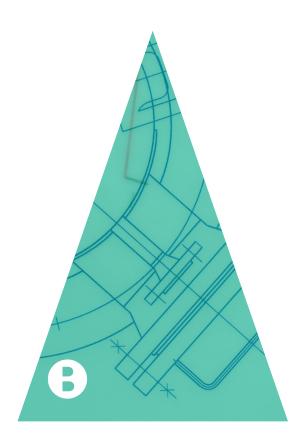
Review of Patent Cases

in the English Courts in 2019





This edition of Patent Review of the Year is dedicated to Laura Anderson and Joe Sako, our dear friends and colleagues whom we miss every day.

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Quotation of the Year:

"It would be an exercise in jurisdictional imperialism to foist this Court's view ... on an unknown foreign jurisdiction"

Per Floyd LJ in <u>TQ Delta v ZyXEL</u> [2019] EWCA Civ 1277, at paragraph 52.

The information contained in this document is intended for general guidance only. If you would like further information on any subject covered by this Bulletin, please email Brian Cordery (brian.cordery@bristows.com), Dominic Adair (dominic.adair@bristows.com) or the Bristows lawyer with whom you normally deal. Alternatively, telephone on + 44 20 7400 8000.

Introduction

2019 was a busy year in the English Patents Courts and a return to high output: the total case count of 86 decisions being the highest of the past 4 years. As with 2017 and 2018, there were two decisions from the Supreme Court: one of which addressed an issue of widespread application, in this case the question of inventive step and expectation of success in relation to a dosage regimen patent for the drug, tadalafil¹. However, in contrast to the Actavis² decision of 2017, the tadalafil ruling from the Supreme Court³ did not change the landscape in any significant way. 2019 also brought interesting decisions in both the life sciences and technology arenas from the lower courts, although some aspects of the former remain unchanged: for example, the 2019 developments in the law relating to supplementary protection certificates ("SPC") illustrates that it continues to confuse and confound many practitioners.

The Unified Patent Court ("UPC") spent another year in a holding pattern, but in light of Brexit and the expected decision from the German Federal Constitutional Court, there are signs that the next year or two will bring significant and rapid developments. Returning from retirement for one last outing, Alan Johnson tells us that the project may not be dead yet.

The year also included the following events:

- In the autumn, Mr Justice Arnold was promoted to the Court of Appeal. His decade of first instance patent jurisprudence represents a remarkable achievement. He has addressed almost every substantive area of patent law and will no doubt continue to develop it from a higher bench.
- The Supreme Court heard, but did not decide, the joined Unwired Planet and Conversant cases on fair reasonable and non-discriminatory ("FRAND") licence terms and related issues. Hundreds, if not thousands of practitioners, tuned-in to the live video feed to watch the proceedings and seek an answer to the big question on many minds: will English Courts retain the ability to set the terms and royalty rate(s) of a global licence? Watch this space in early 2020 to find out. In the meantime, disputes relating to jurisdiction dominated cases concerning FRAND and encumbered many standard essential patents ("SEPs").
- Jurisprudence on the doctrine of equivalents continues to develop. His Honour Judge Hacon gave some interesting judgments, including on the application of equivalence to numerical ranges and on a Germanstyle Formstein defence.

• Finally, and sadly, a long shadow was cast over the year by the passing away of Mr Justice Henry Carr in July. Both as a barrister and later as a Judge, Henry Carr J provided great inspiration to a generation of intellectual property lawyers. He was kind-hearted, fair-minded and warm-spirited and the whole IP community is still coming to terms with the loss.

As with previous years, this review attempts to summarise the most important decisions on a topic-bytopic basis. The UK Patents Act 1977 is referred to as the "Act", the European Patent Convention 2000 as the "EPC", Regulation (EU) No. 1215/2012 of the European Parliament and of the Council of 12 December 2012 as the "Brussels Regulation Recast", Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products as the "SPC Regulation" and Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market as the "Plant Protection **Products Regulation**".

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

In his own words, the *Lilly v Genentech*⁴ dispute, involving a patent to IL-17 A/F antibodies to treat certain autoimmune disorders, was one of the most complex cases Arnold J, as he then was, has ever heard. Certain aspects of the judgment dealing with validity and SPCs will be summarised later in this review. However, readers who made it to the final sections of the decision were rewarded with some interesting, albeit obiter, observations on construction and infringement. In particular, Arnold J opined that for EPC 2000-style purpose limited product claims, it would be appropriate to consider infringement pursuant to the indirect infringement provisions contained in section 60(2) of the Act. Thus, following the principles laid down by the Court of Appeal in cases such as *Grimme v Scott*⁵, there would be infringement by a supplier of means relating to an essential element of an invention where the supplier knew or it was obvious that end-users would put the invention into effect in the UK. The Judge held that, for a second medical use claim in EPC 2000 form, the means essential was the drug substance and that Lilly would have known, or it was at least obvious, that ultimate users would put the invention into effect in the UK because the drug substance was authorised by the regulatory

² Actavis v Eli Lilly [2017] UKSC 48

³ Actavis v ICOS [2019] UKSC 15

⁴ [2019] EWHC 387 (Pat) ⁵ [2010] EWCA Civ 1110

¹ The second being Shanks v Unilever [2019] UKSC 45

authorities for the treatment of the second indication. **Arnold J**'s treatment of EPC 2000 claims may be contrasted with his approach to Swiss-type claims where it has been held in cases such as <u>Warner-Lambert v</u> <u>Generics</u>⁶ that the claim is directed to the act of manufacture and only acts prior to the manufacture of the medicine could be considered under an allegation of indirect infringement.

A plethora of construction issues arose in <u>Garmin v Philips</u>⁷ in relation to which **Henry Carr J** emphasised that purposive construction requires the patent to be interpreted objectively, and without regard to, or knowledge of, the grounds of invalidity. He also confirmed the approach in <u>Virgin Atlantic v</u> <u>Premium Aircraft</u>⁸ that there is no presumption that the patentee necessarily intended the widest possible meaning be given to their words consistent with their purpose.

In <u>Technetix v Teleste</u>⁹, **HHJ Hacon** considered an argument that a certain construction should be rejected, as it would render the patent invalid over the common general knowledge ("**CGK**"). Examining **Floyd LJ**'s judgment in <u>Adaptive Spectrum v BT</u>^o, he held that there is no absolute rule that the Court should be slow to arrive at a construction that would render a patent anticipated or obvious over the CGK and, on the facts, the skilled person may conclude quite readily that a patent is anticipated by the CGK. He rationalised this by concluding that the patentee was either isolated from or overlooked that part of the CGK.

Doctrine of Equivalents

Following the Supreme Court decision in Actavis v Lilly11, the doctrine of equivalents continues to be a burgeoning area of law. Understandably, there remain areas of uncertainty when it comes to the proper approach to application of the doctrine. One area in which there appears to be divergence is whether infringement by equivalents should be addressed integer by integer, or by considering the variant as a whole. Arnold J and Nugee J in Conversant v Huawei¹² and E Mishan v Hozelock¹³, respectively, considered infringement of each of the integers of the claim separately. On the other hand, HHJ Hacon in Technetix v Teleste¹⁴ considered that the patentee is not "invariably required to assert equivalence in relation to each integer of the claim" but rather an accurate identification of the inventive concept "may be enough to focus attention on the integers that matter". HHJ Hacon, sitting as a High Court Judge, also took a similar approach in Regen v Estar¹⁵ where he considered the variant as a whole. Some guidance on the definition of the elusive inventive concept came from HHJ Hacon in BDI Holding v Argent Energy¹⁶, an entitlement dispute over a patent for converting waste material into biodiesel. The Judge confirmed that the identification of the inventive concept of a patent for the purpose of an entitlement dispute is the same as that identified by the Supreme Court in <u>Actavis</u>. Whilst so doing, he also confirmed that the inventive concept could be found outside the claims, following **Jacob LJ** in <u>Markem v Zipher</u>¹⁷.

Also in Regen v Estar¹⁸ HHJ Hacon, sitting as a High Court Judge, had to grapple with how numerical ranges should be handled under the doctrine of equivalents. Regen alleged that its patent for preparing a platelet-enriched blood plasma product via a polyester-based thixotropic gel was infringed by Estar. The Judge found that Regen's patent was invalid but went on to consider infringement on an obiter basis. One of the main differences between Estar's product and the claims, which prevented Estar from infringing as a matter of normal interpretation, was that its anticoagulant had a molarity of 0.136M, rather than 0.10M as required by the claim. The Judge highlighted the importance of the inventive concept to the third re-formulated Improver19 question and found that a numerical limit does not drive the skilled person to the view that the patentee intended strict compliance with the relevant number unless it is part of an essential element of the inventive concept, i.e. a numerical limit should be treated like any other integer as per Jushi²⁰ and Smith & Nephew²¹. HHJ Hacon found that Estar's product exploited the inventive concept of Regen's patent in substantially the same way to achieve substantially the same result, with no intended strict compliance to the claims. As such Estar would have infringed under the doctrine of equivalents had the patent been valid.

In a lengthy decision from **HHJ Melissa Clarke**, sitting as a High Court Judge, in <u>Excel-Eucan v Source Vagabond</u> <u>Systems</u>²², the issue of infringement by equivalents was considered in the context of a declaration of noninfringement. The <u>Actavis</u>²³ questions were applied and the request for the declaration was denied. Interestingly, separate validity proceedings were afoot in the UK IPO and Source sought to rely on the non-binding opinion from the UK IPO on validity of the patent to rebut Excel-Euan's arguments under limb (i) of the <u>Actavis</u> test. However, applying the guidance from <u>Actavis</u> on when the contents of a prosecution file may be used in Court proceedings, **HHJ Melissa Clarke** declined to consider the opinion in her analysis.

The Court has also had to consider the interplay between the doctrine of equivalents and validity. In <u>Technetix v Teleste²⁴</u>, the issue before **HHJ Hacon** was whether Teleste would be afforded a defence to infringement under the doctrine if the product lacked novelty or inventive step over the prior art (the *Formstein* defence, as it is known under German law). On the facts,

¹⁰ [2014] EWCA Civ 1462

- ¹² [2019] EWHC 1687 (Pat)
 ¹³ [2019] EWHC 991 (Pat)
 ¹⁴ [2019] EWHC 126 (IPEC)
- ¹⁵ [2019] EWHC 63 (Pat)
- 16 [2019] EWHC 765 (IPEC)
- ¹⁸ [2019] EWHC 63 (Pat)
 - ¹⁹ <u>Improver v Remington</u> [1989] 5 WLUK 162

17 [2005] EWCA Civ 267

- ²⁰ <u>Jushi v OCV Intellectual Capital</u> [2018] EWCA Civ 1416
- ²¹ <u>Smith & Nephew v ConvaTec</u> <u>Technologies</u> [2015] EWCA Civ 607
- ²² [2019] EWHC 3175 (Pat)
- 23 [2017] UKSC 48
- ²⁴ [2019] EWHC 126 (IPEC)

^{6 [2015]} EWHC 2548 (Pat)

^{7 [2019]} EWHC 107 (Ch)

^{8 [2010]} RPC 8

⁹ [2019] EWHC 126 (IPEC)

HHJ Hacon considered it would have been obvious to adapt CGK devices to create a device like Teleste's cable tap unit and therefore, if a *Formstein* defence exists in English law, Teleste would be entitled to it. However, **HHJ Hacon** did not have to consider whether such a defence in fact existed in English law as he held that the patent was invalid.

The question of the possibility of an added matter squeeze based on the arguments run under the doctrine of equivalents came up in <u>Conversant v Huawei</u>²⁵. **Arnold J** rejected this as a possibility, explaining that infringement by equivalents cannot give rise to an added matter objection as it is "an argument about scope of protection, not about disclosure".

Validity

The Skilled Person and their CGK

Can claim amendments change the identity of the skilled person? This was the question that was before Birss J in Conversant v Apple²⁶ where the unamended claims related to a "computing device" but the claims as amended related to a "smart phone". Birss J explained that whilst it will be unusual, the identity of the skilled person relevant to an amended claim may be different from the identity relevant to the unamended claim. This is because a patent is taken to be directed to those with a practical interest in its subject matter (following Catnic²⁷) and the subject matter is the invention, which is defined in the claims28. Therefore, in this case, although the patent specification and unamended claims related to computing devices more generally, Birss J held, in relation to the amended claims, that the skilled person was someone with a practical interest in smart phones.

Arnold J's view that an English case requires an English outlook gained further momentum with his judgment in Illumina v TDL Genetics²⁹. Building on his findings in Generics v Warner-Lambert³⁰ that a case concerning a UK designation of a patent requires consideration of the CGK as it was in the UK, which may be different to the CGK elsewhere, in Illumina, he considered the position of foreign prior art. The Judge held that, for a UK designation of a patent, the skilled person is located in the UK and is, therefore, deemed to read an English language translation of any non-English language prior art document, rather than the document in its original language. He also provided a reminder that evidence relating to a disputed translation is a form of expert evidence, as per Sobrinho v Impresa Publishing³¹ and Umeyor v Ibe32, and that the Court's permission must be sought to adduce it under the Civil Procedure Rules ("CPR") Part 35.

Patentability

The subject matter of a patent cannot comprise mere presentation of information as that is excluded by section 1(2) (d) of the Act. The issue arose in Garmin v Philips³³ as to whether a conditional claim amendment, which added a new feature consisting of music volume reduction during the audio playback of real-time athletic performance information from a GPS-based athletic performance monitoring device, was purely presentational in nature. Henry Carr J emphasised that "the key point is that the claimed feature is not in substance a claim to information content". He held that the combined feature of audio entertainment and volume dimming during presentation of real time performance information was technical and solved the technical problem (how to enable the athlete simultaneously to listen to music from an audio entertainment system and also be provided with aural feedback on their performance). The technical contribution was therefore not the presentation of information as such and was patentable.

Novelty

The UK approach to the issue of anticipation remains that set out by the House of Lords in <u>Synthon³⁴</u>; namely, that the prior use or disclosure must both disclose and enable something falling within the claims of the later patent. This can often be a relatively simple test to apply but there are nuances and one such nuance came to the fore in relation to a dispute between <u>Takeda v Roche</u>35 regarding the latter's patent to glycosylated antibodies in which the claimed antibodies were fully fucosylated. The issue under consideration was whether, for anticipation, the prior use or disclosure must be capable of precise repetition. Disagreeing with the approach taken in two EPO Technical Board of Appeal cases³⁶, Birss J held that the fact that the skilled person's repetition of the prior art would likely not produce a product that was identical to the prior art did not matter as long as the differences did not take the product outside the scope of the claims. The Judge illustrated the point by reference to an example, if a prior art document disclosed an antibody whose amino acid sequence could be analysed and reproduced without undue burden, a later claim to a product with an identical amino acid sequence would be anticipated. The fact that the prior art antibody might possess certain features that could not be identically reproduced, such as a different glycosylation pattern, would not make a difference to a claim stated at the level of the amino acid sequence.

- 11 WLUK 270
- ²⁸ Section 125 of the Act

²⁹ [2019] EWHC 1497 (Pat)
 ³⁰ [2015] EWHC 2548 (Pat) at [123]-[124]
 ³¹ [2015] EWHC 3542 (QB)
 ³² [2016] EWHC 862 (QB)

³³ [2019] EWHC 107 (Ch)

- ³⁴ <u>Synthon v SmithKline Beecham</u> [2005] UKHL 59
- ³⁵ [2019] EWHC 1911 (Pat)

³⁶ T 1833/14 and T 2045/09

²⁵ [2019] EWHC 1687 (Pat)

^{26 [2019]} EWHC 3266 (Pat)

²⁷ Catnic v Hill & Smith [1980]

The test from <u>Synthon</u> also played a role in <u>Technetix v Teleste</u>³⁷, where **HHJ Hacon** held that novelty can be destroyed by working the prior art even if the skilled person doesn't realise it. In his decision, the Judge explained that it does not matter whether or not the skilled person would appreciate that what the prior art disclosed fell within the scope of the claims. What matters is what in fact would happen when the prior art is performed.

Prior Disclosure/Use

In the case of <u>E Mishan v Hozelock</u>³⁸, **Nugee J** had to consider whether the inventor's work in his front garden amounted to a relevant prior disclosure. The Judge found that information is not made available to the public when no member of the public could have accessed it. On the facts, the inventor's evidence that he would have stopped his work if he had noticed someone watching him was sufficient to prove that there was no prior disclosure. Therefore, it seems that the "brightline" test for prior use in <u>Milliken v Walk Off Mats</u>³⁹ may not be as tight as previously thought.

HHJ Hacon heard an unusual application in <u>Regen v</u> <u>Estar</u>⁴⁰ when Estar applied to re-open the trial prior to judgment based on new evidence relating to an alleged prior disclosure contained in witness statements filed in opposition proceedings before the EPO. He dismissed Estar's application because: (i) it was an abuse of process as the prior use could and should have been pleaded at trial⁴¹; (ii) it would not make a difference to the overall outcome of the trial; and (iii) the extra Court time and cost that would be required to deal with the issue was not proportionate, as per the overriding objective.

Obviousness/Inventive step

To many practitioners, the biggest surprise about the <u>Actavis v ICOS</u>⁴² case concerning a patent to a dosage regimen for the PDE5 inhibitor tadalafil, was that permission was granted at all for an appeal to be taken to the Supreme Court following a finding of invalidity by a strong panel in the Court of Appeal. When the Supreme Court's decision was handed down, readers looking for a significant change in approach to the issue of inventive step were disappointed. However, **Lord Hodge**'s judgment, with which the other four Judges concurred, is interesting as it sets out some relevant considerations which a Court should take into account in assessing obviousness in a case of this kind. These include:

i. whether something was "obvious to try". The Court addressed this together with whether there was a reasonable or fair prospect of success. The Court agreed that the results of some experiments can be obvious even if there is no expectation of success;

- ii. whether the research was routine in nature. However, the Court noted that this had no primacy and certainly no paramount status as a consideration;
- the burden and cost of the research programme. The Court noted here that the need to facilitate expensive pharmaceutical research is an important policy consideration;
- iv. the need to make, and the nature of, value judgments during a research programme;
- the existence of alternative or multiple paths of research. The Court noted that multiple paths will often, although not necessarily, be an indicator of non-obviousness;
- vi. the motivation of the skilled person to undertake certain technical trials;
- vii. whether the results of the research were unexpected;
- viii. the need to avoid hindsight43;
- ix. whether the feature of the claimed invention is an added benefit and the claimed innovation is obvious for another purpose, referring to the well-known UK authority in <u>Hallen v Brabantia⁴⁴</u>; and
- x. in relation to dosage regimen patents, the Court reiterated that there is no blanket prohibition on such patents but that there should be no relaxation of the rules relevant to the assessment of inventive step.

Concerned with the possible general applicability of some of the statements from the Court of Appeal judgment, several industry bodies had intervened before the Supreme Court. However, Lord Hodge held that the judgments of the Court of Appeal did not support "any general proposition that the product of well-established or routine enquiries cannot be inventive" and so the fears of the industry bodies were, by and large, unfounded. As well as the substantive considerations, the judgment also re-states the established law in the UK from cases such as *Biogen v Medeva*⁴⁵ that an appellate court should exercise caution when reversing a first instance judge's evaluation of the evidence on the issue of inventive step. Further, although the Court had heard submissions about judgments of courts of other countries in relation to parallel patents, these were found to be of limited use in the evaluation of the UK patents.

The fact that the approach taken by the Supreme Court in tadalafil⁴⁶ was no different from than the previous law was later confirmed by **Arnold J** in <u>Allergan v Aspire</u>⁴⁷, in which Allergan's patent for a formulation of the prostaglandin analogue bimatoprost and the preservative benzalkonium chloride was held to be obvious.

- ³⁷ [2019] EWHC 3106 (Pat)
- ³⁸ [2019] EWHC 991 (Pat)
- ³⁹ [1996] F.S.R. 292
- 40 [2019] EWHC 63 (Pat)

 ⁴¹ Following <u>Henderson v Henderson</u> (1843) 3 Hare 100
 ⁴² [2019] UKSC 15 ⁴³ The Court noted that the "obvious danger of a step by step analysis is that the combination of steps by which the inventor arrived at his invention is ascertained by hindsight knowledge of a successful invention", but went on to say that there may be cases in which "the steps which the notional skilled person would take can readily be ascertained without the taint of hindsight". ⁴⁴ [1991] RPC 195

- ⁴⁵ [1997] RPC 1
- ⁴⁶ <u>Actavis v ICOS</u> [2019] UKSC 15
 ⁴⁷ [2019] EWHC 1085 (Pat)

It is well known that making a mosaic from the prior art is not permitted under English law in almost all circumstances, the exception being where there is a cross-reference and motivation to follow it. In <u>*E Mishan v Hozelock*⁴⁸</u>, **Nugee J** had to grapple with whether the various occasions on which the inventor had worked on his prototype garden hose in his front garden could be put together via mosaicing. He held that they could not. This was because it would not have been clear to the skilled person watching the inventor that he was testing a prototype that he had made on a previous day.

Further commentary on the skilled person's approach to complex documents was provided by Henry Carr J in TQ Delta v ZyXEL⁴⁹, where the Judge distinguished (i) cherry picking using impermissible hindsight from, and (ii) the skilled person's ability to identify relevant parts of documents having read and assimilated them properly and with interest. Therefore, although the prior art was a 320-page technical standard, the skilled person would read the relevant sections with interest. The skilled person in this case was used to confronting and solving technical problems and would be aware of a real problem if one existed. The Judge found that no "superhuman ability" was required to identify the problem from the prior art. As it was accepted that if the problem were known the patented solution would have been obvious, the patent was found to be invalid.

A question on the impact of the claims on the way prior art is treated came up in the Court of Appeal decision in <u>Philips v Asustek</u>⁵⁰ in which the defendants sought to argue that the first instance Judge ought to have treated the prior art with a comparable level of generality to that of the invention. **Floyd LJ** dismissed this argument, explaining that the nature of the invention "cannot logically impact on the way in which the skilled person approaches the prior art". Whilst a simple invention provides that same simple idea as the target for an obviousness attack, this does not entitle the Court to strip out detail from the prior art or ignore paths down which the skilled person would probably be led.

As well as conventional obviousness, it is now commonplace to challenge a patent's validity by arguing that the patent is obvious due to a lack of technical contribution and/or failure to solve the technical problem. As noted by **Birss J** in the <u>Takeda v Rochest</u> case, the general principle is that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art. In the same case, the Judge noted that this argument is sometimes put on the basis that the patent makes no technical contribution over a given item of prior art and such an allegation was made out on the facts of this case, in the Judge's opinion.

Insufficiency

It is settled law that a patent will be held insufficient if it is ambiguous in the sense that the skilled person genuinely cannot tell if a given product or process falls inside or outside the scope of a claim. In <u>Takeda v Roche⁵²</u>, **Birss J** commented that the principles are not too hard to state, but they can be tricky to apply. Nevertheless, the Judge considered that this was a case where the claim was ambiguous as a product could fall within the claim when measured on one machine but could fall outside the claim if measured on another machine and both were reasonable testing methods to use. This was held not to be a case of a fuzzy boundary at the edges of the claim, but one of true ambiguity.

However, the <u>Takeda v Roche</u> decision may well be the last time we see the use of the term "ambiguity" in the context of sufficiency. One of the take home points from the Court of Appeal's judgment in <u>Rhodia v Neo</u>⁵³ is that practitioners should no longer use it. The better term is "uncertainty". As **Lewison LJ** observed, "[s]omething is ambiguous when it is capable of having two (or more) meanings, and ultimately the Court will be able to decide which of them is the correct meaning. Rather the issue here is that of uncertainty. If the Court cannot ascertain the boundary [of the claim] it must conclude [that it is insufficient]".

The leading judgment of Floyd LJ in Rhodia v Neo⁵⁴ also serves as a useful guide to the law on this type of insufficiency, and also on breadth-of-claim or Biogentype insufficiency. On the first point, insufficiency due to uncertainty, he upheld the first instance judgment that the wording of Rhodia's claim in the form "consisting essentially of ceric oxide" did not present the skilled person with an insurmountable burden when deciding whether any other elements present in small amounts materially affected the essential characteristics of the product. On *Biogen*-type insufficiency, **Floyd LJ** probed the leading House of Lords authorities of *Biogen*⁵⁵ and Lundbeck⁵⁶. He extracted several principles to help navigate the general principle from **Biogen** that a claim's breadth should not exceed its technical contribution, and the application in Lundbeck of that principle to product claims. In what is clearly a very fact-sensitive area of the law, Floyd LJ held that although the insufficiency objection made by Neo was viable in law, the evidence it relied upon did not go far enough to meet the burden of proof.

⁵¹ [2019] EWHC 1911 (Pat)

⁴⁸ [2019] EWHC 991 (Pat)

⁴⁹ [2019] EWHC 745 (Pat)

⁵⁰ [2019] EWCA Civ 2230

⁵² [2019] EWHC 1911 (Pat)

⁵³ [2019] EWCA Civ 1646

⁵⁴ [2019] EWCA Civ 1646

⁵⁵ <u>Biogen v Medeva</u> [1997] RPC 1

⁵⁶ <u>Generics v Lundbeck</u> [2009] UKHL 1

Added Matter

As readers may be aware, the English courts generally currently adopt a more permissive approach to added matter than the various tribunals of the EPO. A good example of this was provided by Novartis v Dr Reddy's⁵⁷ in the context of an interim injunction application. The EPO's Opposition Division had found that Novartis' patent for a combination of everolimus and exemestane for use in the treatment of hormone positive breast cancer was invalid for added matter. Novartis had appealed against this decision. In response to Novartis' application for an interim injunction in the UK, Dr Reddy's made an application for summary judgment on its counterclaim that the patent was invalid for added matter. After reading the papers, Birss J informed the parties that he had "formed a provisional but clear view there was no added matter" and thus the patent was not invalid. The Judge even asked Dr Reddy's if he should give judgment on the main claim then. However, given Novartis had made no application to that effect, he did not. After the summary judgment hearing, the Judge maintained his view on added matter. He held that if he were to follow the case law set out in the EPO's case law book "there is a danger of taking a rather too rigid approach" to added matter. He considered the Opposition Division's approach to be unduly technical and confirmed that added matter is primarily a matter of construction and not of expert evidence.

<u>Arrow</u> Declarations

When seeking an <u>Arrow</u>⁵⁸ declaration, the applicant asks the Court to make a finding that a particular product or process was known or obvious at a particular date. It is now settled law that such declarations can be made by the Court where it is in the interests of justice to do so and where the declaration would serve a useful purpose. However, the exact circumstances in which an <u>Arrow</u> declaration may be granted is a developing area of law.

A further small increment of clarity in this regard was delivered by <u>Pfizer v Roche</u>⁵⁹, a case relating to patents for bevacizumab, a monoclonal antibody used to treat certain types of cancer. Pfizer wished to be able to sell a bevacizumab biosimilar upon expiry of an SPC for the patent to bevacizumab. However, Roche held several pending patent applications at the EPO to the use of bevacizumab in various oncological indications. Upon commencement of proceedings by Pfizer in late 2017, Roche de-designated the UK from all relevant patent applications such that there could never be a patent in the UK for the indications of potential concern to Pfizer. Having taken such steps, Roche contended that the Court ought not to grant an <u>Arrow</u> declaration.

Unusually, Roche also elected not to adduce expert evidence on the technical issues in the case and did not cross-examine Pfizer's experts, thereby underlining its position that a decision on the technical issues was not appropriate. Birss J concluded that Roche's motive for de-designating the patent applications from the UK was to shield its portfolio from the risk of an adverse decision from the English Court, as there was "no other rational explanation". The Judge also concluded that an Arrow declaration would be of real commercial value to Pfizer including that it would likely be influential in any patent case brought by Roche in Belgium, from which country Pfizer proposed to supply the UK. Nevertheless, notwithstanding that if there had been any pending UK applications, there would be a "plain case for an Arrow declaration" on the technical evidence before him and he would have examined the merits of the Gillette⁶⁰ defences in detail, Birss J considered that the true purpose of the Arrow declaration sought in the case was for it to be used in courts in other jurisdictions and that this was not enough. Having distinguished the facts of this case from those of *FujiFilm*⁶¹ (where there was a degree of uncertainty regarding AbbVie's UK rights so as to justify the granting of an Arrow declaration), the Judge declined to consider the Gillette defence in any detail as to do so would be to do the very thing that he had decided he should not do.

The Court was not prepared to grant an application for summary judgment or strike out of a claim for Arrow relief in Mexichem v Honeywell⁶². Mexichem had sought declarations of invalidity in respect of six granted patents and, given its knowledge of pending patent applications, an Arrow declaration in relation to those applications. Honeywell considered that the Arrow declaration sought was too broad and not clearly linked to any of Mexichem's products. Considering Floyd LJ's decision in Glaxo v Vectura⁶³, HHJ Hacon, sitting as a High Court Judge, disagreed that the relief sought was too broad and noted that Floyd LJ had not ruled out the possibility of a general Arrow declaration. He held that even if any resulting declaration would not provide total freedom for Mexichem to sell its product, it would go at least some way to so doing. Whether that was sufficient to allow the grant of Arrow relief was a matter for the trial judge to consider.

FRAND, Competition Defences and FRAND Jurisdiction

In January, the Court of Appeal confirmed **Henry Carr J**'s first instance decision in <u>Conversant v Huawei</u>⁵⁴ that the English Court has jurisdiction to determine global FRAND licence terms even in circumstances where the vast majority of infringing acts were taking place in another jurisdiction. FRAND enthusiasts are now

^{57 [2019]} EWHC 92 (Pat)

⁵⁸ <u>Arrow v Merck</u> [2007] EWHC 1900 (Pat)

^{59 [2019]} EWHC 1520 (Pat)

⁶⁰ <u>Gillette v Anglo-American Trading</u> [1913] 1 WLUK 39

⁶¹ <u>Fujifilm Kyowa Kirin Biologics Co Ltd v AbbVie</u> [2017] EWHC 395 (Pat)

^{62 [2019]} EWHC 3377 (Pat)

^{63 [2018]} EWHC 3414 (Pat)

^{64 [2019]} EWCA Civ 38

awaiting the Supreme Court's decision in the combined appeals in <u>Unwired Planet v Huawei</u> and <u>Conversant v</u> <u>Huawei</u>. This will deal with both the substantive issues of the applicable FRAND licence terms but also some of the jurisdictional questions raised if these FRAND terms sought lead to a global licence. It is also expected to address the availability of injunctive relief for SEP infringement. In the meantime, however, 2019 also saw an array of additional jurisdictional and procedural issues being raised in SEP litigation where a FRAND determination was in issue.

The Court of Appeal previously made clear in Unwired Planet v Huawei65 that the English Court cannot adjudicate on the validity of foreign patent rights and so it "ought not to grant relief of what amounts to damages and royalties under those rights, save with the agreement of the parties". One might think that it would follow that evidence on validity of the patent holder's portfolio would be irrelevant to the FRAND determination; it turns out that is not the case. Nugee J concluded in Conversant v Huawei66 that there is no principle of law precluding the Court from hearing arguments as to the validity of foreign patents for the purpose of determining how a hypothetical willing licensor and licensee would perceive the patents in question in terms of attributing value to them setting FRAND licence terms. It is for the FRAND trial judge to determine on the evidence whether, and if so, the extent to which, validity should in fact be taken into account when concluding the licence terms that hypothetical willing parties would negotiate. On that basis, Nugee J gave the defendant permission to adduce technical evidence regarding, inter alia, the validity of any of the patents in Conversant's portfolio.

Birss J commented on the possibility of irreconcilable decisions arising from multijurisdictional SEP disputes leading to a stay of cases under **Article 30** of the **Brussels Regulation Recast** when hearing a jurisdiction challenge in *IPCom v Vodafone⁶⁷*. Although the issue was ultimately settled between the parties, the judge noted that there was a strong argument that litigation in Germany concerning different patents in IPCom's portfolio, which could lead to a consideration of whether a FRAND offer had been made in the context of assessing whether to grant an injunction following a finding of infringement, was related to the English litigation (which included a claim for a declaration that a certain offer made by IPCom was FRAND).

Jurisdictional gamesmanship reached new heights in the case between <u>IPCom v Lenovo⁶⁸</u>. In his last decision before retirement, **Norris J** considered whether to grant an anti-anti-anti-suit injunction. Unsurprisingly, such an application has a complicated history. IPCom had commenced infringement proceedings against two UK Lenovo and Motorola companies in relation to one of its patents, notwithstanding the pre-existence of proceedings in California brought by Lenovo and Motorola's US affiliate companies for an adjudication of the terms of a FRAND licence to the entire IPCom portfolio. This caused the following cascade of anti-suit motions and applications:

- i. First, the Lenovo and Motorola US companies launched in anti-suit motion in California to enjoin IPCom from pursuing the English infringement proceedings and to prevent it from requesting an anti-suit injunction of its own from any foreign tribunal.
- ii. In response, IPCom brought their own anti-suit application in the UK to restrain the Lenovo and Motorola UK defendants from pursuing an application in California that affected the progress of the English action.
- iii. In turn, the US companies applied to expedite their Californian anti-suit motion on an ex parte basis to ensure that it is heard before IPCom's application.

The substantive application considered by Norris J was, therefore, IPCom's further application to restrain the Lenovo and Motorola UK companies from pursuing the Californian expedition motion until the English Court had considered the substance of IPCom's first anti-suit application. The Judge noted that caution should be applied to granting anti anti-suit injunctions but determined that the substance of IPCom's first application needed to be considered by the English Court, and not effectively decided in an ex-parte motion in the United States, not least because the Lenovo defendants in the English action had positively chosen to accept jurisdiction here and filed an invalidity counterclaim against the UK patent in suit. Norris J, therefore, restrained the UK Lenovo and Motorola entities on a temporary basis from assisting or sanctioning their US counterparts from seeking to prevent the English Court from addressing these issues substantively. This task fell to **HHJ Hacon** (sitting as a High Court Judge)⁶⁹, who heard IPCom's original application a week later. In restating the principles pertaining to anti-suit injunctions set out by Touson LJ in *Deutsch Bank*⁷⁰ and Sir Terrence Etherton, Master of the Rolls in *Michael Wilson*⁷¹, the Judge highlighted that there was an even greater danger of interfering improperly with the conduct of foreign proceedings when considering an anti-anti suit injunction. The Judge added a simple corollary: if improper interference is less likely, the English Court will be more likely to grant the injunction. HHJ Hacon noted that, in this case, if the English proceedings were halted, IPCom would be deprived of its right to litigate the infringement and validity of its UK patent and would lose the only

^{65 [2018]} EWCA Civ 2344

^{66 [2019]} EWHC 3471 (Pat)

^{67 [2019]} EWHC 1255 (Pat)

^{68 [2019]} EWHC 2980 (Pat)

⁶⁹ [2019] EWHC 3030 (Pat)

⁷⁰ [2019] EWCA Civ 725

⁷¹ <u>Michael Wilson v Emmott</u> [2018] EWCA Civ 51

realistic means of moving on negotiations between the parties to settle FRAND terms. Preventing that alone, however, was not considered to be unconscionable behaviour by the UK Lenovo and Motorola companies. When taken together, though, with statements made in the US that could lead the US Court to understand that the UK Lenovo and Motorola companies approved of and supported the US anti-suit application (notwithstanding their embracing of the UK jurisdiction previously), it led to an increased likelihood that IPCom's rights in relation to its patent in the UK would be extinguished. In granting IPCom's anti-anti-suit injunction, the Judge noted that the principle of comity would not be significantly infringed, as the injunction would not interfere with the bulk of the issues before the US Court.

Implementers seeking to take advantage of the Court's willingness to set the terms of a global FRAND licence might have thought that bringing a case in England would enable them to seek some clarity in situations where negotiations with SEP holders are not bearing fruit. However, in the case of Vestel v HEVC Advance⁷², HHJ Hacon (sitting as a Deputy High Court Judge) held that, on the arguments raised by that implementer, the Court did not have jurisdiction to hear the claim in question. To "break the deadlock" in licensing negotiations relating to patents that had been declared essential to the High Efficiency Video Coding standard, Vestel sued both Advance and Philips, claiming that they had abused their dominant position by offering unacceptably high "supra-FRAND" rates⁷³ and sought a determination of the applicable FRAND licence terms (which would therefore by definition be fair). Seeking to establish the English Court's jurisdiction to hear the claim, Vestel argued that, as a result of the group having to pay royalties above what it considered to be a FRAND rate, it would suffer damage in the UK because the cost increase would be passed down the chain to Vestel UK. However, the Court noted that if the patents were ever asserted, the ultimate outcome would be that the relevant Court would settle FRAND terms. As Vestel would only ever be paying royalties on that basis, the royalties it paid would not exceed the FRAND rate and no damage would be suffered. Vestel also argued against Advance (the jurisdictional regimes the Court had to apply were different) that jurisdiction was established as the claim related to property within the jurisdiction but this too was rejected because less than 5% of the patents in the relevant pool were UK designated European Patents. It is yet to be seen whether the English Court will ever consider it has jurisdiction to hear a stand-alone FRAND declaration claim brought by an implementer.

A related issue arose in Optis v Apple⁷⁴, where the Court was also similarly asked to consider a question of jurisdiction in the context of abuse of a dominant position. This time, the first defendant (a US Apple entity) applied to set aside the previously granted permission to serve the first defendant out of the jurisdiction. The application was made on the basis that there was no reasonable prospect of Optis defeating Apple's defence under Article 102 of TFEU (i.e. that Optis had abused its dominant position) and therefore there was no serious issue to be tried on the merits. Apple argued that there were a number of terms within the licence offered by Optis, which could not conceivably be regarded as FRAND terms. Whilst Nugee J considered it possible that a Court hearing a FRAND trial might conclude that the licence offer made by Optis was not FRAND, he decided that it would be premature for the Court to conclude at this stage that Optis had abused its dominant position. The Judge explained that the time for determining whether or not an implementer should be injuncted comes only after there has been a finding of infringement and after the Court has settled FRAND terms which the implementer has had an opportunity to take. Although this differs in approach to that taken by Henry Carr J in <u>TQ Delta</u>⁷⁵ (discussed below), **Nugee J** noted in a hearing between the same parties the following day⁷⁶ that this understanding was based on the submissions before him and that he need not resolve the question of when it is appropriate to put the defendants to the election of committing to a court determined FRAND licence.

FRAND Injunctions

Earlier in the year, upon finding that one of TQ Delta's patents was valid, essential and infringed77, Henry Carr J granted an injunction with immediate effect when ZyXEL, before any FRAND determination, refused to undertake to enter into a licence on whatever terms the Court determined to be RAND⁷⁸,⁷⁹. ZyXEL's position was, notwithstanding its previously pleaded position that it was a willing licensee, it would not now commit to taking a licence from TQ Delta as the patent was due to expire in only a few months' time. In the face of that election, and despite not having been expressly asked to do so, the Judge found that ZyXEL were guilty of "hold-out" for blowing hot and cold on whether it would enter into a RAND licence and having never paid any royalties for any of the relevant SEPs. He found that while ZyXEL was now refusing to submit to the outcome of a RAND determination, it was still trying to claim the benefit of the RAND undertaking and avoid the injunction. Interestingly, this appears to move the point of election for an infringing implementer earlier than in previous cases (e.g. after the actual determination of FRAND terms as in the <u>Unwired Planet</u> case). As noted above, there is some uncertainty as to whether this is a new generally

- ⁷⁴ [2019] EWHC 3538 (Pat)
- ⁷⁵ [2019] EWHC 562 (Pat)
- 76 [2019] EWHC 3561 (Pat)
- 77 [2019] EWHC 562 (Pat)
- 78 [2019] EWHC 745 (Pat)
- ⁷⁹ For those readers not accustomed to the world of SEPs, **Birss J** provided helpful guidance in <u>TQ Delta v ZyXEL</u> [2019] EWHC 1089 (Pat) on the

distinction between FRAND and RAND: "This action concerns standard essential patents which relate to the ITU-T standard concerned with DSL. The obligation which the standard essential patent holders have relation to this standard setting environment is to give licences on a RAND basis. The obligation is RAND rather than FRAND. I will almost certainly use the expression FRAND by force of habit but it makes no difference whotsoever"

^{72 [2019]} EWHC 2766 (Ch)

⁷³ In breach of Article 102 of the Treaty on the Functioning of the European Union ("TFEU")

applicable principle or a consequence of the proximity of the patent's expiry in this particular case. The Judge dismissed arguments that it was disproportionate to grant an injunction with only a few months left in the life of the patent and stated that refusing to grant the injunction would effectively amount to a compulsory licence that would wrongly and unjustly deprive the patentee of its rights. Both **Henry Carr J** and **Floyd LJ** refused permission to appeal the imposition of the injunction.

When can a party avoid a FRAND enquiry then?

Having been injuncted, ZyXEL took action. It expressly waived any right it might have had as a result of TQ Delta's RAND obligations in the UK and sought to strike out the declaratory aspects of TQ Delta's claim, stating that in the face of the injunction and the shutting down of ZyXEL's relevant UK business there could no longer be any basis for a RAND enquiry. TQ Delta took the opposite approach; it started a new infringement action with a new patent and applied to amend its pleadings in connection with the declaratory relief sought at the scheduled RAND trial, which had been scheduled to follow the technical trial. The question of whether to vacate the RAND trial was first considered by Birss J, who was deeply sceptical about the workability of ZyXEL's waiver and thought that it was simply more of the same "hold-out" tactics that Henry Carr J had noted. The Judge held that there was still a "real and lively" dispute between the parties and noted that ZyXEL was reserving the right to still argue the RAND obligation should still apply against TQ Delta in other jurisdictions; in his view, the RAND trial should proceed as planned.

The Court of Appeal, however, reversed this decision. Floyd LJ, with whom Lewison LJ agreed, found that a declaration to determine the scope and terms of the RAND licence would no longer serve a useful purpose now that the licence would never be deployed. Whilst noting that it might not be open to an implementer to selectively claim the right to be granted a RAND licence, an implementer was able to say that it no longer wanted to rely on any licence to which it was entitled in order to resist the grant of relief in a particular jurisdiction following a finding of infringement of a local (in this case, UK) patent. The Judge commented that the Unwired Planet decision did not suggest that a patent owner had an independent right to seek a declaration of the relevant licence terms if the implementer has no interest in taking the licence. Further, Floyd LJ saw a number of "quite serious problems" with TQ Delta's new request for a declaration, that ZyXEL were not willing licensees, that being sought for export to foreign jurisdictions as a res judicata finding. Not only were there no foreign proceedings (either afoot or in contemplation), but also the Judge noted that the lack of a unified approach to

the interaction between the RAND undertaking and relief for patent infringement, as well as the fact that *"willing licensee"* was not an internationally recognised term of art, meant that any declaration might be of no use at all. Furthermore, the declaration may equally be of no use if it were exported to a jurisdiction that did not have a doctrine of res judicata or that did not recognise foreign judgments. Additionally, the wider ZyXEL group of companies would need to be involved for there to be consideration of whether or not they were *"willing global licensees"*. Finally, it would be contrary to the overriding objective to consider granting declaratory relief that had no utility, would occupy 10 days of court time and cause an estimated £4 million in costs to be incurred.

Supplementary Protection Certificates ("SPC")

Just as practitioners were starting to believe that maybe, just maybe, some clarity on the interpretation of the **SPC Regulation** would be forthcoming, 2019 demonstrated that the law in this vitally important area to life sciences companies remains in a state of flux. It is true that, by and large, most SPCs are applied for, granted, exist and expire without much fuss but several important questions remain.

One area of uncertainty familiar to all SPC practitioners is the interpretation of the ostensibly simple requirement of Article 3(a) of the SPC Regulation that the product should be "protected by a basic patent in force". In 2018, the Grand Chamber of the CJEU set down what it appeared to consider to be a definitive test in the Teva v Gilead⁸⁰ case. This test, in the context of a product consisting of a combination of two active ingredients, was that to be protected; (i) the combination must necessarily fall under the invention covered by the patent and (ii) each of the active ingredients had to be specifically identifiable in light of all the information disclosed in the patent. In September 2018, applying the test as best as he could, Arnold J held that Gilead's SPC for the combination of tenofovir disoproxil and emtricitabine was invalid⁸¹. Just before Christmas 2019⁸², the Court of Appeal upheld Arnold J's decision, focussing only on the first limb of the test and opining that since the presence of the further active ingredient in the relevant claim of the patent was optional, the combination product did not fall under the invention disclosed in the patent.

Despite the CJEU's apparent final word on **Article 3(a)** in the <u>Teva v Gilead</u> case, it is clear to all practitioners that many difficulties remain. Two particular problems relate to (i) Markush claims and (ii) functional claims. As many readers will know, these issues, respectively, were the subject of references in the <u>Sandoz v Searle⁸³</u>

⁸⁰ C-121/17
 ⁸¹ [2018] EWHC 2416 (Pat)
 ⁸² [2019] EWCA Civ 2272
 ⁸³ C-114/18

and Royalty Pharma⁸⁴ cases. The Opinion of Advocate General ("AG") Hogan, covering both cases, was issued on 11 September 2019 but, besides confirming that the Gilead test applied across the board and not just to combination products and that Arnold J's core inventive advance test was not appropriate, the Opinion contained little of any substance. It is to be hoped (but not to be expected) that the CJEU's ruling will offer the guidance that practitioners so crave.

Article 3(d) of the SPC Regulation provides that the marketing authorisation ("MA") relied upon for the SPC must be the first MA for that product. In December 2018, there was much dismay amongst practitioners at the Opinion of AG Saugmandsgaard Øe in the Abraxis⁸⁵ case relating to the availability of SPCs for new and inventive formulations of existing active ingredients when the AG appeared to cast doubt on the soundness of the earlier Neurim⁸⁶ ruling on the availability of SPCs for second medical uses as well as inventive new formulations. The CJEU ruling issued on 21 March 2019 does not appear to go as far as the AG in that it does not expressly overrule the Neurim decision. However, it seems to leave the possibility open. Thankfully, some clarity should be given in the Santen⁸⁷ case relating to a new use of the immunosuppressant drug, cyclosporine. In particular, the CJEU has been asked to rule on whether <u>Neurim</u> is limited solely to a new human application, following an earlier veterinary application of a given product or whether the ruling is more general than that and if so, how general. A hearing took place before the Grand Chamber on 5 November 2019 suggesting that the CJEU hopes to issue a definitive ruling on the topic⁸⁸.

In June 2019, the Swedish Court referred a question to the CJEU in the context of Article 3(c) of the SPC **Regulation**, which provides that the product should not previously have been the subject of an SPC⁸⁹. By virtue of Recital 17 of the Plant Protection Products Regulation, Article 3(c) should be interpreted in light of Article 3(2) of the Plant Protection Products Regulation, which provides "the holder of more than one patent for the same product shall not be granted more than one certificate for that product. However where two or more applications concerned the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders". Novartis holds a patent for the use of canakinumab in the treatment of systemic juvenile idiopathic arthritis and, based on this patent and an MA for the treatment of this condition, sought an SPC. Novartis was the owner of an existing SPC based on a patent for the antibody per se and an MA for the use of canakinumab in the treatment of Cryopyrin-Associated Periodic Syndromes. The question referred asked whether the existence of the earlier SPC precluded Novartis

obtaining an SPC based on a new therapeutic application and a new basic patent.

Last but not least, the question of the necessity of a relationship between the patentee and the MA holder remains outstanding. Hopes were raised when Arnold J made a reference to the CJEU on the issue in the Lilly v Genentech⁹⁰ IL-17 A/F antibodies case in early March 2019. This reference was made notwithstanding the Judge's finding that the underlying patent was invalid, because of the then looming 31 March Brexit deadline. He asked, in essence, whether it mattered that Genentech had filed for SPCs based on Lilly's MA for ixekizumab, the active ingredient in Taltz®, when Lilly's consent to such SPCs had not been obtained and would not be forthcoming. Unfortunately for those seeking clarity on this issue, on 5 September 2019, the CJEU issued a Reasoned Order⁹¹ rejecting the reference because of its hypothetical nature. The CJEU considered that the shadow of Brexit did not override the CJEU's policy not to answer hypothetical questions. Undeterred by this ruling, Lilly asked the English Court to give a reasoned decision on the issue but Arnold J refused to do so, preferring to leave things to the Court of Appeal⁹².

Procedural Issues

Pleadings

Providing proper particulars of a pleaded case is important but parties must be realistic in their expectations of what is possible at an early stage. In Emtelle v Hexatronic93, Mann J refused an application requesting that Hexatronic provide further particularisation of its statement of case in relation to obviousness over several pieces of prior art. Whilst the Court was sympathetic to the need of the parties to understand the case pleaded against them, without consulting with an expert, it was difficult for a particularised case to be put forward that would not require amendment further down the line.

Joint Tortfeasance

Company control at the executive level rather than the constitutional level is required for one group company to be a joint tortfeasor with another. In other words, it is well-established law that something more than mere governance or corporate control is required94. The question on appeal in Anan Kasei v Molycorp⁹⁵ was whether the judge below, Nicholas Caddick QC⁹⁶, sitting as Deputy Judge, was correct to dismiss the possibility of joint tortfeasance between a parent company and its subsidiary. Floyd LJ decided that, on the limited evidence available (disclosure had yet to be given), it was at least arguable that the parent company exercised executive control because: (i) it was involved in the running of a

84 C-650/17 ⁸⁵ C-443/17 ⁸⁶ C-130/11 ⁸⁷ C-673/18 ⁸⁸ An Opinion from AG Pitruzella was handed down on 23 January 2020 and proposes as a primary position that the interpretation of Article 3(d) in Neurim should be abandoned.

89 C-354/19

90 [2019] EWHC 388 (Pat); C-239/19 ⁹¹ C-239/19

92 [2019] EWHC 3260 (Pat)

93 [2019] EWHC 2230 (Pat)

- ⁹⁴ See, for example, <u>MCA v Charly</u> Records [2001] EWCA Civ 1441
- 95 [2019] EWCA Civ 1646
- 96 [2018] EWHC 3459 (Pat)

business unit that included personnel common to the parent and subsidiary in which decisions were taken about activities across the group; and (ii) that although the ownership of the parent company had changed during the relevant period, the new parent was liable for the acts of the old parent under a court-approved insolvency arrangement. A related procedural appeal against a decision of **HHJ Hacon**⁹⁷, sitting as a High Court Judge, that limited any assessment of damages for joint tortfeasance only to goods seized during a particular period of corporate ownership (ruling out the possibility of claiming for other infringements during that period), was also allowed.

Non-FRAND Jurisdictional Issues

Interesting issues relating to jurisdiction were discussed in the appeal case of Ablynx v VHSquared⁹⁸. Ablynx had sought to serve proceedings for patent infringement in the UK, but VHSquared contested the jurisdiction of the English courts on the basis that the patent was the subject of a licence dispute where the licence in question conferred exclusive jurisdiction on the Belgian Court. Ablynx argued that should proceedings go ahead in the UK, VHSquared would bring a defence of patent invalidity (amongst other defences) which would mean the English Courts had jurisdiction. At first instance⁹⁹, HHJ Hacon, sitting as a High Court Judge, held that Article 24(4) of the Brussels Regulation Recast should be interpreted widely such that the English Court had exclusive jurisdiction over the claim. However, the Court of Appeal disagreed with HHJ Hacon's approach and held that it was first necessary to consider Article 31(2) of the Brussels Regulation Recast. In deciding whether Article 31(2) was engaged, the English Court held that it was necessary to determine whether there was a prima facie case that there was an exclusive jurisdiction clause in favour of another Member State (here, Belgium). Having found that there was, it was then necessary to consider Article 25(4) and Article 24(4) on a prima facie basis. When considering whether a prima facie case is present, the principles in the Supreme Court decision in Koza v Akçil¹⁰⁰ are relevant (this judgment was handed down after the decision of HHJ Hacon). In that case, the Supreme Court had also held that Article 24(4) should be construed narrowly and that, even where a claim relating to exclusive jurisdiction falls to one Court, it can be severed from another claim which does not (even if the claims are linked). Following these principles and based on the fact that VHSquared would likely raise defences other than patent invalidity, the Court of Appeal found there was a prima facie case that Article 24(4) would not be engaged for all matters. As such, it was not right that all claims would be pulled into the English Court and the case was stayed pending a decision on jurisdiction from the Belgian Court.

Interim Injunctions

As mentioned above, in January 2019, Birss J decided an interim injunction application in Novartis v Dr Reddy's¹⁰¹ and in so doing, considered some important questions relating to the scope of relief in relation to second medical use patents. Dr Reddy's stated it would launch a medicine during the term of the patent, which was indicated for the patent-protected use. Dr Reddy's also stated that it believed the patent to be invalid for added matter in light of the finding to the same effect from the EPO Opposition Division. In granting Novartis' application for an interim injunction, Birss J noted that there would be a real risk of unquantifiable harm to both sides. When considering the terms of the order, Dr Reddy's sought some carve-outs, including that they be allowed to sell for the non-patented indications. While there is a clear principle not to injunct a party from doing something that is plainly a lawful act, there were not considered to be any appropriate safeguards which could accommodate this, given Dr Reddy's product label covered all uses and that 90% of Novartis' sales are for the patent-protected indication. Dr Reddy's also asked for permission to supply clinical trials but this was not formally pleaded and the Judge did not rule on it. The Department of Health did not appear at the hearing but a letter was sent by the Court to the NHS to confirm if it wished to apply to take the benefit of the cross undertaking¹⁰².

In Evalve & Abbott v Edwards¹⁰³, Abbott was granted a speedy trial for patent infringement. In support of its application, Abbott submitted that if expedition was allowed, it was possible there would be no need for an application for an interim injunction. This was not to be though and two months later, Henry Carr J heard an application for an interim injunction. The interim injunction was not granted, in the main because Edwards provided undertakings pending judgment or further order to limit the use of its device for mitral valve regurgitation (to 10 implantations in two hospitals) and in the circumstances, it was held that Abbott would not suffer any irreparable harm. Henry Carr J issued a note of caution in relation to the production of evidence for interim injunction applications. Both parties had spent considerable time and money in putting forward several statements from clinicians on the clinical superiority of their respective products. For this application, the Court was not required to consider them, and in any event, the Judge considered the Court would have difficulty in resolving this type of issue on an interim basis. He advised the parties to think very carefully before setting such a ball rolling on an interim application. The costs of this evidence were borne by each party despite Edwards being the overall winner of the application.

⁹⁷ [2019] EWHC 881 (Pat)

^{98 [2019]} EWCA Civ 2192

^{99 [2019]} EWHC 792 (Pat)

¹⁰⁰ [2019] UKSC 40

^{101 [2019]} EWHC 92 (Pat)

¹⁰² This case came before the update to the Patents Court Guide in April 2019 which requires parties to inform the NHS of applications for interim injunctions (as well as their outcomes)

¹⁰³ [2019] EWHC 1158 (Pat)

Whilst interim injunctions are not uncommon in the context of pharmaceutical patent litigation, an interim injunction application in litigation concerning a FRANDencumbered SEP is practically unheard of. However, HHJ Hacon, sitting as a High Court Judge, heard such an application in the case of IPCom v Xiaomi¹⁰⁴. The decision is noteworthy in several respects. First, the Judge confirmed that the SEP/FRAND context of the dispute did not affect the applicability of the American Cyanamid¹⁰⁵ test. IPCom had asserted a patent against Xiaomi that had previously been found to be valid and essential to the UMTS standard by the Court of Appeal on two occasions. As the patent was due to expire in February 2020, at the start of the action, IPCom asked Xiaomi to undertake to enter into a licence on terms deemed to be FRAND by the Court if, at trial, the patent was found to be valid. essential and infringed. When Xiaomi refused to give such an undertaking, IPCom applied for an order that Xiaomi be injuncted from dealing with UMTS compliant devices unless and until the requested undertaking was given. The basis for IPCom's application was that the patent would expire before the Court could reach a decision that might result in Xiaomi being injuncted if it did not submit to a determination of the terms of a FRAND licence. IPCom argued that Xiaomi could simply refuse to give the requested undertaking and would essentially be given a compulsory licence allowing it to take the benefit of the patent until its expiry. This would, IPCom submitted, lead to it suffering irreparable harm by losing the opportunity to seek a global and portfolio wide licence in a FRAND determination. Xiaomi's position was that it would not give the requested undertaking even if the Court injuncted it, and in those circumstances, there was no connection between IPCom's loss of opportunity (to gain a licence) and the proposed injunction. IPCom's application was, ultimately, rejected by the Judge who noted that there was no right to force Xiaomi into taking a licence, no right to any royalties and, therefore, there was no lost opportunity at this point in time. HHJ Hacon commented that this was not parallel to the TQ Delta¹⁰⁶ case, as there was no finding in these proceedings that the patent was valid and infringed by this particular defendant and, therefore, no starting presumption that a final injunction should be granted. It is also worth noting that, despite there being an outstanding jurisdiction challenge, the Judge confirmed that the Court still had jurisdiction to grant interim relief¹⁰⁷.

In April, Sandoz (and potential additional defendants) sought to fortify a cross undertaking in damages provided by Napp following the interim injunction awarded to Napp in February 2016¹⁰⁸ so as to better protect Sandoz's financial position in an ongoing damages enquiry. The application was given short shrift by **Henry Carr J** who, following earlier case law, held there was no jurisdiction to fortify a cross undertaking once the interim injunction had been discharged. The cross undertaking is the price a claimant is willing to pay in return for the grant of an interim injunction. Once the injunction is discharged, there is no price worth paying given there is no request for the injunction to continue.

Disclosure

The beginning of 2019 brought with it a new headache for practitioners in the form of the Disclosure Pilot Scheme¹⁰⁹, which will run for two years, the aim of which is to bring a "cards on the table" approach much earlier in proceedings using tools such as Initial Disclosure (given with statements of case) and the early disclosure of Known Adverse Documents. Practitioners who may have thought that disclosure was all but dead in patent cases after *Positec*¹¹⁰ must think again under the scheme. Although it is still too early for any decisions that offer significant guidance as to how the scheme should operate in patent cases, there are indications that disclosure is alive and well. For example, in MSD v Wyeth^m, Arnold J ordered a search for "laboratory notebooks, internal reports, e-mails, meeting minutes or presentations created, modified or received" by the authors of a prior art presentation cited in MSD's grounds of invalidity, two of the authors being employees of the patentee, Wyeth. It is also clear from Akebia v FibroGen¹¹² that although the Judge declined to extend the scope of disclosure already agreed between the parties under the pilot scheme, that scope was already considerable, dealing with test data on the functional and therapeutic properties of certain molecules in the context of an allegation of insufficiency.

It is not unusual for a patentee to request samples so that it can test for infringement before a potentially infringing product comes to market. However, applications for an order that such samples be provided before proceedings are commenced are rare. Such an application was heard by Henry Carr J in Boehringer Ingelheim v Mylan¹¹³ concerning Boehringer's patent for a polymorphic form of the active ingredient in its dry powder inhaler product, Spiriva®. The Judge granted the order sought by Boehringer noting that, although its evidence on infringement was provided at a high level of generality, it was sufficient, and Mylan had offered no evidence against it. The Judge was also content that the purpose of obtaining samples was for experiments to be performed. Turning next to the "important issue of principle", Henry Carr J considered whether the results of such experiments could be used outside of the UK. Although, in principle, he acknowledged that the English Court had jurisdiction to make such an order, he thought that to do so was premature in this case.

¹¹⁰ Positec v Husqvarna [2016] EWHC 1061 (Pat)

^{104 [2019]} EWHC 3074 (Pat)

¹⁰⁵ [1977] 10 WLUK 126

¹⁰⁶ <u>TQ Delta v ZyXEL</u> [2019] EWHC 745 (Pat)

¹⁰⁷ Pursuant to Article 35 of the Regulation (EU) 1215/2012 and the Civil Jurisdiction and Judgment Act 1982

¹⁰⁹ CPR PD 51U

^{111 [2019]} EWHC 1692 (Pat)

^{112 [2019]} EWHC 1943 (Pat)

¹¹³ [2019] EWHC 584 (Ch)

The Court considered in detail the status of a product and process description ("PPD") in <u>JC Bamford Excavators</u> v Manitou¹¹⁴ in the context of JC Bamford's application for use of the PPD in other jurisdictions. Although the **Evidence (Proceedings in other Jurisdictions) Act 1975** expressly envisages that disclosed documents could be used in foreign proceedings if there is a request from or on behalf of a foreign Court, the Court considered that a PPD is not a disclosed document within the meaning of the categories of documents in the 1975 Act. A PPD is an artificial document prepared, in lieu of disclosure, for the purposes of litigation in the UK; it is not the same as a document that has been disclosed more generally. Furthermore, whilst the Court can order a party to disclose a pre-existing document, it has no power to order a party to create and to provide a PPD against its will¹¹⁵. Nevertheless, once a PPD has been provided, it is treated as if it is a disclosed document. Ultimately, Nicholas Caddick QC, sitting as a Deputy Judge, did not have to decide the issue as his concerns regarding confidentiality in other jurisdictions overshadowed the issue and therefore practitioners are none the wiser about what application of the law would be appropriate in this situation.

Experts

Readers will be familiar with the strict approach Arnold J has taken in relation to the way experts are instructed and in particular the order in which they are directed to read the documents in the case (so-called "sequential unmasking"¹¹⁶) so as not to be tainted with hindsight. However, Conversant v Huawei¹¹⁷ illustrates that the Court can trust an expert to put hindsight to one side. Huawei sought to argue that Conversant's expert's evidence was tainted by hindsight because he (i) had considered the patent as proposed to be amended rather than the application as filed and (ii) was aware of the infringing functionality when he considered the disclosure of the patent. Arnold J agreed that the procedure had the potential to lead the expert to interpret the patent with hindsight but considered it did not necessarily follow that his interpretation was hindsight-tainted.

In <u>Illumina v TDL</u>¹⁸, **Henry Carr J** applied <u>Rogers v Hoyle</u>¹⁹ and <u>Mondial Assistance v Bridgewater Properties</u>¹²⁰ and held that the evidence of an expert witness in a previous patent case could be relied on by Illumina under a hearsay notice without requiring the Court's permission under CPR 35 as the expert (i) had not been instructed by either of the current parties in the earlier case and (ii) was not instructed by either of the current parties in the current case and, therefore, CPR 35 did not apply. However, the Judge made it clear that the Court still has discretion to exclude evidence under CPR 32.1 if, for example, it is considered to be duplicative of other evidence already being adduced by one of the parties.

¹¹⁴ [2019] EWHC 3071 (Pat)

¹¹⁵ CPR PD 63 6.1(1)

¹¹⁶ See, for example, <u>Medimmune v</u> <u>Novartis</u> [2011] EWHC 1669 (Pat) at [118] ¹¹⁷ [2019] EWHC 1687 (Pat)
 ¹¹⁸ [2019] EWHC 1159 (Pat)
 ¹¹⁹ [2014] EWCA Civ 257
 ¹²⁰ [2016] EWHC 3494 (Ch)

Costs

Readers will appreciate that the general rule for determining costs is that the losing party should pay the winning party's costs (both in the context of trials and in the context of applications). However, the position is often not that straightforward. For example, in the context of applications, it may be that deciding the application requires a consideration of case management issues. This was the case in an application to bring in two divisional patents into the <u>Conversant v Huawei</u>¹²¹ proceedings where **Birss J** held that the application involved considering significant case management questions which took up the bulk of the hearing, such that the appropriate order was costs in the case.

The same case came before Arnold LJ (hearing the case in the High Court) to decide the form of order following the trial¹²². The decision is a cautionary tale to parties on the number of points they bring to trial. The Judge took the unusual stance of ordering that the successful party, Huawei, should pay 70% of Conversant's costs. Huawei submitted that, having been successful in invalidating the patent and thereby defending the infringement claim, it should recover the entirety of its costs of this part of the litigation. Arnold LJ found this suggestion "preposterous" given they were in fact only successful in 1 of 20 issues, noting that the way in which its case was presented was "in significant respects unsatisfactory and unreasonable" and referring to Stena Rederi v Irish Ferries Ltd (No. 2)123; another case in which a successful defendant was ordered to pay 80% of the patentee's costs on the basis that the issues could have been narrowed in order to reduce the time to be spent by the parties and the Court dealing with the issues at trial.

Summary Judgment

The provisions of the CPR dealing with summary judgment are generally unsuitable for the disposal of patent cases given that proceedings are factually complex and often depend upon the opinion evidence of expert witnesses. However, occasionally, circumstances do arise in which summary judgment is appropriate. One such case came before Douglas Campbell QC, sitting as a High Court Judge, in *Price v Flitcraft*¹²⁴. There was no denial as to the substance of the infringement case, nor any counterclaim for invalidity. Rather, the defence was mounted solely on the basis that an assignment had been made such that the Flitcraft, rather than Price, was the owner of the patents in suit. However, no documents were put forward to support Flitcraft's defence and it was found to be unlikely that any further evidence would turn up if the matter proceeded to trial. Summary judgment was therefore given in Price's favour.

¹²¹ [2019] EWHC 973 (Pat)

- 122 Conversant v Huawei [2019] EWHC 3130 (Pat)
- ¹²³ [2003] R.P.C. 37

¹²⁴ [2019] EWHC 1965 (Pat)

The proceedings came back before **Douglas Campbell QC**, sitting as a High Court Judge, some months later in the form of committal proceedings in respect of two directors for contempt of Court¹²⁵. Here, the Judge found that the injunction ordered following his summary judgment decision had been breached, inter alia, by offers for sale of infringing products in the form of the distribution of old brochures. Ultimately, a custodial sentence of two months' imprisonment was ordered¹²⁶, suspended for six months.

Employee Inventor Compensation

More than 13 years after Professor Ian Shanks initiated his claim against Unilever for compensation under the statutory scheme prescribed by section 40(1) of the Act, a final decision has been reached, thanks to the unanimous judgment of the Supreme Court, given by Lord Kitchin¹²⁷. Shanks prevailed and was awarded £2 million, but not before climbing the rungs of the English Court system from the bottom to the top, starting from a UK IPO hearing (with an early appeal on a discrete point going up as far as the Court of Appeal before coming back down again). The protracted proceedings were attributable mainly to the difficulty experienced by the various tribunals in applying the legal framework to the unusual facts of the case; without doubt, Shanks had invented something special and successful but it was outside Unilever's core business and therefore not exploited by Unilever except via licensing revenue, revenue which was dwarfed by the profits of Unilever's corporate group. Furthermore, Shanks was employed by a Unilever subsidiary company specialising in R&D that did not have much of a role in generating revenue. The decision is only the second successful case of compensation being awarded under the section 40 scheme¹²⁸ and has therefore attracted considerable interest.

The key issue, on which the Supreme Court overturned all the instances below, was the question of whether the patent was of "outstanding benefit" to the employer, being the immediate employer (not the wider corporate group), having regard to the size and nature of the employer's undertaking. Lord Kitchin held that the patent, covering disposable biosensor devices used for measuring blood glucose, was of outstanding benefit when interpreting that term according to the ordinary English meaning of the words, i.e., "exceptional" or "to stand out". Where he differed from the decisions below was in putting that in the context of Unilever's undertaking. Acknowledging the difficulty of this task in the present case where the immediate employer is a research facility, the benefits of whose research are shared by the group, and taking the approach to section 40 "that does the least violence to its language", he decided that the benefit to the employer could be equated to the benefit to the group and the comparison should be between the benefit conferred by the patent in question relative to the benefit to the group from other patents deriving from the same research company. Although Unilever had made billions from ice creams, spreads and deodorants, Lord Kitchin was not satisfied these returns were linked to the underlying patents rather than the commercial machinery, including sales and marketing, found within any large multinational company. He cautioned against the approach that had been characterised as "too big to pay" and noted, "a tribunal should be very cautious before accepting a submission that a patent has not been of outstanding benefit to an employer simply because it has had no significant impact on its overall profitability or the value of all of its sales". Elsewhere in the judgment, Lord Kitchin opined on how benefit may be found more generally within a company, noting it may derive from a higher-than-expected income, a risk-free income, an extraordinarily high rate of return, or even in pure opportunity: either to develop a new line of business or to engage in unforeseen licensing activity. With the bar seemingly lowered, employee inventors may be emboldened to bring claims.

Once outstanding benefit has been decided, the next step is to check that it is just to award compensation, to decide what the "fair share" should be, and to award what effectively amounts to interest by taking into account the time value of money that has been at the employer's disposal and not the employee's. On the facts of the case in hand, Lord Kitchin agreed with the UK IPO Hearing Officer that a fair share for Professor Shanks would be 5%, amounting to £2 million, once the time value of money was included.

Expedition/Speedy trial

It is an inevitability of the current European patent system that EPO proceedings and national proceedings will run in parallel. An option to try to reduce the risk of inconsistent decisions is to ask a national court to request acceleration of EPO opposition proceedings. Parties should consider whether to do so or they may face criticism, as was the case in Lilly v Genentech129 when the judge opined that it was "particularly unfortunate" that the Court had not been asked to request acceleration.

Birss J considered the behaviour of a potential licensee when hearing IPCom's application to expedite certain aspects of its case against *Vodafone*¹³⁰ in May 2019. Here again, IPCom had requested that Vodafone give an undertaking to enter into a licence on terms determined by the Court to be FRAND should the patent was found to be valid, infringed and essential. When Vodafone refused to do so, IPCom requested that both the patent

¹²⁹ [2019] EWHC 387 (Pat)

^{125 [2019]} EWHC 2476 (Pat)

¹²⁶ [2019] EWHC 2772 (Pat)

¹²⁷ <u>Shanks v Unilever</u> [2019] UKSC 45

¹²⁸ The other case being <u>Kelly & Chiu v GE Healthcare</u> [2009] EWHC 181 (Pat)

¹³⁰ IPCom v Vodafone [2019] EWHC 1255 (Pat)

liability and FRAND trials be expedited to take place prior to expiry of the patent. IPCom argued that it needed an injunction to be an available remedy to be able to put Vodafone to a choice of submitting to the FRAND determination or being injuncted. Without expedition, IPCom submitted that this would not be possible and it would be limited to seeking more limited historic damages only. In ordering expedition, Birss J noted that he could see no flaws in the undertaking being requested and that ultimately, Vodafone was at risk of being characterised as an unwilling licensee in refusing to give the requested undertaking. Having ordered expedition, the judge commented that the defendants should be aware that there was a serious risk of an injunction being granted if IPCom were successful at trial and "woe betide" Vodafone should they say at that stage they needed time to think about the implications of that injunction.

Adjournment of Trial

Litigants should consider whether they should seek an adjournment to ensure a point conceived just before trial is properly considered at trial. It is fiendishly difficult for a party to re-open the issue after the judgment has been provided. Case law is littered with reminders of this fact. A good example in 2019 came from the Court of Appeal in <u>L'Oréal v Liqwd</u>¹³¹ where **Arnold LJ** emphatically endorsed **Birss J's** decision to deny L'Oréal the opportunity to re-open an issue after trial for various reasons including that L'Oréal did not seek an adjournment of the trial. In contrast, in relation to the expedited trial itself in <u>IPCom v Vodafone</u>¹³², **Douglas Campbell QC**, sitting as a Deputy Judge of the High Court, reminded us that the appropriate time to apply to adjourn a trial is probably not the day before it is due to commence.

Transfer Applications

In 2019, several litigants considered the IPEC as an alternative to the Patents Court. In <u>IOT IP v Haandle</u>¹³³, **Arnold J** considered the circumstances in which a case should be transferred from the Patents Court to the IPEC. Haandle requested the transfer on the basis that the value of the claim was low and the trial would only last for two days. However, **Arnold J** disagreed and refused to transfer the action. He found that the financial value of any injunction had not been made out in the evidence before him and the multiple validity attacks pleaded by IOT IP meant that a trial estimate of four days was more realistic.

Conversely, in <u>Kwikbolt v Airbus Operations</u>¹³⁴, Airbus applied to transfer the action out of IPEC and into the Patents Court but was unsuccessful. The case was a classic "David and Goliath" situation in which Airbus had deep pockets but Kwikbolt had more limited means. In refusing the request to transfer the case to the Patents Court, **HHJ Hacon** considered that the case could be heard fairly in two days and that keeping the IPEC costs cap in place was desirable in circumstances where forcing the parties in a forum with unlimited costs could severely prejudice the claimant.

Unitary Patent / Unified Patent Court

Déjà vu all over again

2018 began with the seemingly positive news in February that the Bundesverfassungsgericht ("**BVerfG**" – the German Federal Constitutional Court) had listed the UPC case for hearing that year. There was a hope that if it heard the case, and gave a decision favourable to the project, the UPC might open for business in 2019, perhaps even before Brexit (about which, more later). The year ended, however, with no hearing, still less a decision.

So too then, in February 2019, was the case listed for hearing that year. Again there was a hope that if the BVerfG heard the case, and gave a decision favourable to the project, the UPC might open for business in 2020, perhaps before a postponed Brexit, or at least before the end of the half-in, half-out, Brexit transitional period, with the UPC provisional phase having been commenced. Again, however, the year ended with no hearing still less a decision. And so again, UPC supporters were disappointed (and in your author's case, retired!)

A positive end to the year

However, by the end of the year, there was at least a glimmer of hope for a BVerfG hearing with the UPC crawling up the list of cases to be heard as various other cases above it were decided; and a positive beacon of hope with a statement in a press interview in mid-November from the case rapporteur, Judge Huber, that he intended to issue a decision early in 2020. Now, unless between sending this piece for print and publication there has been a decision, we should take "early" with a pinch of salt. Nonetheless, the timing of the interview, so late in the year, with a prediction of a decision in early 2020, and hence within a very few months, is surely positive? What is more, with Brexit finally actually having happened on 31 January 2020, the UK's position as a non-EU member state has crystallised, and any hope or fear (depending on your perspective) of a further delay or indeed cancellation of Brexit has removed the uncertainty which that has added to the future of the project and in particular the UK's participation in it.

^{131 [2019]} EWCA Civ 1943

^{132 [2019]} EWHC 3323 (Pat)

^{133 [2019]} EWHC 534 (Pat)

^{134 [2019]} EWHC 2450 (IPEC)

The Brexit Effect

Much can be said about Brexit and its relevance to the UPC, but having left the EU without either the UPC opening or even the provisional phase beginning, some would undoubtedly argue that the UK simply cannot be part of what has been seen in recent years as an EU project. This is not the place to enter into a detailed debate about this point, but suffice to say that the fact that the UPC, and especially the unitary patent, would undoubtedly be more popular where the UK participates remains crucial. This has meant that there still appears to be broad industry and political support, within both the UK and the participating EU states, for the project to include the UK. Hence, the oft quoted words of Margot Fröhlinger: *"where there's a will, there's a way"*, remain apposite.

This is not to imply that there are not legal issues, but generally, these can always be overcome by agreement. So for example, when the UPC Agreement refers to an "EU Member State", the parties can agree that what is meant is a state which was an EU Member State when the agreement was signed (which is actually quite logical). Other issues are more difficult and will require some more detailed thought but are not insurmountable, as your author has explained on numerous occasions. Of these, so far as concerns the UPC itself (i.e. the Court) probably the most tricky is caused by the mis-match between the Brussels Regulation jurisdictional regime, which the UK will leave, and the Lugano Convention regime, which it hopes to join, but let us not ponder here on such a technical issue. More significantly perhaps for patent attorneys in industry and private practice alike, are the difficulties of participating in the unitary patent part of the package when not an EU member state. That is genuinely more difficult. If it is possible to participate in that, then why not also the EUTM system? But again, agreements are possible, and whether the unitary patents can cover the UK may depend on the shape of the longerterm arrangement now being thrashed out (one hopes) between the UK Government and the EU.

This last point illustrates, however, that whilst the most major element of uncertainty caused by Brexit has been removed, there are nonetheless important remaining uncertainties. Hence, a huge question is the attitude of the contracting parties to allowing the project to start without complete certainty as to the political and legal landscape post-Brexit. And since Germany is not only first among EU equals, but also holds the key to the project with its ratification being mandatory but outstanding, everything depends, it would seem, on the German position.

Can then we say anything about the possible timing of a UPC opening? Absent being a fly on the wall of any German Government discussion which may or may not be going on regarding the dossier, the best we can do is to note the words of the Chair of the Preparatory Committee, Alexander Ramsay, Following Judge Huber's statement, he predicted a start date of early 2021. This is significant in being after the (at least current) end of the Brexit transitional period due to end 31 December 2020. It would signal a start only when the dust has really settled on the UK's position, but (and it is a very important "but") would require the start of the UPC provisional phase in mid-2020 at latest. It suggests a potential major push forward on the UPC (and implicitly German consent) really rather soon and within a very few months of the BVerfG decision - at least if positive.

As usual, of course, we are now in the realms of speculation – and in that sense, it is again a case of déjà vu all over again – but there are genuine reasons for a degree of optimism that rumours of the UPC's death are greatly exaggerated.

Looking Ahead to 2020

The end of January 2020 brought the UK certainty with regard to the fact of Brexit, although the terms of our future relationship with the EU remain to be resolved. An aspect of this future relationship of upmost importance to the patent industry, though perhaps not front and central in the mind of the UK government, is the question of our participation in the UPC and the Unitary Patent System. Practitioners will wait with bated breath both as to the outcome of the German Federal Constitutional Court challenge and the ongoing negotiations with Brussels. However, there is every reason to be confident that, whatever the outcome, the UK patent system will remain one of the flagship jurisdictions of Europe.

2020 is also expected to bring the following significant developments in UK patent litigation and practice:

 the Supreme Court's decision in the <u>Unwired Planet</u> and <u>Conversant</u> cases is expected to be handed down in the first few months of the year. This will answer the thorny questions of the Court's jurisdiction over and the exercise of its discretion to set global FRAND licence terms, the scope for a patentee to offer discounted rates to any licensee whilst still complying with the "non-discriminatory" aspects of their FRAND obligation, and the rigidity of the <u>Huawei v ZTE</u> CJEU framework. Practitioners are hopeful that this will be applied in one of the upcoming FRAND determinations listed before the High Court in the first half of the year (in the Conversant and Philips trials). 2020 may also bring guidance as to the principles applicable to damages for historic infringement of an SEP when there is no forward looking FRAND licence;

- in February 2020, the Supreme Court will hear the appeal in <u>Regeneron v Kymab</u>. This appeal is likely to tackle important questions relating to insufficiency and in particular the issue of what amounts to a "principle of general application";
- SPC enthusiasts remain ever hopeful that year ahead will bring clarity in relation to several issues including the long running debate on the meaning of "protected by a basic patent", whether the principles set down in <u>Neurim</u> are sound and whether SPC applications based on third party MAs are allowable. Experience suggests that very little clarity will be forthcoming; and
- the summer of 2020 is likely to see the appointment of several new judges to the Patents Court. It is a requirement of any flourishing patents Court system to have specialist judges who are diligent and fair-minded. We await with interest any news of the appointments.

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