BRISTOWS

Review of Patent Cases in the English Courts in 2017

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Quotation of the Year

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

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

Index

Introduction

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

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

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

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

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

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

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

Claim construction and infringement

For a dozen years, the authors of this review have repeatedly stated that the law of construction of patent claims in the UK is governed by the single, "bedrock" question derived from the decision of the House of Lords in *Kirin-Amgen*, namely: what would the skilled person have understood the patentee to be using the language of the claim to mean?[5] Furthermore, it was generally understood that this is all that needs to be assessed when considering infringement. Year after year we noted that, although they had never been formally disapproved or abandoned, the *Improver*[6]/Protocol[7] questions belonged to a different era, and had, like the office fax machine, by and large fallen into disuse.

In what was clearly the most important UK patent case of the year by a country mile, 2017 witnessed the renaissance of the *Improver*/Protocol questions, albeit in a modified form, in the decision of the Supreme Court in *Actavis v Eli Lilly*[8] concerning pemetrexed. The facts of the case are well known. Put shortly, Lilly owned a patent claiming the use of pemetrexed disodium in combination with vitamin B_{12} to treat cancer. The background to the invention was that pemetrexed had been found to be an effective treatment for certain types of cancer but with significant side effects. The patent taught that administering pemetrexed together with vitamin B_{12} caused a noticeable reduction of those side effects. Actavis did not challenge the validity of the patent but sought a declaration of non-infringement (DNI) in respect of various other salts of pemetrexed, including pemetrexed dipotassium which will be used as the exemplar here. Actavis contended that the skilled person would understand very well the meaning of pemetrexed disodium and that, in contrast to terms such as "vertically", the word on which *Catnic*[9] turned, a clearly defined chemical substance did not allow for variance in interpretation. Actavis also sought a DNI in respect of certain other European designations of the patent. To the surprise of many practitioners, **Arnold J** chose to assess the issue of the construction and infringement using the *Improver*/Protocol questions[10] and, having done so, found that there was no infringement, direct or indirect.[11]

[1] [2017] UKSC 48.

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

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

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

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

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

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

[8] See footnote 1, *ante*.

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

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

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

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

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

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

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

1. Does the product or process in question ("the variant") fall within any of the claims as a matter of normal interpretation, i.e. applying the normal principles of interpretation of documents?

2. If not, does the variant vary from the invention in a way or ways which is or are immaterial? That raises a question that normally would have to be answered by reference to the facts and expert evidence.

When addressing the second question, i.e. whether the variation is immaterial, the Supreme Court held that one should ordinarily ask three questions:

i. Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent?

ii. If yes, would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?

iii. If yes, would a reader of the patent have concluded that the patentee nevertheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

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

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

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

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

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

[14] [2017] EWHC 2629 (Pat).

[15] *Ibid* at para 138.

decision on the assessment of novelty, which we consider in more detail in the relevant section below.

- *Illumina v Premaitha*[16] – **Henry Carr J** agreed with the analysis of **Arnold J** in *Generics (UK)* and also set out a very neat summary of the principles laid down in *Actavis*.

- *Actavis v ICOS*[17] – the Court of Appeal was happy to proceed on the basis, agreed by the parties, that the question of construction *per se* involved the assessment of what the skilled person would have understood the patentee to be using the language of the claim to mean and that *"nothing in the recent decision of the Supreme Court in Actavis affects the application of this approach in the context of this case."*[18]

- *Fisher & Paykel v Resmed*[19] – **Richard Meade QC** (sitting as Deputy Judge) made the point that, going forward, it may be preferable to refer to "claim scope" rather than to "claim construction", to indicate that, at least for the purposes of infringement, it is no longer permissible to use the one-stage purposive construction.

- *Eli Lilly v Genentech*[20] – **Birss J** outlined the potential impact of some of the questions left undecided in *Actavis* on the jurisdiction of the English courts to hear cross-border disputes.

- *Magnesium Elektron v Neo Chemicals*[21] – **Daniel Alexander QC** (sitting as Deputy Judge following his appearance as counsel in *Actavis*) noted that, if anything, the Supreme Court decision would increase the role of expert evidence in cases concerning equivalents.

- *Saab Seaeye v Atlas Elektronik*[22] – the Court of Appeal noted that its assertion in *Virgin Atlantic*[23] that there is no general doctrine of equivalents was no longer correct, however the Court was not required to consider equivalents in this instance.

Reflecting on matters nearly six months on, it is clear that the full impact of the decision has yet to be felt. In the past, where the Supreme Court has made a decision which is out of step with the established practice, the Court of Appeal has deftly restored a measure of orthodoxy in its interpretation of the ruling in subsequent cases.[24] It is, however, impossible for the Court of Appeal to ignore the clear guidance from the highest court in the land. Such was the interest/concern of the profession that well over 700 practitioners attended a seminar held at University College London in early November 2017 at which **Lord Neuberger** and **Lord Sumption** spoke, along with several distinguished judges from other countries. At the end of the event, a show of hands revealed a large degree of concern, if not confusion, from barristers, solicitors and patent attorneys alike. The authors' view is that the *Kirin-Amgen* bedrock question, as it had come to be applied,[25] was probably too restrictive to reflect **Article 69 EPC** and its **Protocol**[26] but that the *Actavis* questions are too permissive, particularly with the introduction of hindsight into the second question. The authors consider that the correct interpretation probably lies somewhere between the two rulings. The authors also wonder whether it may be helpful in future cases to change the order of the questions, such that the third question – would the skilled person have concluded that strict compliance with the primary meaning was an essential element of the claim? – is addressed first. This was the way that the issue of construction was addressed by **Lord Diplock** in *Catnic*,[27] which followed on from previous House of Lords decisions considering non-literal infringement. Putting the third question first may simplify the analysis since the Court may well decide that the skilled person could conclude that strict compliance was intended, and that will resolve the question without further analysis.

We look forward to reporting next year on how *Actavis* was interpreted in 2018, but the magnitude of the Supreme Court decision should not overshadow other interesting decisions on construction given last year.

From time to time, the question arises in claim construction: should one be persuaded to reject a particular construction because of the legal consequences it has for the validity of the patent? The general principle, referred to by **Lord Russell** in *Electric and Musical Industries v Lissen,*[28]is that *"if possible, a specification should be construed so as not to lead to a foolish result or one which the Patentee could not have contemplated."* **Jacob J** explained in *Beloit v Valmet (No 2)*[29] that this should lead one to avoid a construction that covered prior art specifically acknowledged in a patent specification, but that this principle need not apply to prior art not mentioned (there being no reason to suppose that the patentee had that art in mind). This was applied by **HHJ Hacon** in *Jushi*[30] in February 2017. But what about the case where the prior art in question is not specifically acknowledged in the specification but could be said to be in the contemplation of the patentee by reason of being within the CGK? *Terrell* suggests that a construction reading on to such prior art should be avoided.[31] However, **Floyd LJ** had expressed reservations about such an approach in *Adaptive v BT*[32] when the objection concerned is obviousness,

[16] [2017] EWHC 2930 (Pat).
[17] [2017] EWCA Civ 1671.
[18] *Ibid* at para 44.
[19] [2017] EWHC 2748 (Ch).
[20] [2017] EWHC 3104 (Pat).
[21] [2017] EWHC 2957 (Pat), at para 223.
[22] [2017] EWCA Civ 2175.
[23] *Virgin Atlantic v Premium Aircraft Interiors* [2009] EWCA Civ 1062.
[24] An example of the Court of Appeal moulding the jurisprudence of the Supreme Court to achieve a practical outcome is *IPCom v HTC* [2013] EWCA 1496, given shortly after the Supreme Court's decision in *Virgin Atlantic v Premium Aircraft Interiors* [2013] UKSC 46, where Floyd LJ noted the Supreme Court's criticism of the guidelines in *Glaxo v Genentech* [2008] EWCA Civ 23 on when UK litigation should be stayed pending resolution of EPO Opposition proceedings, but nonetheless took a nuanced approach to their review, retaining the Court's discretion to weigh all relevant circumstances in deciding whether a stay must be granted.
[25] Several readers are likely to have heard Lord Hoffmann speak publically on his judgment in *Kirin-Amgen*. One analogy that Lord Hoffmann used to explain his reasoning was that of a sign at the entrance to a field stating "NO FOUR-WHEELED VEHICLES." Would this prohibit entry to (i) a standard car? (ii) a tank with tracks? (iii) a four-wheeled children's buggy? and/or (iv) a bicycle? Clearly the bicycle can enter and the car cannot. However, assuming that the sign is there to alert people to the unsuitability of the ground to heavy vehicles, then the tank is barred but the buggy is not. It seems that this interpretation of the bedrock question is closer to *Improver* than many practitioners came to understand.
[26] Protocol on the Interpretation of Article 69 of the EPC.
[27] See footnote 9, *ante*.

given that lack of inventive step is a value judgment on which widely differing views are possible.

The question arose again before **Floyd LJ** in *Stretchline v H&M*,[33] an appeal from a decision of **Henry Carr J**[34] on the construction of the claims of Stretchline's patent for underwired bra technology for the purpose of assessing whether H&M were in breach of a settlement agreement containing a condition not to infringe.

The Judge at first instance had rejected the argument that the claims should not be interpreted in such a way so as to be thought obvious by the skilled addressee in light of the CGK. The evidence on the CGK was lacking. **Floyd LJ** agreed, noting that this situation was several steps removed from *Beloit v Valmet (No 2)*[35] and, as a result, although the skilled addressee might disagree with the patentee's claim to an invention, he would not consider it a foolish result and hence would not avoid construing the claim in that manner.

Another question which has arisen in the past, and which is likely to arise more frequently in the future, concerns infringement of process claims where part of the claimed process is carried out in the UK and other parts are carried out overseas. In *Illumina v Premaitha*,[36] **Henry Carr J**, following the earlier decisions of *Menashe v William Hill*[37] and *RIM v Motorola*,[38] held that the crucial question to ask was: where, in substance, was the alleged infringing process taking place? In *Illumina*, although parts of the process which involved testing blood samples were carried out in Taiwan, the sampling of the blood and the preparation of the raw data took place in the UK, which was also the destination of the final report. The Judge had little hesitation in confirming that the claimed process had been used in the UK.

Use of the prosecution history as an aid to construction

Another point of interest from the *Actavis*[39] decision related to the potential use of the prosecution history as an aid to the construction of the patent. As many readers will be aware, during the prosecution of its patent application at the EPO, Lilly had first requested a claim to "an antifolate". The Examiner objected to this on grounds of lack of disclosure and clarity, following which Lilly had suggested to replace "antifolate" with "pemetrexed". This amendment was rejected by the Examiner on added matter grounds, which led Lilly to introduce the claim to "pemetrexed disodium", which was accepted. Actavis contended that this made it clear that use of other pemetrexed compounds could not infringe. Looking first at the general point of the use of the prosecution history to decide whether a variant could infringe, **Lord Neuberger** agreed with **Lord Hoffmann** in *Kirin-Amgen*[40] that the English courts should discourage, if not prohibit, the use of the patent office file as an aid to construction, suggesting that the English courts should adopt a sceptical but not absolutist attitude to the issue. Recourse to the patent office file should only be made where: (i) the point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point; or (ii) it would be contrary to the public interest for the contents of the file to be ignored. In relation to the facts at hand, **Lord Neuberger** did not consider that the contents of the patent office file justified a departure from the finding of infringement. Thus, the UK law remains that the contents of the prosecution file will seldom be taken into account by the Court (although, as more than one commentator has observed, the prosecution file had to be considered by the Supreme Court in order to reach its conclusion on the facts).

The question of the admissibility of the prosecution history arose in *IPCom v HTC*,[41] (prior to *Actavis*) when HTC argued that **Birss J** had wrongly exercised his discretion in allowing IPCom's claim amendment because he had not taken due account of IPCom's avowed intention to obtain a claim which was equivalent in scope to that approved by the Technical Board of Appeal (TBA) of the EPO.[42] Contrasting the Judge's construction of *"as a bit pattern"* and his finding as to the "better translation" of that phrase, HTC asserted that the amended English claim was now wider in scope than the TBA-approved German claim. **Floyd LJ** endorsed the Judge's finding that IPCom's averred intention was irrelevant to the question of discretion. The Court of Appeal went on to hold that **Birss J** had not been in a position to make a finding that the scope of the TBA-approved German claim was different from that of the amended English claim. In doing so, the Court drew a subtle, but important, distinction between the exercise of translation and construction of a foreign language claim. **Floyd LJ** noted that in reaching his conclusion as to the "better translation" of the German claim, **Birss J** had relied on the evidence of a translator which had been coloured by events before the TBA. The Court reiterated its view that what happened at the TBA was not a legitimate aid to construction. Referring to its own decision in *Actavis v Eli Lilly*,[43] the Court took the opportunity to comment on the "impossible burden" that reliance on such aspects of the prosecution history places on the skilled reader if they were always to be recognised as a legitimate aid to construction. In light of the Supreme Court's subsequent *dicta*, it will be interesting to see how the Court of Appeal deals with such issues in the future.

[28] (1936) 56 R.P.C. 23.
[29] [1995] R.P.C. 255.
[30] *Jushi Group v OCV Intellectual Capital* [2017] EWHC 171 (IPEC).
[31] The Hon. Mr Justice Birss et al., *Terrell on the Law of Patents*, 18th edn. (London, Sweet & Maxwell, 2017), at paras 9-254.
[32] [2014] EWCA Civ 1462.
[33] [2017] EWCA Civ 199.
[34] [2015] EWHC 3298 (Pat).
[35] [1995] R.P.C. 705.
[36] See footnote 16, *ante*.
[37] [2002] EWCA Civ 1702.
[38] [2010] EWHC 118 (Pat).
[39] See footnote 1, *ante*.
[40] See footnote 5, *ante*.
[41] [2017] EWCA Civ 90.
[42] *IPCom v HTC* [2015] EWHC 1034 (Pat).
[43] [2015] EWCA Civ 555.

Indirect infringement

Having found that there was direct infringement of Lilly's patent, the Supreme Court in *Actavis*[44] did not analyse deeply the question of whether there was indirect infringement when lyophilised pemetrexed

dipotassium was supplied with instructions to reformulate the medicine in saline solution (which would provide a source of sodium ions). However, **Lord Neuberger** expressed himself to be in agreement with the Court of Appeal on all aspects of its reasoning. Thus, Actavis was found to have supplied means (lyophilised pemetrexed dipotassium) relating to an essential element of the invention, knowing that it was suitable for putting, and intended to put the invention into effect (by reconstitution in saline solution) in the UK. This finding potentially raises an interesting issue with regard to the indirect infringement of second medical use patents with claims in the Swiss form, a question which may be addressed by the Supreme Court in the pregabalin appeal early in 2018.[45]

FRAND and competition defences

In April 2017, **Birss J** handed down the first UK decision[46] to grapple with the thorny topic of what constitutes a fair, reasonable and non-discriminatory ("FRAND") royalty rate under a patent licence. The decision arises out of the litigation between Unwired Planet and Huawei[47] that included five patents said to be standard essential ("SEPs"), as well as one other non-essential patent. This judgment deals with a lot of important issues that arise in every SEP-based case and provides important clarity as to how a FRAND rate could be calculated by the Court.

First, **Birss J** held that the FRAND undertaking given by a patentee when declaring its patent as essential to the European Telecommunications Standards Institute (ETSI) gives rise to a legally enforceable obligation that can be relied upon by those implementing the standards. As the ETSI undertakings are governed by French law, the Judge held that the doctrine of "*stipulation pour autrui*" (third party benefit) applied to give rise to this obligation. This obligation arises even when, as was the case with Unwired Planet, the declarant is not an ETSI member.

The Judge also dealt with the so-called "*Vringo* problem",[48] where two different offers made by the parties could both be FRAND, giving rise to a situation where, if both offers fell within a FRAND range, there was no basis upon which a Court could determine whether to accede to a patentee's request for an injunction or not. To resolve this conundrum, **Birss J** decided that there was only a single set of FRAND terms for a given set of circumstances. The Judge noted that this ruling would *"promote certainty"* and *"make the enforcement of the ETSI FRAND undertaking conceptually straightforward."*[49] **Birss J** squared this finding with the CJEU's decision in *Huawei v ZTE*[50] that both parties should make FRAND offers (which might not be the same) by distinguishing between the FRAND negotiating process, where each party should take a FRAND approach to making reasonable proposals, and the final single FRAND rate determined by the Court. However, he noted that making extreme offers and taking an intransigent approach which prejudices negotiations is not a FRAND approach.

Birss J approached the calculation of the applicable FRAND rate using two methods. The first involved looking at comparable licences; and the second, "top down" approach, calculated the share of the aggregate royalty burden for a given standard that was assigned to a given portfolio. The Judge commented that, given the size of the portfolios usually being considered, patent counting was the only practical approach, as assessing the individual strengths of each invention would soon become disproportionate. It was noted that if a "keystone invention", the sort of exceptional invention that underpinned the technical approach taken, was being considered then a consideration of technical strength could be warranted. However, Unwired Planet's patents were all said to make an "average contribution".

To arrive at the applicable FRAND royalty rate, **Birss J** "unpacked" the terms of various Ericsson licences[51] to arrive at an effective royalty rate for each. This was necessary as the various licences had different terms that made them difficult to compare. The Judge then calculated an adjusted rate for the Ericsson portfolio. He calculated the strength of the Unwired Planet portfolio based on the number of "relevant SEPs". This calculation attempted to compensate for the well-known problem of over-declaration of patents as essential at ETSI, and was based on an assessment of how many of Unwired Planet's declared essential patents were actually truly essential. The Ericsson rate was multiplied by the Unwired Planet strength ratio to give the FRAND rate for Unwired Planet's portfolio. He found that different rates were applicable to handsets and infrastructure. As a cross-check exercise, **Birss J** reverted to his other method and calculated Unwired Planet's share of the total number of relevant SEPs for each standard to calculate Unwired Planet's share of the overall royalty burden per standard. He found that this came within an acceptable range of the rates he had calculated using the comparables method.

[44] See footnote 1, *ante*.
[45] At the time of writing, the Supreme Court was due to hear this appeal on 12-15 February 2018.
[46] *Unwired Planet v Huawei* [2017] EWHC 711 (Pat).
[47] Samsung and Google were involved in the case at an earlier stage but had settled with Unwired Planet before the FRAND trial.
[48] After *Vringo v ZTE* [2013] EWHC 1591 (Pat) and *Vringo v ZTE* [2015] EWHC 214 (Pat).
[49] *Unwired Planet v Huawei* [2017] EWHC 711 (Pat), at para 156.
[50] *Huawei v ZTE* (C-170/13).
[51] Unwired Planet had acquired the patents in question from Ericsson and, as a result, Ericsson licences including these patents were said to be relevant comparables.

Birss J also held that a FRAND licence involving a global SEP portfolio would be worldwide in territorial scope. He found that insistence on a UK-only licence by Huawei was not FRAND. If the licence were to have been for the UK only, the Judge held that there should be a 100% uplift on the global rate.

In terms of remedies, **Birss J** held that, if Huawei refused to enter the licence on the FRAND terms he had found, Unwired Planet would be entitled to damages on the UK sales at the FRAND rate he had determined. The Judge also suggested in this judgment that an injunction would be granted if Huawei refused to enter into the worldwide FRAND licence on the terms determined by the Court. This was revisited in a later decision[52] after Huawei had belatedly offered undertakings that it would enter into the licence once the appeal was finally determined and that they would abide by the terms set by the Court until that time. However, **Birss J** rejected these undertakings and granted Unwired Planet a "FRAND injunction" that was stayed on terms pending the appeal. Such a "FRAND injunction" would restrain infringement in the usual way, but included a proviso that it would be lifted if the defendant entered into the FRAND licence, and would not automatically be re-imposed after the expiry of the licence (the parties being free to return to the Court at that point).

Although **Birss J**'s main decision is under appeal,[53] there has been a wave of SEP cases since, looking to follow in its footsteps. In one of these cases, *TQ Delta v Zyxtel*,[54] **Henry Carr J** noted that, although it has become practice in the UK to have the FRAND trial after the technical trials in this type of case, it may now be time to consider having the FRAND trial first if the real dispute is about the terms of a global portfolio licence.[55] However, as the parties in this case had already agreed to hold the technical trial first, the Judge noted that this was not the case to rule upon this question.

Validity

Patentable subject matter

Until the Intellectual Property Enterprise Court's (IPEC) decision in *Epoch v Character Options*,[56] the English courts had not considered the exclusion of aesthetic creations from patentability. Although the exclusion in **Article 52(2)(b) EPC** was given a different wording upon its implementation in **section 1(2)(b)** of the **Act**, **HHJ Hacon** followed **Jacob LJ**'s suggestion in *Aerotel*[57] that both provisions must have the same meaning, so it is better to work directly from the source. Referring to previous UK IPO and EPO decisions, the Judge held that the claimed polyhedral fusible toy beads were not excluded from patentability because, although the contribution to the art of the patent, i.e. imparting brilliance to a decorative object, could reasonably be described as an aesthetic effect, an aesthetic effect is not, of itself, an aesthetic creation. In particular, the effect in the present case was also technical in nature and was not achieved by the creation of a particular design or group of designs.

Novelty

In our 2015 review, we reported that **Birss J** had found that a novelty destroying piece of prior art that was uploaded to the internet at a time such that it would be available on the day before the priority date in some jurisdictions did not form part of the state of the art.[58] The Judge held that the time of publication must be determined with reference to the controlling time zone at the patent office at which the priority document was filed. This decision has now been upheld by the Court of Appeal,[59] **Floyd LJ** concluding that the priority date is the 24-hour period of the day on which the priority filing took place, in the time zone of the patent office where the filing was made. Therefore, to decide whether a publication is part of the state of the art one must look at the reference time zone of the patent office of filing.

Prior to the Supreme Court decision in *Actavis v Lilly*[60] it was a well-settled principle of English patent law that the scope of a claim for the purposes of infringement and validity was co-terminous. Indeed, judges had highlighted this as an advantage of the English litigation system when compared to a bifurcated system, as it prevented patentees taking the so-called "Angora cat" approach: *"When validity is challenged, the patentee says his patent is very small: the cat with its fur smoothed down, cuddly and sleepy. But when the patentee goes on the attack, the fur bristles, the cat is twice the size with teeth bared and eyes ablaze."*[61] But what now? Had a gap opened up between validity and infringement? Are Angora cats allowed?

In *Generics (UK) v Yeda Research*,[62] **Arnold J** briefly considered the issue with respect to novelty. The Judge caveated his decision by stating that he would not consider the matter at length given that he found Yeda's patent invalid for obviousness. The case concerned Yeda's dosage regimen patent for glatiramer acetate (exclusively licensed to Teva and marketed as Copaxone®). So is there a gap, such that a claim can be infringed by a person who did exactly what the prior art taught, whilst still being novel over that prior art? The answer is yes. **Arnold J** explained that

[52] *Unwired Planet v Huawei* [2017] EWHC 1304 (Pat).
[53] At the time of writing, this appeal was due to be heard in May 2018.
[54] [2017] EWHC 3305 (Pat).
[55] *Ibid*, at para 2.
[56] [2017] EWHC 556 (IPEC).
[57] *Aerotel v Telco Holdings* [2006] EWCA Civ 1371.
[58] *Unwired Planet v Huawei* [2015] EWHC 3366 (Pat).
[59] *Unwired Planet v Huawei* [2017] EWCA Civ 266.
[60] See footnote 1, *ante*.
[61] Jacob LJ relaying Prof Mario Franzosi's famous analogy in *European Central Bank v Document Security Systems* [2008] EWCA Civ 192, at para 5.
[62] See footnote 14, *ante*.

infringement can be found by equivalence, yet a claim would only lack novelty if the prior art constituted an enabling disclosure of the features of the claim on its proper, or "normal", interpretation.

In reaching this conclusion, the Judge accepted Yeda's arguments that: (i) *Synthon*,[63] an authority that claims should be interpreted in the same manner for both novelty and infringement, had not considered the question of anticipation by equivalents because at that time it was not possible to infringe by virtue of the doctrine of equivalents; (ii) it was established jurisprudence of the EPO Boards of Appeal that a claim is not deprived of novelty by an obvious equivalent of a feature in a prior publication; and (iii) *Actavis*[64] was based on **Article 2** of the **Protocol on the Interpretation of Article 69 of the EPC**, which is concerned with the extent of protection conferred by a European patent and therefore with infringement and not validity.

Arnold J's analysis on this issue was subsequently affirmed by **Richard Meade QC** (sitting as Deputy Judge) in *Fisher & Paykel v ResMed*.[65]

A reminder that the law of anticipation is strict came in *Edwards Lifesciences v Boston Scientific*,[66] where **HHJ Hacon** noted that, although an integer of a claim may be disclosed by inference, this must be an inevitable inference from the prior art. If the prior art allows for even the possibility that its performance would not result in the claimed invention, it would not deprive an invention of novelty.

In Jushi's revocation action against OCV's patent relating to fibreglass with a specific composition,[67] **HHJ Hacon** became the first judge to make a (non-*obiter*) finding on how to approach overlapping numerical ranges. In deciding whether an overlap was sufficient to result in a finding of anticipation, the Judge reviewed the previous case law from the EPO Boards of Appeal as well as **Floyd J**'s decision in *Lundbeck v Norpharma*.[68] The approach arising from the EPO in several cases[69] was to find that no novelty exists if the skilled person would, in light of all of the technical facts, seriously contemplate applying the technical teaching of the prior art in the range of the overlap. The Boards had expressly commented that this was fundamentally different from the approach to inventive step, as it did not involve any technical gap between the prior art and the patent. However, **Floyd J** commented that he found this approach *"difficult to follow"* as it created a special case for the law of novelty.[70] This was, however, an *obiter* comment, and it fell to **HHJ Hacon** to decide the correct approach. In following the EPO's "serious contemplation" approach, the Judge contrasted cases where the disclosed overlap was 99% rather than 1%, and explained that the EPO's test was the criterion that should be used to establish the point at which the prior art does indeed anticipate the patent. Applying this test, he found that the claimant had not shown that the skilled person would seriously contemplate making fibreglass within the range of overlap disclosed in the prior art and, consequently, the novelty attack failed.

Entitlement to priority and enablement

It is established jurisprudence in the UK that, for a patent to be entitled to priority, the priority document must contain an enabling disclosure of the claimed invention. In a lengthy but interesting judgment in *Illumina v Premaitha*[71] relating to non-invasive pre-natal testing, **Henry Carr J** confirmed this analysis, noting that it is possible to frame a claim in general terms if the teaching of the patent is to a principle of general application. The claim would, however, be insufficient if it was shown that the invention did not work with substantially everything falling within the scope of the claim. Some of the defendants decided to run a squeeze argument in relation to infringement and validity, namely that, if the claims of the patent extended to cover one of the allegedly infringing tests, then this approach was not enabled in the priority document and the patent would not be entitled to priority and would therefore be invalid. However, the patentee argued that the patent claimed a principle of general application and could extend to improvements which utilised that principle even if such improvements were not anticipated or enabled by the priority documents.

Noting that this was a *"key issue which requires a detailed analysis of the legal principles,"*[72] **Henry Carr J** considered statements of **Lord Hoffmann** in *Kirin-Amgen*[73] and **Lord Neuberger** in *Actavis*[74] in concluding that: *"fairness to the patentee may require that unforeseeable variants, enabled for the first time by new technology, fall within the scope of protection, although the patentee is unlikely to succeed where the variant was unforeseeable at the priority date. A variant which represents an inventive step may nonetheless infringe... It would not make sense if, in those circumstances, the patent was found to be insufficient solely because such an immaterial variant, which it did not enable, fell within the scope of its claims."*[75] On this basis, this squeeze by the defendants was unsuccessful.

In *Icescape v Ice-World*,[76] certain features of the claimed ice rink heat exchanger had not been expressly disclosed in the priority document. The

[63] *Synthon v SmithKline Beecham* [2005] UKHL 59
[64] See footnote 1, *ante*.
[65] See footnote 19, *ante.*
[66] [2017] EWHC 405 (Pat).
[67] See footnote 30, *ante*.
[68] [2011] EWHC 907 (Pat).
[69] See e.g. *TOSHIBA/Thickness of Magnetic Layer* T 26/85, and *UNILEVER/Washing Composition* T 666/89.
[70] *Lundbeck v Norpharma* [2011] EWHC 907 (Pat), at para 89.
[71] See footnote 16, *ante*.
[72] *Ibid*, at para 138.
[73] See footnote 5, *ante.*
[74] See footnote 1, *ante.*
[75] See footnote 16, *ante*, at para 144.
[76] [2017] EWHC 42 (Pat).

patentee argued that the skilled person reading the priority document with his CGK in mind would nevertheless understand those features to be implicitly disclosed, as they would have been present in any ice rink using such heat exchangers. However, **John Baldwin QC** (sitting as Deputy Judge) relied on the reasoning in *HTC*[77] to reject the patentee's submission that the priority document implicitly incorporates (and therefore discloses) the CGK, and held that the disclosure in the priority document of information that would merely prompt the skilled person, applying his CGK, to use it within the claims was not sufficient to establish a direct and unambiguous disclosure according to those claims.

The factual situation is rather complicated in *Accord v RCT*.[78] The case was about whether an inventor, Kohn, had properly transferred to RCT (a technology transfer company), via the University of Houston, his right to claim priority for the anti-epileptic drug lacosamide. Kohn invented lacosamide whilst working at the University and made the priority filing during that time. Prior to filing the application for the patent in suit, Kohn executed a written assignment of the invention of lacosamide to RCT. However, under an overarching agreement, all inventions made by University staff were assigned to the University, who could then choose to offer them to RCT. This was the normal course of conduct, which was supported by evidence. However, on the question of whether Kohn had jumped the gun in assigning the invention to RCT, no evidence was provided to the Court, either showing that Kohn had told the University he had made the invention before assigning it to RCT, or that the University had made a decision to offer the invention to RCT and then directed Kohn to execute an assignment in RCT's favour. Therefore, Accord alleged that Kohn had not properly transferred his right to claim priority to RCT, and that the patent in suit therefore was not entitled to priority because: (i) the written assignment to RCT only took effect as an assignment of the legal title to lacosamide and not the equitable title; and (ii) the equitable title was held by the University at the date of filing of the patent in suit.

Birss J found that, under US law, RCT was a bona fide purchaser for value without notice of the equitable title of the invention because the written assignment from Kohn to RCT made it clear that Kohn was assigning his rights to RCT as the University's designee and pursuant to the University's obligations to RCT. This must have been on the footing that the invention had already been offered by the University to RCT. Additionally, all indications available to RCT were that the University was aware of what was going on and that Kohn was executing the written assignment because he was obliged to do so pursuant to his obligations to the University. Therefore, RCT did take good title and, accordingly, the patent in suit was entitled to its priority date.

Obviousness

It is quite rare for an appellate court to interfere with a trial judge's findings of obviousness.[79] Nevertheless in 2017, the Court of Appeal overturned **Birss J**'s first instance decision[80] on this issue in relation to a patent belonging to ICOS claiming a dosage regimen for tadalafil for the treatment of male erectile dysfunction[81].

The Court held that the trial judge had erred in concluding that the patent was inventive and, in so doing, made some interesting comments on whether, for a patent to be obvious, the invention must not only be obvious to try but there should also be an expectation of success on the part of the skilled person. Unusually, all three appeal judges[82] gave written opinions, **Kitchin LJ** preparing the leading judgment. The key question on inventive step was whether the patent teaching a 5mg daily dose of tadalafil was obvious over a prior art teaching of 50mg daily dose of the same active ingredient. At trial, **Birss J** had concluded that a 5mg dose would not have been tested by the skilled person with a reasonable expectation of success and therefore that the invention was not obvious. However, **Kitchin LJ** considered that the Judge had placed too much emphasis on expectation of success, which was only one consideration in a multi-factorial analysis. **Kitchin LJ** was of the view that the question of expectation of success was not relevant because it was very likely that a 5mg daily dose would have been investigated as a matter of routine. He found that, in light of the prior art 50mg daily dose, a series of routine pre-clinical and clinical studies would have been carried out with the aim of finding out the dose-response relationship. As a result of these studies, the skilled person would very likely test 5mg per day (even if it was not in the first round of testing) and find it to be safe and efficacious. In his judgment, **Floyd LJ** opined on so-called "bonus effects", observing that routine enquiries would not be inventive even if they led to surprising results. Although many commentators have expressed concern that the decision could spell the end of dosage regimen patents in the UK, **Kitchin LJ** was keen to point out that this is not the case – the circumstances of each case will need to be considered.

Ever since the ruling of the Court of Appeal in *Molnlycke v Procter & Gamble*,[83] the English courts have separated evidence on inventive step into primary evidence from suitably qualified experts, on the one

[77] *HTC v Gemalto* [2014] EWCA Civ 1335.
[78] [2017] EWHC 2711 (Pat).
[79] In fact, over the past five years, the English Court of Appeal has only interfered with the lower court's view on obviousness in 16% of appeals.
[80] *Actavis v ICOS* [2016] EWHC 1955 (Pat).
[81] *Actavis v ICOS* [2017] EWCA Civ 1671.
[82] Kitchin, Floyd and Lewison LJJ.
[83] [1994] R.P.C. 49.

hand, and all other evidence, termed "secondary" evidence, on the other. The authors have long considered that contemporaneous material surrounding the invention can shine objective light on the issue, and were therefore encouraged by the judgment of **Jacob LJ** in *Schlumberger v Electromagnetic Geoservices*,[84] which held that secondary evidence *"can and often does play an important role"* in determining the question of obviousness.[85] In *Edwards Lifesciences v Boston Scientific*,[86] the patentee Boston Scientific, defending a revocation claim, went on the offensive by alleging that Edwards had not introduced an outer skirt into its product line until many years after Boston Scientific had patented this feature, thus suggesting that its use was not obvious. **HHJ Hacon** held that the evidence generated a suggestion that the use of an outer skirt was not something that the skilled person would have considered at the priority date. He found that to be relevant, but not conclusive, and ultimately held the patent to be obvious.

Insufficiency

As **Pumfrey J** pointed out in *Halliburton*,[87] what constitutes "undue burden", when questioning whether the teaching of a patent can be implemented by the skilled addressee of the specification, is a matter of fact that is highly dependent upon the nature of the invention and the attributes of that skilled addressee. In *Varian v Elekta*,[88] Elekta had identified a number of blind alleys in Varian's patent for a combined MRI and radiotherapy system that the skilled team would encounter when trying to carry out the invention, and argued that, either alone or taken as a whole, overcoming them would be unduly burdensome. Elekta further argued that the skilled team would notice that the patent did not describe a machine that had been actually built, and this would affect their motivation in addressing those blind alleys. **Birss J** agreed that the skilled team would be more likely to persevere after initial failure had the patent taken its proposal all the way to a demonstrably working system, and that motivation may well play a relevant role in the assessment of what constitutes undue burden in the context of insufficiency, as it does for obviousness. However, the Judge noted that, although the patent did not inspire confidence, the team would nevertheless expect that a combined machine could be made and each of the blind alleys identified by Elekta could be overcome through routine work. Taken together, it would require *"an awful lot of essentially routine work by a substantial team over a lengthy period"* to make a working prototype but, in the field where the technical contribution was made, this was not an undue burden.[89]

Added matter

The concept of intermediate generalisation is not easy. Typically, it arises when the application contains two disclosures: a broad disclosure and a narrow disclosure (usually an exemplification of the invention). In circumstances where the broad disclosure was the one on which the granted claims were based, but those broad claims cannot then be maintained, added matter problems may arise where the patentee seeks to generalise out from the narrow disclosure in the example to an extent which cannot be justified. Such generalisation is intermediate in nature: broader than the narrow disclosure of the example, but not as broad as the originally granted claims. Intermediate generalisations are impermissible for adding matter if there is no teaching to that effect in the application. This is where the concept becomes most difficult – it is possible for the amended claim to have a broader scope than the example without necessarily disclosing new information.

Birss J in *Hospira v Genentech*[90] provides a neat summary of the English jurisprudence in this area, concluding that *"the EPO does not approach added matter this way at all"*[91] – a fact familiar to anypractitioner who has experienced the strict approach to added matter at the EPO.

Edwards Lifesciences v Boston Scientific[92] is notable for adding a further example to the short list of cases that have found an intermediate generalisation to be permissible, with **HHJ Hacon** considering the explanation of the concept given by **Floyd LJ** in *AP Racing v Alcon*[93] and concluding: *"I interpret this paragraph to mean that if the skilled person reading the application as filed would understand that the narrower class disclosed exemplifies a broader class, then a claim in the granted patent to the broader class discloses no new technical information and does not offend the prohibition against added matter."*[94] For example, in this case, the term "bunched up" in the context of a fabric seal of a heart valve was not adding any new information over the creation of "flaps, pockets and pleats" disclosed specifically in the application, the Judge taking the view that *"the skilled team would understand [the creation of flaps and pockets, or pleats] to mean the folding of the fabric seal in various ways, which is a necessary consequence of there being excess fabric"* and that the term "bunched up" connoted the exact same thing.[95]

Arrow declarations

Perhaps signalling from the start that it was going to be a significant year, the first case out of the traps in 2017

[84] [2010] EWCA Civ 819.
[85] *Ibid*, at para 77.
[86] See footnote 66, *ante*.
[87] *Halliburton v Smith* [2005] EWHC 1623 (Pat).
[88] [2017] EWHC 712 (Pat).
[89] *Ibid*, at para 274.
[90] [2014] EWHC 3857 (Pat).
[91] *Ibid*, at para 172.
[92] See footnote 66, *ante*.
[93] [2014] EWCA Civ 40.
[94] See footnote 66, *ante*, at para 231.
[95] *Ibid*, at para 242.

was the Court of Appeal's judgment in the *Arrow* declarations case, *Fujifilm v AbbVie*.[96] As readers will be aware, the purpose of an *Arrow* declaration[97] is to say that a product represents nothing more than the state of the art (or an obvious modification thereof) at the priority date of the patent family concerned, thereby providing immunity from infringement through the operation of a *Gillette* squeeze.[98] The *Fujifilm* saga, in which such a declaration was sought in respect of Fujifilm's biosimilar version of the world's top-selling drug, Humira® (adalimumab), had finished with a cliff-hanger at the end of 2016: the third attempt by AbbVie to strike out the declaration case had failed[99] and the case was proceeding to trial, to be heard by **Henry Carr J** from mid-January. But before it got there, the Court of Appeal had to give judgment on the question of whether the decisions of **Henry Carr J**[100] and **Arnold J**[101] dismissing the first two strike out applications were correct.

Interestingly, the Court of Appeal took the opportunity not just to decide whether those earlier decisions were, themselves, correct, but to answer the bigger question as a point of principle: is the concept of an *Arrow* declaration legally valid? The answer, said **Floyd**, **Kitchin** and **Longmore LJJ** unanimously, was "yes". And so was born a new weapon in the arsenal of generics, biosimilars, and any other competitor against a patentee owning a patent family, members of which have not yet granted, where certainty from non-infringement cannot easily be obtained by other means.

However, the affirmation was not without qualification. 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. Furthermore, the mere existence of a pending patent application is not, of itself, reason enough to apply for an *Arrow* declaration. The patent application in question may never grant, or it may grant with limited scope such that it no longer poses a problem. Competitors are expected to wait and see unless good reasons exist to the contrary.

It was the existence of such reasons which underpinned the decision of **Henry Carr J** on the merits case at first instance.[102] Having found, as a matter of fact, that the priority date was validly claimed, the Judge also made findings that the dosage regimen proposed for treatment of rheumatoid arthritis by the biosimilar adalimumab product in suit was obvious at the priority date (and anticipated or obvious for the treatment of psoriasis under a similar regimen) in light of certain prior art. He then turned to the question of whether, in his discretion, the declaration sought should be granted. Essentially, this reduced to a question of whether the declaration would serve a useful purpose, and whether special reasons existed for the grant of the declaration.

On the "useful purpose" point, **Henry Carr J** decided that the declaration was necessary to provide Fujifilm with commercial certainty. Although AbbVie argued that certainty had been achieved by its offer of undertakings to keep the UK clear of its patents concerning the dosage regimen, the Judge decided that the undertakings lacked clarity. Furthermore, he considered that the declaration was necessary to promote settlement by changing the parties' negotiating positions, and to protect the supply chain for the biosimilar product to the UK by making the grant of injunctions abroad less likely (albeit the decision would be of persuasive value only). Perhaps significantly, the Judge stressed that he had not taken the "spin-off value" of a UK judgment into account other than in this limited way.

On the "special reasons" point, the Judge focussed on AbbVie's behaviour, and particularly the fact that AbbVie, seemingly in response to the litigation challenge, had taken steps leading to the revocation of some patents at the EPO level and de-designated the UK from the coverage of other European patents: *"I consider that the intention and the objective effect [of AbbVie's conduct] is to shield its patent portfolio from examination of validity whilst continuing to file further divisionals and to threaten litigation proceedings against biosimiliars, wherever they may be launched."*[103] Other special reasons included the amount of money at stake for Fujifilm (including the necessary investment made in conducting clinical trials), and the further need for commercial certainty given AbbVie's threats to sue for infringement throughout the world.

As with any new tool in the toolbox, the power or utility of the tool becomes apparent over time, and following many episodes of use. Perhaps understandably, the *Arrow* declaration is now being widely pleaded and practitioners will, therefore, not have to wait long to receive further clarity from the Courts as to its appropriate application. A further request for an *Arrow* declaration was decided towards the end of 2017 in *Generics (UK) v Yeda Research*.[104] Here, however, the application was denied. **Arnold J** took the view that it was not necessary to grant the declaration because he was able to give a judgment on the revocation of the granted patent, following which it was open to the successful claimants to seek summary judgment on an issue estoppel basis (with reference to the original revocation decision on the parent) in respect of any

[96] [2017] EWCA Civ 1.
[97] Named after the interim decision of Kitchin J (as he then was) in *Arrow v Merck & Co.* [2007] EWHC 1900 (Pat).
[98] From *Gillette v Anglo-American Trading* (1913) 30 R.P.C. 465, in particular Lord Moulton's speech at paras 480-481.
[99] *Fujifilm v AbbVie* [2016] EWHC 3383 (Ch).
[100] *Fujifilm v AbbVie* [2016] EWHC 425 (Ch).
[101] *Fujifilm v AbbVie* [2016] EWHC 2204 (Ch).
[102] *Fujifilm v AbbVie* [2017] EWHC 395 (Pat).
[103] *Ibid*, at para 388.
[104] *Generics (UK) t/a Mylan v Yeda Research* [2017] EWHC 2629 (Pat).

future granting divisionals, assuming their subject matter was sufficiently similar. Although the claimants had argued that some aspects of the patentee's behaviour justified an *Arrow* declaration; for example, the fact that it had withdrawn the case pending before the EPO's Technical Board of Appeal, the Judge held that it could not be said that the patentee was shying away from scrutiny of validity because it had fully engaged with the revocation case before him.

Supplementary Protection Certificates (SPCs)

Who would have thought that over six years after the CJEU handed down its ruling in *Medeva*/*Georgetown*,[105] the question of the meaning of "protected by a basic patent" for the purposes of **Article 3(a)** of the **SPC Regulation**[106] would still be the subject of hot debate? Unfortunately, and much to the consternation of many European patents judges, this is the current situation. 2017 witnessed several further references from the English Court on this and other issues. Back in January 2017, the first case to be referred led to a sense of *déjà vu* for many practitioners. This was the case concerning Gilead's SPC for tenofovir disoproxil and emtricitabine, which Gilead sells in the UK as a treatment for HIV under the brand name Truvada®. The basic patent relied on by Gilead to protect this product was a patent with a claim essentially to tenofovir disoproxil "and optionally other therapeutic ingredients". In 2008, **Kitchin J** held that such a claim was sufficient to protect the combination and that the SPC was valid.[107] In light of the subsequent CJEU jurisprudence on **Article 3(a)**, further challenges were launched. In his January 2017 judgment,[108] which summarised the relevant case law since *Medeva*, **Arnold J** concluded that it was clear that, for a product to be protected by a basic patent, it was insufficient that the product would infringe the relevant basic patent according to national laws of patent infringement. Thus, the product A+B would not be protected by a patent to A, even though sales of A+B would infringe a patent to A. The Judge also concluded that it was necessary that the product should fall within the scope of the claim as interpreted under national laws of claim interpretation, but that something more was required. It was that "something more" that was the subject of the referral, the Judge feeling compelled to re-ask the question: what are the criteria for deciding whether "the product is protected by a basic patent in force" in **Article 3(a)** of the **SPC Regulation**? As he had done in *Actavis v Sanofi*,[109] **Arnold J** opined that the "something more" should be the product which embodies the inventive advance (or technical contribution) of the basic patent. If the CJEU agrees with **Arnold J**, Gilead's SPC will be held invalid.

On the same day as the Gilead judgment was handed down, **Arnold J** made a further reference in *Abraxis Bioscience*.[110] This reference concerned **Article 3(d)** of the **SPC Regulation**, which requires that the first marketing authorisation (MA) should be the MA that put the product on the market. Readers will recall that, in the seminal *Neurim*[111] case, the CJEU held that the first MA meant the first *relevant* MA, i.e. the first authorisation which fell within the scope of the basic patent relied upon. *Neurim* has been interpreted as opening the door to SPCs for second medical uses for active ingredients. The question under consideration in *Abraxis* was whether the principles of *Neurim* extended to new and inventive formulations, as well as new uses. Although **Arnold J** opined, with a tinge of regret, that SPCs should not be granted for new formulations of existing drugs, he elected to refer the question to the CJEU. An additional argument run by Abraxis, that a formulation called nab-paclitaxel, where the paclitaxel particles were formulated as albumin bound nanoparticles, was a different active ingredient to paclitaxel, was dismissed by **Arnold J** and not referred.

Later in the year, **Arnold J** handed down *Sandoz v G.D. Searle*,[112] a further decision in relation to **Article 3(a)** of the **SPC Regulation**. This time, the issue was whether a Markush formula which contemplated literally billions of individual compounds with a common chemical backbone protected a compound called darunavir, which was one of the compounds contemplated by the formula but not otherwise identified in the patent. Despite the ongoing uncertainty regarding the exact scope of **Article 3(a)**, **Arnold J** held that the decision of the CJEU in *Eli Lilly*[113] made it clear that **Article 3(a)** was satisfied if the active ingredient in the claim was identified by means of a structural formula, and that it was not necessary for the claim to individually name or depict the active ingredient in question; darunavir was protected by the patent and it was not necessary to make a reference to the CJEU.[114]

If parties entered a pharmaceutical patent settlement agreement, a term of which was that a generic product would not launch until the SPC expiry date, and the term of that SPC was subsequently extended under the **Paediatric Regulation**[115] (a "Paediatric Extension"), would the generic have to wait until that later date before launching? This question came before the Court of Appeal in November 2017 in *Teva v AstraZeneca*,[116] on appeal from the Commercial Court (**Leggatt J**),[117] which had decided, in the context of a summary judgment application by Teva, that the unextended SPC expiry date should apply. In the lower court's view, the consequences of a different

[105] *Medeva v Comptroller-General of Patents* (C-322/10), and *Georgetown University v Comptroller-General of Patents* (C-422/10).
[106] See footnote 3, ante.
[107] *Gilead Sciences* [2008] EWHC 1902 (Pat).
[108] *Teva v Gilead Sciences* [2017] EWHC 13 (Pat).
[109] *Actavis v Sanofi* (C-443/12).
[110] *Abraxis Bioscience v Comptroller-General of Patents* [2017] EWHC 14 (Pat).
[111] *Neurim v Comptroller-General of Patents* (C-130/11).
[112] [2017] EWHC 987 (Pat).
[113] *Eli Lilly v Human Genome Sciences* (C-493/12).
[114] Readers may be aware that the Court of Appeal has recently given its judgment on this case: [2018] EWCA Civ 49. Floyd LJ also considered that darunavir is a product protected by the patent but in his opinion it was necessary to make a reference to the CJEU on the matter. The appeal proceedings have been stayed in the interim.
[115] Regulation (EC) No. 1901/2006 on medicinal products for paediatric use.
[116] [2017] EWCA Civ 2135.
[117] *Teva v AstraZeneca* [2017] EWHC 1852 (Comm).

construction of the definition "Patent" (specified to be the patent and its SPC by number) would be *"so commercially absurd"*, in that it would give AstraZeneca an *"uncovenanted windfall"*, that could not reasonably have been intended.[118] The Court of Appeal took a different view, holding that the definition of "Patent" should be construed as including any extension to the SPC. This was the clear and natural meaning of the definition, without ambiguity. The Paediatric Extension was not a different kind of right but an extension of the SPC itself.

Damages

Account of profits

Henry Carr J dealt with an interesting point on accounts of profits in *GlaxoSmithKline v Wyeth*[119] following his decision in May 2016[120] that Wyeth's patent for a product used in a meningitis B vaccine was valid and infringed by GlaxoSmithKline (GSK). In light of the public health requirement for effective vaccines and Wyeth's own vaccine not yet being approved in Europe, Wyeth did not seek injunctive relief. Instead, in its pleadings it sought "*an inquiry as to damages for the claimant's infringements of the patent or, at the defendant's election, an account of profits*" and "*an inquiry as to damages in lieu of a final injunction*". It also sought "*further or other relief*". The Order following trial provided for an account of profits or damages, but only for past infringement. Wyeth then applied for an account of profits *in lieu* of an injunction for future infringement. GSK submitted that the pleadings did not cover such an Order. The Judge agreed with GSK and refused Wyeth's application, reminding the parties that the basic principle of an account of profits was that there had to be unconscionable or improper conduct[121] of which GSK were not guilty because Wyeth had decided to allow GSK to continue supplying its vaccine. The Judge also noted that if GSK had to account for its future profits then it would have to continue supplying the vaccine without making any profit (which would not be commercially viable), or cease supply, which would have the same effect as an injunction. **Henry Carr J** left it to the judge at the damages inquiry to decide whether a rolling royalty, lump sum or other mechanism to compensate for future infringement should be payable.

Employee compensation

An unusual appeal on employee compensation came before the Court of Appeal in *Shanks v Unilever*.[122] Shanks challenged the decision of the Comptroller-General of Patents,[123] as affirmed by **Arnold J**,[124] that he was not due compensation under **section 40** of the **Act** because several patents owned and exploited by Unilever covering an invention concerning blood glucose testing made by him during the course of his employment at Unilever did not confer an "outstanding benefit" on Unilever. The Court of Appeal noted that there was no statutory definition of "outstanding", but that **section 40(1)** required that the Court looked *inter alia* at the size and nature of the employer's undertaking. As such, Unilever argued that the benefit to it was dwarfed by its profits such that it was not outstanding. In contrast, Shanks argued that if all that was required was a simple comparison between the benefit and the profit of the undertaking, it would be all but impossible for an employee to establish an outstanding benefit on any large company. "Too big to pay" was not a fair defence. The Court dismissed the appeal, finding that the Comptroller had properly taken into account all of the relevant factors (and not just the size and nature of Unilever) when reaching his decision. These factors included the average valuation of Unilever's patents, Unilever's licensing activities, the benefits derived from Unilever's other activities and whether the patents were crucial to Unilever's success. It also found that the benefit should not be reduced to take account of corporation tax, such that the benefit conferred on Unilever was £24.5 million.

Tort of unlawful interference

In parallel with proceedings commenced by the European Commission against Servier for entering patent settlement agreements with generics that are alleged to be anti-competitive (fine of over EUR 400 million imposed on Servier and five generics; appeal ongoing), the UK Government is pursuing a damages action against Servier. The allegations include the complaint that Servier abused the patent system and, but for Servier's patent for perindopril in the alpha polymorphic form (revoked by **Pumfrey J** in 2007),[125] the NHS would have paid less for perindopril during the relevant period. In short, the Government wants its money back. The proceedings are ongoing and are unlikely to reach trial any time soon. However, an interim decision last August by **Roth J**[126] may hold some interest for patent practitioners. It finds in Servier's favour on a strike-out application, removing from the Government's case a claim based on the tort of causing loss by unlawful means. More specifically, it was alleged that Servier had practised deceit upon the EPO and English Court by maintaining and enforcing a patent it knew to be bad, and that this had caused loss to the Government. **Roth J** applied the House of Lords authority *OBG v Allan*,[127] in which it was made clear that, for this tort to apply, the unlawful means

[118] *Ibid*, at para 18.
[119] [2017] EWHC 91 (Pat).
[120] [2016] EWHC 1045 (Ch).
[121] *Spring Form v Toy Brokers* [2002] F.S.R. 17.
[122] [2017] EWCA Civ 2.
[123] BL O/259/13.
[124] [2014] EWHC 1647 (Pat).
[125] *Les Laboratoires Servier v Apotex* [2007] EWHC 1538 (Pat).
[126] *Secretary of State for Health v Servier Laboratories* [2017] EWHC 2006 (Ch).
[127] [2007] UKHL 21.

must affect the freedom of the third party to deal with the claimant. In this case, there are no dealings as such between the UK Government and the EPO (or the Patents Court), and hence the claim was bound to fail.

Costs

Indemnity basis

Readers may recall Thoratec's successful revocation of AIS's medical device patent on the basis of a public prior use of a ventricular assist device in the Netherlands after overcoming an argument that the prior use was subject to confidentiality,[128] but would be forgiven for not remembering that this point was decided under Dutch law. This is because, as **Arnold J** noted in the main judgment, AIS's introduction into the proceedings of Dutch law in relation to the confidentiality of that disclosure, and the evidence required to sustain it, had proved to be a waste of money; its own counsel had conceded in closing that there was no relevant difference between Dutch and English law on that point. In addition to ordering AIS to pay 75% of the claimant's costs and an interim payment of 60% of that sum, the Judge held that the Dutch law point had been sufficiently out of the norm for that issue to be assessed on an indemnity basis.[129]

Procedural issues

Jurisdiction

While we wait for the entry into operation of the UPC to simplify the resolution of international patent disputes, cross-border litigation has become relatively standard practice in the English courts, which in recent times have given multiple decisions clarifying the jurisdictional aspects of this practice. In fact, 2017 was something of a bumper year for decisions on jurisdiction.

In *Eli Lilly v Genentech*,[130] Lilly sought declarations of non-infringement in relation to the UK, French, German, Spanish, Italian and Irish designations of one of Genentech's European patents. One of Genentech's grounds to challenge the Court's jurisdiction was that the non-infringement claim was "concerned with" the validity of non-UK patents (therefore within the exclusive jurisdiction of those foreign courts under **Article 24(4)** of the **Brussels I Regulation**[131]). Lilly had advanced a "squeeze" argument on construction that would affect the validity of the UK designation of the patent, but maintained that the validity of foreign designations was not formally in issue, either in the UK or in the patents' home jurisdictions, so **Article 24(4)** could not be engaged, whereas Genentech contended that one must look at the substance of what is being alleged and not only the form. Having reviewed the relevant authorities, including the CJEU decision in *GAT v LuK*[132] and the Patents Court decision in *Anan Kasei*,[133] **Birss J** was not convinced that the question of the Court's jurisdiction should turn upon whether a party chooses to deploy rhetorical points in support of a given construction, even if it had consequences for validity. In any event, ultimately, any challenge to the validity of the UK patent could not affect the validity of the foreign patents, which would remain in the register regardless of the outcome of these proceedings. Interestingly, Lilly was not prepared to undertake not to put the validity of foreign designations in issue should Genentech decide to bring a counterclaim for infringement, in which case **Birss J** noted that **Article 24(4)** would be engaged and *"this entire exercise would be something of a charade"*.[134] Although the Judge was ultimately satisfied that there were unusual circumstances making it unfair to pre-empt what each party may decide to do, he made it clear that allowing service in these circumstances should be at Lilly's risk as to costs.

Arnold J heard an application by KGJS under **CPR Part 11** to set aside the service of a claim form served on it by Parainen Pearl for declarations of exhaustion, consent to use and non-infringement of various designations of a patent owned by KGJS on the basis that the Court did not have jurisdiction in respect of the non-UK designations of the patent.[135] The patent concerned a system for the discharge of bulk material from a ship which was installed on one of KGJS' vessels which had come to be owned by Parainen Pearl. First, with regard to the declaration of exhaustion, Parainen Pearl contended that KGJS had exhausted its rights under all EEA designations of the patent by selling the ship and that, if the Court was to find that the UK designation of the patent had not been infringed because of exhaustion, then the other 11 designations of the patent should also not be infringed for the same reason because the doctrine of exhaustion gives effect to the fundamental European principle of free circulation of goods. However, the Judge clarified that KGJS was confusing the issue of jurisdiction with enforceability, and that it is for the foreign courts to: (i) order a stay of any foreign proceedings on the basis that the UK court was first seised (and not that the court first seised has jurisdiction over all other designations); and (ii) recognise the decision of the court first seised and accord it *res judicata* effect. Secondly, with regard to the declaration of consent to use, **Arnold J** found that such a declaration depends on the application of the relevant national laws to determine whether there

[128] *Thoratec v AIS* [2016] EWHC 2637 (Pat).
[129] *Thoratec v AIS*, 25 January 2017 (unreported).
[130] [2017] EWHC 3104 (Pat).
[131] Regulation (EU) 1215/2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Recast Brussels Regulation).
[132] *Gesellschaft für Antriebstechnik v Lamellen und Kupplungsbau* (C-4/03).
[133] *Anan Kasei v Molycorp* [2016] EWHC 1722 (Pat).
[134] *Eli Lilly v Genentech* [2017] EWHC 3104 (Pat), at para 84.
[135] *Parainen Pearl Shipping v Kristian Gerhard Jebsen Skipsrederi* [2017] EWHC 2570 (Pat).

has been consent amounting to a defence to patent infringement and, therefore, the Court did not have jurisdiction over that claim. Finally, with regard to the non-UK declarations of non-infringement sought, the Judge found that the Court had no jurisdiction over such claims by virtue of **Article 5(3)** of the **Lugano Convention**[136] (country where the harm occurred), and that Parainen Pearl could bring an action for declarations of non-infringement in respect of all 12 designations of the patent under **Article 2(1)** of the **Lugano Convention** (country of domicile) in Norway where KGJS was based.

An interesting point on jurisdiction arose when **Henry Carr J** had to consider if the Court had the power to hear a dispute that related to the infringement of a US patent but arose from a licence agreement which gave exclusive jurisdiction to the English Court. In *Chugai v UCB Pharma*,[137] Chugai sought a declaration that no royalties were due under the licence agreement as there was no infringement. The sole patent remaining in force was a US patent. UCB sought to strike out the claim on the basis that a dispute concerning the validity of a foreign patent was not justiciable under the *Moçambique* rule.[138] Following *Lucasfilm*[139] and *Actavis*,[140] it is clear the Court will accept jurisdiction of an infringement claim (but not a validity claim), but here UCB argued that the issues of infringement and validity were inextricably linked. **Henry Carr J** noted that not every infringement case concerned validity and the Court was simply being asked to consider, as part of construing the US patent, the theoretical consequences for validity. Moreover, he held that the exclusive jurisdiction clause gave the English Court the power to hear disputes concerning the scope of the claims. Further, the Judge dismissed the argument that the foreign act of state doctrine (i.e. the Court should not determine issues that relate to the sovereign acts of a foreign state) prevented the English Court from hearing the issue based on the fact that the exclusive jurisdiction clause meant that the parties had agreed to submit to the jurisdiction of the English Court.

Disclosure

Both **Birss J** and **Daniel Alexander QC** had to grapple with the issue of disclosure of work-up experiments in the case of *Magnesium Elektron*. The first decision, from **Birss J**,[141] dealt with the question of whether disclosure of work-up experiments, as considered in *Mayne Pharma*,[142] could be ordered if the experiments were not concerned with showing anticipation by inevitable result. In *Mayne Pharma*, **Pumfrey J** had ordered such disclosure and reasoned that legal privilege in the documents relating to experimental work-up had been waived when the Notice of Experiments had been served. Ordering such disclosure in the case at hand, **Birss J** noted that the principle was not confined to experiments to prove anticipation by inevitable result, but concerned the question of work-up experiments *"irrespective of the legal conclusion on which they are being deployed to prove."*[143]

In a subsequent decision in the same case,[144] **Daniel Alexander QC** (sitting as a Deputy Judge) had to consider the scope of this type of disclosure. Following the disclosure of a significant amount of work-up material by the claimants, the defendants contended that further material should have been included. In rejecting the application, the Deputy Judge conducted a thorough review of the law on privilege and waiver. It was noted that the *Mayne Pharma*[145] approach can be clearly and easily applied to inevitable result cases and completeness of data cases. However, in other cases, its application is less straightforward and a more cautious and focused approach to the question of waiver of privilege and disclosure is required. This is because in such cases it is harder to determine whether the material could properly be described as "work-up" or directly relating to the experiment deployed, or if there would be any cherry-picking in not disclosing it. The Deputy Judge noted that there were other tools at a party's disposal, such as requests for further information or written questions to experts, which might be a more appropriate mechanism for seeking information in such cases.

Interim injunctions

As noted above, in *Actavis v ICOS*[146] the Court of Appeal overturned the first instance ruling on inventive step of ICOS' 5mg daily dose patent for tadalafil. Following this decision holding the patent invalid, ICOS sought an interim injunction to restrain entry into the market by several generic manufacturers pending an application for permission to appeal to the Supreme Court. However, **Henry Carr J** refused the application.[147] Applying the criteria laid down by the Court of Appeal in *Novartis v Hospira*,[148] the Judge found that there was no real prospect that ICOS would succeed on its appeal and so the application fell at the first hurdle. In case he was wrong on the first question, **Henry Carr J** went on to consider whether the interests of justice would be better served by granting or refusing the injunction and concluded that the latter approach was appropriate, particularly in light of the considerable and quantifiable loss of first mover advantage to those generics companies which were ready to launch.

[136] Lugano Convention of 16 September 1988 on jurisdiction and the enforcement of judgments in civil and commercial matters.
[137] [2017] EWHC 1216 (Pat).
[138] *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, an immovable situated out of England, or the recovery of damages for its trespass.
[139] *Lucasfilm v Ainsworth* [2011] UKSC 39.
[140] *Actavis v Eli Lilly* [2012] EWHC 3316 (Pat).
[141] *Magnesium Elektron v Molycorp* [2017] EWHC 1024 (Pat) (unreported).
[142] See footnote 2, *ante*.
[143] *Magnesium Elektron v Molycorp* [2017] EWHC 1024 (Pat), at para 22.
[144] *Magnesium Elektron v Molycorp* [2017] EWHC 2957 (Pat).
[145] See footnote 2, *ante*.
[146] See footnote 17, *ante*.
[147] [2017] EWHC 2880 (Pat).
[148] [2013] EWCA Civ 583.

Although most interim injunction applications are made in relation to patents for pharmaceutical products, it is of course the case that interim injunctions are available in all fields of technology, provided that the Court is satisfied that the *American Cyanamid*[149] criteria are met. In *Permavent v Makin*,[150] **Daniel Alexander QC** (sitting as a Deputy Judge) granted an interim injunction to prevent the defendant transferring or licensing various patents and patent applications relating to roofing products pending the outcome of an entitlement dispute between the parties.

Stays

By way of reminder, at first instance in *Accord v Astellas*,[151] Accord brought pre-emptive declaratory proceedings against Astellas in order to deal with its assertions that Accord's generic MA application for chemotherapy agent bendamustine was not valid under **Article 10** of **Directive 2001/83/EC**[152] because it partly relied on Astellas' original MA for bendamustine which had not been granted correctly and/or had since been nullified. In fact, Accord's UK MA was granted just before trial, at which **Morgan J** found that Accord's MA was valid. Astellas appealed. However, in the meantime, Astellas had also brought proceedings in Finland asserting that the Finnish Regulatory Authority had incorrectly granted Accord's Finnish MA and the Finnish Supreme Administrative Court had made a reference to the CJEU on whether it could independently assess the validity of a Finnish MA when Finland was not the Reference Member State. Therefore, **Floyd LJ** heard an application from Astellas seeking an order to stay its appeal of **Morgan J**'s decision pending a decision from the CJEU with regard to the Finnish case.

Floyd LJ refused Astellas' application for a stay of the appeal[153] for the following reasons: (i) any wasted costs of the appeal hearing were unlikely to significantly add to the overall cost of the EU-wide litigation strategy; (ii) the decision of the CJEU would only render the appeal unnecessary if it went against Astellas; (iii) rulings of the CJEU often require a further national hearing; (iv) the Finnish action could settle before the CJEU ruled; (v) the reference to the CJEU was not a point still in issue in the UK proceedings; (vi) significant commercial prejudice would be caused to Accord by delaying its commercial certainty; (vii) a stay would cause an increase in any potential damages claim against Accord; (viii) all other generics selling bendamustine were also in an uncertain position; and (ix) an early UK decision may have an impact on other courts considering the same question. He highlighted that any potential costs saving from staying the appeal was of less weight than achieving, sooner rather than later, commercial certainty for Accord, the other generics, and the public.

Expedition

In *Generics (UK) v Yeda Research*,[154] **Arnold J** heard an application by Mylan for an order to expedite the trial of its claim for the revocation of Yeda's dosage regimen patent for 40mg glatiramer acetate (exclusively licensed to Teva and marketed as Copaxone®) on the grounds that Mylan's MA for its generic 40mg glatiramer acetate product was due to be granted shortly, and before the expected date of the trial. Upon consideration of the four factors to be applied upon an application for expedition from *WL Gore v Geox*[155] and *Petter v EMC Europe*,[156] the Judge granted the order sought by Mylan stating that: (i) the market for glatiramer acetate was very valuable; (ii) Teva were the only supplier of 40mg glatiramer acetate; (iii) the Patents Court diary could accommodate an earlier trial; (iv) there was no evidence that any harm would be caused to Yeda/Teva; and (v) the prior art relied upon was already familiar to Yeda/Teva.

Shorter Trials Scheme

In light of the success with which the IPEC has been handling cases since its procedures were reformed, the Judiciary introduced by **Practice Direction 51N** the Shorter and Flexible Trials Pilot Schemes, which are running between 2015 and 2018 and are aimed at streamlining proceedings in other courts, including the Patents Court. Among the qualifying criteria for use of the Shorter Trials Scheme (STS) are that suitable cases must be tried in a maximum of four days, including reading time, and must not require extensive disclosure or expert evidence. In *Cantel Medical v Arc Medical Design*,[157] **Iain Purvis QC** (sitting as Deputy Judge) held that proceedings commenced under the STS concerning two simple and closely-related mechanical patents, and various forms of design right relating to endoscopic devices, did not meet either of those requirements and so were not suitable for the scheme. From the patent perspective, the Deputy Judge noted that, even if the technology was not complex, the defendant patentee's reliance on a large number of independently valid claims and the claimant's failure to narrow down its invalidity arguments were likely to extend the volume of expert evidence and hearing time required beyond the standard.

Public interest

As is common practice, a copy of the draft judgment in *Varian v Elekta*[158] was provided ahead of the hand-down hearing to the parties' representatives, who

[149] *American Cyanamid v Ethicon* [1975] A.C. 396.
[150] [2017] EWHC 2077 (Pat).
[151] [2015] EWHC 3676 (Ch).
[152] Directive 2001/83/EC on the Community code relating to medicinal products for human use.
[153] *Accord v Astellas* [2017] EWCA Civ 442.
[154] See footnote 104, *ante*.
[155] [2008] EWCA Civ 622, at para 28.
[156] [2015] EWCA Civ 480, at para 17.
[157] [2017] EWHC 1202 (Pat).
[158] [2017] EWHC 712 (Pat).

in turn informed **Birss J** that a settlement had been agreed, and requested that he did not hand down the judgment. The Judge however exercised his discretion under *Prudential Assurance*[159] to hand down the judgment where the public interest is concerned and the draft judgment has been provided to the parties. As the Judge explained in a post-script to his judgment, the validity and proper scope of a patent are matters which affect the public as well as the parties. It would therefore seem that where these issues are in suit and the draft judgment has already been provided to the parties, judges will be likely to hand down their judgments on public interest grounds despite the parties having already disposed of the matter.

Issues from the IPEC

The IPEC is no stranger to the appearance of litigants in person and sometimes, without professional representation, comes the danger that unmeritorious claims are pursued and vexatious cases commenced. The solution to this, when happening persistently, is the civil restraining order (CRO), an exceptional remedy for extraordinary behaviour. Mr Richard Perry was made subject to a general CRO by a decision of **HHJ Hacon** in March last year,[160] the latest chapter in a story that began with a claim of patent infringement brought by Mr Perry in 2014. Readers familiar with the story will recall that Mr Perry's previous behaviour included episodes as remarkable as the impersonation of a judge, in writing a letter to himself awarding compensation to the tune of five million pounds (in an apparent reversal of the Judge's previous decision). The most recent decision of **HHJ Hacon** may put an end to such behaviour once and for all. It escalates the sanction to which Mr Perry was already made subject – the extended CRO – following the decision of **HHJ Hacon** in 2015.[161] An extended CRO requires the subject to obtain the permission of the court before starting new proceedings related to the proceedings in which the Order was made. A general CRO allows any proceedings obtained without permission automatically to be struck out. Mr Perry is subject to the Order for two years. Tune-in again in March 2019 to find out what, if anything, happens next.

Unitary Patent / Unified Patent Court[162]

The UPC's year of two halves

Given the history of the UPC, it would be a bold claim to suggest that 2017 was its most dramatic yet, but it was certainly a year of twists and turns. It opened against the backdrop of the post-Brexit referendum uncertainty being replaced with optimism following the 29 November 2016 announcement that the UK would proceed to ratify, Brexit notwithstanding. Reflecting this optimism, the year opened with a statement from the UPC Preparatory Committee that:

> *"The Preparatory Committee is now working under the assumption that the Provisional Application Phase (PAP) will start end of spring 2017, presumably in May, and that the Agreement on the Unified Patent Court (UPCA) can enter into force and the Court become operational in December 2017."*

The following few months saw preparations continue apace. The UPC Preparatory Committee met in The Hague for the "last time" on 15 March 2017, contemplating its replacement with the UPC Administrative Committee as the PAP began, and a carefully choreographed plan was put in place for the second part of the year so that judges could be interviewed and appointed. Steps toward UK and German ratification progressed well. In Germany, the process was all but completed at the end of March, leaving only the formality of signature of the legislation by the President. Then the first spanner of 2017 was lobbed into the works: the announcement of a UK General Election.

The timing of this could hardly have been worse, although only the most extreme of conspiracy theorists could suggest with a straight face that the Prime Minister had chosen to call a General Election so as to interfere with the progress of the UPC. The problem created, however, was that it would be immensely difficult to complete ratification and have the UK consent to the Protocol on Provisional Application of the UPC Agreement within the timescales contemplated in January 2017. Moreover, it was not a simple case of the timetable being shunted back a couple of months. Rather, the timing of the start of the PAP, being uncertain, would mean that the timetable for judges' appointments would potentially have to be scrapped and could only be re-fixed once it was known when the PAP would actually start. The problem, however, was not just with the UK. A number of other countries had failed to take the steps necessary under their own constitutions to approve the start of the PAP. For example, one early ratifier of the UPC Agreement itself, Austria, had simply not done anything about the Protocol on Provisional Application. Another, Malta, appeared to be deliberately sitting on its hands. Hence, the day before the UK election, the UPC Preparatory Committee somewhat gloomily said:

[159] *Prudential Assurance v McBains Cooper* [2000] EWCA Civ 172.
[160] *Perry v FH Brundle* [2017] EWHC 678 (IPEC).
[161] *Perry v FH Brundle* [2015] EWHC 2737 (IPEC).
[162] The authors are grateful to Alan Johnson of Bristows for drafting this section of the review.

> *"As announced after the last meeting of the UPC's Preparatory Committee on 15 March 2017, the timetable for the start of the period of provisional application and for the entry into force of the UPC Agreement is relying on the timely finalisation of national procedures concerning the ratification of the UPC Agreement and the participation in the Protocol on Provisional Application. In particular, a few Member States must still agree to be bound by the Protocol before the period of provisional application can start. Due to some delays with these procedures, the previously announced target date for the entry into operation of the UPC, envisaged for December 2017, cannot be maintained."*

The delay in the UK timetable caused howls of protest from some quarters abroad, and your author well remembers attending a meeting with a foreign industry association in early May 2017, and spending most of the time explaining that the UK remained fully committed to the UPC and that there was no reason to doubt its intentions. Ironically, that meeting was in Germany; ironic, of course, because unbeknown to any of us, the German President had already agreed to hold off, *sine die*, from signing off on the critical German ratification legislation. This was because immediately after the last stage of the German parliamentary procedure, Dr Ingve Stjerna, a lone German citizen, and a lawyer rather than a politician, had lobbed a far bigger spanner into the UPC works, namely his constitutional challenge.

The nature of the challenge is something which remains officially shrouded in mystery. No copy of it has been made truly public, although very many people in the IP world have seen it or the English translation, and a number of the responses to it have been published in full which rather give the game away. However, rather than risk accusations of breach of something (it is not clear what) by Dr Stjerna, it suffices to say that there are a number of grounds of attack, that the complaint is very long, and it can fairly be said to be a good piece of work, given the material with which he was working. Leastways it was sufficient in quality and/or quantity to convince the German Constitutional Court (the BVerfG), a few days after its receipt, to call the President's office and ask that he should not for the time being take his UPC-signing pen out of his pocket. Hence, Dr Stjerna had, remarkably, in effect obtained an *ex parte* interim injunction against his President and thereby completely stalled the UPC without anyone in the IP world having the faintest idea.

That was in early April, and it was over two months before the existence of the complaint became public, seemingly through some form of leak to the press. Whilst this took the pressure off the UK, it was disastrous for the progress of the UPC. It was hoped initially that the BVerfG would reach a quick decision and rule the complaint inadmissible (as is a common occurrence). Positive news was obtained from the UK that the ratification process was resuming after the election and in early July 2017 it deposited its consent to the Protocol on Provisional Application. However, time passed and the BVerfG, rather than dismissing the complaint as had been hoped, decided to seek views of various organisations on the Stjerna complaint. This, in late September 2017, caused the UPC Preparatory Committee to relent and state openly that it simply could not announce any new timeline.

And so the year ended with a Christmas message from the Chair of the UPC Preparatory Committee, Alexander Ramsay, which ended with these words:

> *"Looking ahead to 2018 I am hopeful the New Year will bring closure to our endeavours and the Unified Patent Court will become a reality providing benefit of growth and European competitiveness."*

The use of the word "hopeful" rather than "optimistic" is perhaps telling. But is he right even to be hopeful? Is the glass half full or half empty?

The pessimist would say that the UK has still not actually ratified, and we have no idea at all as to when the BVerfG will make a decision, let alone whether it will be positive for the UPC. What is more, it is entirely possible that the BVerfG may refer the matter to the CJEU, or rule the complaint admissible, and then decide after a full hearing that the complaint has merit and the problem may or may not be capable of a quick fix. Hence, lengthy delay is entirely possible, and could easily take commencement of the project beyond Brexit, thereby adding a whole new layer of complication and quite possibly kill off the project for another generation.

The optimist would say that the UK is almost there with ratification, meaning that this will not be the rate limiting step, and with rumours of an April 2018 hearing (and perhaps some form of summary judgment hearing), the BVerfG could easily clear the way to German ratification in time for the PAP to begin in May 2018 and see the UPC open in late 2018, or at least comfortably before Brexit.

Which of those is right is anyone's guess. What is certain is that European industry still wants the UPC (and, more importantly for many, the unitary patent), and that there remains huge political will for the project to succeed. This will is also highly relevant to the prospects for the UK's long term participation. As the saying goes: where there's a will there's a way. The problems with participation in the UPC at least appear surmountable legally, and no political objection exists given the UPC and the EU are strictly unconnected. On the other hand, participation in the unitary patent part of the package is potentially more challenging legally as well as politically, given that it is an EU instrument. At the very least, it is tied into the wider Brexit negotiations in a way the UPC is not. Whilst it would be unfortunate for patentees to have to pay extra renewal fees for a UK validation at the EPO, were the UK in the UPC but excluded from the unitary patent system, the UK part of the European patent, EP(UK), could still, of course, be enforced in the UPC alongside the unitary patent, EP(EU). Hence, such a schism would not be the end of the world.

But, for now, we await news from the BVerfG. At least it is a court from which no appeal is possible such that its verdict will be the final word. Will it allow one person out of some 400,000,000 people in the potential "UPC zone" to derail the entire project? It must uphold the German constitution, but surely one individual lawyer will not end the efforts over quite literally decades of countless people from a broad church of professions, judges, Government officials, industry representatives, and politicians of all political persuasions? Surely…

Looking Ahead to 2018

After the upheaval of 2017, 2018 is likely to be a year of consolidation with the lower courts getting to grips with the new rules on equivalence which are now to be applied to cases involving immaterial variants. The law on the issues of plausibility, abuse of process and the construction of Swiss-type claims will be aired before the Supreme Court in the pregabalin case,[163] and it will be interesting to see if the Judges who hear that case are in the mood for another radical upheaval. 2018 will also bring more FRAND rulings, including the Court of Appeal's decision in *Unwired Planet*.[164] As to the UPC, what can we say? Expect the unexpected.

[163] On appeal from *Generics (UK) v Warner-Lambert* [2016] EWCA Civ 1006.
[164] On appeal from *Unwired Planet v Huawei* [2017] EWHC 711 (Pat).

The Authors

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Brian specialises in contentious intellectual property matters. He has been involved in numerous patent disputes, mostly concerning pharmaceuticals but also in other fields. Brian's first Patent Review of the Year was published in 2001 and writing the review has occupied the long winter evenings for him ever since.

02

Dominic Adair

Partner

Dom is a partner in the Intellectual Property department at Bristows. His practice mainly involves patent litigation and particularly the co-ordination of international patent litigation. Prior to joining Bristows, Dom obtained a PhD in Zoology.

03

Naomi Hazenberg

Associate

Naomi specialises in intellectual property litigation. Although she has experience with a broad range of IP rights, her practice is largely focused on patent disputes. She has a particular interest in technical and telecoms matters having obtained a masters degree in Physics prior to joining Bristows.

04

Emma Muncey

Associate

Emma is an associate in the Intellectual Property department at Bristows and specialises in patent litigation. She particularly enjoys pharmaceutical patent disputes having obtained a masters degree in Chemistry and worked as a research scientist for a global pharmaceutical company prior to joining Bristows.

05

Manuel Rey-Alvite Villar

Professional Support Lawyer

Manu is a PSL in the Intellectual Property department at Bristows. He is involved in the co-ordination of international patent litigation in the field of pharmaceuticals and the management of patent litigation know-how from multiple jurisdictions.

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