restricted to named individuals on provision of appropriate confidentiality undertakings. The question of documents in proceedings limited to "external eyes only" (i.e. external solicitors, counsel and independent experts, not clients) has cropped up a few times this year. One such instance was in *TQ Delta v Zyxel*,[117] heard by **Henry Carr J**. Whilst such agreements have been put in place in English proceedings previously, for example in *IPCom v HTC*[118] and *Unwired Planet v Huawei*,[119] **Henry Carr J** considered it was "*wrong in principle*" to order a general external eyes only tier of documents enabling one party to decide to exclude all representatives of the opposite party from having access to any document it chose. He held that such exclusion to relevant parts of key documents was incompatible with the right to a fair hearing under **Article 6** of the **European Convention on Human Rights** and with the principles of natural justice. However, the Judge acknowledged that the parties may choose to agree an external eyes only tier, and that a party has the right to request the court to restrict access to specific documents to external eyes only, but the onus for justifying such limitation must be on those seeking the limitation, rather than the party who *prima facie* is entitled to see the documents.

When entering into terms governing a confidentiality club, is it reasonable to expect a party's legal representatives, including junior team members handling the information, such as paralegals and secretaries, to sign individual undertakings? "No", said **Henry Carr J** in *Merck Sharp & Dohme v GlaxoSmithKline*.[120] Such undertakings should not be necessary in a situation where a firm agrees to take all reasonable steps to ensure those subject to the confidentiality regime comply with their obligations and has a duty of care to its client. The consequences of breaching that duty (a negligence action against the firm) are incentive enough to keep a tight ship. **Henry Carr J** also refused to order a term which prevented GSK and its representatives from using information on MSD's allegedly infringing product and process to amend the patent, should that be necessary during the course of proceedings.

Assessment of evidence

Arnold J continues to adopt a strict approach to the way in which experts are instructed and whether the views they express might be tainted by hindsight. This was the case in the first of the *Koninklijke Philips v Asustek* trials,[121] where **Arnold J** considered that the defendant's expert was influenced by hindsight, as evidenced by the fact that he copied one of the sentences from the patent in issue in the CGK section of his report where none of the pre-priority sources he relied upon disclosed that feature.

Another example of **Arnold J**'s firm guarding against hindsight was shown in the second *Koninklijke Philips v Asustek* trial,[122] where the Judge considered an expert who knew about the invention before reading the prior art (due to his involvement in earlier parallel proceedings) gave rise to a real risk of hindsight and therefore that his evidence should be approached with caution.

Injunctive relief

The direction of travel in the English Patents Court with regard to injunctions is towards demonstrating more flexibility, particularly in the context of life-saving medicines and medical devices.

An interesting judgment on the limits to injunctive relief in the case of life-saving products is provided by Arnold J's decision in *Edwards Lifesciences v Boston Scientific*.[123] Dealing with the issues remitted after the Court of Appeal affirmed the first instance finding that one of Boston's patents was valid and had been infringed by Edwards' "Sapien 3" trans-catheter heart valve,[124] it fell to **Arnold J** to decide the duration of stay and the scope and duration of the qualification

116 *Ibid*, at para 27.
117 [2018] EWHC 1515 (Ch)
118 [2013] EWHC 52 (Pat).
119 [2017] EWHC 3083 (Pat).
120 [2018] EWHC 3425 (Ch).
121 See footnote 41, *ante*.
122 [2018] EWHC 1732 (Pat).
123 See footnote 98, *ante*.
124 [2018] EWCA Civ 673.

of the injunction to which Boston was entitled. The stay was necessary to allow clinicians time to receive training on a non-infringing heart valve. The qualification recognised that there were some patients for whom only the Sapien 3 would do, such patients then falling outside the scope of the injunction. These savings on the injunction made the relief acceptable, notwithstanding that Boston were not themselves working the patent concerned in the UK. **Arnold J** took a sympathetic approach, very much led by public interest, and concluded on the evidence before him that it would take a year for clinicians to re-train and that the qualification on patients who required the Sapien 3, defined by reference to a clinician's declaration, should be unlimited with respect to duration. In both cases, he gave permission for the parties to apply to vary the order if it transpired that more time was needed to re-train, or an acceptable non-infringing product could safely supplant the Sapien 3.

Policy considerations involving patients also played into the reasoning behind the Court of Appeal staying the order for a final injunction in *Regeneron v Kymab*,[125] pending the outcome of Kymab's application for permission to appeal to the Supreme Court. Having restored the validity of Regeneron's patents and found Kymab to be infringing, the Court had to grapple with complex circumstances in which Kymab's business was built only in part on its infringing use of Regeneron's invention, having other significant interests, for example involving malaria research for the Bill & Melinda Gates Foundation. It was acknowledged that imposing the injunction would cause Kymab serious loss and damage, which would be extremely difficult to quantify and would bring to an end, or at least seriously disrupt, such projects. The injunction was stayed upon Kymab giving undertakings not to commercialise anything deriving from its infringing use, and Regeneron being given liberty to apply for a springboard injunction if it transpired that Kymab's infringing use had given it a post-expiry commercial bridgehead. Orders were also made, and suspended, for delivery up of infringing materials and disclosure in relation to infringing materials in the UK which were no longer in Kymab's possession. Protecting Kymab's humanitarian work was also cited as a motivation for refusing Regeneron's request that Kymab ring-fence funds sufficient to meet a likely award of damages, something which, had it been ordered, would drive Kymab out of business, according to its CEO, who gave evidence on the point.

Faced with an application to stay a final injunction pending an appeal in *Illumina v Premaitha*,[126] **Henry Carr J** accepted his inability to do perfect justice between the parties in the circumstances, and opted for the lesser of two evils as per *HTC v Nokia*.[127] Refusing a stay would go a long way towards putting the defendant out of business and causing it irreparable reputational damage, whereas staying the injunction would only cause a loss of licensing revenue to the patentee. The Judge ordered Premaitha to put 10% of its sales revenue in escrow and stayed the injunction pending appeal.

Stay of proceedings

One of the questions before the court in *Conversant v Huawei*[128] was whether allowing the proceedings to continue pending an appeal of the decision on jurisdiction would constitute submission to the jurisdiction, rendering the appeal nugatory and thus causing irreparable harm. This was a fact-sensitive analysis. In coming to his decision, **Henry Carr J** considered the case of *Goldman Sachs v Novo Banco*[129] and in particular that: (i) he was able to make an order to the effect that the steps taken between now and the appeal decision would not constitute a submission to the jurisdiction; and (ii) the other side had offered an undertaking not to take any such point on submission to the jurisdiction. The Judge also considered the prejudice which would be suffered by the respondent to the appeal if the requested stay were granted.

Expedition

The timely and speedy resolution of patent disputes is an ever present priority for the English courts, which in recent times have made significant achievements in this area, such as the expedited resolution of a complex pharmaceutical patent dispute in *Napp*,[130] where a final decision on appeal was reached less than six months after the first instance claim was issued. There must however be a good reason for expediting proceedings, and **Arnold J** was not persuaded that the claimants in *Samsung Bioepis v Fresenius*[131] had provided one. Despite having cleared the way as between themselves and AbbVie to launch their biosimilar adalimumab product from 16 October 2018 (on expiry of AbbVie's SPC), the claimants had missed a relevant patent owned by Fresenius which granted in mid-2018. The claimants moved to revoke the patent, but their claim was issued only in late August 2018, with a request for a great degree of expedition following suit a few weeks later. **Arnold J** noted that, even in the best case scenario for expedition, there was simply no prospect of a decision being given

[125] [2018] EWCA Civ 1186.

[126] [2018] EWHC 180 (Pat).
[127] [2013] EWCA Civ 1759.
[128] See footnote 40, *ante*.
[129] [2016] EWHC 346 (Comm).
[130] *Napp v Dr Reddy's Laboratories* [2016] EWCA Civ 1053.
[131] [2018] EWHC 2657 (Pat).

before the end of the period within which the NHS had planned to switch 90% of new patients to biosimilar products. Expedition would therefore not remove any of the commercial uncertainty caused by the pendency of these proceedings, and would in turn cause prejudice to Fresenius by forcing it to find and instruct an expert witness within a very limited timeframe. The Judge still provided for a modest degree of expedition, directing a trial in early summer 2019.

Abuse of process

One of the issues under consideration in the *Warner-Lambert*[132] case was abuse of process. As many readers will recall, Warner-Lambert sought to make a post-trial validating amendment to one of the claims in the patent in suit. Permission to amend was refused by **Arnold J** as being an abuse of process, and this finding was upheld by the Court of Appeal. The appeal of this issue to the Supreme Court was quickly dismissed, with all five judges agreeing that the law as stated in *Nikken v Pioneer*[133] was correct and that, as **Lord Briggs** noted, "*there was ample material upon which the Judge and the Court of Appeal could properly have concluded that the attempts to make a post-trial amendment was an abuse of process*".[134] Going forward, patentees should keep in mind constantly in the run-up to trial possible amendments that could or should be brought whether conditionally or unconditionally because the chances are that after the trial it will be too late to change the position.

Earlier in the year, **Henry Carr J** had adopted a strict approach to what constitutes abuse of process in refusing a strike-out application in *Illumina v Premaitha*.[135] The parties had been engaged in proceedings concerning the validity and infringement of five patents, decided mostly in favour of the patentee, but a new claim had been brought for infringement of a sixth patent in respect of the same products. The defendants argued that the claim was a *Henderson v Henderson*-type abuse of process[136] and that the claimants had failed to comply with the *Aldi* guidelines.[137] The Judge was of the view that the claimants' in-house patent attorney should have been aware of the existence of the sixth patent. However, absent evidence that the patent had been deliberately held back, the Judge accepted that the claimants had not appreciated that they had a cause of action against the defendants' products, so there was no breach of the guidelines. The Judge also pointed out that the sixth patent would have turned up on a diligent patent search, so the defendants had either been aware of its existence and took a risk with their eyes open, or had failed to conduct searches and closed their eyes to the risk of infringement.

Shorter and Flexible Trials Schemes

Following their implementation as Pilot Schemes between 2015 and 2018, the Shorter and Flexible Trials Schemes became permanent on 1 October 2018. These schemes are aimed at streamlining proceedings before the Business and Property Courts, including the Patents Court, and follow in the footsteps of the successful experience with the Intellectual Property Enterprise Court ("IPEC") reform in 2010. However, not every patent case qualifies for using these schemes and the judges are careful not to stretch the qualifying criteria beyond what is reasonable. **Henry Carr J** removed a revocation action from the Shorter Trials Scheme ("STS") in *Dynaenergetics v Geodynamics*,[138] following the claimant's failure to comply with the requirements in **CPR Practice Direction 51N**. The claimant had not sent a letter of claim before starting proceedings so as to allow the defendant to investigate the claim and to state whether it agreed to using the STS, and the existence of parallel proceedings concerning patents with different claims was not a good reason not to have done so. The claimant had also failed to provide a summary of the dispute and anticipated issues, its particulars of claim stating no more than the obvious detail (that is, whether the patent was valid or not). The Judge was also of the view that the trial was more likely to take five days than the estimated four and noted that, although there was flexibility to allow for a five-day trial in the STS, that should be the exception and not the rule.

The flexibility introduced by the new schemes also allows for more efficient case management and allocation, blurring the line between IPEC and Patents Court procedure. The existence of the Flexible Trials Scheme allowed **HHJ Hacon** to transfer the proceedings in *Smart Reamer v NOV*[139] from the IPEC to the Patents Court, in circumstances where the trial was likely to last longer than the three days allowed as an exception in the IPEC, but where the expense involved in turning this into a regular Patents Court action may have put the claimant in a difficult position. The defendant agreed to abide by the procedural rules applicable in the IPEC, including its costs cap, and the Judge requested the Patents Court to bear the claimant's circumstances in mind when giving directions.

[132] See footnote 2, *ante*.
[133] [2005] EWCA Civ 906.
[134] *Warner-Lambert v Generics (UK)* [2018] UKSC 56, at para 120.
[135] [2018] EWHC 615 (Pat).
[136] After *Henderson v Henderson* (1843) 3 Hare 100, which is authority for the principle that, where reasonably possible, parties should litigate all issues relating to a particular subject matter in the same litigation.
[137] Stemming from *Aldi Stores v WSP Group* [2017] EWCA Civ 260, the guidelines require that, in a situation where the claimant becomes aware of a cause of action that could be raised in ongoing proceedings, it must raise it with the court, so the latter may take a view as to the proper use of its resources and the effective and economical conduct of litigation.
[138] [2018] EWHC 287 (Pat).
[139] [2018] EWHC 2469 (IPEC).

Issues from the IPEC

Unlike proceedings before the Patents Court, the rules of procedure in the IPEC provide a fairly rigid procedural structure for the conduct of litigation up until trial once directions have been provided at the case management conference ("CMC"). This was tested in *Marflow Engineering v Cassellie*,[140] where Marflow sought to re-amend its Reply and Defence to Counterclaim to introduce new information related to the case on the CGK after the CMC. **HHJ Hacon** refused this application to amend, making clear that the CMC generally marks the last opportunity to make amendments, as it is important that all cards are on the table by the time evidence is filed. For an application to amend to be made after the CMC there would have to be "exceptional circumstances": the court would have to be satisfied the amended case could not with reasonable diligence have been brought at the CMC, and that the amended case was likely to have a significant influence on the outcome of the case. The circumstances in *Marflow* were held not to be exceptional on the facts of the case and, accordingly, the application to amend failed.

Sometimes, however, late may not be too late, but it will certainly not come in cheap in the IPEC. In *Technetix v Teleste*,[141] **HHJ Hacon** had to make a unique order to adjourn the trial on the day it started. This was to allow the claimant to amend its pleadings and serve new evidence, in order to avoid having to concede the invalidity of its patent. The costs repercussions of such an order were unsurprisingly not dealt with in the IPEC costs regime, so the Judge had to decide whether any caps should apply. The IPEC costs caps should only be lifted in truly exceptional cases, and this was such a case. The Judge decided to make an order for an independent assessment of the costs from the adjournment (including those of the amended pleadings and new evidence) to which neither the overall costs cap or any stage cap would apply, to be paid in full by the claimant.

Unitary patent / Unified Patent Court[142]

The UPC: down but not out

2017 was a classic case of a year of two halves for the UPC. It was a year when in the first half there was not just optimism, but a very real and well-founded expectation that the project would finally start on 1 December 2017. In the second half, however, the existence of the constitutional challenge by Dr Stjerna in the BVerfG landed a metaphorical body blow to the project. And so 2018 began with the UPC still on its knees, reeling from the attack by Dr Stjerna, unable to pick itself up off the floor pending the BVerfG's decision.

However, it was not long until the first small item of good news of the year arrived, on 11 January 2018, in the shape of an announcement that Latvia had ratified the UPC Agreement ("UPCA"). More significantly, in February the important news came from the BVerfG that the UPC case was on the list of cases for decision in 2018 following the submission of the last of the amicus briefs at the end of January. Moreover, it was rumoured that every single one of the twenty-odd amicus briefs suggested rejection of the arguments of Dr Stjerna in favour of the legality of the system. Surely this would mean that it would not be long before a decision favourable to the UPC, and business as usual could be resumed and the system could start later in the year or in early 2019?

In April there was yet further (and very significant) good news: the UK chose World IP Day to complete its own ratification process by lodging its instrument of ratification of the UPCA in Brussels. With more than 10 non-mandatory ratifications of the UPCA also in place, this meant that it really was now entirely down to Germany to see the project start – albeit one or two more countries still had to approve the UPCA's Protocol on Provisional Application ("PPA") to allow the start-up period (provisional phase) to come into existence.

Sadly, this was the end of the good news from 2018. True, there were little snippets of positivity, such as Bulgaria's approval of the PPA in July, and continuing preparations at a technical level between Governments. But with the clock ticking away toward Brexit on 29 March 2019, the chances of the system starting before then diminished with every passing month of silence from the BVerfG. And so it was that, despite many rumours, not least one emanating from the Annual European Patent Judges' conference in Venice in October that a decision would be handed down before the end of the year, 2018 ended with not so much as a peep from the German Court.

What next, and what of Brexit?

One of the other more negative features of the year, other than the silence from the BVerfG, was the

[140] [2018] 11 WLUK 182 (Unreported).
[141] [2018] EWHC 1941 (IPEC).
[142] The authors are grateful to Alan Johnson of Bristows for drafting this section of the review.

publication of a paper by two research fellows of the Max Planck Institute for Innovation and Competition, entitled 'The Impact of Brexit on Unitary Patent Protection and its Court'.[143] The paper concluded in no uncertain terms that the UK could not, post-Brexit, participate in the UPC project. Happily, this is but one view, and without being too dismissive of what is certainly (at 182 pages long) a detailed piece of work, a rebuttal published[144] under the pseudonym Atticus Finch was not only pithier but far more compelling in concluding the opposite. However, there are certainly issues connected with Brexit which are worthy of discussion.

The central point is whether the UPC is an EU-only "club" in the eyes of the CJEU. That is a question, however, which only the CJEU itself can answer, and sadly there is no mechanism to ask it the question unless and until the system starts and is challenged – plainly not a happy state of affairs.

Despite this, there is relative certainty that, if there is a transition period post-Brexit such as is contemplated under the EU exit arrangement agreed by the EU and the UK Government (notwithstanding its rejection by Parliament and the ongoing uncertainty surrounding a deal), the UK will be able to participate until at least 31 December 2020. Without going into detail, this is because under this arrangement all EU Regulations will continue to apply to the UK. These, of course, include the unitary patent and translation regulations, which in turn require a court (the UPC) in which to litigate unitary patents. This means, in your author's view at least, that even if it is unaware of this fact, the EU itself has agreed by Treaty that the UK can, indeed must, participate in the UPC until end-2020 if it can be started before then. Of course, as at the time of writing, the existence of a transition period is very far from certain. On the other hand, the prospect of an extension to the Article 50 period, perhaps of nine months, or even longer as is apparently being discussed in the corridors of Brussels, opens up the simpler scenario that the system is ready to start whilst the UK is still a fully-fledged Member State.

If, on the other hand, there is a Brexit without any agreement, the position is certainly trickier for everyone. The trite point that the UPCA refers in express terms to EU Member States is not the issue. A simple protocol stating that by "EU Member State" the parties mean "an EU Member State as of the date of signature of the agreement" would take care of this. More significant is whether the CJEU would be satisfied that membership of the UPC by a non-Member State is not problematic? And whether, absent certainty on this legal question, the parties (in effect Germany given it holds the key to the project starting) would be willing to proceed to start up the system in a post-Brexit world, and work together to iron out potential other legal issues such as the UK dropping out of the Brussels Regulation, and not being a member of the Lugano Convention, one or other of which is seemingly a necessity under the UPCA (Article 31). At the very least one might think the parties might work on a contingency agreement to cater for the possibility of the CJEU finding that the system was not lawful and that the UK needed to be ejected.

This is where political will remains vital. With the possible exception of Italy, motivated perhaps by the desire to see Milan host the London branch of the Central Division, everyone in the UPC club appears still to wish the UK to remain a part of the system. Critically, so too does European and British industry. And in the much repeated words of Dr Margot Fröhlinger on this topic, "*where there's a will, there's a way*".

Political will is, of course, a fickle thing. Will the goodwill toward the UK's participation survive a no-deal Brexit? What if the BVerfG does not reject Dr Stjerna's complaint, but its decision requires Germany to re-pass its ratification legislation, or even make a constitutional amendment to legalise transfer of powers to the UPC? How would Germany react? Could the project survive a further extended delay? Frankly it is pointless even to try to guess the answers to these questions. All that can be said with any certainty is that, at any point in time, we stand at least eight or nine months away from the UPC starting, as that is the period required for the provisional phase during which the final preparations must be sorted out, notably appointment of the UPC judges. Hence as of now, the most optimistic timing is for a start date of 1 December 2019. But your author does not recommend readers to hold their breath, for as some weary observer stated at a UPC conference a few months ago: "*the UPC is always something that will happen next year*".

[143] Lamping, M. and Ullrich, H., 'The Impact of Brexit on Unitary Patent Protection and its Court', *Max Planck Institute for Innovation and Competition Research Paper*, no. 18-20, 2018.

[144] http://eplaw.org/wp-content/uploads/2018/10/2018-10-05_Reply_to_Lamping_Ullrich_Brexit_UP_UPCA.pdf.

Looking ahead to 2019

As 2019 gets underway, the UK remains in a state of disarray as to the timing and terms of Brexit. Plainly, the "deal" (if there is to be one) will influence the role of the UK in any future unitary patent system and the UPC. The early part of 2019 should bring the third patent decision from the Supreme Court in two years, this time in relation to the question of inventive step and a dosage regimen of tadalafil.[145] 2019 is also set to bring further developments in relation to FRAND, and already the Court of Appeal has confirmed the first instance decision of **Henry Carr J** that the UK Court is competent to decide FRAND terms on a global basis.[146] It will be interesting to see if the UK judges continue their creative and flexible approach to jurisdiction and relief. Finally, SPC enthusiasts will be hoping for (but certainly not expecting) some clarification from the CJEU on second medical use SPCs.[147] A CJEU reference on the issue of SPCs based on third party MAs also seems inevitable from the ongoing *Eli Lilly v Genentech* case.

[145] Appeal from *Actavis v ICOS* [2017] EWCA Civ 1671, heard on 19-20 November 2018.
[146] *Conversant v Huawei* [2019] EWCA Civ 38.
[147] *Santen* C-673/18.

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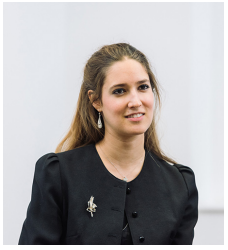

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