



THE RISE OF LITTLE BRITAIN
A REVIEW OF PATENT CASES IN 2019
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This paper is dedicated to the memory of

David Barron

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Mr Justice Henry Carr

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The Rise of Little Britain

(A Review of Patent Cases in 2019)

1. Introduction

Every year I wonder if any of the great controversies in UK patent law will be resolved, so that we can "park them" and just revisit for a small tweak from time to time. You would think, after over 30 years of litigating patents that I would have learned better by now! Not only do the old controversies grow new limbs and need further attention, but new issues emerge almost annually which occupy the attention of the courts and the professions and fill our shelves with yet more jurisprudence.

This is just a long way round to saying that no, this year's paper will not be any shorter and simpler than previous years. There is a vast amount of material, legal, procedural, regulatory and in some cases just plain bizarre.

Obviously, over the last few years we have been highly preoccupied with the settling in of the doctrine of equivalents in the UK. This year we have seen it in full flow across a range of technical areas, and I have begun to develop a suspicion. I was an active supporter of the doctrine of equivalents long before it was cemented into our system by Lord Neuberger. I was also a supporter of using technology to resolve disputed decisions in football. The two have emerged in parallel, and in my view both need to be constrained before they run out of control. I will save my more detailed comments to the relevant cases below.

I have, as usual, adopted the format of starting with construction, infringement and remedies, before moving on to the validity issues, then winding up with procedural and "oddball" issues. This year that means you will have to remain patient for the highlight – the final resolution of the long-running saga of Dr Shanks' reward for his valuable invention.

Let us begin.....

2. Infringement

a) Construction

The approach to construction following *Actavis v Eli Lilly*

Back in 2017, in *Actavis v Eli Lilly*¹, the UK Supreme Court ruled that ([54]):

"...a problem of infringement is best approached by addressing two issues, each of which is to be considered through the eyes of the notional addressee of the patent in suit, ie the person skilled in the relevant art. Those issues are: (i) does the variant infringe any of the claims as a matter of normal interpretation; and, if not, (ii) does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial? If the answer to either issue is "yes", there is an infringement; otherwise, there is not."

This gave rise to a two-limbed approach to the assessment of infringement in the UK, a departure from decades of practice under the "purposive approach".

¹ *Actavis UK Limited & Ors v Eli Lilly and Company* [2017] UKSC 48

Some of the most interesting questions arising from the Supreme Court's judgment in *Actavis v Eli Lilly* concerned the law regarding validity, and would be influenced by the approach to the interpretation of patent claims for the purpose of assessing validity.

Under the old purposive approach (as laid down in *Catnic*², *Improver*³ and *Kirin-Amgen*⁴), patent claims were interpreted (or 'construed'), both for assessing validity and for assessing infringement, by giving effect to what the person skilled in the art would have understood the patentee to be claiming. This was an objective interpretation of the language of the claim, through the eyes of the skilled addressee (who brought with them their common general knowledge) in light of the description and drawings of the patent.

The purposive approach was a contextual interpretation, intended to be contrasted with "old English literalism", which had characterised the approach to the interpretation of commercial documents under English law until the 1970s. Such old English literalism did not permit consideration of the contextual background to the making of a commercial document when considering its objective interpretation, and so in that sense it could be described as acontextual.⁵ The purposive approach was also to be contrasted with assigning meaning to claim language according only to the conventional rules for the use of language, such as one finds in a dictionary or the rules of grammar.⁶ In the interpretation of patent claims under the purposive approach, the employment of the person skilled in the art, imbued with their common general knowledge, imported contextuality, along with the necessary consideration of the description and drawings of the patent specification. Claim language could not be ignored if it did not appear to make any difference to the inventive concept.⁷

Under the purposive approach, it was also permissible for the court to have regard to the alleged infringing product or process, using the *Improver* or "Protocol" questions to assist in deciding whether the alleged infringing product or process fell within or outside the claim, and therefore in the interpretation of the claim language.

In *Actavis v Eli Lilly*, Lord Neuberger said that conflating the issue of claim interpretation with the issue of whether a variant was immaterial was wrong in principle and could lead to error. But Lord Neuberger did not expressly state how much of the purposive approach he intended to undo – so how much remained intact?

In March 2019, Arnold J answered this question fairly succinctly, in *Eli Lilly v Genentech*⁸. He said ([294]):

"There is no dispute as [to] the legal principles to be applied. The claim must be given a "normal" interpretation: *Actavis UK Ltd v Eli Lilly & Co* [2017] UKSC 48, [2017] RPC 21 at [54], [58] (Lord Neuberger). This means a "purposive" interpretation, that is to say, an interpretation which takes into account the purpose of the Patent, which is to describe and claim an invention to a person skilled in the art: *Icescape Ltd v Ice-World International BV* [2018] EWCA Civ 2219 at [60] (Kitchin LJ, as he then was) and [96] (Floyd LJ). As HHJ Hacon sitting as a High Court Judge pointed out in *Regen Lab SA v Estar Medical Ltd* [2019] EWHC 63 (Pat) at [202]-[207], it is no longer necessary to take equivalents into account in such an interpretation, because it is now possible for a patentee to contend that a patent has

² *Catnic Components Ltd & Anr v Hill & Smith Ltd* [1982] RPC 183

³ *Improver Corp v Remington Consumer Products Ltd* [1990] FSR 181

⁴ *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd (No.2)* [2004] UKHL 46, [2005] RPC 9

⁵ *Kirin-Amgen - The End of Equivalents in England?* (2009) 40 IIC 3

⁶ *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd (No. 2)* [2004] UKHL 46, [2005] RPC 9

⁷ *Société Technique de Pulvarisation (STEP) v Emson Europe Ltd & Ors* [1993] RPC 522

⁸ *Eli Lilly and Company & Ors v Genentech Inc* [2019] EWHC 387 (Pat) (1 March 2019) Arnold J

been infringed by virtue of the doctrine of equivalents even if it is not infringed when the claims are given a normal interpretation."

Ten days later, in his last substantive judgment (*TQ Delta v ZyXEL (11 March 2019)*⁹), Henry Carr J reached the same conclusion, albeit drawing upon slightly different authority ([70]):

"The correct approach to claim interpretation, which is purposive, is set out at [18] and [19] of the judgment of Floyd LJ in *Saab Seaeye Limited v Atlas Elektronik GmbH* [2017] EWCA Civ 2175. The parties were agreed that no issues arise as to equivalents in the present case. Therefore, the further principles explained in *Actavis UK Ltd v Eli Lilly & Co* [2017] RPC 21 and *Icescape Limited v Ice-World International BV & Ors* [2018] EWCA Civ 2219 are not relevant."

Consistently with this, in *Philips v Asustek*¹⁰, the Court of Appeal confirmed that Arnold J had been right to approach an issue of construction of the claim language by considering the entirety of the specification and not just the introductory paragraphs as contended for by the defendants.

In short, the principles which apply to the construction of patent claims remain as summarised by the Court of Appeal in *Virgin v Premium*¹¹ with the exception that the *Improver/Protocol* questions, which could be drawn upon in the construction of a patent claim on the old purposive approach, may not now be drawn upon in the context of construction. The process of construing a patent for the purpose of assessing its validity is the same as the 'normal interpretation' stage of the assessment of infringement.

Purposive construction would not intend a person to substitute for a system

*Garmin v Philips*¹² was a case about a Philips patent concerned with GPS-based personal athletics performance monitoring. Philips accepted that claim 1 as granted was anticipated by certain of the cited prior art (although it maintained that the anticipation was "accidental"). Multiple proposed amendments were in issue, which raised several issues of construction. Beyond its challenge to the validity of the patent, Garmin did not contest infringement.

On the principles regarding claim interpretation, the parties were agreed that the correct approach was purposive, as set out at [18] and [19] of the judgment of Floyd LJ in *Saab Seaeye v Atlas Elektronik*¹³ (in which Floyd LJ applied the principles of *Virgin v Premium* adapted to ignore equivalents).

Garmin had argued for the widest possible meaning that the words of the claims were capable of bearing, with a view to rendering them invalid. However, Henry Carr J said (at [161] and [181]):

"As noted in *Virgin*, there is no presumption that the patentee necessarily intended that the widest possible meaning consistent with his purpose be given to the words that he used. Furthermore, purposive construction leads one to eschew the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge...."

⁹ *TQ Delta, LLC v ZyXEL Communications Limited & Anr* [2019] EWHC 562 (Ch) (11 March 2019) Henry Carr J

¹⁰ *Koninklijke Philips N.V. v Asustek Computer Incorporation & Ors* [2019] EWCA Civ 2230 (17 December 2019) Patten, Floyd & Henderson LJ

¹¹ *Virgin Atlantic Airways Limited v Premium Aircraft Interiors UK Limited* [2009] EWCA Civ 1062

¹² *Garmin (Europe) Limited v Koninklijke Philips NV* [2019] EWHC 107 (Ch) (29 January 2019) Henry Carr J

¹³ *Saab Seaeye Limited v Atlas Elektronik GmbH* [2017] EWCA Civ 2175

Purposive construction requires the Patent to be interpreted objectively, and without regard to, or knowledge of, grounds of invalidity. Garmin's approach does not provide fair protection to the patentee, nor reasonable certainty for the public."

For example, one claim feature in issue was "*said feedback system comprises means for verifying actual exercise activity*". Garmin contended that such means did not have to be automatic and could be satisfied by a human being who witnessed and verified the relevant activity. The judge disagreed ([162]):

"...the entirety of the disclosure of the Patent is concerned with an electronic device in an electronic system. The "use" claims are process claims where the functions are achieved, automatically, and without human intervention....Having regard to [the] disclosure of the Patent, the advantages of an automated system, including automatic verification in a GPS system would be clear. No skilled person would conclude that the word "means" in a claim to a system, was intended to include human beings."

Similarly, when interpreting "*adapted to receive athletic performance data*", the possibility that this requirement could be satisfied by human entry of data was one that "might occur to a lawyer" but the skilled person would not consider the language chosen, in context, as intended to do this.

Parametritis / Parameteritis

I think there was a drinks party this summer, attended by some of the Chancery Division's IP specialists, in which the chat went to attempts to patent the prior art. This would make sense, in view of the *Formstein* question that had arisen in the case law earlier in the year (on which see below). But why am I guessing at wine-o'clock time chat?

Well, in July 2019, two judges - Birss J (on 17 July) and HHJ Hacon (on 31 July) - handed down judgments dredging up a term that would seem to be spelt "parameteritis" (Birss J) or "parametritis" (Judge Hacon).

Birss J said, in *Takeda v Roche*¹⁴ ([94]):

"The word "parameteritis" was coined by patent lawyers long ago to describe the technique of inventing a new spurious parameter to use in a patent. The great thing about a new parameter is that by definition no item of prior art uses it. So it is impossible at a glance to tell whether the prior art falls within the claim. It may require costly experiments to find out and no patent office is going to embark on that. There was a famous light hearted article written I think in the 1970s by a British patent attorney called "How to patent the prior art". One of the techniques described in the article was to invent a new parameter and claim the prior art that way."

Birss J thought that some "crazy math" arguments in the *Takeda v Roche* case arose in such a context ([95]):

"The %-Roche works in a similar way because it is limited to the specific list of glycans in Table 3. Nowhere in the prior art have I been shown an example of the same calculation. Unless one has a complete list of all the glycans found in an analysis, one cannot apply the %-Roche and cannot tell if a prior product is within the claim. That is not fair

¹⁴ *Takeda UK Limited v F. Hoffmann-La Roche AG* [2019] EWHC 1911 (Pat) (17 July 2019) Birss J

protection for the patentee nor does it give reasonable certainty for third parties (see the Protocol on Art 69 EPC)."

HHJ Hacon managed to find an authority noting the term, and in *Quinn v Linpac*¹⁵, called out an argument for an apparently similar reason ([49]):

"Claim 5 seems to me to suffer from what is sometimes called 'parametritis', i.e. stipulating that a feature of the alleged invention must be present within a stated range, where the range is entirely arbitrary. In such cases the apparent novelty and inventiveness conferred by the range is illusory, see for example *LG Philips LCD Co Ltd v Tatung (UK) Ltd* [2006] EWCA Civ 1774; [2007] RPC 21, at [39]. Since there is no expert support for any technical advantage of the range of thickness set out in claim 5, for that reason alone the claim lacks inventive step."

The role of the priority document

Nugee J's judgment in *Emson v Hozelock*¹⁶ concerned patents to a new type of garden hose. In the context of a dispute about the interpretation of the word "coupler", the judge noted that it had been used in a particular way in the priority document. Could this help with resolving the dispute? Nugee J said ([74]):

"...The priority document is cross-referred to in each of the Patents and as I understand it, that means that it is admissible to construe the Patents, and that the skilled addressee who was left in doubt as to the meaning of the Patents could refer to the priority document to help resolve those doubts: *Terrell on the Law of Patents (18th edn, 2016)* ("*Terrell*") at §9-231, *Milliken Denmark AS v Walk Off Mats Ltd* [1996] FSR 292 ("*Walk Off Mats*") at 299 per Jacob J. I was not however addressed on any of this so I have placed no reliance on this particular point; but it does seem consistent with the view I have come to. "

"Consisting essentially of"

Finally, in *Anan Kasei ("Rhodia") v Neo*¹⁷, Rhodia's patent was concerned with catalysts for purifying vehicle exhaust gas. Claim 1 was in the following terms:

"A ceric oxide **consisting essentially of a ceric oxide**, and wherein said ceric oxide has a specific surface area of not smaller than 30.0 m²/g when subjected to calcination at 900°C for 5 hours."

Calcination is high temperature heating. At the priority date, it was well known to add zirconia to ceric oxide to stabilise the specific surface area (SSA) of the oxide material by preventing sintering (i.e. coalescence into a solid mass by means of heating, and usually compression, without liquefaction).

Floyd LJ noted that the claim "has some implicit limitations as well as the express ones" ([9]):

"As calcination will not increase SSA, it is implicit that the ceric oxide has a SSA of not less than 30.0 m²/g before the calcination test as well i.e. in the product as supplied. Further, it is implicit that the ceric oxide is in solid form (i.e. not in solution): if it were otherwise there could be no measurement of SSA, and the calcination test would not make sense either."

¹⁵ *Quinn Packaging Limited v Linpac Packaging Limited & Anr* [2019] EWHC 2119 (IPEC) (31 July 2019) HHJ Hacon

¹⁶ *E. Mishan & Sons, Inc t/a Emson v Hozelock Limited* [2019] EWHC 991 (Pat) (17 April 2019) Nugee J

¹⁷ *Anan Kasei Co. Inc & Anr v Neo Chemicals and Oxides Limited* [2019] EWCA Civ 1646 (9 October 2019) Lewison, Floyd, Peter Jackson LJ

While perhaps tautologous, "consisting essentially of a ceric oxide" would be understood as excluding from the claim mixed oxides such as ceric oxide/zirconia mixtures.

The patent also included claims to methods of making the ceric oxides of claim 1 – methods which were described in examples of the patent. There was no attack on the validity of the method claims, just on the product claims, which were potentially broader because they were not limited to products made by the claimed/described methods. It was in this context that the interpretation of "consisting essentially of" was considered.

Floyd LJ observed that the terminology was something of a hybrid of the more usual "consisting of" and "comprising". Using a readily understandable analogy, he said ([13]):

"The first formulation will normally be taken to impose a requirement that nothing else is present, while the latter formulation is simply a minimum requirement, agnostic as to whether other things are present as well. So a claim to a cake mix "consisting of sugar, eggs, butter and flour" is not infringed by one containing chocolate chips, but that would not be the case if the word "comprising" was substituted for "consisting of"."

Turning to the issue in the present case, Floyd LJ continued ([14]):

"The words obviously do not restrict the claim to the specified ingredient alone, and might be said to give rise to some uncertainty in the absence of some further guidance as to what it means. The parties are agreed, however, that the skilled person would have regard to a practice of the EPO to regard such claims as meaning that, apart from the mandatory ingredient (in this case ceric oxide), no other ingredients are present which materially affect the essential characteristics of the product. That this is a legitimate approach to construction gains support from the observations of Jacob LJ in *Virgin Atlantic v Premium Aircraft* [2009] EWCA Civ 1062 at [12] - [15], to the effect that the skilled reader of a patent has some knowledge of patent law and practice. The words would therefore be understood to provide a penumbra around the core of the claim, which is to pure ceric oxide having the required characteristics. How much of a penumbra is determined by the point at which the added ingredient starts to have a material effect on the essential characteristics of the product."

b) Infringement

Reverting to Lord Neuberger's statement of the approach to the assessment of infringement in *Actavis v Eli Lilly*¹⁸, in 2019, the jurisprudence has continued to develop and settle the new approach.

Normal interpretation

The first limb of Lord Neuberger's approach asks "does the variant infringe any of the claims as a matter of normal interpretation"?

Under the old purposive approach (as laid down in *Catnic*, *Improver* and *Kirin-Amgen*) it was permissible, when construing the claim language, to have regard to the alleged infringing product or process.

In *Actavis v Eli Lilly*, Lord Neuberger said that the old purposive approach was incorrect and instead set out a new approach to the assessment of infringement (which is quoted at the start of section 2(a) above). However, Lord Neuberger did not expressly state how aligned the 'normal interpretation' part

¹⁸ *Actavis UK Limited & Ors v Eli Lilly and Company* [2017] UKSC 48

of the infringement test remained with the construction of patent claim language for the purpose of assessing validity.

I have noted above the principles that have emerged since *Actavis v Eli Lilly* on how claim language should be interpreted (or 'construed'). The same principles have emerged in the case law addressing the first limb of the infringement test. This has the consequence that 'normal interpretation' is both how you interpret claim language for the purpose of assessing validity and a part of the first limb of the test for infringement. The first limb asks whether the alleged infringing product or process falls within the scope of the claim when it has been interpreted in this way.

The settling of the case law in this way really started to become clear in October 2018, when the Court of Appeal, in *Icescape v Ice-World*¹⁹, held that the first limb of the infringement test involved purposive interpretation but the question of equivalence was to be addressed in the second limb. In other words, 'normal interpretation' was a purposive interpretation because it was the ascertaining of the objective meaning of the words of the claim in their context to the skilled addressee.

This meant that Lord Neuberger's 'normal interpretation' was, in fact, the pre-*Actavis v Eli Lilly* purposive approach but without the *Improver*/Protocol questions. The jurisprudence emerging in 2019 has confirmed this.

In *Regen v Estar*²⁰ (a case that will come up in many contexts this year), Regen's patent was to a method for the preparation of blood plasma enriched in platelets and other factors. HHJ Hacon took the opportunity to join the debate on what exactly was required by the 'normal interpretation' limb of infringement, saying ([206]-[208]):

"...although one way of approaching the single purposive construction of a claim used to be to go through the three *Improver* questions, this would not be a correct way of approaching the first step in *Actavis*, the normal construction of a claim. The three *Improver* questions, in revised form, have been relocated to the second step exclusively.

It would follow that the normal construction of the claim is confined to interpreting the words of the claim in the context of the specification as a whole. This is to be done in a manner akin to, although of course it could never be identical to, the interpretation of a contract according to the principles explained by Lord Hodge in *Wood v Capita Insurance Services Ltd* [2017] 2 WLR 1095, at [8] to [15], see *Actavis* at [58]. Lord Hodge said:

"[10] The court's task is to ascertain the objective meaning of the language which the parties have chosen to express their agreement. It has long been accepted that this is not a literalist exercise focussed solely on a parsing of the wording of the particular clause but that the court must consider the contract as a whole and...give more or less weight to elements of the wider context in reaching its view as to that objective meaning."

In the case of a patent, the objective meaning is ascertained through the eyes of the skilled person who will bring the wider context by reason of his or her common general knowledge."

Estar's process employed a gel that was not polyester-based (as required by the claim) and the buffered sodium citrate employed was 0.136 molar rather than 0.10 molar (as required by the claim). This meant there was no infringement on the normal interpretation.

¹⁹ *Icescape Limited v Ice-World International BV & Ors* [2018] EWCA Civ 2219

²⁰ *Regen Lab SA v Estar Medical Ltd & Ors* [2019] EWHC 63 (Pat) (18 January 2019) HHJ Hacon

In *Marflow v Cassellie*²¹, Marflow's patent concerned a mounting plate for pipes for use with a fluid-using appliance. A claim integer required that the "locking member" be "in or thereon" the mounting member (i.e. the plate). In the alleged infringing product, rather than a singular locking member, Cassellie employed an old-fashioned screw thread and nut. The judge concluded that on the normal interpretation, before the nuts were tightened, they were neither in nor on the plate, and so the nuts could not be the locking member for the purpose of claim 1.

Cassellie also contended that the screw threads on its "intermediate pipes" were the locking member and the nuts the locking elements. However, the screw thread also was not provided in or on the body of the mounting member but (as the judge had construed the claim) on the fluid pipe. Accordingly, on the normal construction, the Cassellie product was not within the scope of claim 1.

*TQ Delta v ZyXEL*²² was a SEP/[F]RAND dispute that kept Gowling WLG pretty busy in 2019. TQ Delta's '268 patent claimed a method for controlling the transmission rate of an overhead communication channel. ZyXEL accepted that in some situations ($G_p < T_p$), the features of claim 1 were fulfilled, but argued that in other situations ($G_p \geq T_p$) they were not, and so infringement should not be found. The judge was satisfied that essentiality and infringement (on the normal interpretation) were established.

Now to the case of *Emson v Hozelock*²³, about garden hoses. Between the 1950s and 2012 there was very little change in garden hose technology. Such "conventional" hoses would be made of a number of layers of plastic bonded together. They were (and remain) bulky, heavy and with a tendency to kink. *Emson's* patents concerned the next generation of hoses, in particular a hose with an outer tube secured to an inner tube only at the ends. When connected to a pressurised water supply (such as a tap), the inner tube would expand – up to six times its length and width; and would contract again upon release of the pressurised water. The outer tube constrained both the axial (i.e. length) expansion and the radial (i.e. width) expansion of the inner tube by the length and diameter, respectively, of the outer tube. In its contracted state, the outer tube was ruffled along its length. As the outer tube expanded, the ruffles unfurled; the ruffles reformed when the pressure was released and the hose contracted.

Emson's two patents employed slightly different language, but this was not suggested to be significant. The wording of claim 1 of Emson's GB patent, for example, was "said outer tube being unattached from said inner tube between said first and second couplers".

So, on the **normal interpretation**, whether "unattached" was met depended on what was understood by "coupler".

The judge described the joining of the inner and outer tubes at the two ends of the alleged infringing "Superhoses" in the following terms ([59]-[61]):

"At each end there is a short 'sleeve', made of a clear thermoplastic elastomer, which encloses the inner tube (and is therefore between the inner and outer tube). This is about 300mm long. The ends of the inner tube, sleeve and outer tube are all secured by a metal ferrule to a (grey) hard plastic connector. That connector is in turn connected to a fitting called an 'Aquastop', a (yellow) plastic end fitting which can be connected either to a water tap connector or an outlet nozzle, and which allows water to pass when so connected, but which incorporates a valve preventing water flow when not so connected. The Aquastop can

²¹ *Marflow Engineering Limited v Cassellie Limited* [2019] EWHC 410 (IPEC) (26 February 2019) HHJ Hacon

²² *TQ Delta, LLC v ZyXEL Communications Limited & Anr* [2019] EWHC 562 (Ch) (11 March 2019) Henry Carr J

²³ *E. Mishan & Sons, Inc t/a Emson v Hozelock Limited* [2019] EWHC 991 (Pat) (17 April 2019) Nugee J

be easily removed by the consumer. A short distance from the ferrule – about 150mm in its unexpanded state and about 300mm in its expanded state – is a component that was referred to as a 'joiner'. This is a hard plastic tube about 40mm long which sits around the inner tube and sleeve, and so between them and the outer tube.

The joiner is glued to the inner tube. This is effected as follows. The joiner has two oval apertures, one on each side. These correspond to similar apertures in the sleeve. The apertures in the joiner are filled with silicone adhesive which bind to the edges of the apertures in the joiner and the sleeve, and to the faces of the inner tube exposed by each of the apertures. The joiner is not glued to the outer tube. Instead it is bonded to the outer tube by ultrasonic welding.

There is no connection of the outer tube to the inner tube between the two joiners. This allows the outer tube to ruffle up around the inner tube when the hose is in its contracted state, as it also does in the much shorter sections at each end between the ferrule and the joiner."

Emson contended that "coupler" was an ordinary English word meaning something that joins two things together, and so used in the patent it meant something that joined the inner and outer tubes together. In the case of the Superhoses, this was the entire end assembly, from the ferrule to the joiner.

Hozelock, however, contended that the couplers were the items connecting to a tap at one end and a fitting, such as a spray nozzle, at the other.

The judge said that while it was agreed that "coupler" did not have any technical meaning, the language required construction in the context of the description and drawings (article 69(1) of the EPC, section 125(3) of the Patents Act). He quoted from many paragraphs of the specification, which he said made plain that the draftsman was not using "coupler" to mean a component which coupled or joined the inner tube to the outer tube, but was using it to enable the hose as a whole to be coupled or connected to something else, such as a source of pressurised water.

So the judge preferred Hozelock's construction of "coupler", distinguishing *Fabio v LPC*²⁴, in which "slit" was held to be an ordinary English word. The judge also found support for his understanding in the priority document.

This meant that in the Superhoses, the complete end assembly, from the ferrule to the joiner, could not be regarded as a coupler within the meaning of the claims. The second point at which the inner and outer tubes were joined in the Superhoses (approx. 150mm from the end joining at the ferrule) prevented the inner and outer tubes from being "unattached" between the two end couplers according to the normal interpretation.

The doctrine of equivalents

In *Actavis v Eli Lilly*, Lord Neuberger described limb (ii) as addressing the following issue: "does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial?" Lord Neuberger considered that the *Improver/Protocol* questions provided helpful assistance but needed some reformulation. He proceeded to undertake the reformulation, emphasising that the 'reformulated questions' remained only guidelines, not strict rules, and that they might sometimes have to be adapted to apply more aptly to the specific facts of a particular case.

²⁴ *Fabio Perini SpA v LPC Group plc & Ors* [2010] EWCA Civ 525

In October 2018, in *Icescape v Ice-World*²⁵, the Court of Appeal (Kitchin LJ) subtly adjusted the reformulated questions to the following ([66]):

- a) Notwithstanding that it is not within the literal (that is to say, I interpolate, normal) meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent?
- b) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?
- c) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

In order to establish infringement in a case where there is no literal infringement, a patentee would have to establish that the answer to the first two questions was "yes" and that the answer to the third question was "no".

From the Supreme Court's judgment in *Actavis v Eli Lilly* to the end of 2019, there were fifty substantive judgments in which issues of infringement and/or validity were considered. The court considered a question of infringement under the doctrine of equivalents in eleven of those cases. Eight of those judgments were in 2019 – in each, the doctrine of equivalents was satisfied. However the court's reasoning on equivalents presently may be considered *ratio* only in two of those cases, *Marflow v Cassellie*²⁶ and *Excel-Eucan v Source Vagabond*²⁷. In the other six cases, the patent(s) in issue were found invalid.

In *Regen v Estar*²⁸, HHJ Hacon said that if there are multiple differences between the claim and the variant, the differences should be considered together. (On the other hand, in *Emson v Hozelock*²⁹, Nugee J took the opposite approach). Judge Hacon also said that in the application of the doctrine of equivalents, numerical claims should be treated no differently to any other claim. Judge Hacon noted too that Lord Neuberger's reformulation of the *Improver* questions, in particular the first and third questions, had made significant changes. The focus had been shifted from the invention as claimed to the "core of the inventive concept or core of the invention", this being "the new technical insight conveyed by the invention - the clever bit - as would be perceived by the skilled person", assessed by reference to the specification and the evidence.

Regen's patented method for obtaining platelet-rich plasma involved taking blood from a patient, transferring it to a tube containing a thixotropic gel and an anticoagulant, and centrifuging it at a slow rate. The variant alleged to infringe employed a gel that was not polyester-based and a buffered sodium citrate solution at 0.136M, not 0.10M as required by the claim language. As noted above, applying the normal interpretation, the claim did not stretch to cover the variant. However, applying the doctrine of equivalents, the judge concluded that neither of the differences mattered much; it was

²⁵ *Icescape Limited v Ice-World International BV & Ors* [2018] EWCA Civ 2219

²⁶ *Marflow Engineering Limited v Cassellie Limited* [2019] EWHC 410 (IPEC) (26 February 2019) HHJ Hacon

²⁷ *Excel-Eucan Limited v Source Vagabond Limited* [2019] EWHC 3175 (Pat) (21 November 2019) HHJ Melissa Clarke

²⁸ *Regen Lab SA v Estar Medical Ltd & Ors* [2019] EWHC 63 (Pat) (18 January 2019) HHJ Hacon

²⁹ *E. Mishan & Sons, Inc t/a Emson v Hozelock Limited* [2019] EWHC 991 (Pat) (17 April 2019) Nugee J

the density of the gel that mattered. Accordingly, if the patent had been valid, the variant would have infringed.

This is a very strange turn of events. It would have seemed that, on considering the third amended question in the test for assessment of equivalence under limb (ii), the existence of clearly delineated numerical limits would have been a very clear signpost of the patentee intending strict compliance. I simply do not understand the thinking here. There is a lot of language which can be used to identify "fuzzy margins". However, if a patentee chooses to place the area of protection between specifically identified numerical limits, aside from the much litigated issue of mathematical rounding, I would have thought that there could be no clearer manifestation of the intention that "strict compliance with the literal meaning" was intended. I hope that we will see some control from the higher courts on this development.

The change in emphasis in Lord Neuberger's reformulated questions, to the focus on the core of the invention rather than the claim language, seems to have underpinned the court's findings of infringement by equivalents in several judgments in 2019.

For example, in *Marflow v Cassellie*³⁰ - the case about a mounting plate for pipes for use with a fluid-using appliance - the variant screw thread and nut did not infringe on the normal interpretation because the nut was not in or on the body of the mounting member. Turning to limb (ii), Judge Hacon considered the inventive concept of the patent to be the idea of using a plate (mounting member) to install a fluid-using appliance by securing the plate to the wall receiving the fluid pipes extending out of the wall through apertures in the plate, and using a locking means to lock the pipes to the plate. The inventive concept did not include a specific locking means. The variant screw and nut arrangement achieved the results that were achieved by the inventive concept and the judge concluded that the first reformulated question was answered 'yes'. Since the defendant did not separately contest the second and third reformulated questions, a finding of infringement on the doctrine of equivalents was reached.

Nevertheless, the judge noted that there remained a question of whether an advantage consequent upon the use of an inventive concept is invariably a "result" achieved by the inventive concept, as contemplated by Lord Neuberger in the first and second reformulated questions.

In *Emson v Hozelock*³¹ - the garden hose case - in which "said outer tube being unattached from said inner tube between said first and second couplers" was not infringed on the normal interpretation, Judge Hacon again considered the doctrine of equivalents. He said that at its most general, the invention could be described as an expandable hose consisting of an elastic inner tube and a non-elastic outer tube which expanded when filled with water and contracted when not. This was the "clever bit": freedom of movement between the two tubes along the entire length of the hose was at its heart.

In the Superhoses, the effect of the tubes being connected at the joiners as well as at the ferrules was that the tubes could not move freely with respect to each other along the entire length of the hose. Nevertheless, the Superhoses achieved substantially the same result in substantially the same way as the invention. For the great majority of their length the two tubes were unattached and could move freely with respect to each other. The hoses were therefore light, not bulky and not liable to kink. The fact that the joiner might have other advantages was not relevant. The first *Actavis* question was therefore answered 'yes'.

³⁰ *Marflow Engineering Limited v Cassellie Limited* [2019] EWHC 410 (IPEC) (26 February 2019) HHJ Hacon

³¹ *E. Mishan & Sons, Inc t/a Emson v Hozelock Limited* [2019] EWHC 991 (Pat) (17 April 2019) Nugee J

The second *Actavis* question was not independently contested by Hozelock.

Turning to the third *Actavis* question, the judge noted that it was implicit that the mere fact that the language of the claim did not cover the variant could not, itself, be decisive, otherwise the question would never arise. Relevant considerations appeared to include whether a plausible reason could be advanced why any rational patentee should want to place such a limitation on his invention, and whether the inventive core of the patent had anything to do with the particular way in which the variant differed from the claims. The judge saw no such reason in the present case. So if the patent had been valid, the variant would have infringed.

In ***Conversant v Huawei (4 July 2019)***³², Conversant's patent, as sought to be amended, claimed a method executed by a mobile station for autonomous enhanced uplink transmission. Claim 1 included integer 'C', in the following terms ([148]):

"checking to determine whether the medium access control entity is transmitting data packets in a current air interface transmission time interval, by checking whether the medium access control entity is able to empty the radio link control buffer in the current air interface transmission time interval".

On Conversant's own construction of the claim language, there was no literal infringement because the status check was by reference to whether the radio link control (RLC) buffer was able to be emptied in the *previous*, rather than the *current*, TTI. However, the judge said that the defendants had no coherent answer to Conversant's case that Uplink DRX was equivalent to integer C, in that it achieved substantially the same result in substantially the same as the invention, this would be obvious to the skilled person and the skilled person would not think that strict compliance was required. Accordingly, if the patent had been valid, it would have been infringed.

In another Tech case, ***Technetix v Teleste (18 November 2019)***³³ Technetix's patent to a cable transmission network comprising a high-pass filter was invalid but would have been infringed. Technetix had conceded infringement in respect of two products. In respect of a third product, the "ASH4P", Teleste's case was not helped by its case also being that the skilled person's view of the relevant feature of the ASH4P was that the inductor would act like a short-circuit and burn the device. Judge Hacon said ([62]):

"I imagine that burning out is not an advertised feature of an ASH4P unit...".

The ASH4P was found to infringe too.

Teleste also, eventually, conceded infringement in respect of two further hypothetical products, in respect of which it had sought declarations of non-infringement. The concession was made in light of Technetix's doctrine of equivalents case, which was supported by a view of the inventive concept that suited Teleste for validity purposes.

So beware, pleading a doctrine of equivalents case may help pin-point a target for invalidity.

³² *Conversant Wireless Licensing SARL v Huawei Technologies Co. Limited & Ors* [2019] EWHC 1687 (Pat) (4 July 2019) Arnold J

³³ *Technetix BV & Anr v Teleste Limited* [2019] EWHC 3106 (Pat) (18 November 2019) HHJ Hacon

Before leaving the doctrine of equivalents, I would like to note also the judgment of HHJ Melissa Clarke in *Excel-Eucan v Source Vagabond*³⁴. This was a case in which Excel-Eucan succeeded in establishing that Source's ammunition bag infringed its patent pursuant to the doctrine of equivalents, and so (apparently) that Source had breached a licence agreement. Judge Clarke adopted a fairly broad approach to the identification of the inventive concept in the first reformulated question, noting that the whole point of the doctrine of equivalents is not to be bound by the claim language.

Prosecution history

In *Actavis v Eli Lilly*³⁵, Lord Neuberger concluded that it was appropriate for the UK courts to adopt a "sceptical, but not absolutist, attitude to a suggestion that the contents of the prosecution file should be referred to when considering a question of interpretation or infringement" i.e. to any arguments of file wrapper estoppel. He said there would be occasions when justice may fairly require this. However, Lord Neuberger's view was that such circumstances should be limited, that reference to the file would only be appropriate where:

- i. the point at issue is truly unclear if one confines oneself to the specification and claims of the patent and the contents of the file unambiguously resolve the point; or
- ii. it would be contrary to the public interest for the contents of the file to be ignored.

In *Regen v Estar*³⁶ - the case concerning a method for obtaining platelet-rich plasma – the defendants alleged to infringe relied, when attempting to restrict the application of the doctrine of equivalents, upon a letter from Regen to the EPO sent during the prosecution of Regen's patent. The letter stated ([254]):

"Hence for each tube, a specific combination of a particular tube's material, particular thixotropic gel and particular anticoagulant is claimed. In addition, depending on the tube used, the anticoagulant is to be present in a specific state (solution or anhydrous) and at a specific concentration. In summary, the primary feature of the processes which distinguishes them from those disclosed in [Smith] is the use of specific tubes."

Dismissing the defendants' arguments, the judge said ([255]):

"I think that the letter of 31 May 2013 satisfies neither requirement specified by Lord Neuberger. There is no issue of construction or scope which is truly unclear if one confines oneself to the specification and claims of the patent, for the reasons discussed above. Nor would it be contrary to the public interest for the letter to be ignored. Regen argued before the EPO that the scope of the claim they were advancing did not overlap the disclosure of Smith. It does not. That is consistent with Regen's argument on scope before me."

So the prosecution history had no effect on the scope of the claim. Had the patent been valid, it would have been infringed under the doctrine of equivalents.

³⁴ *Excel-Eucan Limited v Source Vagabond Limited* [2019] EWHC 3175 (Pat) (21 November 2019) HHJ Melissa Clarke

³⁵ *Actavis UK Limited & Ors v Eli Lilly and Company* [2017] UKSC 48

³⁶ *Regen Lab SA v Estar Medical Ltd & Ors* [2019] EWHC 63 (Pat) (18 January 2019) HHJ Hacon

An argument made in reliance upon what the patentee had said during prosecution, to the UK IPO, was unsuccessful in *Excel-Eucan v Source Vagabond*³⁷ too.

In the context of answering reformulated question 1, Source highlighted Excel's own reliance on the ammunition bag's openable closure as a part of the invention: (a) to distinguish it from the prior art, which had no "openable closure"; and (b) to counter the issue of obviousness, stating that it would not be obvious to incorporate an additional opening that could potentially allow an ingress point for dirt and dust. Source submitted that by doing so, Excel had recognised at the IPO that the openable closure had real significance as part of the inventive concept and was inseparable from it, and so should the court.

Excel, on the other hand, said that it had made a number of submissions distinguishing the invention from the prior art and to counter the issue obviousness, of which the openable closure point was only one. Excel submitted that it was not appropriate for the court to consider the IPO's preliminary report (which recorded these submissions) where neither of Lord Neuberger's two criteria applied.

Judge Clarke accepted Excel's submission, saying that even if the openable closure considered was adjudged a significant part of the claim, the whole point of the doctrine of equivalents was that it entitled a patentee to contend that the scope of the protection afforded by the patent extended beyond the ambit of its claims as construed according to the normal principles of interpretation.

Given the alacrity with which the courts have adopted the doctrine of equivalents, I am quite surprised with the peremptory fashion in which they have dismissed file wrapper estoppel. I am aware of at least one case working its way through the system where statements made in the prosecution process on behalf of the patentee would appear to present an excellent opportunity for the courts to adopt a more constructive and open-minded approach to this question. We shall see.

Swiss form claims

In *Eli Lilly v Genentech*³⁸, a case concerning therapeutic antibodies inhibiting the heterodimeric complex IL-17A/F, claims 12 and 20 were in Swiss form. Genentech alleged that Eli Lilly had infringed them pursuant to the Patents Act section 60(1)(c) i.e. by dealings in the direct product of the Swiss form process claim.

This engaged the question of the correct interpretation of a Swiss form claim – an area in which the UK Supreme Court had been both split and in disagreement with the lower courts in *Warner-Lambert v Generics*³⁹ in late 2018. So how should a first instance judge take this forward? On the facts of the *Eli Lilly v Genentech* case, Arnold J found a side step ([614]-[615]):

"In *Warner-Lambert* ... the Supreme Court divided 2:2:1 on [the] question of whether infringement of Swiss form claims pursuant to section 60(1)(c) involved a mental element, and if so what it was. Moreover, all of the judgments on this question were obiter.

In the present case, however, I do not think it matters which test is to be applied for the purposes of claims 12 and 20. This is because (i) the parties alleged to infringe and the

³⁷ *Excel-Eucan Limited v Source Vagabond Limited* [2019] EWHC 3175 (Pat) (21 November 2019) HHJ Melissa Clarke

³⁸ *Eli Lilly and Company & Ors v Genentech Inc* [2019] EWHC 387 (Pat) (1 March 2019) Arnold J

³⁹ *Warner-Lambert Company LLC v Generics UK Limited (t/a Mylan) & Anr* [2018] UKSC 56

manufacturers of Taltz are Lilly companies, (ii) Lilly intend that Taltz is to be used for the treatment of psoriasis and (iii) the outward presentation of Taltz makes it clear that it is for use for the treatment of psoriasis. Counsel for Lilly submitted that there was no evidence of (ii) and (iii), but I disagree: both facts are plain from the marketing authorisation for Taltz."

Supply of "means essential"

An important strand of patent infringement law is founded upon section 60(2) of the Patents Act, which states:

"Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom."

Continuing with our discussion of *Eli Lilly v Genentech*⁴⁰, claims 13-15 and 22 of Genentech's patent were EPC2000 purpose-limited product claims. Genentech alleged infringement pursuant to section 60(1)(a), alternatively section 60(2), of the Patents Act. The judge said it was sufficient to consider s.60(2). He cited *Grimme v Scott*⁴¹ and *KCI v Smith & Nephew*⁴², before summarising that ([610]):

"... it is enough if (at the time of supply or offer to supply) the supplier knows (or it is obvious to a reasonable person in the circumstances) that some ultimate users will intend to put the invention into effect in the UK using the "means essential".

It followed that Eli Lilly's ixekizumab was means essential. The first and eighth claimants (both within the Eli Lilly group) would know (or at least it was obvious) that some ultimate users would intend to put the invention into effect for the treatment of psoriasis and that inhibition of IL-17A/F marked a more than significant contribution to the therapeutic effect. This latter knowledge requirement was reached as a result of the evidence given at trial, the last date of which was 1 February 2019.

Accordingly, if claims 13-15 and 22 had been valid, the first and eighth claimants would have infringed them by acts committed since 1 February 2019.

Finally, in *Emson v Hozelock*⁴³ - the garden hose case - the judge addressed Emson's argument that the attachment of the inner tube to the joiner was relatively weak and in practice broke during use, so that the supply of the Superhoses was supply of means essential with the relevant knowledge. However, the judge said that each of the hoses tested in the experiments in the case had been stretched before use, so Emson had not established that the joiner was likely to break during normal use.

⁴⁰ *Eli Lilly and Company & Ors v Genentech Inc* [2019] EWHC 387 (Pat) (1 March 2019) Arnold J

⁴¹ *Grimme Maschinenfabrik GmbH & Co KG v Scott (t/a Scotts Potato Machinery)* [2010] EWCA Civ 1110

⁴² *KCI Licensing Inc v Smith & Nephew plc* [2010] EWCA Civ 1260

⁴³ *E. Mishan & Sons, Inc t/a Emson v Hozelock Limited* [2019] EWHC 991 (Pat) (17 April 2019) Nugee J

c) Defences, acts of infringement, stays, evidence

A *Formstein* defence in the UK?

As noted above, a consequence of the purposive approach to the construction of patent claims, which was the law under *Catnic*, *Improver* and *Kirin-Amgen* before the Supreme Court's judgment in *Actavis v Eli Lilly*⁴⁴, was that the reach of a claim for the purpose of assessing its infringement was the same as the scope of the claim for the purpose of assessing its validity. This meant that in order to anticipate a patent, matter relied upon as novelty-destroying prior art had to disclose subject matter which, if performed, would necessarily result in an infringement of the patent. So whenever the prior disclosure was capable of being performed and was such that, if performed, it must result in the patent being infringed, the disclosure condition (of anticipation) was satisfied.⁴⁵

The purposive approach, in the context of the UK's unbifurcated patent litigation system, facilitated squeeze arguments. Parties alleged to infringe a patent often ran a squeeze between infringement and validity such that if the claim was broad enough to cover the product or process complained of, then it must be invalid.

For example, there could be a squeeze between infringement and sufficiency: a party alleged to infringe could argue that if the claims were to be interpreted broadly enough that the alleged infringing product or process fell within their scope (and so infringed) then they would be insufficient because the patent did not enable a claim of such scope e.g. the claim was of excessive breadth. Arguments of this nature succeeded, for example, in the House of Lords in *Kirin-Amgen*⁴⁶ and the Court of Appeal in *AHP v Novartis*⁴⁷.

There could also be a squeeze made between obviousness and infringement i.e. if the claim language was interpreted broadly enough that the alleged infringing product or process fell within the scope of the claim, then it would encompass material that was obvious in the light of the prior art and the claim would therefore be invalid. For example, such an approach was successful for the party alleged to infringe in *Chiron v Evans*⁴⁸ and *SKB v Apotex*⁴⁹. Similarly, a squeeze between infringement and anticipation could be employed, invoking the principle illustrated by the House of Lords' judgment in *Synthon v SKB*⁵⁰. Such an approach was successful, for example, in *Apimed v Brightwake*⁵¹.

The so-called '*Gillette* defence' to infringement is a type of squeeze between infringement and validity (anticipation or obviousness). First recognised in the judgment of Lord Moulton in *Gillette v Anglo-American* (1913)⁵², it stems from the principle that, it being impossible for an ordinary member of the public to keep watch on all patents, "*he is entitled to feel secure if he knows that that which he is doing differs from that which has been done of old only in non-patentable variations, such as the*

⁴⁴ *Actavis UK Limited & Ors v Eli Lilly and Company* [2017] UKSC 48

⁴⁵ *Synthon BV v Smithkline Beecham plc* [2005] UKHL 59

⁴⁶ *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd (No.2)* [2005] RPC 9

⁴⁷ *American Home Products Corporation & Anr v Novartis Pharmaceuticals UK Limited & Anr* [2000] EWCA Civ 231

⁴⁸ *Chiron Corporation v Evans Medical Limited & Ors* [1997] EWHC 359 (Pat)

⁴⁹ *Smithkline Beecham plc & Anr v Apotex Limited & Ors* [2004] EWCA Civ 1568

⁵⁰ *Synthon BV v Smithkline Beecham plc* [2005] UKHL 59

⁵¹ *Apimed Medical Honey Limited v Brightwake Limited* [2012] EWCA Civ 5

⁵² *Gillette Safety Razor Co v Anglo-American Trading Co Ltd* (1913) 30 RPC 465

substitution of mechanical equivalents or changes of material shape or size". More recently, in *Merrell Dow v Norton*⁵³, Lord Hoffmann put it this way ([17]):

"Ever since the power of the Crown to grant monopolies was curbed by parliament and the courts at the beginning of the seventeenth century, it has been a fundamental principle of United Kingdom patent law that the Crown could not grant a patent which would enable the patentee to stop another trader from doing what he had done before."

A so-called *Gillette* defence to a claim for infringement therefore concerns the obviousness or lack of novelty of the defendant's own product or process as at the priority date of the patent alleged to be infringed (i.e. the date at which the novelty or inventive step of the patent is to be assessed). This is subtly different to a more general infringement/anticipation or infringement/obviousness squeeze, which concerns the validity of the patent directly. The *Gillette* defence is therefore a type of short-cut, but while its conceptual importance has continued to be recognised, the courts have been slow to rely upon it, since it is seen to be in the interests of the parties and the public that issues of infringement and validity be severally adjudicated on.

Nevertheless, recent English case law has developed the use of the *Gillette* defence into a type of shield from future patents, in the form of *Arrow* declaratory relief. *Arrow* relief is a declaration that the applicant party's own product or process, or aspects of it, were known or obvious at a relevant date - this being the priority date of a relevant patent or application. *Arrow* relief was awarded in 2017, in *FKB v AbbVie*⁵⁴, and in 2018, in *GSK v Vectura*⁵⁵.

As noted in sections 2(a) and (b) above, since the Supreme Court's judgment in *Actavis v Eli Lilly*, it appears to have been established that for the purpose of assessing validity, patent claim language is interpreted in a purposive way but **without** any consideration of equivalents. The scope of a claim for the purpose of assessing its validity is the same as the reach of the claim under the normal interpretation limb of the infringement assessment. However, if infringement is not found under the first limb of the infringement assessment, the application of the second limb - the doctrine of equivalents - may extend the reach of the claim, for infringement purposes, beyond the scope of the claim against which validity is assessed.

Shortly after the Supreme Court's judgment in *Actavis v Eli Lilly*, the existence of such a 'validity gap' was flagged by Arnold J in *Generics v Yeda*⁵⁶, who said that it no longer appeared to be the law that a patent claim lacked novelty if the prior publication disclosed subject-matter which, if performed, would infringe the claim. In order to anticipate, such infringement must be on the normal interpretation (rather than the doctrine of equivalents). As noted above, subsequent case law appears to have confirmed this.

If there is now a validity gap, then if a variant is found to infringe on the doctrine of equivalents (and so, by definition, not on the normal interpretation), the patentee could side-step a conventional anticipation, obviousness or insufficiency squeeze by merely establishing the novelty, inventiveness or sufficiency of the claim as normally interpreted. A conventional squeeze argument, even if successful, would not provide a comprehensive defence.

⁵³ *Merrell Dow Pharmaceuticals Inc & Ors v H.N. Norton & Co. Limited* [1995] UKHL 14

⁵⁴ *Fujifilm Kyowa Kirin Biologics Company Limited & Ors v AbbVie Biotechnology Limited* [2017] EWHC 395 (Pat)

⁵⁵ *Glaxo Group Limited & Ors v Vectura Limited* [2018] EWHC 3414 (Pat)

⁵⁶ *Generics (U.K.) Limited & Anr v Yeda Research and Development Company Limited* [2017] EWHC 2629 (Pat); see also *Fisher & Paykel Healthcare Limited v ResMed Limited* [2017] EWHC 2748 (Pat)

A validity gap would not, however, seem to offer a side-step around a *Gillette* defence. The difference with a *Gillette* defence is the focus upon the alleged infringing product or process and the employment of the principles explained in *Gillette* and *Merrell Dow*: if an alleged infringer had been doing no more than what had been done of old or non-patentable (e.g. obvious) variations of what had been done of old, a finding of infringement would not be justified.

Consistently with this, in ***Technetix v Teleste* (29 January 2019)**⁵⁷, HHJ Hacon said that it would be surprising if the Supreme Court in *Actavis v Eli Lilly* had intended to abandon the *Merrell Dow* principle without expressly saying so. He then observed that ([94]):

"One way of reconciling the *Merrell Dow* principle with the doctrine of equivalents would be to say that if an accused product or process is an equivalent and for that reason is nominally within the scope of the claim, but the equivalent would have lacked novelty or inventive step over the prior art at the priority date, then it is deemed to fall outside the scope of the claim, thus providing a defence to infringement."

Judge Hacon noted that in each of Germany (where the case name '*Formstein*' originates), the Netherlands and the US, the law provides an alleged infringer with a defence to the claim for infringement in such circumstances. In the UK, the Supreme Court or the Court of Appeal could take such a route in due course.

In the *Technetix v Teleste* (29 January 2019) case, Technetix's patent was to a "cable tap unit" (used in a cable TV wire network). As proposed to be amended, it was found invalid for anticipation and obviousness. Had it been valid, the patent would have been infringed under the doctrine of equivalents by Teleste's "Tap Bank". In case such an infringement finding had been reached in respect of a valid claim, Teleste had argued for a defence based on the *Merrell Dow* (or *Gillette*) principle. The judge concluded that at the priority date of the patent, it would have been obvious to adapt the common general knowledge to create a unit the same as Teleste's Tap Bank (i.e. a *Gillette* defence). Therefore, the judge said that if a *Formstein* type defence existed in English law, Teleste was entitled to it.

Shortly afterwards, in ***Emson v Hozelock***⁵⁸, Nugee J also concluded that the patents in issue, to a new type of garden hose, were invalid for obviousness, but had they been valid they would have been infringed under the doctrine of equivalents. Again, the party alleged to infringe had argued for a *Formstein* defence. In view of the invalidity of the patents, the judge declined to address whether such a defence might have a place in English law. However, Nugee J noted the judgment in the *Technetix* (29 January 2019) case and said that a decision on the subject should be left to a case where it would make a difference, and very probably to a higher court.

So watch this space – perhaps a *Formstein* defence will be found to exist in 2020.

Evidence

In several patent cases in 2019, judges have considered some of the evidence relied upon, of fact and expert witnesses, to be poor, with consequences for the relevant party's case. There have also been some notable comments of a more positive nature, illustrating a firm grip by the judges on the real world context in which evidence is given.

⁵⁷ *Technetix B.V & Ors v Teleste Limited* [2019] EWHC 126 (IPEC) (29 January 2019) HHJ Hacon

⁵⁸ *E. Mishan & Sons, Inc t/a Emson v Hozelock Limited* [2019] EWHC 991 (Pat) (17 April 2019) Nugee J

Regen v Estar⁵⁹ concerned Regen's patent to a method for the preparation of blood plasma enriched in platelets and other factors. Estar challenged the validity of the patent in a number of ways, including lack of novelty based on prior disclosure by Regen's sales of its Vacutainer kits.

For Estar, evidence was given by three CEOs of customers of Regen, to whom the disclosures were said to have been made. For Regen, evidence was given by its CEO, Mr Turzi. However, the judge's view was that Mr Turzi was not a reliable witness, his first concern being to do all he could to advance Regen's case. For example, he made concessions in cross-examination only when he felt that he had no other credible choice. Judge Hacon proceeded to conclude that Regen's patent had indeed been anticipated by its prior disclosure.

The case of **Eli Lilly v Genentech**⁶⁰, about therapeutic antibodies inhibiting the heterodimeric complex IL-17A/F, involved many experts. Lilly called five and Genentech called four.

On the subject of dermatology (and so of relevance to the claims concerned with treatment of psoriasis), Lilly's expert was a Professor Krueger and Genentech's expert was a Professor Prens. The judge accepted that Prof Krueger occasionally found difficulty in answering questions from the perspective of the skilled person rather than his own perspective. However Arnold J thought this was a common problem, eminence being a common attribute of expert witnesses in patent litigation in this country, and that Prof Krueger was "impressive".

On the other hand, the judge considered that Prof Prens' evidence on the topic of "Abcream" (a topical anti-IL-8 therapy developed by Canadian biopharmaceutical company Anogen) was "deeply unsatisfactory". In particular, Prof Prens had made statements about Abcream being approved in China for psoriasis treatment, and being "on the market", based on publications available only in Chinese and without reading references (also available only in Chinese). Prof Prens said that he had "checked a clinical paper" (also in Chinese) but when challenged he said that actually he had scrolled through and looked at pictures and the English abstract. It later transpired that the abstract he had looked at was of a different paper. And only when pressed did he concede that he had no evidence that Anogen had conducted any trials after May 2002. Arnold J said that while this did not necessarily affect Prof Prens' evidence on the other issues in the case, it reduced his confidence in Prof Prens' evidence and thus the weight which he was able to give to it.

Another expert in the case, Lilly's antibody expert Professor Lesk, had "singularly failed" in his main task of producing models that reflected those which a skilled person in 2003 would have produced if humanising certain antibodies. Models were contaminated by post-2003 software and data, Prof Lesk sought to underplay defects and the models could not be relied upon. The sequence of events "did not reflect well on Prof Lesk".

Lilly's patent was found invalid, variously for obviousness (product claims and rheumatoid arthritis (RA) aspects) or insufficiency (psoriasis aspects).

The case of **Emson v Hozelock**⁶¹ was a notable one because it concerned a patent which had been tested in earlier litigation: Emson had succeeded in establishing the patent's infringement and validity in **Blue Gentian v Tristar**⁶². Hozelock, like Tristar in the earlier litigation, alleged that Emson's patent was invalid for obviousness over each of two separate prior publications - "McDonald" and "Ragner". But unlike Tristar, Hozelock succeeded in its obviousness challenge based on McDonald.

⁵⁹ *Regen Lab SA v Estar Medical Ltd & Ors* [2019] EWHC 63 (Pat) (18 January 2019) HHJ Hacon

⁶⁰ *Eli Lilly and Company & Ors v Genentech Inc* [2019] EWHC 387 (Pat) (1 March 2019) Arnold J

⁶¹ *E. Mishan & Sons, Inc t/a Emson v Hozelock Limited* [2019] EWHC 991 (Pat) (17 April 2019) Nugee J

⁶² *Blue Gentian LLC v Tristar Products (UK) Ltd* [2013] EWHC 4098 (Pat); [2015] EWCA Civ 746

In the *Tristar* litigation, Birss J had not been satisfied that the skilled person (an ordinary garden hose designer) working without hindsight would arrive at a product within claim 1 if presented with McDonald (which described a way of providing oxygen to crew on an aircraft). The Court of Appeal dismissed *Tristar's* appeal.

In the present case though, the judge, Nugee J, emphasised the difference in the evidence put before him and that put before the judge in the earlier case.

Hozelock's evidence in the present case was that the skilled person would be familiar with the design and manufacture of all types of hoses, not just hoses for sale to consumers for use in their garden. This included information on twenty-five competitor companies of Tricoflex (a general hose company associated with Hozelock), twenty-four of which made both garden and technical hoses. Nugee J said that Emson's submissions appeared to be that, outside Tricoflex and its competitors, there was a body of hose designers whose experience was limited to garden hoses. However, there was no evidence that there was such a cohort of people i.e. that the bulk of garden hose designers worked specifically for a garden product company (such as Hozelock) as opposed to a general hose company such as Tricoflex. So on the state of this evidence, the judge concluded that he could not find that real-world garden hose designers were generally persons whose experience was limited to designing garden products, or that Hozelock's evidence was anything other than representative of the industry as a whole.

The different evidence led to a different identification of the skilled person and a different conclusion on the issue of obviousness. On the departure from Birss J's judgment, Nugee J said ([40]):

"...whereas on questions of law it is the usual practice for one judge to follow another (even though not bound to do so) unless convinced they are wrong, questions of fact are to be decided on the basis of the evidence admitted at the trial in question and the conclusions of another judge, however eminent, on the evidence they heard at a different trial do not carry any particular weight; indeed, strictly speaking I do not think they are even relevant or admissible (that is, on the well-known principle of *Hollington v Hwethorn* [1943] KB 587, reaffirmed as still good law in *Rogers v Hoyle* [2014] EWCA Civ 257)."

In *Takeda v Roche*⁶³, the validity of Roche's patent to glycosylated antibodies was challenged by Takeda. In two contexts, there was dispute between the parties (and the experts) about what the skilled person would understand from a publication authored by Roche employees (two different articles). The judge, Birss J, said that Roche could have put forward evidence from relevant workers with a view to clarifying the points but chose not to, and the judge concluded against Roche on both points. One of these points concerned the common general knowledge, and its impact contributed to the findings of anticipation and obviousness. The other point concerned claim ambiguity, on which Roche lost too.

Birss J also captured the differing questions needing to be addressed in the evidence in respect of an obviousness case run on the 'conventional' basis as compared with a 'lack of technical contribution' obviousness case [200]:

"In giving her evidence the question asked of Professor Bertozzi was, correctly, "*what, if anything, does the Patent make by way of a technical contribution over Bihoreau*". Professor Parren on the other hand was asked to comment on what the skilled team "*would do, if*

⁶³ *Takeda UK Limited v F. Hoffmann-La Roche AG* [2019] EWHC 1911 (Pat) (17 July 2019) Birss J

anything, if presented with the teaching of Bihoreau". The evidence he gives is therefore based on an incorrect premise."

Takeda's main obviousness case was of **lack of technical contribution**, for which the correct question was that put to Takeda's expert, Professor Bertozzi. Takeda succeeded in establishing that the patent was obvious on this basis.

At the other end of the technology spectrum, the patents in issue in *Quinn v Linpac*⁶⁴ concerned plastic containers of the type typically used in supermarkets for food. Quinn sought the revocation of two different patents owned by two different competitors – Linpac and Færch. The skilled person was agreed as being an engineer engaged in the design and manufacture of plastic packaging for products such as foodstuffs.

The experts for Linpac and Faerch were both considered by the judge to be good witnesses. Linpac's expert had spent many years in plastics, with experience in plastics thermoforming, extrusion and injection moulding, this experience including the design of new packaging products. Faerch's expert was a specialist in the design and manufacture of plastic packaging for food and was one of two named inventors on Faerch's patent.

Nevertheless, the successful party in the case was Quinn, which managed to invalidate both patents. Quinn's expert evidence apparently did not lack for having been given by an individual with a less technical background, of whom the judge said ([13]):

"He was a good witness. He had less direct design experience than the other experts who gave evidence, his views having been formed very largely from a managerial perspective. He was therefore further from the notional skilled person than the other two but I do not believe that this undermined the credibility of his evidence on technical matters."

Arnold J gave some notable commentary, in *Illumina v TDL (17 June 2019)*⁶⁵, on the role of translations of prior art and the resolution of disputes regarding translation.

Illumina's patent concerned pre-natal testing. It claimed a fraction of a blood sample having been submitted to a DNA extraction followed by a size separation process. Inventive step was challenged over one piece of prior art, "Ikeda", which was a conference abstract in Japanese.

It was common ground between Counsel that what mattered was how the original Japanese would be understood. On this, the judge said ([118]):

"I am doubtful that this is correct, since the skilled person is located in the United Kingdom: see *Generics (UK) Ltd v Warner-Lambert Co LLC* [2015] EWHC 2548 (Pat), [2016] RPC 3 at [124]. It seems to me that it follows that the skilled person is deemed to read Ikeda in English translation. This point probably does not matter, however, since, even if it is the meaning of the Japanese that is determinative, an English court must rely upon a translation in order to appreciate that meaning. Either way, it is important that the translation should be as accurate as possible.

⁶⁴ *Quinn Packaging Limited v Linpac Packaging Limited & Anr* [2019] EWHC 2119 (IPEC) (31 July 2019) HHJ Hacon

⁶⁵ *Illumina, Inc & Anr v TDL Genetics Limited & Ors* [2019] EWHC 1497 (Pat) (17 June 2019) Arnold J

Arnold J noted that translation is a form of expert evidence⁶⁶. The court's permission is therefore required to adduce such evidence under CPR Part 35. (A similar approach could be applied for interpreters, although in the case of translations of affidavits and witness statements, it is arguable that permission is supplied by PD32 10.2 & 23.2).

If a translation is agreed, it is common, in practice, for it to be relied upon without any formal order. In the event of dispute as to translation though, permission must be sought and obtained to adduce expert evidence from translators. The translator's certificate should also comply with the Practice Direction to Part 35, in particular giving details of the translator's qualifications. The qualifications of rival translators will go to weight. It is generally accepted that translators should translate into their mother tongue. The necessary procedural steps were complied with in the present case.

The translation issue in the present case concerned the Japanese word "*mata*" which the claimants contended should be translated as "furthermore" or "moreover" and the defendants contended should just be ignored. While accepting the defendants' evidence (from Professor Itoh) that it was not always necessary to translate the word 'mata', the judge agreed with the claimants' expert that fidelity to the original generally required it to be translated. Professor Itoh suggested that the translation could be 'also' or 'in addition'. That being so, the judge thought there was little between the parties and he proceeded to consider what Ikeda disclosed.

Confidentiality regimes

2019 has seen a number of disputes about confidentiality regimes. This is an area in which the outcome of an issue is highly dependent on the particular facts of the case, and even the authorities say this must be the case. In an age of global disputes, it is not surprising that the boundaries of our law are being tested regularly.

In ***Illumina v TDL (22 January 2019)***⁶⁷, the original confidentiality regime had been agreed between the parties and made the subject of a consent order. At the product and/or process description (PPD) stage, the defendants demanded further restrictions in respect of the existing in-house members and the claimants' proposed expert. However, Mann J was unimpressed with the defendants' evidence, by which they sought to justify restricting access to some parts of the PPD in respect of two of the instructing personnel. The judge said that this was inconsistent with the defendants' agreement to include those individuals in the first place. Further, the defendants' "inadequately articulated risk" of leakage, in the form of unintentional use of information in the PPD acquired in this jurisdiction, for the purposes of foreign litigation, was outweighed by the claimants' "understandable and justifiable desire that the same people should be able to oversee patent disputes in a number of jurisdictions".

In ***Evalve v Edwards (9 April 2019)***⁶⁸, the judge permitted the inclusion of two additional individuals (members of second claimant Abbott's internal IP team) in an existing confidentiality club. This followed evidence that Abbott's internal legal team was divided into 'IP' and 'litigation', that in respect of the present case the in-house Abbot team included individuals from both teams, and that unless all the relevant individuals could see the confidential information, Abbott's conduct of the litigation would be impaired. However, the inclusion was permitted on the condition that Abbot provide an undertaking making clear that they would not use the fact that information had been provided to the two individuals to gain an advantage in the US proceedings.

⁶⁶ *Sobrinho v Impresa Publishing SA* [2015] EWHC 3542 (QB), *Umeyor v Ibe* [2016] EWHC 862 (QB)

⁶⁷ *Illumina, Inc & Anr v TDL Genetics Limited & Ors* [2019] EWHC 79 (Pat) (22 January 2019) Mann J

⁶⁸ *Evalve Inc & Ors v Edwards LifeSciences Limited* [2019] EWHC 955 (Pat) (9 April 2019) Henry Carr J

Much later in the year, a notable interim judgment emerged from Nicholas Caddick QC, sitting as a deputy judge, in **J.C. Bamford v Manitou**⁶⁹. The issue before him was whether JCB's internal experts should be permitted access to Manitou's PPD. The judge took a thorough look at the authorities, beginning with *Warner-Lambert v Glaxo*⁷⁰, from which he noted that the courts had refused to allow a party's internal technical experts access to confidential technical information of a competitor, but it was clearly possible (as in *Roussel Uclaf*⁷¹) that justice can require such access. Each case must turn on its own facts and how justice can best be achieved.

Manitou had agreed that the unredacted version of the PPD could be seen by a confidentiality club consisting of JCB's external legal team, two of JCB's internal lawyers (neither with technical expertise) and JCB's external expert for the trial. The deputy judge concluded that it would not be appropriate to give access to JCB's internal experts too. This was because it had to be assumed that there was confidential information in the PPD, JCB's internal experts could not unlearn it once they had access, Manitou had offered to include in the confidentiality club a further external expert of JCB (who would not be subject to the restrictions of a trial expert), and so the convenience (and cost benefits) for JCB of using its internal experts did not outweigh the risks of including them.

d) Remedies and costs

The use of discovery material

Continuing on the theme of confidentiality, Henry Carr J's judgment in **Boehringer Ingelheim v Generics**⁷² addressed a question of a type that is often considered by English lawyers in an advisory capacity: what use may be made of information arising in English proceedings in other jurisdictions?

Boehringer Ingelheim applied for pre-action 'inspection' i.e. provision of samples of capsules and inhaler devices for the purpose of conducting experiments to test for suspected infringement. Some agreement had been reached between the parties on this but the judge settled the dispute on quantity and agreed with Boehringer Ingelheim that a sample of the inhaler device used with the capsules should be provided too.

However Boehringer Ingelheim was not successful, at this point, in its request to be permitted to use the results of such experiments in other jurisdictions.

The judge held that the same policy considerations that underlie the obligation in respect of disclosure also apply to the compulsory provision of samples. The use of such documents should be confined to the litigation⁷³. This did not mean that the court did not have jurisdiction to allow use of the results of experiments for infringement proceedings in other jurisdictions, however special circumstances would be needed to justify such an order.

Boehringer Ingelheim contended that special circumstances existed in the present case *inter alia* because the experiments needed were time-consuming and onerous and if Boehringer Ingelheim were not permitted to use the results in other jurisdictions they would have to seek orders in numerous jurisdictions. But the judge said that while it was not appropriate to shut out the making of

⁶⁹ *J.C. Bamford Excavators Limited v Manitou UK Limited & Anr* [2019] EWHC 3071 (Pat) (18 November 2019) Nicholas Caddick QC

⁷⁰ *Warner-Lambert Co v Glaxo Laboratories Ltd* [1975] R.P.C. 354

⁷¹ *Roussel Uclaf v Imperial Chemical Industries Plc* [1990] R.P.C. 45

⁷² *Boehringer Ingelheim Pharma GmbH & Co KG v Generics (UK) Ltd (t/a Mylan)* [2019] EWHC 584 (Ch) (6 March 2019) Henry Carr J

⁷³ *Tchenguz v Director of the Serious Fraud Office & Anr* [2014] EWCA Civ 1409

such an application in the future, at present, as Boehringer Ingelheim did not know whether or where it wished to use any results in foreign proceedings, such permission would not be given.

Turning to the costs of the application, the judge noted that the law on this point had not previously been tested. He therefore considered that an application to the court had been inevitable in the present case, and so he would not depart from the general rule that Boehringer Ingelheim must pay the respondents' costs of the application as well as of compliance with the order. However, the judge cautioned that the three month delay between Boehringer Ingelheim's original request and Mylan's agreement (after the issue of the present application) broadly along the lines ordered following the application, was too long. If Mylan took a similar attitude in the future the judge might well be persuaded to depart from the general rule on costs.

That should be considered a warning shot for future disputes too!

Nicholas Caddick QC's judgment in *J.C. Bamford v Manitou*⁷⁴ addressed whether JCB should be given permission to use Manitou's PPD (provided, of course, in lieu of disclosure) in proceedings in France and Italy. Contesting the application, Manitou argued its case on two grounds: (i) that JCB's application was an abuse of process as it would circumvent the statutory procedure contained in the Evidence (Proceedings in other Jurisdictions) Act 1975, and (ii) that an order under 31.22(1) would not be appropriate in the circumstances of the case.

Interestingly, this seems to have been the first time that ground (i) had been argued in the context of such an application, but the deputy judge did not think the argument should be precluded just because similar applications had been determined previously without considering it. In short, after considering the 1975 Act and the various authorities, the deputy judge seemed to agree with Manitou that the 1975 Act was a complete statutory code and an attempt to circumvent its provisions by making an application under r.31.22(1) would be an abuse.

For good measure, Nicholas Caddick QC then disposed of JCB's application on ground (ii). He said it had to be assumed that the foreign proceedings were fair and there was no risk of injustice, and there was nothing to suggest to the contrary. If JCB was encountering difficulties with its case in France and Italy, then that was a matter for the French and Italian courts to address using their own processes and procedures. It would be wholly inappropriate for the English court to intervene. In particular, a PPD was alien to the French and Italian systems. It would be wrong for the English Court to give permission for a confidential PPD (produced in the context of and with the safeguards provided by the English system) to be introduced into the French or Italian systems otherwise than in pursuance of a request made by or on behalf of the French and Italian courts and without being satisfied that confidentiality would be appropriately protected.

Injunctions

*TQ Delta v ZyXEL (18 March 2019)*⁷⁵ – one of nine published judgments in the case in the space of thirteen months - was the judge's reasoned form of order judgment following his 11 March 2019 conclusion that one of TQ Delta's two asserted SEPs was valid, essential and infringed. It built on case law and practice established in the *Unwired Planet*⁷⁶ case.

⁷⁴ *J.C. Bamford Excavators Limited v Manitou UK Limited & Anr* [2019] EWHC 3071 (Pat) (18 November 2019) Nicholas Caddick QC

⁷⁵ *TQ Delta LLC v ZyXEL Communications Limited* [2019] EWHC 745 (Pat) (18 March 2019) Henry Carr J

⁷⁶ *Unwired Planet International Ltd v Huawei Technologies Co. Ltd & Anr* [2017] EWHC 711 (Pat); [2018] EWCA Civ 2344

The complication for TQ Delta was that the valid, infringed and essential SEP ('268) would expire on 25 June 2019, before the scheduled hearing of the RAND (to all intents and purposes, FRAND) trial, which had been shifted in the list to Autumn 2019. The purpose of such a trial being to settle the RAND terms which implementer ZyXEL could take (to avoid the usual patent infringement remedy of injunction), or not (and expect to be enjoined), the *Unwired Planet* approach presented a difficulty in this case. Some interesting findings emerged.

First, Henry Carr J noted that TQ Delta had first approached ZyXEL seeking to licence its patents in 2013. ZyXEL had not yet paid any royalties to TQ Delta (or any other patent holder) in respect of any SEP. Of the two patents from TQ Delta's portfolio now litigated in the UK, infringement of '268 had been established. ZyXEL had "blown hot and cold as to whether they will accept whatever licence is considered by the Court to be RAND" and refused to "agree to submit to the outcome of an appropriate [RAND] determination". Yet ZyXEL had claimed the benefit of the RAND undertaking.

Henry Carr J held that this was a case of "hold-out" by ZyXEL. It was the first finding of hold-out by a court in the UK.

Second, the judge awarded immediately effective injunctive relief.

ZyXEL had submitted that granting an injunction at the present stage, with three months remaining on the term of the patent, would be disproportionate because ZyXEL would not know the terms of any RAND licence which it could or could not accept. However the judge said that refusing an injunction would ([13]-[14]):

"...enable ZyXEL to benefit from their strategy of hold-out, including their refusal to submit to the outcome of an appropriate RAND determination, whilst still seeking to benefit from the RAND undertaking. ZyXEL would avoid an injunction, and if the terms of a RAND licence are not as they wish, could refuse to enter into a licence on the terms deemed appropriate by the Court.

...to deprive the patentee of injunctive relief in these circumstances would be unjust. It would, in effect, amount to a compulsory licence by the court in circumstances where the Defendants have elected not to enforce the RAND undertaking in respect of the '268 patent. This, in my judgment, would be wrong in principle."

The judge also refused ZyXEL's requests that any injunctive relief should be stayed for a month and that there be a carve-out from the injunction to allow certain orders to be fulfilled. The former request was rejected because there was no evidential basis for it; the latter because while the "primary thrust" of ZyXEL's evidence was that if they could not fulfil three orders their customers would be inconvenienced, there was no evidence from any of the relevant customers on this, the relevant contracts had not been disclosed and significant unquantifiable prejudice was not really suggested.

Evalve v Edwards (3 May 2019)⁷⁷ concerned the claimants' application for an interim injunction to restrain Edwards from marketing its alleged infringing PASCAL product. Edwards' PASCAL product was a medical device for treating mitral regurgitation, a life-threatening condition in which the mitral valve of the heart ceases to function properly. The PASCAL would be implanted in the mitral valve via a catheter, by a procedure known as transcatheter mitral valve repair (TMVr).

⁷⁷ *Evalve Inc & Ors v Edwards Lifesciences Ltd* [2019] EWHC 1158 (Pat) (3 May 2019) Henry Carr J

The claimants (collectively, 'Abbott') had developed a transcatheter mitral valve repair product, known as the "MitraClip". The MitraClip was described by the judge as a very important medical advance, which had proved to be a life-saver. Abbott's device was not presently funded by the NHS and so UK sales were small, but a reimbursement decision was expected.

Abbott's application for expedition had been granted by Arnold J in March 2019, with the trial listed to take place in December 2019. In its submissions in support of an expedited trial, Abbott had recognised that expedition would have the effect of ameliorating the damage done to the losing party to the interim injunction application. Nevertheless, Abbott sought the interim injunction.

In the course of the hearing of Abbott's application, Edwards submitted that it was prepared to offer an undertaking, until judgment or further order, only to arrange for the implantation of PASCAL devices in ten patients in two hospitals in the UK, subject to a liberty to apply to discharge or vary the undertaking, for example, if reimbursement was granted sooner than was currently expected.

On the principles governing the award of interim injunctive relief, Henry Carr J cited (of course) the leading authority, *American Cyanamid v Ethicon*⁷⁸, as well as a more recent Privy Council judgment in *National Commercial Bank Jamaica v Olint*⁷⁹, in which Lord Hoffmann said ([16]-[17]):

"...As the House of Lords pointed out in *American Cyanamid*... if damages will be an adequate remedy for the plaintiff, there are no grounds for interference with the defendant's freedom of action by the grant of an injunction. Likewise, if there is a serious issue to be tried and the plaintiff could be prejudiced by the acts or omissions of the defendant pending trial and the cross-undertaking in damages would provide the defendant with an adequate remedy if it turns out that his freedom of action should not have been restrained, then an injunction should ordinarily be granted.

17. In practice, however, it is often hard to tell whether either damages or the cross-undertaking will be an adequate remedy and the court has to engage in trying to predict whether granting or withholding an injunction is more or less likely to cause irreparable prejudice (and to what extent) if it turns out that the injunction should not have been granted or withheld, as the case may be. The basic principle is that the court should take whichever course seems likely to cause the least irreparable prejudice to one party or the other..."

Edwards had accepted that there was a serious issue to be tried. However, the judge concluded that Abbott had not satisfied the hurdle of establishing that it would suffer irreparable or unquantifiable harm if the interim injunction sought were not granted. Key factors underpinning this conclusion were:

- The undertaking offered by Edwards, in the context of which the judge was unimpressed by Abbott's arguments about risks of damage from possible cross-selling by Edwards, possible reputational damage to Abbott if an injunction was awarded following trial and a need for retraining of clinicians in respect of Abbott's device.
- Arguments about Edwards' alleged failure to clear the way during the course of its development of PASCAL were not relevant to the assessment of irreparable or unquantifiable harm contended to be suffered by Abbott. As per *SKB v Apotex*⁸⁰ and

⁷⁸ *American Cyanamid Co v Ethicon Ltd* [1975] AC 396

⁷⁹ *National Commercial Bank Jamaica Limited v Olint Corporation Limited* [2009] UKPC 16

⁸⁰ *Smithkline Beecham plc & Anr v Apotex Europe Limited* [2003] EWCA Civ 137

*Warner-Lambert v Actavis*⁸¹, this was a material factor in cases where irreparable harm to both parties was evenly balanced.

In case he was wrong on this (such that the hurdle of irreparable harm to Abbott was met), the judge considered whether Edwards would suffer irreparable harm if an interim injunction was granted but Edwards was subsequently successful at trial. He noted Edwards' evidence that in the context of an expected decision on reimbursement, Edwards needed to have the opportunity to familiarise and train at least some UK clinicians with PASCAL, and to take any necessary associated administrative steps, if it was to be able to compete with Abbott at the outset following the reimbursement decision. If Edwards could not reach this position, it would not be possible, accurately, to look at its subsequent sales to estimate how many sales would have been made if it had been competing at the outset. By contrast, there would be no such difficulty if the injunction was refused, because Edwards had accepted that every sale of a PASCAL was a lost sale of a MitraClip. Edwards had therefore established that it would suffer irreparable harm if the injunction was granted.

Arrow declarations

As noted above, an *Arrow* declaration is a declaration that the applicant's own product or process, or aspects of it, were known or obvious at a particular relevant date. The award of such a declaration provides a shield against a future claim of patent infringement: if the product or process (or aspects thereof) was known or obvious at the priority date of any patent relied upon then no claim can be both valid and infringed. The full usefulness of the remedy and the full reach of the underlying *Gillette* defence have yet to be tested in the context of the doctrine of equivalents and the validity gap that appears to have arisen since *Actavis v Eli Lilly*⁸². Nevertheless, *Arrow* declarations are a powerful weapon for litigants seeking to clear the way through a patent thicket.

Since the first award of an *Arrow* declaration, by Henry Carr J in *Fujifilm v AbbVie*⁸³, the Patents Court has been asked to award this remedy in three further cases. In *Generics v Yeda*⁸⁴, Arnold J refused the award, making clear that the existence of pending divisional applications was not sufficient for the "useful purpose" requirement to be satisfied. In *GSK v Vectura*⁸⁵, Vectura's unexplained unwillingness to give a full undertaking meant that GSK was potentially at risk of a claim for infringement in future. Arnold J concluded that granting an *Arrow* declaration avoided the risk that findings as to the obviousness of GSK's products (i.e. its successful *Gillette* case) might subsequently be interpreted as *obiter* (in view of the judge's findings of non-infringement and sufficiency).

This year, a question of whether to award *Arrow* relief was considered by Birss J in *Pfizer v Roche*⁸⁶. Pfizer sought the award in respect of its bevacizumab medicine, marketed under the brand name Avastin. Roche's SPC protection for bevacizumab itself would expire in June 2020. However, patent filings in respect of medical use were such that some indications for which Avastin was authorised might remain under patent protection for longer – in particular for breast and ovarian cancer.

Pfizer sought *Arrow* declarations from the English court in respect of three patent families. After Pfizer commenced the proceedings, Roche de-designated the UK from filings in the three patent families, which otherwise remained pending in the EPO at the date of the trial. By this time, the filing position

⁸¹ *Warner-Lambert Company, LLC v Actavis Group PTC EHF & Ors* [2015] EWHC 72 (Pat)

⁸² *Actavis UK Limited & Ors v Eli Lilly and Company* [2017] UKSC 48

⁸³ *Fujifilm Kyowa Kirin Biologics Company Limited & Ors v AbbVie Biotechnology Limited* [2017] EWHC 395 (Pat)

⁸⁴ *Generics (UK) Limited (t/a Mylan) v Yeda Research and Development Company Limited* [2017] EWHC 2629 (Pat)

⁸⁵ *Glaxo Group Limited & Ors v Vectura Limited* [2018] EWHC 3414 (Pat)

⁸⁶ *Pfizer Limited v F. Hoffmann-La Roche AG & Anr* [2019] EWHC 1520 (Pat) (20 June 2019) Birss J

was such that Roche could not obtain patents in the UK from any of the three patent families. Nevertheless, Pfizer continued to seek, and Roche continued to resist, the declaratory relief. Pfizer's evidence was that it would be impractical to launch in different European states with different labels, for example by launching in the UK with a full label but using a skinny label elsewhere.

On the law as to declaratory relief, the judge drew upon both *Arrow* declaration case law and case law on declaratory relief more generally. He noted that when considering whether to grant a declaration or not, the court should take into account justice to the claimant, justice to the defendant, whether the declaration would serve a useful purpose and whether there are any other special reasons why or why not the court should grant the declaration⁸⁷. When deciding whether the declaration would serve a *useful* purpose, the approach is pragmatic, a matter of discretion not jurisdiction⁸⁸. There must, in general, be a real and present dispute between the parties as to the existence or extent of a legal right between them but the claimant does not need to have a present cause of action against the defendant⁸⁹.

Birss J said that the above referenced judgments and (with one arguable exception) the cases on *Arrow* jurisdiction were all concerned with the existence or scope of legal rights, public or private. For the purposes of declaratory relief, the existence and scope of a legal right can include a legal right which someone claims might come into existence in the future.

FKB v AbbVie arguably represented the exception because by the time the case reached trial the patentee had abandoned UK patent protection and was offering undertakings that it would not obtain UK patent protection of the relevant scope. However, the undertakings were long and complicated. In circumstances in which the patentee had claimed it had or would have legal rights in the UK and had generated significant commercial uncertainty, including by making threats, Henry Carr J had thought the undertakings offered failed to provide clarity for third parties in the UK. He had therefore considered that there was a useful purpose in awarding *Arrow* relief.

Stepping back in the *Pfizer v Roche* case, Birss J said ([82]):

"...there is no general threshold jurisdictional requirement that the defendant must actually have some kind of legal right in the first place, before the court's wide declaratory jurisdiction can be exercised. After all the declaration sought can be one that the defendant has no right at all."

Turning to the application of the principles, the judge noted that in the present case, the court could readily grant a simple declaration that Roche had no right arising from the defined patent families to prevent importation etc into the UK of the relevant products. This was true because of Pfizer's designation of the UK. However this was not what Pfizer sought (nor what Roche was resisting).

The declarations sought by Pfizer were in the form that importation etc into the UK of Pfizer's bevacizumab product for use in a particular indication would have been anticipated or obvious at the earliest priority date for any member of the relevant patent family. The true purpose of Pfizer seeking

⁸⁷ *Financial Services Authority v Rourke* [2001] EWHC 704 (Ch)

⁸⁸ *Messier-Dowty Ltd & Anr v Sabena SA & Ors* [2000] EWCA Civ 48

⁸⁹ *Rolls Royce Plc v Unite the Union* [2009] EWCA Civ 387, Aitken LJ (dissenting), approved in *Milebush Properties Limited v Tameside Metropolitan Borough Council* [2011] EWCA Civ 270 but with a caveat that this was expressed too narrowly because the dispute could relate to rights which might come into existence in future

declaratory relief in this form was to obtain a reasoned judgment on issues of validity for use in foreign jurisdictions. Belgium was discussed in particular because Pfizer planned to supply the UK market from Belgium and contended that a reasoned UK judgment finding invalidity would assist it in resisting interim injunctive relief in Belgium.

On the merits of the arguments of anticipation and obviousness, the judge noted that by the relevant priority date for each relevant patent family, bevacizumab was known as a treatment with a different mechanism of action from other standard chemotherapy treatments. Further clinical trials were underway or already reported on the efficacy of using bevacizumab with some established standard chemotherapy combinations to treat breast cancer and ovarian cancer. Accordingly, there was "an apparently strong case" that it would have been obvious to combine bevacizumab with the other standard chemotherapy combinations and that a skilled person would have had reasonable prospects of success in providing improved efficacy in that way. This presented a compelling case in favour of a *Gillette* defence.

Birss J said that it was helpful to note the apparent merit of Pfizer's technical case because it could help to explain the motives of the patentee in the management of its filings: "A patentee with faith in its case on the merits would be unlikely to engage in shielding" (i.e. behaviour intended to shield its portfolio from the risk of an adverse decision).

Roche's conduct in respect of its patent filings, the judge said, amounted to shielding. There was no other rational explanation for de-designating the UK. Aborting an appeal from the Examining Division's refusal to grant, and instead filing a divisional at a particular time, was also shielding. While Roche's prosecution practice might be standard industry practice and not unusual, nor unlawful, this did not mean that patentees ought to do these sorts of things. Roche was entitled to try to get a valid patent. However, objectively, its conduct gave rise to significant uncertainty for its competitors as Roche knew "perfectly well".

Roche had also studiously avoided engaging with Pfizer's case on the questions of the anticipation and obviousness of bevacizumab combinations for the relevant cancer indications in the present proceedings, for example by not cross-examining Pfizer's experts. There was one notable exception to this: Roche advanced a case that the relevant priority date for any UK *Arrow* declaration ought to be the filing date of the applications concerned and not their earlier claimed priorities. On this the judge said ([92]):

"However Roche does not really mean that the true priority date of any of these inventions is the filing date. Once exposed, it is obvious that the only purpose of this argument is to seek to limit the damage which might be done in a foreign court by any *Arrow* declaration here by allowing Roche to say in the foreign court that the true priority dates are the earlier claimed dates whereas the *Arrow* declaration was only concerned with a later date."

Roche's failure to engage with the technical evidence was therefore "not based on some high principle" but rather Roche simply seeking to do everything it could to minimise the utility to Pfizer of any relief Pfizer could obtain in this jurisdiction, part of that strategy being to characterise any technical decision here as uncontested.

Following all the above, the judge said that an *Arrow* declaration would therefore be of real commercial value to Pfizer, reducing uncertainty all over Europe and assisting Pfizer in reaching its decision as to whether to launch with a full or skinny label.

However, there was now a complete absence of the possibility of UK rights in the future. The remaining uncertainty relating to the UK market derived from the fact that the goods were to be supplied from a separate jurisdiction (Belgium) in which the uncertainty remained. The true purpose of the declaration sought was therefore its use in foreign courts, in particular Belgium. In the judge's view, this was not enough to satisfy the 'useful purpose' requirement.

The judge distinguished *FKB v AbbVie* on the basis that in that case, there remained outstanding uncertainty about UK rights.

This is a really interesting judgment from Birss J. He seems to be saying that if the patentee has completely de-designated the UK, leaving no uncertainty about the legal position in this jurisdiction, the court will in practice be reticent about awarding an *Arrow* declaration. However, the court would still have jurisdiction to do so, and obtuseness or threatening behaviour intended to leave commercial uncertainty in the UK may still provide the hook for 'useful purpose' and the award of *Arrow* relief.

Perhaps just as importantly for Pfizer in this case, the judge's easily digestible *prima facie* observations that Pfizer had a strong case on obviousness, supported by his observations that Roche's shielding did not reflect what a patentee with faith in its case on the merits would do, might in practice be just as useful to Pfizer in other jurisdictions as a full reasoned judgment on the merits from the English court.

What can patentees do to avoid an intervention of this nature by the English court?

The answer can be gleaned from the case law. A patentee facing a potential request for *Arrow* relief can make a very fast de-designation of the UK, give full and wide undertakings, say nothing to generate commercial uncertainty anywhere, and seek to obtain a strike out despite the Court of Appeal's ruling in the *Glaxo v Vectura*⁹⁰ case that it is the position at trial that counts. Getting a strike out may well require an interim visit to the Supreme Court.

Quantum

Henry Carr J's judgment in *Napp v Dr Reddy's*⁹¹ arose from a dispute that was heard very quickly by the Patents Court and the Court of Appeal in 2016⁹². In the course of the dispute, Napp gave a cross-undertaking for damages in respect of an interim injunction.

The duration of the interim injunction was approximately six months. It was discharged by the Court of Appeal upon its confirmation of the judge's conclusion that Napp's claim of infringement failed. The damages inquiry was now underway, with Sandoz claiming more than £100 million under the cross-undertaking. The second defendant, Sandoz, supported by purported additional applicants (Hexal AG, Salutas Pharma GmbH and Sandoz AG), now sought to fortify Napp's cross-undertaking.

First, the judge considered the jurisdiction of the court to grant a fortification of the cross-undertaking in damages in circumstances where the injunction had been discharged. Drawing upon *Injunctions*, 13th edition, by Sir David Bean, and the authorities cited within it, Henry Carr J concluded as follows ([10]):

⁹⁰ *Glaxo Group Limited & Ors v Vectura Limited* [2018] EWCA Civ 1496

⁹¹ *Napp Pharmaceutical Holdings Limited v Dr Reddy's Laboratories (UK) Limited & Ors* [2019] EWHC 1009 (Pat) (15 April 2019) Henry Carr J

⁹² *Napp Pharmaceutical Holdings Ltd v Dr Reddy's Laboratories (UK) Ltd & Anor* [2016] EWHC 1517 (Pat); [2016] EWCA Civ 1053

"...The starting point is that the court has no power to order a party to give a cross-undertaking in damages. A cross-undertaking in damages is the price that a claimant is willing to pay in return for the grant of an injunction. Once the injunction has been discharged, there is no price that is worth paying because the claimant is not asking for the injunction to continue. In my view, it follows that an application for fortification of a cross-undertaking needs to be made whilst the injunction in respect of which it is given is continuing. This is not inequitable, since the court will not order security for damages, and fortification of the cross-undertaking does not amount to such an order. As Popplewell J said in *Thai-Lao Lignite* (supra), "[r]equiring fortification is an adjunct to the undertaking offered by a claimant, and is only 'required' in the sense of being the price which the claimant will have to pay if he wants his order to operate in futuro." It follows that there is no jurisdiction to grant this application."

However, in case he was wrong about this, the judge then considered whether it would be appropriate to grant the relief sought on the facts of the case. He noted that it was necessary for Sandoz to establish a good arguable case in respect of whatever damages it was seeking fortification for. The judge's view was that Sandoz had no more than a good arguable case for the sums which had already been set aside in Sandoz's latest accounts - £14 million in damages and £5 million in costs. There was no material risk that Napp's assets would drop below a figure which it was obviously able to pay; its net assets were far in excess of that figure. Dismissing Sandoz' submissions about the financial position of Napp in view of its links with the Sackler family, the judge said that it was very healthy and had steadily improved since the injunction was granted.

Accordingly, the judge said that if he had considered that the court had jurisdiction to grant Sandoz' application, he would have dismissed it in the exercise of his discretion on the facts.

It is fundamental that the patentee's representatives consider at the outset of the case where the profits from infringing activities may flow and how the appropriate entities (on both sides) should be joined to ensure the maximum monetary relief. It is no surprise that the representatives of a recipient of a cross-undertaking in damages should do likewise.

On the other hand, in some cases, a patentee has been able to bring in further alleged infringements at the quantum stage. This year, an example of this happening arose in ***Rhodia v Neo***⁹³.

The claimants' (Anan Kasei Co. Ltd and Rhodia Operations S.A.S. – "Rhodia") patent to "a ceric oxide consisting essentially of a ceric oxide..." was confirmed by the Court of Appeal as valid.

The Court of Appeal then considered issues arising in a side dispute about whether Rhodia should be permitted to join the first defendant's (Neo UK's) parent company (Neo Performance Materials Inc - "Neo Canada") in order to hold it responsible for any damages awarded against Neo UK. Rhodia's application to join Neo Canada was made after the first instance finding that Rhodia's patent was valid and infringed and after an inquiry had been ordered.

Rhodia sought to join Neo Canada on the basis that:

- 1) Neo Canada was a joint tortfeasor (as a result of a 'common design') with Neo UK from the point it became Neo UK's patent ("the Neo Canada period"), and

⁹³ *Anan Kasei Co. Inc & Anr v Neo Chemicals and Oxides Limited* [2019] EWCA Civ 1646 (9 October 2019) Lewison, Floyd, Peter Jackson LJ

- 2) Neo Canada had acquired the liabilities of Neo UK's previous parent company "Neo Cayman" for the "Neo Cayman period", in respect of which Neo Cayman had been liable as a joint tortfeasor with Neo UK.

On the issue of joinder, the Court of Appeal was the third instance. Deputy judge Mr Nicholas Caddick QC and HHJ Hacon had reached slightly different conclusions on whether, and to what extent, to permit Rhodia's application. In the Court of Appeal, the issue was addressed by Floyd LJ.

Floyd LJ noted that the question, in respect of both the periods of time for which joinder was sought, was whether there was a triable issue.

On the principles, Floyd LJ noted *MCA Records v Charly Records*⁹⁴: if all that a director is doing is carrying out the duties entrusted to him as such by the company under its constitution, the circumstances in which it would be right to hold him liable as a joint tortfeasor with the company would be rare; but if, in relation to the wrongful acts which are the subject of complaint, the liability of the individual as a joint tortfeasor with the company arises from his participation or involvement in ways which go beyond the exercise of constitutional control, then there is no reason why the individual should escape liability because he could have procured those same acts through the exercise of constitutional control.

In the present case, the evidence was that the Neo group operated globally and that separate "segments" of the group operated across territorial and corporate boundaries. As such, staff from other group entities may have been involved in Neo UK's activities. Only seven people worked for Neo UK. Floyd LJ said that while the precise role of the relevant cross-group segment was not crystal clear, it was a reasonable inference that the running of it involved control of Neo UK by the parent company at executive level. The evidence supported this inference in respect of the Neo Canada period, and it was reasonable to infer, at least to the level necessary to allow the claim to continue, that the arrangements were the same in relation to the Neo Cayman period.

As for the issue of transfer of liability from Neo Cayman to Neo Canada, to an English lawyer's eyes, the language of an "Arrangement" entered into under Chapter 11 of Title 11 of the US Bankruptcy Code, pursuant to which Neo Canada acquired ownership of Neo Cayman, suggested a court-approved scheme of arrangement. One would expect such a scheme to have provided for protection of the interests of creditors, both actual and contingent. Accordingly, it was at least arguable that Neo Canada would have been obliged to protect the interests of creditors, including Rhodia. The fact it was a court-approved scheme of arrangement was confirmed by other material. It was therefore arguable that Neo Canada had assumed the liabilities of Neo Cayman.

It was also common ground that there was a triable issue that Neo Canada was liable as a joint tortfeasor with Neo UK, in respect of two shipments of cerium oxide seized by UK Border Force after the litigation had commenced.

Floyd LJ then explained why it was wrong in principle to hold at this stage of proceedings that the alleged common design extended to particular seized shipments and no further. In the absence of any positive case from Neo, the existence of a wider common design, covering all Neo UK's acts of infringement, was plainly arguable. CPR Part 63 (practice direction) prevents patent proceedings becoming over-complicated by numerous factual allegations of infringement by requiring the patentee only to prove examples of each "type of infringement". The trial then proceeds by reference to the

⁹⁴ *MCA Records Inc & Anr v Charly Records Limited* [2001] EWCA Civ 1441

exemplary infringements alleged, and can focus on whether the accused product or process infringes the claim. This approach means that liability and quantum are invariably split in patent infringement cases, enabling a long and complicated financial inquiry to be avoided if the patent is invalid or not infringed. Further, experience shows that once liability is established, the inquiry can be settled.

Accordingly, as triable issues had been established across the full width of the joinder sought by Rhodia, the inquiry would not be limited to the acts in relation to the seized goods. Rhodia succeeded on both its procedural appeals.

Costs

In December 2018, in *GSK v Vectura*⁹⁵, GSK was awarded an *Arrow* declaration in respect of its dry powder inhalers marketed under the trade mark Ellipta. In 2019, Arnold J handed down his subsequent costs judgment (*GSK v Vectura*⁹⁶), concluding that GSK should recover 90% of their costs, 10% being deducted for issues of construction, obviousness, disclosure and confidentiality, on which GSK had not succeeded.

Another notable costs judgment this year was in *Conversant v Huawei (14 November 2019)*⁹⁷. Earlier in the year, Arnold J had concluded that Conversant's asserted SEP (as sought to be amended) was invalid for added matter but would have been infringed – this all being subject to the defendants' challenge to the jurisdiction of the court which remained pending in the Supreme Court.

It was common ground that the overall winners were the defendants. However, the defendants had relied upon no less than twenty separate points to contend that the patent was either invalid or not infringed. Of those twenty points, the defendants lost on nineteen and won on only one. Further, the judge considered that the defendants had presented their case in a way that was unsatisfactory and unreasonable. For example, they had put forward points unsupported by their own expert, arguments presented as one thing but which amounted to something else, and barely coherent arguments.

Further still, Conversant's patent as granted had faced an added matter difficulty. Conversant did not actively defend the claim as granted but sought amendment to cure the difficulty. The added matter challenge was a very narrow, self-contained, discrete point, essentially a point of law which had involved no expert evidence. So the point the defendants succeeded on could have been argued in half a day. And the point was not so clear that Conversant should have given up – although the judge had found in favour of the defendants, he had given Conversant permission to appeal.

In these circumstances, Arnold LJ considered the defendants' submissions they should recover the entirety of their costs to be "preposterous". Instead he awarded Conversant 70% of their costs, of which he ordered an interim payment of 60%.

e) Threats

No judgments have emerged from the courts in 2019 adjudicating on an allegation of making a threat of patent infringement proceedings.

⁹⁵ *Glaxo Group Limited & Ors v Vectura Limited* [2018] EWHC 3414 (Pat)

⁹⁶ *Glaxo Group Limited & Ors v Vectura Limited* [2019] EWHC 216 (Pat) (6 February 2019) Arnold J

⁹⁷ *Conversant Wireless Licensing SARL v Huawei Technologies Co Ltd & Ors* [2019] EWHC 3130 (Pat) (14 November 2019) Arnold LJ

f) FRAND

In 2018, in *Unwired Planet v Huawei*⁹⁸, the Court of Appeal almost completely confirmed Birss J's ground-breaking judgments⁹⁹ in the case the previous year. Following a finding of infringement of a standard essential patent (SEP), Birss J had awarded a new form of injunctive relief, which he called a "FRAND injunction". This was an injunction to restrain infringement of the UK patent found to have been infringed, which would be enforceable unless the implementer entered into a licence on FRAND terms as settled by the Court. The FRAND terms settled by Birss J in the *Unwired Planet* case were global. And in fact Birss J stayed the FRAND injunction pending appeal. Nevertheless, a path for resolution of SEP/FRAND disputes in the UK courts had been laid down.

2018 also saw challenges to the jurisdiction of the court in SEP/FRAND litigation commenced by Conversant against Huawei and ZTE. The challenges were rejected by Henry Carr J in 2018¹⁰⁰; and the appeals were dismissed by the Court of Appeal in January 2019 (*Huawei v Conversant*¹⁰¹).

The issues before the Court of Appeal in *Huawei v Conversant* were of justiciability and *forum non conveniens*. The former was foreclosed by the Court of Appeal's judgment in *Unwired Planet v Huawei*, so the reasoning addressed the latter.

Floyd LJ noted the three hurdles to be overcome in order for a party to obtain permission to serve proceedings out of the jurisdiction (as was required in respect of the non-UK defendants), namely that:

1. the claim comes within one of the gateways within CPR 6 PDB
2. there is a serious issue to be tried, and
3. England and Wales is the proper place to bring the claim.

The only hurdle in issue in the Court of Appeal was the third. As per Lord Goff in *Spiliada v Cansulex*¹⁰², in 'service out' cases, permission is not to be given unless the court is satisfied that England and Wales is the proper place in which to bring the claim. A stay will only be granted on the ground of *forum non conveniens* when the court is satisfied that there is some other available forum, having competent jurisdiction, which is the appropriate forum for the trial of the action or dispute.

Floyd LJ emphasised that in identifying the forum in which the case can suitably be tried for the interests of all parties and the ends of justice, it is important to recognise that the "case" is not restricted to an analysis of the claim and relief sought by the claimant. The case must be characterised in a way that does not risk pre-judging the analysis of where the appropriate forum lies. A critical question was therefore how to properly characterise the dispute.

Essentially, Huawei and ZTE contended for a broad characterisation: that it was a claim for enforcement of a global portfolio right in the context of which Conversant was choosing to enforce a "local" patent in a jurisdiction representing a very small proportion of the overall dispute, the more appropriate resolution of which was in China.

⁹⁸ *Unwired Planet International Limited & Anr v Huawei Technologies (UK) Co Ltd* [2018] EWCA Civ 2344

⁹⁹ *Unwired Planet International Ltd v Huawei Technologies Co Ltd & Ors* [2017] EWHC 711 (Pat) and [2017] EWHC 2988 (Pat); *Unwired Planet International Ltd v Huawei Technologies Co Ltd & Ors* [2017] EWHC 1304 (Pat)

¹⁰⁰ *Conversant Wireless Licensing s.a.r.l. v Huawei Technologies Co. Ltd & Ors* [2018] EWHC 808 (Pat)

¹⁰¹ *Huawei Technologies Co., Ltd & Ors v Conversant Wireless Licensing SARL* [2019] EWCA Civ 38 (30 January 2019) Patten, Floyds & Flaux LL

¹⁰² *Spiliada Maritime Corp v. Cansulex Ltd* [1987] AC 460

Floyd LJ did not accept this characterisation, which, he said, suggested that it was a matter of indifference to Conversant which national patents they sued upon. He said that the defendants' approach would compel Conversant to seek a remedy in China based on different patents (with different prior art) and different acts of infringement (involving different technical issues). It was "impossible" to view this as the same dispute as that in the English court.

Noting that Conversant's claim in the present case was closely analogous to the claim advanced in the *Unwired Planet* case, Floyd LJ instead described it as follows ([99]):

"It is (i) that the UK patents are essential to the standard, (ii) that it has complied with its ETSI undertaking, in that the offers which it has made are FRAND, (iii) that Huawei and ZTE have not so complied without any reasonable ground for so doing, and (iv) that it is therefore entitled to enforce its UK SEPs and obtain the usual relief for infringement, including a FRAND injunction and damages. Conversant also seeks a determination as to the terms which are FRAND for the licensing of its portfolio. Huawei's and ZTE's answer is likely to be (i) that Conversant's patents are neither essential nor valid, and (ii) that Conversant has not complied with its FRAND undertaking and so is not entitled to an injunction even if it establishes that its UK patents are valid and essential. The content of Conversant's FRAND undertaking is thus an inseparable part of the dispute about whether Conversant is entitled to relief for infringement of valid UK patents."

Agreeing with the judge's characterisation of the case, Floyd LJ thought that the *forum non conveniens* question answered itself: the fact that the dispute concerned UK patents was a matter of substance and not form. The UK was not just the most appropriate forum, but also the only possible forum for the dispute to be tried.

The fact that the two UK defendants were domiciled in the jurisdiction meant that the court could not decline jurisdiction against them unless the case presented an exception to *Owusu v Jackson*¹⁰³, in which the CJEU held that an English court could not apply the doctrine of *forum non conveniens* to decline jurisdiction over a claim against a person domiciled in a contracting state on the ground that the natural forum for the claims was the courts of a non-contracting state. Further, in evaluating the arguments, it was necessary to be alert to artificial attempts to anchor proceedings against a foreign defendant in this country when the true connection of the case was with some other jurisdiction, and the proceedings against the UK company had no substantial purpose in their own right¹⁰⁴.

However, Floyd LJ did not accept that that was what was happening in the present case, in which Conversant sought relief for infringement of its UK SEPs. It followed that the judge was right that the case would have to continue against Huawei UK and ZTE UK in any event, and he could not be criticised for relying on that fact in his *forum non conveniens* assessment.

Since the first instance judgment, Guidelines had been issued by the Guangdong High People's Court "on Adjudicating Cases of Disputes Over Standard-Essential Patents (Trial)". The defendants sought to adduce further evidence in relation to them. For **Huawei**, Alexander Layton QC argued that the Guidelines made it plain that the Chinese court would entertain a dispute as to the terms of a global FRAND licence even where the other side did not consent, and including where necessary determining infringement and essentiality of foreign patents. For **ZTE**, Michael Bloch QC submitted that it was unrealistic to imagine that the Chinese courts are going to decline to determine global

¹⁰³ *Owusu v Jackson* [2005] QB 801

¹⁰⁴ *OJSC Oil Company Yugraneft v Abramovich & Ors* [2008] EWHC 2613 (Comm); *American Motorists Insurance Co (Amico) v Cellstar* [2003] EWCA Civ 206; *Microsoft Mobile OY (Ltd) v Sony Europe Limited & Ors* [2017] EWHC 374 (Ch)

licences in a world in which other courts are determining global licences. Whatever the Chinese courts might have done before other courts started to determine global licences, the Chinese courts are hardly going to cede the matter to foreigners on a blanket basis. The Court noted the following about Huawei's submissions in the *Unwired Planet* case in respect of the same Guidelines ([124]-[125]):

"The court raised with Huawei's counsel how its contentions in this case as to the state of Chinese law related to Huawei's case in *Unwired CA* which contended that the English court was out of step with other courts, including the courts in China, in being prepared to determine a global FRAND rate. We were subsequently provided with a copy of a letter sent by Huawei's counsel in the *Unwired* case in connection with its petition for leave to appeal to the Supreme Court. The letter refers to paragraph 16 of the Guidelines and continues:

"The Guidelines provide guidance on how Chinese courts determine disputes related to SEPs, but they have not been construed or applied in any case in China to date. Huawei understands them to indicate that a global royalty-setting exercise may proceed with the consent of the parties (which has never been in dispute in these proceedings). There is no decided case in which the Chinese courts have gone further, as the English courts did in these proceedings, by conducting a global royalty-setting exercise without the consent of the parties and then imposing the result thereof as a condition of avoiding a territorial injunction. Whether they might do so in the future remains unknown to Huawei and the Chinese courts may well be influenced by the approach of the courts in other jurisdictions, which further underlines the importance of this case."

I think this passage realistically states the effect of the Guidelines. In the end therefore, I do not think the further evidence materially advances the appellants' case. It raises as many questions as it answers."

Consequently, while the Court of Appeal accepted that the Guidelines could not have been available for the trial (hence the first *Ladd v Marshall*¹⁰⁵ criterion was met), the court was not satisfied that the new evidence assisted the defendants on the correct characterisation of the dispute. Nor did passages of a judgment of the Shenzhen Intermediate Court in *Huawei v Samsung*, saying that it indicated that a Chinese court can preside over a global licensing dispute.

Consequently the appeal on *forum non conveniens* was dismissed.

In October 2019, the UK Supreme Court heard the joined appeals in the *Unwired Planet* and *Conversant* cases. The arguments reflected the divergent views on the appropriate resolution of SEP/FRAND disputes. Very briefly -

On the one hand, the SEP owners, *Unwired Planet* and *Conversant*, emphasised the nature of the dispute as one of patent infringement. Following a finding of infringement of a valid patent, in the usual course injunctive relief would be awarded. Qualifying this down to a "FRAND injunction" instead gave the defendant a choice: take the injunction or take the licence on the terms settled by the court. The implementer was not forced to take, or forced into, the FRAND licence.

On the other hand, the implementers argued that what the SEP owners were really seeking from the English court was a global determination or imposition of a FRAND licence, and this was not a matter that was appropriate for determination by the English court, at all (as argued by Huawei) or on the

¹⁰⁵ *Ladd v Marshall* [1954] 1 WLR 1489

relevant facts of the dispute before the English court (as argued by ZTE). Huawei's position was that the effect of the SEP owner's undertaking to offer licences on FRAND terms was to mean that injunctive relief should not be awarded to restrain infringement of a SEP. The implementers characterised the SEP owners' cases as using a UK patent as a hook with which to establish jurisdiction in respect of a distinct issue – the setting of FRAND licence terms.

The Supreme Court's judgment is expected in early 2020.

In the meantime, there has been a notable increase in SEP/FRAND cases filed in the Patents Court. 2019 saw twenty-three judgments (mostly interim) emerging in nine different SEP/FRAND disputes. On issues of jurisdiction, the court has been following the path laid down so far in the *Conversant* case – see for example *Optis v Apple*¹⁰⁶ and *Mitsubishi v Archos*¹⁰⁷.

In contrast, in *Vestel v HEVC*¹⁰⁸, rather than the claimant being the SEP owner asserting patent infringement, the claimant was an implementer asserting abuse of dominance and seeking relief in the form of a variety of declarations, including as to FRAND terms. Neither of the defendants was domiciled in the UK, and Judge Hacon concluded that the tests under neither the Brussels regime nor the common law gateways were satisfied. The defendants' challenge to the jurisdiction of the English court therefore succeeded.

The case of *IPCom v Lenovo*¹⁰⁹ is worth noting too. One may recall that in the *Conversant* case¹¹⁰ in 2018, Henry Carr J found, in the context of a dispute about costs, that if he had been required to decide *Conversant's* application for an anti-suit injunction against aspects of ZTE's proceedings in the Shenzhen People's Court, he would have granted it. In *IPCom v Lenovo*, the court actually awarded an anti-anti-suit injunction.

IPCom had sued Lenovo and Motorola in the Patents Court for infringement of a patent ('286) said to be essential to the UMTS standard. At the time the proceedings were brought, there were existing proceedings before the District Court for Northern California, whereby associated US companies (of Lenovo and Motorola) were seeking against IPCom an adjudication of appropriate terms of a FRAND licence for the entire IPCom portfolio, including '286. In the English proceedings, Lenovo and Motorola had challenged the validity of '286.

Proceedings similar to the English proceedings had been brought in France against the French Lenovo and Motorola companies.

On 18 September 2019, the US companies brought to the California court an anti-suit motion in respect of the English and French proceedings, *inter alia* seeking to enjoin IPCom from prosecuting the English proceedings. The motion was listed for hearing on 14 November 2019. In response, on 25 October 2019, IPCom brought an application for an anti-anti-suit injunction in the English proceedings, which was listed "without abusing the process in any way" for 8 November 2019. The

¹⁰⁶ *Optis Cellular Technology LLC & Ors v Apple Retail UK Limited & Ors* [2019] EWHC 3538 (17 December 2019) Nugee J

¹⁰⁷ *Mitsubishi Electric Corporation & Anr v Archos SA & Ors* [2019] EWHC 3477 (Pat) (19 December 2019) deputy judge Nicholas Caddick QC

¹⁰⁸ *Vestel Elektronik Sanayi VE Ticaret AS & Anr v HEVC Advance LLC & Anr* [2019] EWHC 2766 (Ch) (21 October 2019) HHJ Hacon

¹⁰⁹ *IPCom GmbH & Co. KG Lenovo Technology (United Kingdom) Limited & Anr* [2019] EWHC 2980 (Pat) (30 October 2019) Norris J; *IPCom GmbH & Co. KG v Lenovo Technology (United Kingdom) Limited & Anr* [2019] EWHC 3030 (Pat) (8 November 2019) HHJ Hacon

¹¹⁰ *Conversant Wireless Licensing SARL v Huawei Technologies Co. Ltd & Ors* [2018] EWHC 2549 (Ch) Henry Carr J

US companies then sought an order in California to expedite their anti-suit motion and have it heard *ex parte*. In England, IPCOM then applied for an interim injunction, addressed to Lenovo UK and Motorola UK, but really aimed at their US affiliates, to restrain the prosecution of the *listing motion* until such time as the English court had, as intended on 8 November 2019, made a ruling on the anti-anti-suit injunction.

Norris J noted that there was no doubt that the English proceedings were properly constituted by parties who both submitted to and asserted the jurisdiction of the English Court, and there was "a great deal of gamesmanship going on". Lenovo UK and Motorola UK had declined to give an undertaking to the English court that they would avail themselves of any licence settled by the Californian court. Absent that undertaking, there were live issues in the English dispute about the validity of '268, whether it had been infringed and if so the consequences. He considered that the propriety of the English court granting an anti-anti-suit injunction should be determined at the 8 November hearing in England, not determined on an *ex parte* expedition application in the United States.

So a temporary anti-anti-suit injunction was awarded, which was then continued by Judge Hacon when the issue returned to the court on 8 November. On the principles, after drawing upon Court of Appeal authorities¹¹¹, Judge Hacon said ([24]):

"...the less that an anti-anti-suit injunction granted in England would interfere with the foreign proceedings to which it is directed, the more likely it is that the court will exercise its discretion to grant such an injunction".

The judge noted that the anti-suit injunction sought by the US Lenovo entities in the US was against the proceedings for infringement and validity of the UK patent (EP '268) in the UK. If successful, it would extinguish the action in the English court and prevent issues of infringement and validity of EP '268 being heard anywhere. The substantive action in the US court did not directly concern those issues but rather the settlement of a global FRAND licence and two US patents.

The effect of the anti-anti-suit injunction sought in the present application would also be more limited than would usually be the case with such an injunction. The UK companies would be prohibited from sanctioning or assisting any application before the US court which would have the effect of restraining the pursuit of the present action. So the order would make it clear to the US court that, contrary to the impression it might otherwise form, the anti-suit injunction sought in the US did not have the approval of the UK companies. It would not prevent the anti-suit motion going ahead in the US or interfere with the substantive proceedings in the US.

An anti-anti suit injunction was granted by the Paris court too, in slightly broader terms.

So the SEP/FRAND arena has been very active in 2019, and the lower courts are clearly waiting for guidance from the Supreme Court confirming, one way or another, the correct approach in the UK.

¹¹¹ *Deutsche Bank AG v Highland Crusader Offshore Partners LP* [2009] EWCA Civ 725 (Toulson LJ) and *Michael Wilson v Emmott* [2018] EWCA Civ 51

3. Validity

a) Common general knowledge (CGK) / the skilled person

The geographical reach

Regen v Estar¹¹² is the case concerning a method for obtaining platelet-rich plasma. There was a dispute about whether a prior art kit called "Cascade" was part of the common general knowledge (CGK). There appeared to have been a greater awareness of the Cascade kit in the United States and Italy than in the UK.

The judge said that he would follow the principle which had emerged from Arnold J's judgment in *Generics v Warner-Lambert*¹¹³, drawing on *Teva v Merck*¹¹⁴, that to count as common general knowledge the matter in question must be shown to have been common general knowledge in the UK. However, he added some commentary of his own ([46]-[49]):

"Section 2(2) of the Patents Act 1977 ('the 1977 Act') must be taken into account. It provides:

"(2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of the invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way."

The state of the art consists of items of information. The skilled person does not consider them with a blank mind. He or she applies to them his or her collective common general knowledge and understands the information accordingly.

The various aspects of the common general knowledge will be entirely contained within the state of the art. An item of information forming part of the state of the art may be sufficiently familiar to the skilled person (by which I include sufficient familiarity with the existence of an item of information which can be routinely consulted) such that it attains the status of being part of his or her common general knowledge. It follows that although the state of the art consists of information made available anywhere in the world, the common general knowledge could vary from place to place, even among the Contracting States of the European Patent Convention, if one starts with the premise that the relevant common general knowledge is that of the skilled person in a particular State. The point is that there is no necessary inconsistency between s.2(2) and a territorial view of common general knowledge.

Such a territorial view implies that a European Patent could be vulnerable to revocation in one Contracting State but not in another solely because of different common general knowledge among persons skilled in the art across Europe. It also implies that the common general knowledge contemplated by the Examining and Opposition Divisions of the EPO is in principle different to the common general knowledge of the skilled person in each Contracting State. I am not aware of any discussion of the topic by the tribunals of the EPO and I need not speculate about what the EPO's perspective may be. Whatever it is, the attributes of the skilled person in national proceedings, including territorial issues, are left to be determined by

¹¹² *Regen Lab SA v Estar Medical Ltd & Ors* [2019] EWHC 63 (Pat) (18 January 2019) HHJ Hacon

¹¹³ *Generics (UK) Ltd & Ors v Warner-Lambert Company LLC & Anr* [2015] EWHC 2548 (Pat)

¹¹⁴ *Teva UK Limited v Merck & Co., Inc* [2009] EWHC 2952 (Pat)

national courts. It would be desirable for the courts of the Contracting States to adopt a similar approach, but I have not seen any observations on this from outside England."

The defendants' expert clinician, Dr O'Connell, accepted that in August 2006 (at the priority date) those skilled in the art in Northern Europe, including the UK, would not have known about the Cascade Kit. Dr Connell had searched for published papers on the Cascade kit and found one, published in June 2006, a paper which neither expert had come across before the proceedings, and which reported poor data.

For good measure, the judge also considered whether the Cascade kit had been CGK elsewhere in August 2006, in particular the US and Italy, and concluded on the evidence that it had not been. The defendants' expert, Dr O'Connell, had been employed by Cascade to promote its kit so he knew about it, but Regen's expert, Dr Marx, had not been aware of it. There was no evidence of the Cascade kit being discussed in a text book or a widely read review paper. US sales had been \$800,000 in 2005 and \$680,000 in the first three months of 2006. The judge concluded that the Cascade kit had not been CGK outside the UK either.

Marflow v Cassellie¹¹⁵ was a case in which the common general knowledge might have been different, had it extended across the English Channel.

Marflow's patent concerned a plate for mounting on a wall, with apertures for receiving and extending water pipes, for use when connecting a fluid-using appliance. The parties agreed that the skilled person was a plumber with experience in fitting showers and/or other fluid-using appliances. Both experts stated that UK plumbers were conservative when it came to practices in the trade, which the judge took to mean that the skilled person would not have had an enthusiasm for abandoning his or her established way of doing things.

The patent referred to a mounting plate said to be commonly used in continental Europe. However, both counsel submitted that only the CGK in the UK was relevant and so the 'Continental Plate' was not CGK in the UK. The case proceeded on this basis and the patent was found to be valid (not obvious).

In ***Adolf Nissen Elektrobau v Horizont***¹¹⁶, a case about road traffic signage boards, the UK-specific identity of the person skilled in the art (and so the CGK too) underpinned the findings of obviousness reached. The difference from the prior art to the claimed invention consisted of conventional aspects of road signage in the UK: the use of a constant (not flashing) red cross was CGK in the UK and the skilled person would have known how to achieve two-colour LEDs which could emit alternative colours.

All of this is, of course, logical in a system where all patent rights are national. However, what happens when rights become supra-national? When Unitary Patents are available how can nationally defined CGK remain relevant? Of course none of that may be of any concern to the UK if, as seems highly likely, we find ourselves outside the UPC/UP systems. However, the question may still arise in other contexts. And what if we do join up? Are we really saying that something which is CGK in the Republic of Ireland would not be CGK in Northern Ireland?

¹¹⁵ *Marflow Engineering Limited v Cassellie Limited* [2019] EWHC 410 (IPEC) (26 February 2019) HHJ Hacon

¹¹⁶ *Adolf Nissen Elektrobau GmbH & Co KG v Horizont Group GmbH* [2019] EWHC 3522 (IPEC) (18 December 2019) HHJ Hacon

The identity of the skilled team

In *Garmin v Philips*¹¹⁷, Henry Carr J gave a comprehensive summary of the legal principles as to the identity of the skilled team, saying ([85]):

"i) A patent specification is addressed to those likely to have a real and practical interest in the subject matter of the invention (which includes making it as well as putting it into practice).

ii) The relevant person or persons must have skill in the art with which the invention described in the patent is concerned. As Aldous LJ stated in *Richardson Vicks Inc's Patent* [1997] RPC 888 at 895:

"Each case will depend upon the description in the patent, but there is no basis in law or logic for including within the concept of "a person skilled in the art", somebody who is not a person directly involved in producing the product described in the patent or in carrying out the process of production."

iii) The skilled addressee has practical knowledge and experience of the field in which the invention is intended to be applied. He/she (hereafter "he") reads the specification with the common general knowledge of persons skilled in the relevant art, and reads it knowing that its purpose is to disclose and claim an invention.

iv) A patent may be addressed to a team of people with different skills. Each such addressee is unimaginative and has no inventive capacity.

v) Although the skilled person/team is a hypothetical construct, its composition and mind-set is founded in reality. As Jacob LJ said in *Schlumberger* at [42]:

"... The combined skills (and mindsets) of real research teams in the art is what matters when one is constructing the notional research team to whom the invention must be obvious if the patent is to be found invalid on this ground."

There was a dispute between Garmin and Philips as to the identity of the skilled person for the purposes of obviousness. Philips alleged that the invention changed the art by combining two previously unrelated fields, of GPS and athletic performance monitors; and that defining the skilled person for the purposes of obviousness by reference to those fields involved impermissible hindsight¹¹⁸. Philips also contended that the skilled team comprised persons skilled in GPS, wearables and exercise physiology but that the rest of the team did not communicate with the GPS specialist.

However, the judge held that the patent was primarily addressed to those practically involved in manufacturing athletic performance monitoring devices (APMDs), who would be able to call on a GPS specialist and a sport exercise physiologist. Further, the evidence was that it was conventional for APMD companies to make more than one type of product.

¹¹⁷ *Garmin (Europe) Limited v Koninklijke Philips NV* [2019] EWHC 107 (Ch) (29 January 2019) Henry Carr J

¹¹⁸ *Schlumberger Holdings Limited v Electromagnetic Geoservices AS* [2010] EWCA Civ 819

The general principles underpinning the identification of the skilled team were looked at also in **Conversant v Apple**¹¹⁹, a case in which Apple's iPhone was alleged to infringe Conversant's patent to a "smart phone".

There was a stark difference between the parties on the identity of the skilled team. Birss J observed that the case was really a dispute about whether the invention concerned mobile phones (whatever that meant) or computers in general or somewhere in between.

Conversant's patent had a priority date in July 2000. It described the invention as relating to a computing device with an improved user interface for applications. The term 'mobile telephone' was defined very widely and included personal digital assistants (PDAs – handheld mobile computer devices such as the Palm Pilot), which was materially wider than the meaning the skilled person would give the term if they had not read the patent.

The judge surmised that the actual invention that the inventor came up with was to address a problem on mobile telephones, because of their small screens. However ([26]):

"...having made their "subjective" invention, the inventor (and no doubt the patent attorneys working for the inventor's employer) recognised that it might have a much wider potential application, to computing devices in general. So the patent is written in the way it is. However today it does not suit the patentee to maintain such a wide claim. Hence the amendment to bring the whole thing back to where it started – ideally to mobile telephones. However even then there is a problem because in a fit of enthusiasm, the term mobile telephone itself was given a very wide definition in the specification. So the patentee has used the rather vague term "smart phone", aiming as it does to catch the well known Apple smart phone product, the iPhone."

Conversant argued that the skilled person was a user interface designer for, and specifically for, mobile phones, by which they meant "true" mobile phones rather than things within the scope of the definition in the patent. Although the patent referred to a broad range of computing devices, the proposed amended claim language was limited to smart phones, and so Conversant argued that it was this language that should be looked at and should guide the identification of the skilled person.

Apple argued that when identifying the skilled person, the patent should be looked at as a whole.

On the principles, Birss J said ([32]-[33]):

"The person skilled in the art is a legal construct used to provide an objective legal standard by which various legal questions can be answered. Nevertheless the court will always have regard to the reality of the position at the time (**Schlumberger v EMGS** [2010] EWCA Civ 819). Apple's case seems to involve a point of principle that the way to identify the skilled person as a matter of law is to look at the field the patent itself locates the invention in and posit a person in that field as the relevant person. The problem with that approach is that one could end up in this case with a person working in the field of (say) PDAs, even though they are no longer within the claims. The point is wrong because a patent is taken to be directed to those with a practical interest in its subject matter (**Catnic v Hill & Smith** [1982] RPC 183). Its subject matter is the invention, and the invention is what is defined in the claims (s125 of the Act). It follows that while it will be unusual, there is nothing wrong in principle for the effect of a

¹¹⁹ *Conversant Wireless Licensing s.a.r.l. v Apple Retail UK Limited & Ors* [2019] EWHC 3266 (Pat) (29 November 2019) Birss J

claim amendment to mean that the notional person skilled in the art relevant to an amended claim may be different from the one applicable to the unamended claim.

Therefore, applying these principles to the facts of this case, for the purpose of assessing the claims as proposed to be amended, the skilled person is someone with a practical interest in smart phones."

So the judge proceeded to adopt a middle ground, holding that the skilled team encompassed people of the types described by both parties' experts. Ultimately, although the skilled team was not as broad as was contended for by Apple, it was broad enough to include as CGK the idea of notifications (about stored data), pop ups, short cuts and/or user summoned shortcut menus, and this was enough to render the patent obvious in light of the 'Simon' prior art.

Multiple skilled persons

In *Eli Lilly v Genentech*¹²⁰, it was common ground that, as proposed to be amended, the patent in issue was addressed to two different, but overlapping, teams of persons skilled in the art. These were a psoriasis team and a rheumatoid arthritis (RA) team.

The psoriasis team consisted of (i) a dermatologist with both clinical experience of, and a research interest in, the treatment of psoriasis and (ii) one or more persons with expertise in antibody engineering. The RA team consisted of (i) an immunologist with both clinical experience of, and a research interest in, the treatment of RA and (ii) one or more persons with expertise in antibody engineering.

On the common general knowledge, the experts agreed that there was a good expectation on the part of the skilled person that blocking IL-17A by administration of an antibody or a soluble receptor would be effective to treat RA. (IL-17A could induce IL-6, IL-8 and G-CSF production by synovial fibroblasts and neutralising IL-17A suppressed arthritis and reduced joint damage in animal models, whereas overexpression of IL-17A worsened inflammation and damage). Of the other members of the IL-17 family, IL-17F had the highest amino acid homology with IL-17A. IL-17F had similar effects to IL-17A but was less potent.

It was also common ground that IL-17 was not considered to be therapeutically relevant to psoriasis in July 2003.

This distinction, between the CGK as to the relevance of IL-17 for psoriasis on the one hand and RA on the other, fed directly into the conclusions on obviousness and insufficiency: the claims concerning RA were obvious; the claims concerning psoriasis were insufficient.

The importance of evidence to support the identity of the skilled person and their CGK

I have discussed above, in section 2(c), the importance of the evidence submitted on the identity of the skilled person and their CGK, by the party challenging the validity of the patent, to the ultimate outcome of the dispute in *Emson v Hozelock*¹²¹.

The judge's conclusion in earlier litigation about the same patent – in which the patent had been found valid - had depended on the identity of the skilled person and what, imbued with their CGK, they would think about prior art called 'McDonald'. Hozelock, in its more recent challenge, duly submitted

¹²⁰ *Eli Lilly and Company & Ors v Genentech Inc* [2019] EWHC 387 (Pat) (1 March 2019) Arnold J

¹²¹ *E. Mishan & Sons, Inc t/a Emson v Hozelock Limited* [2019] EWHC 991 (Pat) (17 April 2019) Nugee J

evidence seeking to reach a different identity for the skilled person and their CGK, and having succeeded in doing so, succeeded also in establishing that Emson's patent was obvious over McDonald.

On the principles as to the identity of the skilled person, Nugee J emphasised the practical interests and knowledge of the skilled person, saying ([35]):

"A patent specification is addressed to those skilled in the art, that is those persons likely to have a practical interest in the subject matter of the invention, and such persons will have practical knowledge and experience of the kind of work in which the invention is intended to be used: *Medimmune Ltd v Novartis Pharmaceuticals UK Ltd* [2012] EWCA Civ 1234 at [72]."

The judge also noted, from *Conor v Angiotech*¹²² that "when assessing the attributes of the skilled person, it is essential to try to reflect, to the extent that the evidence permits, the actual ordinary skills of the real-life contemporaries of the skilled man at the priority date". Further, from *Schlumberger v EGS*¹²³, "the combined skills (and mind-sets) of real research teams in the art is what matters when one is constructing the notional research team".

The judge said that while there was no dispute as to this in principle, there was dispute as to its application to the facts in the present case. In particular, the parties disputed whether the skilled person's experience and knowledge would be limited to garden hoses or would include both garden and other (industrial or technical) hoses.

In the assessment, the judge adopted an approach suggested by Hozelock's counsel, Michael Hicks, of separating the analysis into three stages:

- i) to whom were the patents addressed (this was common ground: a person interested in the design of garden hoses);
- ii) what sort of persons in the real world are designers of garden hoses (this was the key battleground); and
- iii) what common general knowledge do such people have?

The identity of the skilled person and their CGK may determine what has been made available to the public

Moving to the field of antibody glycosylation, in *Takeda v Roche*¹²⁴, Birss J said that the skilled team "would either have sufficient expertise themselves to carry out whatever glycoprotein analysis was required or they would have access to that expertise either directly or by approaching a third party". This meant that the relevant CGK was "very extensive" and included the following ([31]):

- "i) The use of monoclonal antibodies as therapeutic agents;
- ii) How to make antibodies for therapy and for research relating to therapy;

¹²² *Conor Medsystems Inc. v Angiotech Pharmaceuticals Inc & Anr* [2006] EWHC 260 (Pat)

¹²³ *Schlumberger Holdings Limited v Electromagnetic Geoservices AS* [2010] EWCA Civ 819

¹²⁴ *Takeda UK Limited v F. Hoffmann-La Roche AG* [2019] EWHC 1911 (Pat) (17 July 2019) Birss J

iii) The biochemistry of antibodies - particularly glycosylation, its nature and importance, the various monosaccharides and oligosaccharide structures encountered;

iv) Immunology and in particular antibody effector functions; and

v) Techniques for analysing glycosylation."

And so ([43]):

"Starting from a given target, i.e. an antigen, the skilled person would be able to raise antibodies to that target, select a suitable antibody to that target and carry out the necessary genetic engineering to produce an amino acid sequence for it. If they wanted to target a particular epitope, again they could do that. If they wished to do so they could make antibodies of this kind which were chimeric, humanized or human antibodies. They could make a pharmaceutical composition comprising such antibodies and they could use them for the manufacture of a medicament comprising the antibody. In this brief paragraph is encapsulated an enormous amount of work of a fairly large team of well funded people. However all of it is common general knowledge and none of it involves an undue burden either in the context of sufficiency or novelty. In that sense the simple phrase "a pharmaceutical composition of a human antibody to target X" is an enabling disclosure."

In a similar vein, determining the full amino-acid sequence of a therapeutic antibody product available at the priority date (April 2006), Simulect, would have taken a team of 2-3 scientists around 3 months. The full analysis would have included the amino acid sequence, glycosylation and formulation; and three quarters of the work would have been on the amino acid sequence. Nevertheless, while a lot of work, it was not an undue burden. This meant that the amino acid sequence of the antibody, as well as the other aspects – glycosylation and formulation – were made available to the public.

b) Anticipation/priority

In *Eli Lilly v Genentech*¹²⁵, Genentech's patent was expressed to "relate generally to the identification and isolation of a novel human cytokine designated as interleukin-17A/F (IL-17A/F)". The technical background included knowledge of a number of interleukin cytokines, which had been identified in human cells and designated IL-17A to IL-17F. All were homodimers e.g. IL-17A/A.

As proposed to be amended, the patent claimed an antibody "which specifically binds to an isolated IL-17A/F heterodimeric complex and which inhibits the activity of the IL-17A/F heterodimeric complex". The patent included also Swiss form claims to such antibodies in the preparation of a medicament for the treatment of rheumatoid arthritis or psoriasis, and EPC2000/purpose-limited product claims for such use.

Lilly challenged the validity of the patent for lack of novelty over the "IL-17A/A prior art". Lilly relied upon this as disclosing the homodimer IL-17A/A as a target for RA therapy. This part of the case involved **experiments** and considerable argument in relation to them.

An initial stumbling block to the preparation of protocols arose in the form of the Animals (Scientific Procedures) Act 1986, which prohibits experiments on animals for the purposes of patent litigation. So rather than adopting protocols which included steps of immunising animals and generating hybridomas, the experiments began with three antibodies (mAbs 5, 16 and 25) generated in 1994 by

¹²⁵ *Eli Lilly and Company & Ors v Genentech Inc* [2019] EWHC 387 (Pat) (1 March 2019) Arnold J

Schering Plough using cell lysate for the initial immunisations. Arnold J was satisfied mAbs 5, 16 and 25 were representative of those that would have been made following the prior art in July 2003, and in any event represented an obvious way of implementing the prior art in 2003. (The experiments were also directed to questions of obviousness).

The judge noted that the subsequent methodology employed used obvious options, albeit not necessarily things the skilled person inevitably would have done in 2003. He concluded that the majority of the humanised antibodies produced in Lilly's experiments were representative of what the skilled team would have produced implementing the IL-17A/A prior art using obvious methods.

Turning to the inevitability of binding to and inhibition of IL-17A/F, the parties' cases were "like the proverbial ships sailing in the night". Genentech's Prof Carr approached it from the perspective of a structural biologist and not an immunologist; Lilly's Dr Tite approached it as an immunologist and not a structural biologist. Lilly submitted that Prof Carr's instructions, to consider the matter from a theoretical perspective based on current knowledge, asked the wrong question, and that he should have been instructed to consider what the skilled person would in fact have achieved by working he prior art. The judge disagreed ([485]):

"Prof Carr's evidence was directed to the issue of inevitability. For that purpose, it was appropriate for Genentech to instruct him in the manner it did."

The judge then turned to the structures of IL-17A/A, IL-17A/F and IL-17F/F and their binding to receptors. Despite five "key papers" reporting the structures of these dimers, either alone or bound to the IL-17 receptor, the judge said that the precise manner in which complexes bound was unknown and could not reliably be predicted. It was common ground that there were two possible ways in which antibodies which bind to and inhibit IL-17A/A may operate. The experts' views differed on this and also on the possibility of antibodies which bound to and inhibited IL-17A/A but not IL-17A/F. Lilly's expert (Dr Tite) accepted that it was theoretically possible for there to be antibodies which bound to and inhibited IL-17A/A but not IL-17A/F, although this begged the question of why no such antibody had yet been reported; Genentech's Prof Carr speculated that 4-20% of antibodies to IL-17A/A might do this. The judge concluded that it was clear that the great majority of antibodies would bind to both IL-17A/A and IL-17A/F.

However, while this meant it was highly probable that a skilled team implementing the IL-17A/A prior art by obvious methods in July 2003 would produce an antibody that also bound to and inhibited IL-17A/F (and so product claim 1 was obvious), Lilly had not established that it was inevitable. Lilly's anticipation challenge therefore failed. (The product claims, and the medical use claims to the extent directed to RA, were, however, obvious in light of the IL-17A/A prior art).

Biologics

It is clear from the House of Lords' judgment in *Synthon v SKB*¹²⁶ that for a patent claim to lack novelty over the prior art there are two requirements: disclosure and enablement. But what is it that has to be disclosed and enabled? The very thing in the prior art? Or just something falling within the claim of the patent?

It is probably not surprising that this issue fell to be addressed in the context of a biologics patent.

¹²⁶ *Synthon BV v SmithKline Beecham plc* [2005] UKHL 59

In *Takeda v Roche*¹²⁷, the patentee, Roche, argued that the EPO decisions about prior use provided that for a product to form part of the state of the art it must be possible for the skilled person to **reproduce it** (i.e. the prior art product) without undue burden. So, in T2045/09, there was a patent claim to an antibody for a target. The glycosylation pattern of the antibody was not a feature of the claim. There was a prior used antibody, also to the claimed target. The TBA was not convinced that the skilled person could determine its amino acid sequence (in 1994), which was enough to find the claim novel. However the TBA went further and held that even if the skilled person could determine the amino acid sequence of the prior antibody, they could not know in which cell line it had been made and so the glycosylation pattern of the prior antibody, and therefore the prior art antibody could not be "reproduced" in accordance with G1/92. So the prior antibody was not part of the state of the art at all. A similar approach was taken in T1833/14. Roche said the same principle should apply to documentary prior art.

When the prior disclosure was an antibody, Roche's case meant that in order for it to anticipate, the skilled person would need to be able to reproduce not just the amino acid sequence but also the glycosylation pattern of the prior art antibody, even when this was irrelevant to a claim feature.

Roche's patent concerned antibody glycosylation. Claim 1 was in the following terms ([3]):

"Monoclonal antibody of human IgG1 or IgG3 type being glycosylated with a sugar chain at Asn297,

said antibody being characterized in that **the amount of fucose** within said sugar chain, related to the sum of G0, G1, G2 without mannose 4 and mannose 5 as 100% and as analyzed by Liquid Chromatography/Mass Spectrometry (LCMS) peptide map analysis **is at least 99%**

and in addition **the amount of NGNA** within said sugar chain, related to the sum of G0, G1, G2 without mannose 4 and mannose 5 as 100% and as analyzed by Liquid Chromatography/Mass Spectrometry (LCMS) peptide map analysis, **is 1% or less,**

and **the amount of N-terminal alpha 1,3 galactose** within said sugar chain related to the sum of G0, G1, G2 without mannose 4 and mannose 5 as 100% and as analyzed by Liquid Chromatography/Mass Spectrometry (LCMS) peptide map analysis **is 1% or less."**

Birss J, however, did not think there was anything in G1/92, the leading EPO authority, which took the principle as far as contended for by Roche. The core of G1/92 in this respect was that ([124]):

"...Where it is possible for the skilled person to discover the composition or the internal structure of the product and to reproduce it without undue burden, then both the product and its composition or internal structure become state of the art."

Rather, in order to anticipate, Birss J ruled that the making available to the public must be of **something the skilled person can use to produce a practical result – their own version (TOV) – of the prior art product which is covered by the patent claim**. The fact that the TOV-product was not identical with the old product (i.e. that of the prior art or prior use) in every particular did not matter as long as those differences did not take it outside the claim. However, if the skilled person could not make their own version of the old product at all, then the claim would be novel.

On that basis, the judge concluded that several claims of Roche's patent were variously anticipated by four prior publications/uses.

¹²⁷ *Takeda UK Limited v F. Hoffmann-La Roche AG* [2019] EWHC 1911 (Pat) (17 July 2019) Birss J

In *Technetix v Teleste* (18 November 2019)¹²⁸, HHJ Hacon went back to first principles, quoting from Lord Hoffmann's speech in *Synthon v SKB*¹²⁹. Having considered the judgment of Lord Westbury L.C. in *Hill v Evans*¹³⁰ and from the Court of Appeal in *General Tire and Rubber v Firestone*¹³¹, Lord Hoffmann said ([72]):

"[22] ... the matter relied upon as prior art must disclose subject-matter which, if performed, would necessarily result in an infringement of the patent. That may be because the prior art discloses the same invention. In that case there will be no question that performance of the earlier invention would infringe and usually it will be apparent to someone who is aware of both the prior art and the patent that it will do so. But patent infringement does not require that one should be aware that one is infringing: "whether or not a person is working [an] ... invention is an objective fact independent of what he knows or thinks about what he is doing": *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] RPC 76, 90. It follows that, whether or not it would be apparent to anyone at the time, whenever subject-matter described in the prior disclosure is capable of being performed and is such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied. The flag has been planted, even though the author or maker of the prior art was not aware that he was doing so."

Technetix's patent was concerned with improving the signal-to-noise ratio in a cable TV network, by the use of a "high pass filter" to block low frequency signals and so at least partially prevent the generation of intermodulation products. Technetix did not seek to defend the validity of the patent as granted and sought amendment. In one proposed amended claim, the high pass filter comprised an "LC filter" including at least one coil and at least one capacitor.

Prior art '*Jelinek*', a US patent, was concerned with filters used in amplifiers employed in cable TV networks, in which signals typically flowed in two directions. Judge Hacon summarised its disclosure as follows ([73]):

"Two known types of filter are referred to in *Jelinek*. First, a duplex filter which consists of a high pass filter and a low pass filter joined at a common port. Secondly, a surge filter which protects the amplifiers from high energy transients. The invention claimed in *Jelinek* is a combination of the two types of filter in a single modular unit. The high pass filter is dual-function in that it is designed also to serve as a surge filter. It performs the task of blocking low frequency return path signals and also protects the amplifier from high energy transients. The low pass filter, in the form of a plug-in module, attenuates forward signals in the return path."

Teleste argued that *Jelinek* disclosed an LC filter which, by protecting the amplifier ferrite from surges, prevented the generation of intermodulation products in the amplifier.

Technetix argued that as there was no express reference to the prevention of intermodulation products, *Jelinek* did not disclose such prevention. Since the link between surges and intermodulation did not form part of the CGK, nor would the skilled person understand from *Jelinek* that it disclosed a prevention means for the purpose of at least partially preventing the generation of intermodulation products.

¹²⁸ *Technetix BV & Anr v Teleste Limited* [2019] EWHC 3106 (Pat) (18 November 2019) HHJ Hacon

¹²⁹ *Synthon BV v SmithKline Beecham plc* [2005] UKHL 59

¹³⁰ *Hill v Evans* (1862) 31 L.J. Ch (NS) 457

¹³¹ *General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd* [1972] R.P.C. 457

The deputy judge thought *Technetix* was missing the point: it did not matter whether or not the skilled person, reading *Jelinek*, would appreciate what would happen when the *Jelinek* invention was performed. What mattered was *what would* happen. *Jelinek* anticipated the unconditional claims. (Further, the skilled person would have understood as part of their CGK that transient energy peaks would cause intermodulation products in a signal processing means within a cable TV network and therefore that protection against such peaks would reduce intermodulation).

This is an interesting and somewhat problematic finding. What the deputy judge appears to be saying is that if the prior art does actually anticipate in practice, it is irrelevant whether the skilled person would be able to identify that or not. Surely that is not enough to meet the test of disclosure, which requires at least implicit disclosure of the relevant features or that such are the inevitable result?

Priority

In *Emson v Hozelock*¹³² – the garden hose case - Hozelock accepted that claims 1 and 14 of GB '276, and claim 2 of EP '585, were sufficiently disclosed in the first priority document. All of these claims referred to the tubes being unattached except at the couplers. However, Hozelock contended that claim 1 of EP 585, which did not have any such limitation, was not so disclosed.

On the principles, Nugee J drew from *Terrell*. Priority is dealt with in in the Patents Act 1977 at section 5(2), which is stated (in section 130) as intended to have the same effect as the corresponding provision of the EPC – this being article 87(1), which confers a right of priority in respect of "the same invention". After noting the leading case in the EPO on priority date, *Same Invention* G02/98¹³³, Nugee J summarised the law regarding priority as follows ([193]):

"Priority is therefore about disclosure. It is not about whether something not disclosed in the priority document would be obvious, but about whether something is unambiguously disclosed in the priority document. The way it was put by Jacob LJ in *Unilin* (2004) at [48] was as follows:

"...priority is a question about technical disclosure, explicit and implicit. Is there enough in the priority document to give the skilled man essentially the same information as forms the subject matter of the claim and enables him to work the invention in accordance with that claim?"

For the purposes of considering this question, one looks to the priority document as a whole. This includes the claims in the priority document: see *Unilin* (2004) per Jacob LJ at [49]:

"The claims (if there are any – there is no rule that there should be) are not determinative. They are just part of its disclosure. For the purposes of priority one just looks at the disclosure as a whole." "

Turning to the application of those principles, the judge accepted that the body of the specification of the first priority document consistently referred to the tubes being unconnected along the entire length.

However, claim 1 of the first priority document said nothing at all about the tubes being unattached along their entire length. So, although it used similar rather than identical terms, claim 1 of the priority

¹³² *E. Mishan & Sons, Inc t/a Emson v Hozelock Limited* [2019] EWHC 991 (Pat) (17 April 2019) Nugee J

¹³³ *Same Invention* G02/98 [2002] EPOR 167

document disclosed, directly and unambiguously, a hose with the features in claim 1 as granted, without specifying whether the tubes were attached or unattached. By way of sanity check, the judge noted ([197]):

"Indeed when the claim in the priority document and the claim in the patent are in the same terms, it seems very odd to say that the subject-matter of the patent is not disclosed in the priority document."

Hozelock's priority challenge therefore failed.

c) Obviousness

The general principles

Time to dip into the bottomless bran tub of concepts and principles which make up the law of obviousness. From the patent lawyers' perspective this is the gift that goes on giving, and this year has been no exception, with the added fun of a non-IP Supreme court judge taking the opportunity to spell out the principles underpinning the law of obviousness for our delight.

The Supreme Court's first patent judgment of 2019 was in *Actavis v ICOS*¹³⁴, in the dispute about the obviousness (or not) of ICOS/Eli Lilly's patent to a dosing regimen for tadalafil.

A great deal has been said about the legal test of obviousness. The Supreme Court's judgment captured and confirmed the key jurisprudence, while reminding us all that the test remains that set out in section 3 of the Patents Act:

"An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above)."

Like the active ingredient in Viagra, tadalafil is an inhibitor of the enzyme 'PDE5', and is used for the treatment of erectile dysfunction (ED).

ICOS/Eli Lilly's '181 patent claimed tadalafil as a unit dosage composition ("up to a total dose of 5 mg per day"), both in EPC2000 format (claim 7) and in corresponding Swiss form (claim 10). The claimants argued that in light of prior art 'Daugan' (which disclosed the idea of using PDE5 inhibitors for the treatment of ED), it would have been obvious for the skilled team to conduct a routine pre-clinical and clinical trial programme as an oral treatment for male ED at the priority date, and the programme would reveal that 5mg daily was safe, tolerable and effective.

At first instance, Birss J held that the fact that a skilled team would carry out routine testing (e.g. phase I, IIa & IIb, and III) without any expectation as to what any particular result would be did not turn the results of truly routine testing into an invention. However, at each stage, a fair prospect of success was needed for that step to be obvious and in the end the programme had to be considered as a whole. In light of Daugan, the skilled team would undertake a "go no-go" phase IIa study of a single dose of tadalafil in a relatively small group of patients, using a 50mg dose; and following successful results a routine Phase IIb dose ranging study would be conducted in a larger group, of doses including 25mg, 50mg and 100mg. For both studies, there would be a reasonable expectation of

¹³⁴ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 (27 March 2019) Lady Hale, Lords Kerr, Sumption, Hodge & Briggs

success. There would then be a further study, of 5mg and 10mg, but Birss J found that the skilled person, at this stage would not have had a reasonable expectation that the 5mg dose would be a useful treatment for ED, nor any expectation at all that the drug would produce a clinically relevant effect but with minimal side effects. The skilled person would be surprised by this. Standing back, the claimed invention was not obvious in light of Daugan. At least the Swiss form claim was valid (and infringed).

The Court of Appeal unanimously overturned the Patents Court on the issue of obviousness. Unusually, each Lord Justice gave a reasoned judgment. Kitchin LJ said that the judge had "lost sight" of the fact that, on his own findings, the claimed invention lay at the end of the familiar path through the routine pre-clinical and clinical trials process. Floyd LJ said that "the whole purpose of embarking on the routine Phase IIb dose ranging study was to identify a dose response... Completion of the study would inevitably lead the skilled team to test 5 mg/day".

The issue of the obviousness of the '181 patent went to the Supreme Court, which unanimously agreed with the Court of Appeal. The only reasoned judgment was given by Lord Hodge, who took a thorough look at the principles, and whose judgment must now be considered the leading modern authority on obviousness.

Lord Hodge began with the 1623 Statute of Monopolies, since when, he said, the purpose of a grant of a patent has been to encourage innovation. The "patent bargain" is that the inventor obtains a monopoly in return for disclosing the invention and dedicating it to the public for use after the monopoly has expired. Lord Hodge continued (53)-[54]:

"Lord Mansfield stated the point with his characteristic succinctness in *Liardet v Johnson* (1778):

"The condition of giving encouragement is this: that you must specify upon record your invention in such a way as shall teach an artist, when your term is out, to make it - and to make it as well by your directions: for then at the end of the term, the public shall have benefit of it. The inventor has the benefit during the term, and the public have the benefit after ..."...

This overarching principle has survived the amendment of UK patent law after accession to the European Patent Convention."

The judge then moved to *AgrEvo* (T-939/92)¹³⁵ ([54]):

"...it has for long been a generally accepted legal principle that the extent of the patent monopoly should correspond to and be justified by the technical contribution to the art. ... [T]his general legal principle was applied in relation to the extent of the patent protection that was justified by reference to the requirements of articles 83 and 84 EPC, the same legal principle also governs the decision that is required to be made under article 56 EPC, for everything falling within a valid claim has to be inventive."

Turning to the domestic legislation and case law, Lord Hodge said ([56]-[57]):

¹³⁵ *AgrEvo/Triazoles* (Case T-939/92) [1996] EPOR 171

"It is also well established in the jurisprudence of courts in the United Kingdom that our courts, although not bound to do so, should normally follow the settled jurisprudence of the EPO (especially decisions of its Enlarged Board of Appeal) on the interpretation of the European Patent Convention in the interests of uniformity, especially when the question is one of principle.

The general principle that the extent of the patent monopoly should correspond to and be justified by the actual technical contribution to the art is thus part of the jurisprudence of both the EPO and the UK courts and, as Lord Sumption observed in *Generics v Warner-Lambert* (above), para 17, "the principal conditions of validity, novelty, inventive step, industrial application and sufficiency are all, in one way or another, directed to satisfying the principle thus expressed". There is therefore a balance or symmetry in patent law, as Mr Speck submitted."

Lord Hodge then set out sections 3 and 2(3) of the Patents Act. These provisions state that an invention "shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2)", and define the state of the art. These provisions mandate the assessment of obviousness having regard to the state of the art at the **priority** date of the invention. Lord Hodge then said ([59]):

"The notional skilled person, while having the compendious knowledge of the state of the art which section 2(2) requires, has no inventive capacity. But that does not mean that the skilled person has no skill to take forward in an uninventive way the teaching of the prior art. [The]...notional team is treated as exercising the professional skills of its members in responding to the teaching of the [cited prior art].... It follows that uninventive steps which the skilled team would take after the priority date to implement the [cited prior art] are not excluded from consideration in assessing the obviousness of the alleged invention at the priority date."

Lord Hodge then noted that the approach to the assessment of obviousness commonly adopted by the English courts is that set out in *Windsurfing/Pozzoli*¹³⁶. He observed that the fourth *Pozzoli* question is the statutory question and the first three questions or tasks are a means of disciplining the court's approach to that fourth question.

Lord Hodge also noted the alternative approach is that commonly adopted by the EPO, the so-called "problem-and-solution approach", which is helpfully summarised in the EPO's Guidelines.

Comparing the two approaches, Lord Hodge said ([62]):

"While both approaches focus on the inventive concept put forward in the claims, neither approach should be applied in a mechanistic way. Both are glosses on the text of section 3 of

¹³⁶ *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* [1985] RPC 59 as reformulated in *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588 at [23]: "(1)(a) Identify the notional "person skilled in the art"; (b) Identify the relevant common general knowledge of that person; (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it; (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed; (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?"

the 1977 Act and article 56 of the EPC and neither require a literalist approach to the wording of the claim in identifying the inventive concept."

Neither formula should distract the court from the statutory question.

As a matter of principle, Lord Hodge noted (at [87]) that the inventive concept by which a patentee seeks to justify his or her monopoly must apply to all embodiments falling within the claims which are said to have independent validity. Lord Hodge expressed agreement on this with Laddie J's judgment in *Brugger v Medic-Aid*¹³⁷ and noted that a similar rule applies in the EPO's problem-and-solution approach.

Lord Hodge also noted (at [92]) that *Conor v Angiotech*¹³⁸ is not authority for the proposition that, in all circumstances, obviousness must be assessed by reference to the precise wording in the claim.

Lord Hodge referred to Lord Hoffmann's endorsement, in *Conor v Angiotech*, of the following well-known statement of Kitchin J in *Generics v Lundbeck*¹³⁹:

"The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success."

Lord Hodge said that Kitchin J's list of factors was "illustrative and not exhaustive". The Supreme Court did not seek to set out an exhaustive list of factors - the rest of its reasoning concerned the factors relevant to the assessment of obviousness in the present case. They included the following, which Lord Hodge largely expressed in general terms:

1. Whether something was "obvious to try" with a reasonable or fair prospect of success. In many cases the consideration that there was a likelihood of success sufficient to warrant an actual trial is an important pointer to obviousness.
2. The routine nature of the research and any established practice of following such research through to a particular point. This may be weight against a consideration that the claimed product or process was not obvious to try at the outset of the research programme.
3. The burden and cost of the research programme. The weight to be attached to this factor will depend on the circumstances, and it is still only one factor. The need to facilitate expensive pharmaceutical research is an important policy consideration for legislators and others involved in IP law; it was a factor behind the creation of Swiss form claims, SPCs and regulatory data protection.
4. The necessity for and the nature of the value judgments that the skilled team would have in the course of testing.

¹³⁷ *Brugger & Ors v Medi-Aid Ltd (No 2)* [1996] RPC 635

¹³⁸ *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] UKHL 49

¹³⁹ *Generics (UK) Ltd v H Lundbeck A/S* [2007] EWHC 1040 (Pat)

5. The existence of alternative or multiple paths. This will often indicate that the invention was not obvious, but more than one avenue of research may be obvious.
6. The motive of the skilled person. It is not sufficient that a skilled person could undertake a particular trial, it may be necessary to ask whether, in all the circumstances, he or she would be motivated to do so. The absence of motive to take the allegedly inventive step makes an argument of obviousness more difficult. The TBA's reasoning on such a point in *AgrEvo* formed the basis of the EPO's problem-and-solution approach.
7. Whether the results of the research which the inventor carried out were unexpected or surprising. If so, it may point to inventive step/away from obvious to try.
8. The importance of not using hindsight in addressing the statutory question of obviousness, and in particular the obvious danger of a step by step analysis. However, the *MedImmune* requirement would be met if the step by step approach, without the benefit of hindsight, demonstrates that the skilled team would be very likely to pursue the product or process falling within the claims.
9. Whether a feature of a claimed invention was an added benefit in a context in which the claimed invention was obvious for another purpose. (ICOS submitted that this was not relevant in the present case).
10. The nature of the invention. In the present case, this was a dosage patent with Swiss form and EPC2000 claims. While it is possible to obtain a patent for a new and inventive dosing regime, the EPO has not sanctioned any relaxation of the tests of obviousness in relation to dosage patents. In *Actavis v Merck*¹⁴⁰, Jacob LJ cautioned that dosage regimes will nearly always be obvious. In the present case Birss J found that it was common knowledge that regulators were often interested in and could require evidence of the minimum effective dose and that the skilled person would be familiar with multiple dose ranging studies as necessary as a generality. The inventiveness of the dosage regime of the patent therefore fell to be assessed in that context.

As an aside before moving on to the actual outcome of the case, I must say that Lord Hodge's list merely confirms something I courted controversy by saying a few years ago. The jurisprudence behind the law of obviousness has this much in common with the bible – if you look hard enough you can find something to support pretty much every proposition you want to put forward.

The appeal was confined to claims 7 and 10 of the patent (not product claim 1, which did not include a purpose limitation).

Lord Hodge noted that the skilled team were looking for a dose response relationship and that they would know that, as a generality, multiple dose ranging studies were necessary. The logical consequence of the judge's finding, that it was very likely that the skilled team would continue the testing to 10mg and 5mg, was that the patent was obvious. The judge's failure to appreciate this was an error of principle which allowed the Court of Appeal to carry out its own evaluation.

¹⁴⁰ *Actavis UK Ltd v Merck & Co Inc* [2008] EWCA Civ 444

Lord Hodge also carried out a brief assessment adopting the problem-and-solution approach, concluding that he was not persuaded that it would give a different answer from that reached by the Court of Appeal.

In summary, the cited prior art had disclosed the use of tadalafil in the treatment of ED in a manner which enabled the skilled person to perform it. The skilled team would know how to implement it – by conducting routine pre-clinical and clinical tests through to Phase IIb, by which, without hindsight, the skilled team would come to the claimed invention.

Lord Hodge noted too the existence of judgments in parallel disputes in several other countries. In some countries the patentee had so far succeeded (Denmark, Poland & Czech Republic), in others it had not (Belgium & Portugal). Lord Hodge said that he did not find the judgments particularly helpful, explaining ([101]):

"Because of the differences in the evidence led, the manner by which it is tested, and the differing findings to which that evidence gives rise, one may derive support from the approach to the question and methods of reasoning of other national courts but should never rely uncritically on the outcome."

Finally, Lord Hodge noted and commented on interventions from the IP Federation, Medicines for Europe, the British Generic Manufacturers Association and the UK BioIndustry Association. He said that he did not interpret the Court of Appeal's judgments as supporting any general proposition that the product of well-established or routine enquiries cannot be inventive ([103]):

"...there is no policy reason why a novel and inventive dosing regime should not be rewarded by a patent. A fortiori, efficacious drugs discovered by research involving standard pre-clinical and clinical tests should be rewarded with a patent if they meet the statutory tests".

Six weeks later, in *Allergan v Aspire*¹⁴¹, Arnold J provided some digestible commentary on, and interpretation of, the Supreme Court's *Actavis v ICOS* judgment.

Allergan's patent concerned, essentially, a formulation of bimatoprost and benzalkonium chloride (BAK) for the treatment of glaucoma and ocular hypertension. The argument essentially boiled down to a proposed product claim 18, which was in the following terms:

"A composition comprising 0.01% bimatoprost, 0.02% benzalkonium chloride, 0.0268% sodium phosphate dibasic heptahydrate, 0.014% citric acid monohydrate, 0.81% sodium chloride, and water, wherein the pH is 7.3."

By the priority date of the patent in March 2005, the following prostaglandin analogues (PGAs) were available in the UK for the treatment of glaucoma, marketed in formulations containing the preservative BAK as indicated:

- a) latanoprost 0.005% (Xalatan); 200ppm BAK;
- b) travoprost 0.004% (Travatan); 150ppm BAK;
- c) **bimatoprost 0.03% (Lumigan 0.3 mg/ml); 50ppm BAK;**

¹⁴¹ *Allergan, Inc & Anr v Aspire Pharma Limited* [2019] EWHC 1085 (Pat) (3 May 2019) Arnold J

d) unoprostone 0.15% (Rescula); 150ppm BAK.

The skilled ophthalmologist would have known that the side effect 'hyperaemia' was associated with administration of Lumigan 0.03%. BAK was in the majority of ophthalmic formulations. However, the fact that latanoprost, the PGA with the highest level of BAK, had the lowest incidence of hyperaemia, was compelling evidence that it was the active ingredient in Lumigan 0.03% (bimatoprost) which was the cause, not BAK.

The skilled formulator would have known in March 2005 that there were various ways to increase the ocular bioavailability of a drug, including the use of a penetration enhancer.

However, a key area of dispute concerned whether it was common general knowledge that BAK enhanced the corneal permeability, and hence the bioavailability of ophthalmic drugs. On the evidence the judge concluded that this was CGK. In any event, Allergan's ophthalmologist expert accepted that if the skilled person wanted to know about the effects of BAK they could do this from text books. Further, Allergan's "unsatisfactory" formulation expert "had to accept in cross-examination" that "the textbooks and articles convey the general message that BAK enhances corneal penetration". The judge concluded that while BAK was included in formulations as a preservative, "it was well understood that it had the additional benefit of enhancing corneal penetration for a wide range of drugs", and this was a concentration-dependent effect.

On the principles regarding obviousness, Arnold J cited *Actavis v ICOS*¹⁴², saying ([96]):

"The overall tenor of the judgment of Lord Hodge, with whom the other members of the Court agreed, is to confirm the approach which had previously been adopted by the courts to this question. For present purposes, it is sufficient to note five points."

In short, these five points were:

- endorsing, while not mandating, the *Windsurfing/Pozzoli* approach;
- endorsing, while emphasising that it was not exhaustive, Kitchin J's statement in *Generics v Lundbeck*;
- it was relevant to consider whether something was "obvious to try" with a likelihood of success; nevertheless some experiments which are undertaken without any particular expectation as to result *are* obvious;
- the existence of alternative or multiple paths of research will often be an indicator that the invention was not obvious, nevertheless an obvious route is not rendered less obvious from a technical point of view merely because there are a number of other obvious routes as well; implicitly what matters is whether the claimed invention is obvious from a technical point of view, not whether it would be commercially obvious to implement it;
- the motive of the skilled person is relevant: it is not sufficient that a skilled person could undertake a particular trial; one may wish to ask whether in the circumstances he or she

¹⁴² *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 (27 March 2019) Lady Hale, Lords Kerr, Sumption, Hodge & Briggs

would be motivated to do so; the absence of a motive to take the allegedly inventive step makes an argument of obviousness more difficult.

Turning to the assessment of inventive step in the *Allergan* case, Arnold J's judgment was mercifully brief.

Prior art '*Laibovitz*' disclosed that 0.01% bimatoprost lowered intra-ocular pressure (IOP) by 20.7% - sufficient to be clinically useful for glaucoma. *Laibovitz*'s 0.01% bimatoprost formulation contained no preservative. Accordingly, for the skilled ophthalmologist interested in reducing the incidence of conjunctival hyperaemia observed with Lumigan, the obvious course would be to repeat the *Laibovitz* study with better methodology and to ask the skilled formulator to produce formulations for this purpose.

The issue was whether BAK would be included in the formulation, and if so at what concentration. The judge thought that Allergan's arguments that BAK would not be included, because of the possibility of it affecting the incidence of hyperaemia, were "hopeless" ([109]):

"...it would obviously be convenient to be able to use multi-use containers, which would require the use of a preserved formulation. Since BAK was the most commonly used preservative, it would be the obvious choice."

Further, it was CGK that BAK was used in the 50ppm to 200ppm range in the commercially available PGA eye drops. Consequently ([112]):

"While 200 ppm is more than the minimum necessary to achieve adequate preservation of bimatoprost, there was no technical, as opposed to regulatory, reason not to use more BAK than the minimum provided it was safe and tolerable. As discussed above, the skilled team would be satisfied that the inclusion of 200 ppm BAK was safe and tolerable. Furthermore, the skilled team would have no reason to think that the inclusion of 200 ppm BAK in either 0.01% or 0.03% bimatoprost would have any adverse impact on the efficacy of the bimatoprost. It is telling that, when Prof Kompella was asked whether, leaving regulatory issues aside, it would require invention to use 100 ppm BAK, he declined to comment. Thus he was unable to suggest any reason why it would require invention. There is no reason to think that his position would have been any different with respect to 200 ppm."

In the alternative, even if it was not obvious to include 200 ppm BAK purely as a preservative, it would have been obvious to try to optimise the bioavailability of bimatoprost by using BAK's additional property as a corneal permeation enhancer, and for this purpose 200ppm BAK was obvious to try.

It followed that new claim 18, and all granted claims of the patent, were invalid.

The judge then considered and dismissed the secondary evidence relied upon by Allergan. The notable points here were that he considered the evidence of what Allergan did when developing its earlier, Lumigan 0.3 mg/ml, drops did not show that 200ppm (rather than 50ppm) was not obvious. And Allergan's factual evidence on the making of its later 'invention' did not change this. In particular, the ability of the witness to speak to the issue was limited. The project was not, in any case, focused simply on reducing hyperaemia but was broader than that.

A number of points of principle regarding the assessment of obviousness were made by Floyd LJ in *Philips v Asustek*¹⁴³. In this case the Court of Appeal dismissed each of the appeals against the three technical judgments delivered by Arnold J in the parties' SEP/FRAND dispute in 2018.

Floyd LJ noted, from *Pozzoli*¹⁴⁴, that you cannot have a patent for something which the skilled person would regard as old or obvious but difficult or impossible to do, if it remained equally difficult or impossible after reading the patent. The perceived problem must be solved by the patent.

Further, from *Brugger v Medi-Aid*¹⁴⁵, when considering obviousness, Floyd LJ said that it was not legitimate to identify aspects of the invention possessed by only a sub-group of embodiments covered by the claim, and then to assess obviousness by reference to the characteristics of that sub-group.

On the role of commercial mindset in the assessment of obviousness, Floyd LJ quoted extensively from *Hallen v Brabantia*¹⁴⁶ and *Dyson v Hoover*¹⁴⁷, before saying ([118]):

"These passages show that a commercially driven mindset can be a relevant aspect of the skilled person's common general knowledge. Thus, what the skilled person does in the light of a given prior disclosure has to be decided with that mindset in mind. If the technical differences from the prior art to the invention are trivial, then the mindset may not matter, but if more substantial changes are involved, the court may conclude that the reluctant and prejudiced skilled person would not make them. If the court reaches the conclusion that the claimed invention would be arrived at by the skilled person, there is no further hurdle to be crossed concerned with whether the invention would be perceived as likely to lead to sufficient commercial success to make its manufacture worthwhile."

This is an interesting passage. The judge seems to be taking the notion of commercial influence and moving it backwards in time, so that it might affect the outcome only if it is influential on the mindset of the skilled person before the identification of the potential invention is arrived at.

The role of an appellate court

Unsurprisingly, in *Actavis v ICOS*¹⁴⁸, Lord Hodge addressed the limits of an appellate court's power to overturn the evaluation of a trial judge in the field of obviousness. He said ([78]-[81]):

"Where inferences from findings of primary fact involve an evaluation of numerous factors, the appropriateness of an intervention by an appellate court will depend on variables including the nature of the evaluation, the standing and experience of the fact-finding judge or tribunal, and the extent to which the judge or tribunal had to assess oral evidence: *South Cone Inc v Bessant, In re Reef Trade Mark* [2002] EWCA Civ 763; [2003] RPC 5, paras 25-28 per Robert Walker LJ.

An experienced patent judge faced with a challenge to a patent on the ground of obviousness, and who has heard oral evidence including cross-examination, carries out an

¹⁴³ *Koninklijke Philips N.V. v Asustek Computer Incorporation & Ors* [2019] EWCA Civ 2230 (17 December 2019) Patten, Floyd & Henderson LJ

¹⁴⁴ *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588

¹⁴⁵ *Brugger & Ors v Medi-Aid Ltd (No 2)* [1996] RPC 635

¹⁴⁶ *Hallen Co v Brabantia UK Ltd* [1991] RPC 195

¹⁴⁷ *Dyson Appliances Ltd v Hoover Ltd* [2001] EWCA Civ 1440, [2002] RPC 22

¹⁴⁸ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 (27 March 2019) Lady Hale, Lords Kerr, Sumption, Hodge & Briggs

evaluation of all the relevant factors, none of which alone is decisive but each of which must be weighed in the balance in reaching a conclusion. In *Biogen Inc v Medeva plc* [1997] RPC 1, 45, Lord Hoffmann emphasised the need for appellate caution in reversing the judge's evaluation of the facts where the application of a legal standard involved no question of principle but was simply a matter of degree. He held that it would be wrong to interfere with the judge's assessment if no question of principle were involved.

What is a question of principle in this context? An error of principle is not confined to an error as to the law but extends to certain types of error in the application of a legal standard to the facts in an evaluation of those facts. What is the nature of such an evaluative error? In this case we are not concerned with any challenge to the trial judge's conclusions of primary fact but with the correctness of the judge's evaluation of the facts which he has found, in which he weighs a number of different factors against each other. This evaluative process is often a matter of degree upon which different judges can legitimately differ and an appellate court ought not to interfere unless it is satisfied that the judge's conclusion is outside the bounds within which reasonable disagreement is possible: *Assicurazioni Generali SpA v Arab Insurance Group (Practice Note)* [2002] EWCA Civ 1642; [2003] 1 WLR 577, paras 14-17 per Clarke LJ, a statement which the House of Lords approved in *Datec Electronic Holdings Ltd v United Parcels Service Ltd* [2007] UKHL 23; [2007] 1 WLR 1325, para 46 per Lord Mance.

Thus, in the absence of a legal error by the trial judge, which might be asking the wrong question, failing to take account of relevant matters, or taking into account irrelevant matters, the Court of Appeal would be justified in differing from a trial judge's assessment of obviousness if the appellate court were to reach the view that the judge's conclusion was outside the bounds within which reasonable disagreement is possible. It must be satisfied that the trial judge was wrong: see, by way of analogy, *In re B (A Child) (Care Proceedings Threshold Criteria)* [2013] UKSC 33; [2013] 1 WLR 1911, paras 90-93 per Lord Neuberger, para 203 per Lady Hale.

The role of an appellate court was discussed too in *Philips v Asustek*¹⁴⁹. Floyd LJ also noted (from *Biogen v Medeva*¹⁵⁰) the need for great respect to be accorded to the trial judge's evaluation of obviousness where s/he has correctly directed themselves as to the law; an appellate court should be "very cautious" before interfering where the application of the legal standard is simply "a matter of degree".

Floyd LJ therefore considered it necessary for the Court of Appeal to focus on the points said to represent an error of principle. Providing examples of the defendants' failure to comply with the practice direction to Part 52 of the CPR, Floyd LJ said ([110]):

"Unless the court and the parties stick to the discipline of attempting to find a defined error of principle in the judgment below, it is too easy to be drawn into a wholesale reassessment of the judge's findings. That is not the function of an appellate court."

Interpretation of the prior art

The correct approach to the interpretation of the prior art was discussed in a number of cases in 2019.

¹⁴⁹ *Koninklijke Philips N.V. v Asustek Computer Incorporation & Ors* [2019] EWCA Civ 2230 (17 December 2019) Patten, Floyd & Henderson LJ

¹⁵⁰ *Biogen Inc v Medeva plc* [1997] RPC 1

In *Quinn v Linpac*¹⁵¹ - the case about Linpac's patents to plastic containers of the type typically used in supermarkets for food – HHJ Hacon explained how a prior art document should be interpreted, for the purposes of understanding its disclosure ([62]):

"Any prior art document must be taken as a whole. All of it is deemed to be considered with interest by the skilled person. If one or more figures in the document would disclose information to the skilled person which is not contradicted or amended by anything said in the text, that information is taken to be disclosed."

He also said ([52]):

"It is possible to imagine a disclosure in which the key feature is so bound up with the rest of the product or method that a skilled person reading the disclosure would regard it as being workable only when used as part of the greater whole. On the other hand, it is also possible that a skilled person could recognise a good idea contained within a disclosure which, taken as a whole, is of no interest – for instance because the whole is hopelessly impractical. The gem of a good idea might shine out from the dross of a bad one. This will be a question of fact and degree. Among the relevant facts are whether there is a long felt want for a solution to a problem in the art and whether, primed by this, the skilled person would be likely to spot the solution."

Adopting this approach, the judge concluded that the skilled person would understand that the method disclosed in prior art patent 'Ono' would include the idea of placing adhesive on a peripheral flange in order to seal the container. This was not something that was "buried in the detail" of *Ono*. The skilled person would have understood that the idea could be used both within the context of the *Ono* method as a whole or outside it.

Claim 1 of Linpac's patent required "a layer of adhesive located on an upper, in use, surface of the peripheral flange". It was common ground that "layer" was not a term of art. The judge said that the skilled person would understand that the 'bead' (of *Ono*) would become what could properly be described as a layer when the lid was applied on to the adhesive. In view of the disclosure of *Ono*, the claim lacked inventive step.

Claim 5 of Linpac's patent limited the claimed container to one having a thickness of the layer of adhesive from 20µm to 100 µm. There was no evidence supporting any technical advantage for this range. Consequently, as noted above, the judge's view was that Linpac's proposed claim 5 was an example of '**parametritis**' i.e. "stipulating that a feature of the alleged invention must be present within a stated range, where the range is entirely arbitrary". In such a case, "the apparent novelty and inventiveness conferred by the range is illusory". Claim 5 was obvious too.

The second defendant, Færch, relied on two differences from *Ono* in support of the inventiveness of its patent. One was that the lid and tray were sealed with a layer, as opposed to a bead, of adhesive – this failed for the reason explained above in respect of Linpac's patent.

The other reason relied upon by Færch was that the tray must be formed from a material comprising more than one layer where each of those layers comprised at least 85% APET. On the evidence though, the judge found that the use of a 3-layer co-extrusion meeting this was entirely routine. There was no suggestion from anyone that the skilled person would have believed that there was a technical

¹⁵¹ *Quinn Packaging Limited v Linpac Packaging Limited & Anr* [2019] EWHC 2119 (IPEC) (31 July 2019) HHJ Hacon

connection between the peripheral flange and the multi-layered APET, such that introducing the former required abandoning the latter. Consequently, there was again little to add to the argument on inventive step over that which applied to the Linpac patent. Claim 1 of Færch's patent lacked inventive step too.

In *Philips v Asustek*¹⁵², Floyd LJ noted that the task for the party attacking the patent on the ground of (conventional) obviousness was to show how the skilled person would arrive at the invention claimed from the disclosure of the prior art. If the invention claimed was a simple idea, then the simple idea would be the target. However ([61] & [72]):

"That does not mean...that the court is entitled to assume that the skilled person takes a different approach to the prior art, stripping out from it detail which the skilled person would otherwise have taken into account, or ignoring paths down which the skilled person would probably be led: (see...*Pozzoli*...). The nature of the invention claimed cannot logically impact on the way in which the skilled person approaches the prior art, given that the prior art is to be considered without the benefit of hindsight knowledge of the invention.

...It is quite possible for the detail of a prior art document to operate as a set of technical blinkers which prevents a skilled person from going down an alternative direction."

Obviousness over information 'made available to the public' by prior use

As noted above, in *Emson v Hozelock*¹⁵³, Emson's two patents in issue, to a new type of garden hose, were invalid for obviousness over prior art '*McDonald*' – a conclusion in which Nugee J differed from the conclusion reached by Birss J and the Court of Appeal in earlier litigation (*Blue Gentian v Tristar*¹⁵⁴) involving the same patents and an obviousness challenge based on *McDonald*.

Hozelock was unsuccessful in its other challenges of obviousness. For one of these, a challenge over prior art '*Ragner*', the outcome was consistent with that reached in respect of the same prior art in the earlier *Tristar* litigation.

A further challenge was of obviousness in light of a prior use made by the named inventor of the patents. Mr Berardi had video recorded work that he did on prototypes in his back (and side) garden. Hozelock relied on this material to support its contention that Mr Berardi's work, based on what the notional skilled person standing on the public road at the front of Mr Berardi's house could have seen, formed part of the state of the art over which the patents were obvious.

On the principles concerning whether information had been made available to the public, the judge noted that the onus was on the person seeking to invalidate the patent to establish that the notional recipients of the information would have been free in law and equity to use the information they received. Under English law (which, it was assumed, was the same as the law in Florida), information is not confidential unless there is some particular reason to treat it as such. The mere fact that something is done on private property does not necessarily mean it is confidential if it is in full view of a public street. However, the judge said ([148]-[149]):

¹⁵² *Koninklijke Philips N.V. v Asustek Computer Incorporation & Ors* [2019] EWCA Civ 2230 (17 December 2019) Patten, Floyd & Henderson LJ

¹⁵³ *E. Mishan & Sons, Inc t/a Emson v Hozelock Limited* [2019] EWHC 991 (Pat) (17 April 2019) Nugee J

¹⁵⁴ *Blue Gentian LLC v Tristar Products (UK) Ltd* [2013] EWHC 4098 (Pat); [2015] EWCA Civ 746.

"...it is one thing to say that if the public is given access to information, in whatever guise, that information is made available to the public and it does not matter that no member of the public in fact took up the opportunity...it is quite another thing to say that the law treats information as available to the public when no member of the public could in fact have accessed it."

Mr Berardi's home was in a small cul-de-sac in a residential area, not a busy road. The only people likely to be there were residents or their visitors. It would have been quite obvious if someone had been standing watching him from the road. On the balance of probabilities, the judge accepted Mr Berardi's evidence that if anyone had stood on the road watching him on a day when he was working on a prototype, he would have packed up his equipment and either waited until the visitor had left, or taken it around the back of his house where it would have been out of sight of the road. This, said the judge, meant that ([150]):

"...although any member of the public could have turned up...and stopped to look, had anyone done so, whether a skilled person or anyone else, he would not have been given access to any information. That seems to me to be very different from a publication left in a library for all to read if they choose, or an article left in a public place for all to see if they choose."

Accordingly, in the present case, the information relied upon as forming the basis of the prior use challenge was found not to have been "made available to the public".

Further, it was not contended that information 'made available' to the skilled person standing on the pavement in front of Mr Berardi's house on any *particular* day rendered obvious the patents. Hozelock's case relied upon the mosaicing of information 'made available' to the skilled person standing on the pavement in front of Mr Berardi's house on different days, which the judge considered not to be permissible.

Mosaicing in the context of the internet

In both *Actavis v ICOS*¹⁵⁵ and the Supreme Court's 2018 patent judgment (*Warner-Lambert v Generics*¹⁵⁶), the Law Lords began their reasoning by quoting from centuries old case law dug out of a history book published in 1902.

Happily, the specialist IP judges in the Chancery Division are used to developing patent law in a rather more contemporaneous way.

In *Regen v Estar*¹⁵⁷, a matter arose concerning inventive step and what the skilled team would have understood from a series of documents available on Regen's website. Following the House of Lords' judgment in *Mills & Rockley v Technograph*¹⁵⁸, it is possible for a court to find that an invention is obvious having regard to the combined teaching of two or more documents, but it must be a mosaic which can be put together by an unimaginative skilled person with no inventive capacity.

HHJ Hacon said that in relation to printed documents, there are three circumstances in which this might occur ([159]-[161]):

¹⁵⁵ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 (27 March 2019) Lady Hale, Lords Kerr, Sumption, Hodge & Briggs

¹⁵⁶ *Warner-Lambert Company LLC v Generics UK Limited (t/a Mylan) & Anr* [2018] UKSC 56

¹⁵⁷ *Regen Lab SA v Estar Medical Ltd & Ors* [2019] EWHC 63 (Pat) (18 January 2019) HHJ Hacon

¹⁵⁸ *Mills & Rockley (Electronics) Limited v Technograph Printed Circuits Limited* [1972] RPC 346, at 355

"First, if the cited document refers to the other document. Secondly, if the other document forms part of the skilled person's common general knowledge. Thirdly, if faced with the problem to which the patent is addressed, the skilled person would as a matter of routine consult the other document (not necessarily part of his common general knowledge, although the distinction may be nuanced) and notionally read it together with the cited document. See *Pfizer Ltd's Patent* [2001] FSR 16 at [65]-[66] and *Richter Gedeon Vegyeszeti Gyar Rt v Generics (UK) Limited* [2016] EWCA Civ 410, at [18]-[24]."

Outside those three circumstances it cannot be assumed that the disclosures of two documents in the same technical field may be combined when assessing inventive step, see *Generics (UK) Ltd v Daiichi Pharmaceutical Co Ltd* [2009] EWCA Civ 646; [2009] RPC 23, at [27].

Within the three circumstances, the teaching of more than two documents might be combined but the evidence must show that, unusually, this is what the skilled person would have done."

Judge Hacon then explained that in principle, the position is no different in the context of a website. He continued ([162]-[163]):

"A website may not invariably be treated as a single document. Some websites are vast. If a single page is cited as prior art, it does not follow that the skilled person can be taken to have read every part of the website from which it came. There may have to be evidence about which pages the skilled person would look at before and/or after reading the cited page with interest.

Also, an argument based on the combined teaching of two or more pages from a website cannot ignore other pages that the skilled person would have read. There should be no inappropriate selection. Assuming the evidence establishes that the skilled person's browsing would have extended widely, all the browsed website pages must be taken into account, including those containing what Floyd J described as "inconvenient details of the kind found in documentary disclosures, such as misleading directions or distracting context", albeit with a different point in mind, see *Ratiopharm GmbH v Napp Pharmaceutical Holdings Ltd* [2008] EWHC 3070 (Pat); [2009] RPC 11, at [158]."

Estar contended that Regen's patent was obvious in light of documents on Regen's website. The judge agreed that it was possible to find all the elements of claim 1 on the website, but he thought there had been a degree of selection by Estar from among the pages. In the judge's view, it had not been established that the skilled team, having read in totality the pages on the website that notionally it would have looked at, distractions and all, would have pulled together the various elements of claim 1 and so realised into mind the claim 1 method.

However, Regen's patent was obvious in light of (and anticipated by), the 'Vacutainer' kits that Regen had supplied to a potential customer before the priority date.

The problem with 'ideas' patents

Garmin v Philips¹⁵⁹ was the case about a Philips patent concerned with GPS-based personal athletics performance monitoring. Philips did not defend the patent as granted and multiple proposed amendments were in issue.

¹⁵⁹ *Garmin (Europe) Limited v Koninklijke Philips NV* [2019] EWHC 107 (Ch) (29 January 2019) Henry Carr J

Henry Carr J said that the key problem of the patent as granted was that it was an "ideas" patent i.e. one in which the invention lay in having the idea or concept prescribed in the claims, rather than in any perceived difficulty of implementation once one had had those ideas. However, if the invention resided in the idea, and not in its manner of implementation, then if the idea was known or obvious then it was not patentable.

Certain prior art published before the priority date of the patent anticipated the idea of a GPS-based athletic performance monitoring device. Proposed amended claim "CA2" incorporated, in addition to the features of claim 1 as granted, means for providing audio presentation of real time performance information; and an audio entertainment system for providing the athlete with music during his/her exercise session, which was reduced in volume during the audio presentation of real-time performance information.

Henry Carr J said that although the audio feedback to runners using a GPS-based APMD was obvious, the interaction with the audio entertainment system was not. In the absence of any common general knowledge of such a system or any commercialised example of such a system which would be found on a routine search at the priority date, Garmin's obviousness case on was "classic *ex post facto* step by step analysis" that would in fact require blue sky thinking.

Biologics in 2019

I have noted above that in *Eli Lilly v Genentech*¹⁶⁰, an anticipation challenge failed because it was only highly probable, not inevitable, that a skilled team implementing the IL-17A/A prior art by obvious methods at the priority date would produce an antibody that also bound to and inhibited IL-17A/F. Highly probable was enough, though, to render obvious Genentech's antibody product claims. In light of the common general knowledge, which included a good expectation on the part of the skilled person that blocking IL-17A by administration of an antibody would be effective to treat RA, Genentech's Swiss form and EPC2000 claims failed to confer inventive step too, in so far as they were **directed to RA**.

The same claims were also obvious in light a US patent ('US344'), which by closing, Genentech did not dispute was an enabling disclosure of the recombinant production of a heterodimer between "human CTLA-8" (i.e. IL-17F) and "human IL-17" (i.e. IL-17A). (Recombinant production of the heterodimer would be implied from a reference to forming heterodimers between human CTLA-8 and rat and herpes CTLA-8 proteins). In light of this, the judge concluded that it would have been obvious to make and isolate antibodies to IL-17A/F. Also in light of US344, the skilled person would have considered it reasonably likely that IL-17A/F existed in nature and, taking into account their common general knowledge, the skilled person would consider IL-17A/F a promising target for RA therapy.

These findings left in play Genentech's Swiss form and EPC2000 claims to anti-IL17A/F antibodies for the treatment of psoriasis – for which the outcome is discussed in section 3(d) below.

"Resourceful" late obviousness challenge failed for lack of evidence

In *TQ Delta v ZyXEL*¹⁶¹, after XyZEL's expert, Dr Jacobsen, had been instructed and had searched through her files, XyZEL had added, by re-re-amendment to its grounds of invalidity, prior art challenge '*Alabama*', but without pleading anticipation by *Alabama*.

¹⁶⁰ *Eli Lilly and Company & Ors v Genentech Inc* [2019] EWHC 387 (Pat) (1 March 2019) Arnold J

¹⁶¹ *TQ Delta, LLC v ZyXEL Communications Limited & Anr* [2019] EWHC 562 (Ch) (11 March 2019) Henry Carr J

At trial, ZyXEL ran four anticipation cases against the '268 patent based on Alabama. When challenged on the lack of pleading, the "resourceful as ever" Mr Purvis (ZyXEL's lead counsel) did not apply to amend but contended that the four alternatives were in fact allegations of obviousness. So the judge addressed them in that context.

First, could ZyXEL rely on the 'not anticipation' challenges as obviousness challenges? The judge said ([157]):

"...obviousness is a matter of evidence. Where the issues were not raised in ZyXEL's evidence, it is necessary to ensure that allowing these matters to be raised during closings is not unfair to TQ Delta. Such unfairness would arise if the new attacks give rise to technical issues in respect of which TQ Delta have been taken by surprise and have not had the opportunity to put in evidence to deal with them."

The judge concluded that it would not be fair to allow the alternative cases to be advanced. They had first been advanced in cross- or re- examination, they each raised technical issues which would, if raised earlier, have been addressed by TQ Delta's expert, and this was not a case in which cross-examination revealed new facts which could not have been anticipated in advance of trial. There was also a practical difficulty with the new cases, in that Dr Jacobsen did not address them and TQ Delta's expert, Dr Ginis, did not accept them.

Nevertheless, in case he was wrong on this, the judge then proceeded to consider and reject each of the alternative cases on the merits.

Obviousness for lack of technical contribution

*Takeda v Roche*¹⁶² concerned Roche's patent to glycosylated antibodies. Claim 1 is set out above in section 3(b). Takeda's main obviousness challenge was of **lack of technical contribution**. On this, Birss J provided a neat introduction to the law ([203]):

"The law is clear enough that a ground of invalidity exists which can be called different things including: lack of technical contribution, *Agrevo* obviousness, and failure to solve the technical problem. Depending on the facts one of these descriptions may be more apt in a given case than another but they are all getting at the same thing. I can do no better than refer to the decisions of the Technical Board of Appeal of the EPO in *EXXON/Fuel Oils* T 409/91 and *Agrevo/Triazoles* T 939/92. The general principle there identified is that the extent of the patent monopoly, as defined by the claims should correspond to the technical contribution to the art. This theme – that the patent monopoly should be justified by the actual technical contribution to the art – has often been referred to with approval in the UK, most recently in by the two recent Supreme Court decisions: *Warner-Lambert v. Generics (UK) Ltd t/a Mylan* [2018] UKSC 65 and *Actavis v ICOS Corp* [2019] UKSC 15.

One way in which this principle has been applied in the context of inventive step is to deny validity to a selection from the prior art "which is purely arbitrary and cannot be justified by some useful technical property". Such a selection "is likely to be held to be obvious because it does not make a real technical advance". These passages are taken from Floyd LJ in *Generics UK Ltd t/a Mylan v Yeda* [2013] EWHC Civ 925, citing Jacob LJ in *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly and Co Ltd* [2010] RPC 9."

¹⁶² *Takeda UK Limited v F. Hoffmann-La Roche AG* [2019] EWHC 1911 (Pat) (17 July 2019) Birss J

As noted above (in section 2(c)), Birss J captured the differing questions needing to be addressed in the evidence in respect of an obviousness case run on the 'conventional' basis as compared with a 'lack of technical contribution' obviousness case. He did not address the relevant date(s) for assessment of such a challenge. For a conventional obviousness challenge, this is clearly the priority date of the patent in issue. For a lack of technical contribution obviousness challenge, there is nothing to suggest that it would not also be the **priority** date: this is noteworthy because such a challenge is very much aligned on the underlying principles with a challenge of insufficiency for excessive claim breadth, but the correct date for assessment of the latter is the **filing** date of the patent in issue (as noted below in section 2(d)).

Takeda's case of lack of technical contribution was over each of prior art *Bihoreau* and the common general knowledge publication *Shields*. Roche argued that the patent made three technical contributions. The judge's analysis addressed and rejected these positive cases put by Roche. In short:

- **Disclosing that CHO cells can be obtained having fucosylation of >99%-TRM** was not a technical contribution because, while it was plausible and true, as had been held under anticipation, the prior art included disclosures of antibodies with fucosylation of >99%, so this was not a new idea; further, to the extent this was limited to CHO cells, this did not support product claims not limited to products made in the CHO cells ([208]-[213]).
- **Disclosing the idea of increasing fucose for a therapeutically useful purpose** was not a technical contribution because, while it was plausible and true, the judge had concluded that the CGK included the idea that increasing fucose would reduce ADCC, and so this was not an advance over what was known ([214]-[216]).
- **Disclosing the idea that increasing fucose to 99%+ would reduce ADCC to background** was not a technical contribution because, while it would be a technical advance, there was no such disclosure in the patent. This was because no such statement was expressly made in the patent, which was silent on what the antibodies of the invention actually did. The skilled person would be entitled to take it that the patentee had told the reader whatever the reader needed to be told and the skilled person would not be expected to extrapolate from results done at one concentration and presented in Figure 1. Although Roche had approached the case on the basis that this was what the patent did, reading the patent in this way was hindsight.

In *Technetix v Teleste (18 November 2019)*¹⁶³, Technetix's proposed amended claim comprising an "LC filter" including at least one coil and at least one capacitor was found to be anticipated by prior art *Jelinek*. Nevertheless, Technetix contended that independent validity would be conferred by two further claim features, requiring the LC filter to have at least two 1nF capacitors and a 3.3µH coil. However, there was no evidence that filters with these additional features had any advantage over other LC filters, and so Teleste's argument of obviousness for lack of technical contribution succeeded.

HHJ Hacon also considered the proposed claim language another example of "parametritis".

¹⁶³ *Technetix BV & Anr v Teleste Limited* [2019] EWHC 3106 (Pat) (18 November 2019) HHJ Hacon

An *AgrEvo* obviousness/lack of technical contribution challenge was defeated in ***Conversant v Apple***¹⁶⁴. In this case Conversant asserted infringement of its patent to a smart phone. As proposed unconditionally to be amended, claim 1 was in the following terms ([6]):

" A ~~computing device~~ **smart phone** comprising a display screen, the ~~computing device~~ **smart phone** being able **configured** to display on the screen a main hierarchical menu system, wherein the ~~device~~ **smart phone** is also able **configured** to display, in addition to the main hierarchical menu system, application summary windows for each of several different applications, in which each summary window serves as a summary of a particular application by virtue of displaying a limited list of (i) several commonly used functions offered within that particular application and/or (ii) stored data commonly accessed by that particular application, **wherein the smart phone is configured to, for a given application: display, in a summary window for the given application, both a limited list of several commonly used functions offered within the given application and stored data commonly accessed by the given application; display the said commonly used functions offered within the given application without opening the given application; display the said stored data commonly accessed by the given application without opening the given application; and open the given application when an item of the said displayed commonly used functions or the said displayed stored data is selected.**

2. The ~~computing device~~ **smart phone** of Claim 1 in which selecting a commonly **used** function listed in the summary window causes the ~~related~~ **given** application to open and that selected commonly **used** function to be activated.

The judge did not consider Apple's *AgrEvo* obviousness challenge to be well founded. He characterised the technical contribution made by claim 1 as being that ([163]):

"...it provides an improved method of navigation to what had been called "the best of the app", i.e. the stored data and commonly used functions. It is improved because it is a better, quicker and/or easier method. The user does not have to use the feature, but the device is still a better device because it makes this function available so that some users can use it."

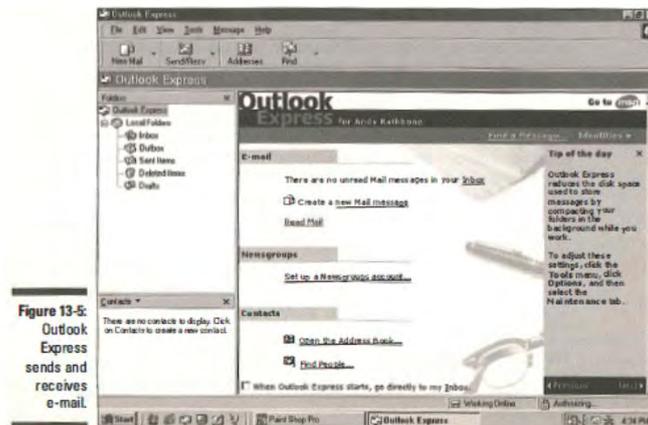
Birss J was satisfied the patent disclosed this contribution, that it was a contribution made by the claimed invention, and that it supported the claim as it stood. It did not matter that claim 1 was not limited to a situation where, once the application was opened, the user was presented with a screen where the data of interest was prominent or the function of interest had been activated – the claim did not have to include this limitation to be commensurate with the technical contribution. The judge wrapped the point up with a nod towards the context in which an *AgrEvo* obviousness challenge might prove more useful ([166]):

"This is not a claim consisting of a chemical formula covering millions of discrete chemical compounds, which may or may not have the biological function on which the invention rests. This claim describes the essential features of the invention in a way the skilled person can understand as fairly supported by the disclosure. It would be possible for the skilled person to put it into practice in a way which does not work very well, but that is not the test."

¹⁶⁴ *Conversant Wireless Licensing s.a.r.l. v Apple Retail UK Limited & Ors* [2019] EWHC 3266 (Pat) (29 November 2019) Birss J

In fact the major grounds of dispute on obviousness in *Conversant v Apple* were two conventional challenges over prior art.

One challenge was over *Windows 98 for Dummies – Outlook express, 2nd edn, 1999*. The focus of the challenge was on two figures, which were identical except in one (not pictured), the task bar at the bottom was not included.



The representation combined current data and commonly used functions presented together to the user in a kind of application summary.

Focusing on the user's view, the judge noted that the window always existed on a desktop arrangement (not a smart phone) in which it was clear from the user's point of view that the application was Outlook Express. Outlook Express had its own main hierarchical menu system, for which this was an alternative. The main hierarchical menu of Outlook Express was not really the main hierarchical menu of the device. When the application summary window was displayed, the application (Outlook Express) was already open, unlike in claim 1.

Rejecting the *Windows 98 for Dummies* challenge, Birss J said ([137]-[138]):

"...having read these pages with interest the skilled team would be left thinking they had seen an interface developed for a completely different world from the one they are considering. Outlook Express is for the user interface on a desktop computer. It is as far as one could be from the user interface of a smart phone. They would know that email had been implemented on mobile devices including PDAs. Even though those are not phones, they are at least mobile devices and have a form factor relevant to the smart phone project. They would be regarded as of much more relevance to the problems the team had to solve...."

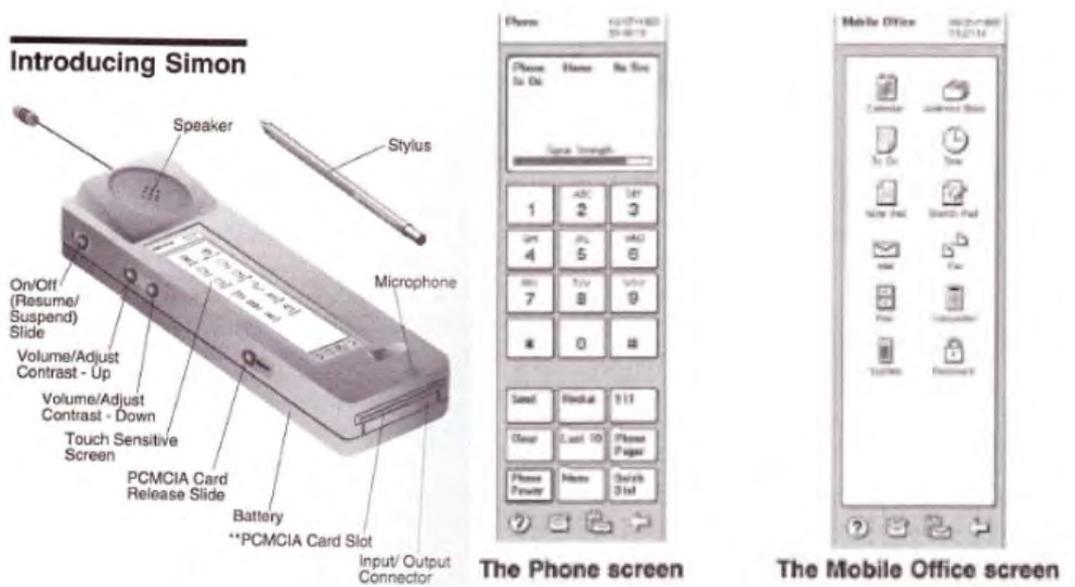
"...It is a complicated and busy screen which contains so much detail one could not possibly compress all that down into a smart phone."

In fact, Birss J thought that Apple's approach involved looking backwards, to see if the screens exhibited features which one could identify as relevant to the invention. While "a worthy approach to the study of user interface design", this was not the way a skilled team in this art would operate.

Birss J noted that as a matter of principle, the prior art is read with interest. But as a matter of law, it is wrong to say that the skilled person is actually told that they must read the document with interest. Birss J explained ([127]):

"The skilled person when they read the cited prior art is not being told or being given a hint that a solution to a problem might be found in that document. Otherwise there is a real risk of injecting hindsight into the analysis."

Apple's other conventional obviousness challenge was over a manual for the 'Simon' cellular phone device, by IBM and telephone company Bell South, dating to 1994. To someone at the priority date the device was a rather brick-like unit built like a telephone handset and with a stylus based touch screen. There was no separate physical keypad. It had a single display screen but presented two main interfaces to the user, a 'Phone screen' and a 'Mobile Office screen':

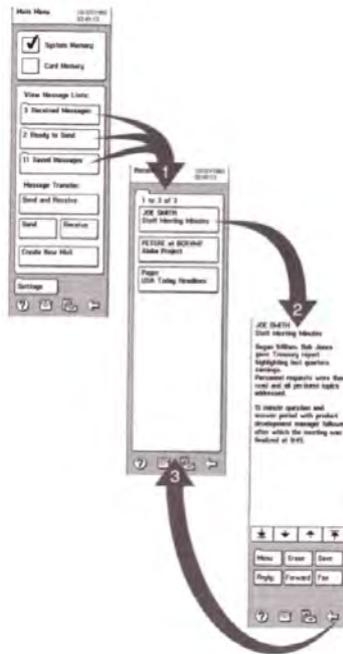


The Simon device was not a commercially successful product and to the skilled team in 2000 it would also have been an old product. Having read the manual with interest, the skilled person would consider it to be an early attempt at what they would regard as a smart phone, but using old technology. Nevertheless, it would be of interest, in view of its attempt to deal with multiple applications on a smart phone.

One of Simon's applications was email. Selecting 'Mail' from the Mobile Office screen's main menu would lead to the following screens, which the user could navigate (see the illustration at the top of the next page).

The first mail screen was a summary window which presented both stored data and commonly used functions at the same time. It was not an alternative way of accessing the functions of the mail application but *the* way to access the mail application. Simon did not have any other windows which could be said to be an application summary window and so the plurality aspect of claim 1 was not satisfied.

The judge said he was struck in cross-examination that both parties' experts (and their defined skilled person) would be interested in the way the screen presented functions and data together – the user interface. The judge believed this represented the reaction of the skilled team, operating without hindsight.



The judge held that in the light of the CGK (which included using notifications, pop ups etc), it would have been obvious to the skilled person that they could use the mode of presentation shown in Simon in a kind of window selected by the user in some way without opening the application. The skilled team's device would have retained its ordinary main hierarchical menu system in order to access the application in the conventional manner. The size of screen they were considering on a smart phone could be comparable to the one in Simon, but the idea would still be obvious using a screen quite a bit smaller. An interest in wanting to be able to use the device "on the go" did not make it any less obvious.

An important aspect of the reasons of Conversant's expert, Mr McGrath, that the invention of the patent was not obvious over Simon, derived from his view of the knowledge and skill of the skilled person as he had defined it. That view had not been accepted by the judge though, who considered the skilled person to have had much wider knowledge and experience.

Further, the fact that the idea was only disclosed for the Mail application in Simon did not make it inventive to apply the idea to multiple other applications too. No other claim was asserted to be independently valid if claim 1 was obvious.

Conversant asked the rhetorical question – if it was obvious why was it not done before? The judge's answer was that if the invention had been a ground breaking idea which revolutionised the industry and solved a long standing problem then there might be something in the rhetoric, but it was not. It was a worthwhile idea, but it was one which was obvious over an item of prior art which was not itself CGK. So the rhetorical question did not help.

Conversant's patent was therefore invalid for obviousness over Simon.

d) Insufficiency

The date of assessment

In *Regen v Estar*¹⁶⁵ – the case about Regen's patent to a method for obtaining platelet-rich plasma – HHJ Hacon noted that the relevant date for assessing sufficiency of disclosure is the filing date, not the priority date, citing the House of Lords' judgment in *Biogen v Medeva*¹⁶⁶ as authority.

This point is not new, as the date of *Biogen v Medeva* suggests. Yet still not everyone gets this right – even judges and leading counsel forget it sometimes. In the *Regen v Estar* case, Judge Hacon said that he had realised after the trial that cross-examination and argument had taken the wrong date, the priority date, but for the purposes of the present case he did not think it mattered. Estar's insufficiency challenge failed, but the patent was invalid for anticipation and obviousness.

Plausibility

In November 2018, the Supreme Court handed down its judgment in *Warner-Lambert v Generics*¹⁶⁷, leaving rather a messy clear up for lower court patent judges on the doctrine plausibility, particularly in the context of sufficiency.

This year, Arnold J took on the task in *Eli Lilly v Genentech*¹⁶⁸.

Genentech's patent concerned anti-IL-17A/F antibodies. Claims 12 and 20 were in Swiss form; claim 22 was in EPC2000 form.

It was common ground that in order for claims 12, 20 and 22 to be valid in so far as they were directed to psoriasis, it must have been **plausible** to the skilled dermatologist reading the patent in July 2003 in light of the CGK that an anti-IL-17A/F antibody would have some therapeutic efficacy for treating psoriasis.

The judge noted that in *Warner-Lambert v Generics*, the Supreme Court was divided on plausibility, with the judgment of the majority given by Lord Sumption. There was no reference in any of the Supreme Court's four judgments to the previous decision of the Supreme Court on plausibility - in *HGS v Eli Lilly*¹⁶⁹ - even though *HGS v Eli Lilly* was applied by the lower courts in the *Warner-Lambert* case and cited in argument before the Supreme Court. Although in *HGS* the context was industrial applicability, the fundamental principle was the same, as Lord Sumption did note in his judgment in *Warner-Lambert*¹⁷⁰.

Genentech submitted that the test laid down in *Warner-Lambert* was the same as that in *HGS*, which was of assistance in the present case because like the patent in issue, the patent in *HGS* concerned a new member of a known family. However, Arnold J said ([531]):

"...I accept that, in applying the principles laid down by *Warner-Lambert* to the facts of [the] present case, it is necessary to take into account the fact that the Patent concerns a new (at

¹⁶⁵ *Regen Lab SA v Estar Medical Ltd & Ors* [2019] EWHC 63 (Pat) (18 January 2019) HHJ Hacon

¹⁶⁶ *Biogen Inc v Medeva plc* [1997] RPC 1, at pp.53-54

¹⁶⁷ *Warner-Lambert Company LLC v Generics (UK) Ltd & Anr* [2018] UKSC 56 (14 November 2018)

¹⁶⁸ *Eli Lilly and Company & Ors v Genentech Inc* [2019] EWHC 387 (Pat) (1 March 2019) Arnold J

¹⁶⁹ *Human Genome Sciences Inc v Eli Lilly and Company* [2011] UKSC 51,

¹⁷⁰ *Warner-Lambert Company LLC v Generics (UK) Ltd & Anr* [2018] UKSC 56 (14 November 2018) at [17]

least in the sense of being newly found to exist in humans) member of a known family. I do not accept that this requires any modification of those principles, if that is what counsel for Genentech was suggesting."

Arnold J noted too that the *Warner-Lambert* case was concerned with a second medical use claim, in Swiss form, of a known pharmaceutical. He continued ([523]):

"The present case is concerned with a first medical use, given that the claimed antibodies were not known, although there are claims framed as second medical use claims both in Swiss form (purpose-limited process claims, namely claim 12 and 20) and in EPC2000 form (a purpose-limited product claim, namely claim 22). There is no dispute that the guidance given by Lord Sumption is applicable, although Genentech contends that it is necessary when applying it to bear in mind the different context. I accept that."

On the principles, Arnold J did a commendable job of extracting a usable way forward in light of the Supreme Court's judgment. He said ([524]-[529]):

"Lord Sumption began at [17] with the fundamental principle that, as it was put by the Board of Appeal of the EPO in T 409/91 *Exxon/Fuel oils* [1994] OJ EPO 63 at [3.3] and [3.4] that "the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art", that is to say, "the patent monopoly should be justified by the actual technical contribution to the art". As he observed, the requirements of novelty, inventive step, industrial applicability and sufficiency are all, in one way or another, directed to ensuring that this principle is satisfied.

At [19]-[20] Lord Sumption noted that the problem with interpreting the requirement of sufficiency in the context of a second medical use claim as merely requiring the disclosure of the new purpose was that "it would enable a patent to be obtained on a wholly speculative basis". Importantly for the present context, he said at [22]:

"The Court of Appeal's reference to 'armchair inventors' suggests that what they meant by speculative claiming was claiming by persons who had done nothing new or inventive at all but had simply sought to patent abstract possibilities. That may well be a particular risk in the case of patents for new uses of known compounds, especially when they are commercially successful in their existing use. In reality, however, speculative claiming of this kind is simply one of a number of ways in which a patentee may attempt to claim a monopoly more extensive than anything which is justified by his contribution to the art. Other ways in which this can happen include claiming a monopoly wider than the disclosure in the patent can support. An over-broad claim will not necessarily be speculative. The inventor may really have invented something corresponding to the full breadth of the claim. Research may subsequently demonstrate this. But the claim will still exceed his contribution to the art if that contribution is not sufficiently disclosed in the patent."

From [23]-[35] Lord Sumption reviewed the case law of the Boards of Appeal, where, as he explained, the concept of plausibility had originated "as a response to over-broad claims".

At [36] Lord Sumption disagreed with the Court of Appeal's statement of the effect of the plausibility test, saying:

“The principle is that the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true. Plausibility is not a distinct condition of validity with a life of its own, but a standard against which that must be demonstrated. Its adoption is a mitigation of the principle in favour of patentability. It reflects the practical difficulty of demonstrating therapeutic efficacy to any higher standard at the stage when the patent application must in practice be made. The test is relatively undemanding. But it cannot be deprived of all meaning or reduced ... to little more than a test of good faith.”

Lord Sumption went on at [37] (emphases and line breaks added):

“Plausibility is not a term of art, and its content is inevitably influenced by the legal context. In the present context, the following points should be made.

First, the proposition that a product is efficacious for the treatment of a given condition must be plausible.

Second, it is not made plausible by a bare assertion to that effect, and the disclosure of a mere possibility that it will work is no better than a bare assertion.

But, **third**, the claimed therapeutic effect may well be rendered plausible by a specification showing that something was worth trying for a reason, ie not just because there was an abstract possibility that it would work but because reasonable scientific grounds were disclosed for expecting that it might well work. The disclosure of those grounds marks the difference between a speculation and a contribution to the art. This is in substance what the Technical Board of Appeal has held in the context of article 56, when addressing the sufficiency of disclosure made in support of claims extending beyond the teaching of the patent. In my opinion, there is no reason to apply a lower standard of plausibility when the sufficiency of disclosure arises in the context of EPC articles 83 and 84 and their analogues in section 14 of the Patents Act. In both contexts, the test has the same purpose.

Fourth, although the disclosure need not definitively prove the assertion that the product works for the designated purpose, there must be something that would cause the skilled person to think that there was a reasonable prospect that the assertion would prove to be true.

Fifth, that reasonable prospect must be based on what the TBA in *SALK* (para 9) called ‘a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se.’

Sixth, in *SALK*, this point was made in the context of experimental data. But the effect on the disease process need not necessarily be demonstrated by experimental data. It can be demonstrated by *a priori* reasoning. For example, and it is no more than an example, the specification may point to some property of the product which would lead the skilled person to expect that it might well produce the claimed therapeutic effect; or to some unifying principle that relates the product or the proposed use to something else which would suggest as much to the skilled person.

Seventh, sufficiency is a characteristic of the disclosure, and these matters must appear from the patent. The disclosure may be supplemented or explained by the common general knowledge of the skilled person. But it is not enough that the patentee can prove that the product can reasonably be expected to work in the designated use, if the skilled person would not derive this from the teaching of the patent."

At [40] Lord Sumption added:

"The question is not whether [the medicament] works but whether the contribution to the art consisting in the discovery that it can be expected to work has been sufficiently disclosed in the patent. The inherent difficulty of demonstrating this before clinical trials is taken into account in the modest standard (ie plausibility) which is applied to test it. ... This does not mean that subsequent data is never admissible in a dispute about sufficiency, but the purpose for which it is admitted is strictly limited. Where the asserted therapeutic effect is plausible in the light of the disclosure in the patent, subsequent data may sometimes be admissible either to confirm that or else to refute a challenger's contention that it does not actually work... But it cannot be a substitute for sufficient disclosure in the specification." "

Turning to the assessment in the *Eli Lilly v Genentech* case, Arnold J noted as common ground that in considering the plausibility of the claims, the dermatologist would obtain and read the key papers cited in the patent (at [0015]-[0019]) and also certain other papers. The judge found that after reading these papers, the skilled person would have concluded that (a) there was some uncertainty as to IL-17's potency *in vitro* and (b) it was not known what potency it had *in vivo*. IL-17 would have been considered to have a narrower range of effects than either TNF α or IFN γ .

It was common ground that the skilled person would understand from the patent (example 1) that IL-17A/F bound to the same receptor as IL-17A/A (i.e. 'IL-17R') and had the same function, but bound with lower affinity. Thus the skilled person would agree with the statement contained in the patent that IL-17A/F may compete with IL-17A/A for binding to IL-17R. However, the patent contained no experimental evidence demonstrating the presence of IL-17A/F in psoriasis lesions or otherwise indicating that IL-17A/F had a pathogenic role in psoriasis.

The opinion of Lilly's dermatology expert (Prof Krueger) was that the skilled person would not have considered it plausible in July 2003 that an antibody to IL-17A/F would be efficacious for the treatment of psoriasis. His reasoning included the broad list of conditions which the patent claimed could be treated with *inter alia* anti-IL-17A/F antibodies, which included no unifying characteristic beyond the fact they involved the immune system in some way, and no unifying rationale or theory for regarding IL-17A/F as of pathogenic relevance. The skilled person would not regard IL-17A/A as a candidate to take forward in a clinical trial and would consider IL-17A/F as even less promising. There were "no reasonable grounds" for expecting that an anti-IL-17A/F antibody might work to treat psoriasis; the claim was "tenuous".

The opinion of Genentech's dermatology expert (Prof Prens) was that the skilled person would regard it as plausible that IL-17A/F had a role in psoriasis and that an anti-IL-17A/F antibody would be beneficial in the treatment of psoriasis, although this would remain a hypothesis that needed further study. The basis for this was the key papers cited in the specification of the patent (at [0015]-[0019]) combined with key teachings of the patent that IL-17A/F stimulated the production of IL-6 and IL-8

with a potency intermediate between IL-17A and IL-17F, and that IL-17A/F was produced by activated T cells. The judge noted that a central aspect of Prof Prens' reasoning on this was his conception of the skilled person's CGK concerning IL-6 and IL-8, this being that they were thought to be key agents with a significant role in the pathogenesis of psoriasis. However, the judge had found that this was not the case. (The judge had also recorded his reduced confidence in Prof Prens' evidence and thus the weight which we was able to give to it, as discussed in section 2(c) above).

The judge noted too the evidence of Genentech's rheumatoid arthritis expert (Prof Kamradt) that "the two pillars of checking if something is a valid therapeutic target" were not present in the patent with respect to psoriasis. These were: "finding it over expressed in the diseased tissue versus control and finding a role in an animal model".

The judge concluded on plausibility ([576]-[577]):

"In considering the question of plausibility, it is important to focus on the right question. As discussed above, claims 12, 20 and 22 are to be interpreted as requiring a discernible therapeutic effect on psoriasis. Accordingly, the question which must be considered is whether the skilled reader would consider it plausible that an IL-17A/F antibody would have such an effect. It would not be enough for the skilled person to conclude that IL-17A/F was a potential target for psoriasis therapy which was worthy of further research to find out whether an anti-IL-17A/F antibody was likely to be efficacious.

In my judgment the skilled person would not regard it as plausible that an anti-IL-17A/F antibody would have a discernible therapeutic effect on psoriasis for the reasons given by Prof Krueger. I would emphasise five points. First, the absence from the Patent of any experimental data concerning the role or effect of IL-17A/F, let alone an anti-IL-17A/F antibody, in psoriasis. Secondly, the absence of any discussion of the role or effect of IL-17A/F in psoriasis. Thirdly, the limited support for IL-17A/A (let alone IL-17A/F) having a pathogenic role in psoriasis provided by the papers cited in the Patent, particularly given the common general knowledge as to all the other cytokines which were implicated in psoriasis. Fourthly, the fact that the Patent shows that IL-17A/F is an order of magnitude less potent than IL-17A/A. Fifthly, the fact that the specification claims efficacy against a broad list of conditions which it is wholly implausible that an anti-IL-17A/F antibody (or any form of IL-17A/F therapy) would be effective against. Moreover, there is no emphasis on psoriasis in the specification. Such emphasis as there is concerns RA, which the skilled dermatologist would appreciate raised different considerations to psoriasis. In short, the claim of efficacy against psoriasis is speculative."

Lilly's challenge of insufficiency was therefore successful, so far as the claims were directed towards psoriasis. Combined with the judge's findings of obviousness, this meant that all the claims in issue were invalid.

Before moving on, I think a couple of points are worth making. First, the principles applied by Arnold J in his assessment of insufficiency for lack of plausibility strike me as very much aligned with those he applied at first instance in the *Warner-Lambert* case¹⁷¹. Second, Arnold J's assessment of insufficiency was as at the priority date of the patent. Nothing in the judgment suggests that the outcome would have been different had the application date been used. However, the judge did note that he had not referred to all the material before him in his judgment.

¹⁷¹ *Generics (UK) Limited v Warner-Lambert Company LLC* [2015] EWHC 2548 (Pat)

Ambiguity / "uncertainty"

In *Takeda v Roche*¹⁷², Takeda's case on insufficiency seems to have had many strands, which the judge boiled down to four. Two of these concerned ambiguity.

Birss J said there was no dispute on the law. Yet it is worth us stopping to capture the principles noted, not least in view of the Court of Appeal's judgment later in the year in *Anan Kasei (Rhodia) v Neo*¹⁷³. Birss J cited three recent judgments. One was *Unwired Planet v Huawei*¹⁷⁴, in which Birss J had comprehensively reviewed the legislative history and jurisprudence, concluding with the following summary ([163]):

"Pulling all this together, I agree that claims can often be difficult to construe. Sometimes those difficulties are due to avoidable obscurity for which the patentee should get no sympathy, but it can be because trying fairly to describe an invention in words is not always an easy task. I also agree with Arnold J that the existence of a fuzzy boundary in a claim is not objectionable. The contrast is between that and a claim which is truly ambiguous. The factual circumstances in which such a truly ambiguous claim has been identified so far in the modern law (*Kirin-Amgen* and *Sandvik*) are ones which depend on carrying out a technical test to find out if a product or process is within the claim or not. If the skilled person cannot know whether they are carrying out the right test, then the claim is truly ambiguous and therefore insufficient. That makes sense. However, while the principle cannot be limited just to technical tests, after all *SmithKline Beecham* was not that sort of case, nevertheless it does not apply simply because one can imagine difficult cases to judge at the edge of a claim. When a defendant has been found to infringe, demonstrating that the claim's scope is at least clear enough to work that out, an argument that the claim should be regarded as truly ambiguous is likely to be met with scepticism."

Drawing upon this reasoning, in *GSK v Vectura*¹⁷⁵, Arnold J noted that the following allegation was capable as a matter of law of amounting to insufficiency, if factually well-founded ([176]):

"GSK contend that the Patents are insufficient because they do not enable the skilled person to determine whether a process or product falls within the claims since they do not enable the skilled person to determine whether or not there are composite active particles with additive particles fused to/smeared over active particles so as to form a coating, and certainly do not enable the skilled person to do so without undue burden."

Roche's patent concerned antibody glycosylation. Claim 1 is reproduced in section 3(b) above. On the evidence before the court in that case, the judge concluded ([254]):

"I find that the skilled person given the patent would think they could use a nano-bore or a micro-bore LCMS system with QTOF. They could set up either system to produce highly precise results. The machine, set up properly would be able to distinguish between either side of the claim boundary. However depending on which machine they used, the result could either fall inside the claim or outside it. Whichever result the skilled person got, they would not know that if they used the other machine they would get a different answer. A product that fell within the claim measured on one machine could fall outside the claim measured on the other

¹⁷² *Takeda UK Limited v F. Hoffmann-La Roche AG* [2019] EWHC 1911 (Pat) (17 July 2019) Birss J

¹⁷³ *Anan Kasei Co. Inc & Anr v Neo Chemicals and Oxides Limited* [2019] EWCA Civ 1646 (9 October 2019) Lewison, Floyd, Peter Jackson LJ

¹⁷⁴ *Unwired Planet International Limited v Huawei Technologies Co. Limited* [2016] EWHC 576 (Pat)

¹⁷⁵ *Glaxo Group Limited & Ors v Vectura Limited* [2018] EWHC 3414 (Pat)

machine. The ambiguity is not of a kind which reveals a fuzzy boundary at the edge of the claim. The claim is truly ambiguous and invalid."

In *Anan Kasei (Rhodia) v Neo*¹⁷⁶, the Court of Appeal had a thorough look at insufficiency for ambiguity, with both Floyd LJ and Lewison LJ giving reasoned judgments.

As a reminder, claim 1 was in the following terms:

"A ceric oxide **consisting essentially of a ceric oxide**, and wherein said ceric oxide has a specific surface area of not smaller than 30.0 m²/g when subjected to calcination at 900°C for 5 hours."

Neo contended that where the alleged infringing ceric oxide contained an ingredient other than ceric oxide, the skilled person was required to perform a test to determine whether the presence of the extra ingredient had a material effect on the essential characteristics of the product. Neo argued that this 'materiality test' would give rise to difficulty: to pursue the cake analogy, one would have to take the ingredient out of the cake after it was cooked; the claim required a focus on the effect of the added ingredient teased apart from process effects.

At first instance¹⁷⁷, deputy judge Roger Wyand QC dismissed Neo's challenge of insufficiency for ambiguity, having concluded that the argument amounted to no more than a contention that there was a "fuzzy boundary" at the edge of the claim.

The Court of Appeal, drawing in particular upon the House of Lords' judgment in *Kirin-Amgen*¹⁷⁸, agreed that there is a difference between a fuzzy boundary and a boundary whose location is impossible to ascertain, and it is only in the latter case that the patent is insufficient.

However the Court of Appeal took issue with the use of the term "ambiguity" in this context. Lewison LJ commented that although patent lawyers have traditionally used the term to describe the ground of insufficiency concerned, its use in that context has not been accurate.

Floyd LJ explained that the term ambiguity usually refers to a situation where words are capable of more than one meaning. As recognised in *Terrell on the Law of Patents* 12th Edn 1971 at paragraphs 240-245, the mere fact a claim was capable of two different constructions did not render the claim invalid for insufficiency if the normal process of construction through the eyes of the skilled person could resolve the issue.

The issue in *Kirin-Amgen* was instead of conceptual **uncertainty**: the process of interpretation could not resolve the question of what uEPO the patentee had in mind for the necessary test, and the consequent burden which this placed on the skilled person meant that the specification was insufficient.

Accordingly, Floyd and Lewison LLJ agreed that this basis for insufficiency is better described as "uncertainty".

Floyd LJ did not accept Rhodia's contention that this form of insufficiency (uncertainty) was only available if it was impossible to tell *in any case* whether a product infringed. (Rhodia's contention was

¹⁷⁶ *Anan Kasei Co. Inc & Anr v Neo Chemicals and Oxides Limited* [2019] EWCA Civ 1646 (9 October 2019)
Lewison, Floyd, Peter Jackson LLJ

¹⁷⁷ *Anan Kasei Co. Ltd & Anr v Molycorp Chemicals and Oxides (Europe) Ltd* [2018] EWHC 843 (Pat)

¹⁷⁸ *Kirin Amgen & Ors v Hoechst Marion Roussel Ltd & Ors* [2004] UKHL 46

that because there was no doubt that pure ceric oxide would infringe, any uncertainty about "consisting essentially of" was irrelevant). Instead, Floyd LJ indicated that a claim could be insufficient for uncertainty if there is a large territory of the claim (more than a fuzzy boundary) which is uncertain.

On the facts of the present case, however, Neo's insufficiency attack failed. Floyd LJ gave three reasons for this:

- 1) This was not a case where there was any argument about the criterion which one needed to apply and possibly test for once argument about the construction of the claim had been resolved (as it had been). It was simply whether the added ingredient had a material effect on the essential characteristics of the product.
- 2) Neo's case was based on a false premise – that the purchaser of the product would not have access to process details in order to make a comparator product. But the test for insufficiency is "whether the patent discloses the invention clearly enough and completely enough for it to be performed by a *person skilled in the art*", not whether a purchaser of the product lacking the relevant skill in the art could determine whether it was infringed. Floyd LJ noted that there are many situations countenanced by patent law (product by process claims being one example) where a purchaser will not be able to test for infringement without access to process details.
- 3) The suggestion that determining whether a product was inside or outside the claim would impose an undue burden on the skilled person was not made out on the evidence. The skilled person would not think that he was being required to create a comparator with the added ingredient removed from the baked composition (i.e. the "impossible"). Rather ([31]):

"...the skilled person would look at the chemical analysis of any individual product, something which was routinely provided in the industry. The skilled person would be able to say from his experience that quantities of zirconia up to 0.1% would not materially affect the properties. As soon as one saw quantities above 1%, however, he would assume it had been added deliberately to achieve an effect, and would do so. Understandably he was not pressed on where the precise edge of the claim would lie between these two values. The judge was fully entitled to conclude that this was no more than a fuzzy boundary, and did not lead to insufficiency by reason of uncertainty."

Excessive claim breadth

In *Anan Kasei (Rhodia) v Neo*¹⁷⁹, Neo also contended that Rhodia's patent was invalid for excessive claim breadth / *Biogen* insufficiency. Neo's case was that the claim merely described an obviously desirable product, namely an essentially pure ceric oxide with high specific surface area (SSA) which it kept after prolonged exposure to high temperature, but only contributed one way of achieving such a product.

Floyd LJ began with a few "well-established but important general points":

¹⁷⁹ *Anan Kasei Co. Inc & Anr v Neo Chemicals and Oxides Limited* [2019] EWCA Civ 1646 (9 October 2019) Lewison, Floyd, Peter Jackson LJ

- the burden of establishing the objection was on the person attacking the patent;
- the specification must enable the invention to be performed across the full width of the claim; there was no general rule that one method of making a product falling within a product claim would always be enough;
- this did not mean that everything that would be an infringement must be enabled – a claim to features A, B and C might be infringed by an embodiment with feature D as well;
- inventions might be claimed in apparently broad terms where the patentee had invented a general principle which would be expected to work equally well not only in relation to embodiments which the skilled person might make with the aid of the patent and his CGK, but also to any others that came along – such a challenge was highly sensitive to the nature of the invention – *Regeneron v Kymab*¹⁸⁰ was an example of this class of case.

Much of the argument concerned the House of Lords' judgments in *Biogen v Medeva*¹⁸¹ and *Generics v Lundbeck*¹⁸².

Floyd LJ explained that in *Biogen*, the claim in issue was to a product, a molecule identified partly by the way in which it had been made ("recombinant DNA") and partly by what it did (express a polypeptide with HBV antigen specificity). The House of Lords proceeded on the assumption that a claim in this form was novel and not obvious, and considered whether it was entitled to its claimed priority, which required an analysis of whether the invention claimed was "supported by matter disclosed" in the priority document. This brought with it the notion of an "enabling disclosure" i.e. whether the invention had been disclosed in a way which enabled it to be performed by a person skilled in the art. Lord Hoffmann concluded his summary of the legal issue in the following way ([70]):

"It is not whether the claimed invention could deliver the goods, but whether the claims cover other ways in which they might be delivered: ways which owe nothing to the teaching of the patent or any principle which it disclosed."

Lord Hoffmann went on to explain that there was more than one way in which the breadth of claim might exceed the technical contribution to the art embodied in the invention ([71]):

"The patent may claim results which it does not enable, such as making a wide class of products when it enables only one of those products and discloses no principle which would enable others to be made. Or it may claim every way of achieving a result when it enables only one way and it is possible to envisage other ways of achieving that result which make no use of the invention."

This last statement was considered further in *Lundbeck*. The background in that case included that citalopram in its enantiomeric form was known. Lundbeck undertook research and devised a method of making the pure (+) enantiomer, the claim to which was held to be novel and not obvious. Generics argued that Lundbeck's contribution to the art was only the method devised, yet product produced by

¹⁸⁰ *Regeneron Pharmaceuticals, Inc v Kymab Ltd* [2018] EWCA Civ 671

¹⁸¹ *Biogen Inc v Medeva plc* [1997] RPC 1

¹⁸² *Generics (UK) Limited & Ors v H. Lundbeck* [2009] UKHL 12

later developed alternative methods could be caught by the claim without owing anything to Lundbeck's contribution to the art.

Floyd LJ explained why the Court of Appeal and the House of Lords had rejected this argument in *Lundbeck* ([46]):

"The flaw in the argument was that it was wrong, in the case of the claim in issue in *Lundbeck*, to define the patentee's contribution to the art by reference to the "inventive step", rather than the technical contribution to the art. Once it was established that the (+) enantiomer was a novel product, the contribution to the art was that product, not the method by which it was made. Provided that the specification enabled the product to be made, the existence of other possible methods did not render the claim insufficient."

From the speeches in the *Biogen* and *Lundbeck* cases, Floyd LJ said that he drew a number of principles ([52]):

1. The principle in *Biogen* is concerned with permissible scope of claim in the light of the patentee's contribution to the art.
2. In general, that principle is that the claim must not extend to embodiments which owe nothing to the patentee's contribution to the art.
3. In the case of a claim to a single novel chemical compound, the patentee's technical contribution is that compound. Such a claim will not be insufficient if the single compound is enabled by a method in the specification, notwithstanding the fact that there may be other methods of making it which owe nothing to the disclosed method.
4. The same must be true of a claim to a class of compounds, each of which can be made by the application of a method disclosed in the specification. There is no requirement that the patentee disclose more than one method, where one method will do.
5. This does not mean that all claims to a class of products by definition comply with the *Biogen* principle. The conclusion in *Biogen* shows that a claim which is formally to a class of products may cover embodiments which owe nothing to the patentee's technical contribution.
6. The reason why the claim in *Biogen* offended the principle was not because it had "process components" but because the language of the claim was so generalised (both in relation to the manner in which the product was made and in relation to its function) that it extended to embodiments which owed nothing to the patentee's contribution to the art. A claim to a product defined by its function (e.g. any heavier than air flying machine referred to by Lord Hoffmann at page 52 in *Biogen*) is capable of extending to subject matter which owes nothing to the patentee's contribution to the art."

Further, Floyd LJ noted that claims defined by reference to desired properties of a product need careful scrutiny, the underlying rule being that the patentee cannot claim more than he has enabled.

Rhodia's claim was to a class of products identified by their composition, physical characteristics (their SSA) and their performance in the calcinating test. It was a class because the claim could be satisfied by a range of degrees of purity and SSA and a range of performance in the test.

Neo argued that the claim extended to subject matter which owed nothing to Rhodia's technical contribution because the SSA would be influenced by morphology (the combination of porosity, pore size distribution and particle size distribution), and there was a wide range of potential morphologies - Rhodia's contribution enabled only those which could be made by the method disclosed in the patent.

Floyd LJ said that Neo were undoubtedly correct that the specification enabled only those structures which could be made by the person skilled in the art by the methods disclosed combined with the common general knowledge. However ([59]-[62]):

"To establish that the claim offended against the *Biogen* principle as explained in *Lundbeck*...Neo had to go further. They had positively to establish that there were structures which were covered by the claim which could not be made with the benefit of that teaching. There is no reason for the court to assume that the claim covers structures which owe nothing to Rhodia's contribution to the art.

In my judgment the evidence on which Neo rely does not take them nearly far enough. The most that appears to have been established is that other methods of manufacture might well affect the morphology of the cerium oxide. Even assuming that to be so, there are two possibilities. One is that the products of those other methods fail to satisfy the calcination test, in which case the claim does not cover them. The other possibility is that the claim does cover those products, in which case it needs to be established that the structure in question is incapable of being replicated by Rhodia's method, or a suitable common general knowledge adjustment to it.

The judge accepted the evidence of Neo's expert that the specification of the patent disclosed sufficient to make a wide range of products having a range of different SSAs after calcinating. The missing link in Neo's case, as it seems to me, is the lack of any evidence that there are structures which fall within the claim but which could not be made using the body of teaching in the patent."

Accordingly, the judge's conclusion that Rhodia's patent was not insufficient was confirmed.

e) Added matter

In *Eli Lilly v Genentech*¹⁸³, added matter had presented difficulties for Genentech's patent in the EPO and an appeal to the TBA remained pending. In the Patents Court, Genentech did not seek to defend the claim as granted but sought unconditional and conditional amendments.

On the principles, Arnold J noted article 123(2) of the EPC, Case Law of the European Patent Office (8th ed) at 401, and some of the key UK authorities¹⁸⁴. He then noted ([329]):

"...the court must compare the disclosure of the Application with the disclosure of the Patent as proposed to be amended. It must do so reading both documents through the eyes of the skilled team with their common general knowledge. Expert evidence directed specifically to this issue is not required."

¹⁸³ *Eli Lilly and Company & Ors v Genentech Inc* [2019] EWHC 387 (Pat) (1 March 2019) Arnold J

¹⁸⁴ *Vector Corporation v Glatt Air Techniques Inc* [2007] EWCA Civ 805; *IPCom GmbH & Co. KG v HTC Europe Co. Ltd* [2015] EWHC 1034 (Pat); *GlaxoSmithkline UK Ltd v Wyeth Holdings LLC* [2016] EWHC 1045 (Ch)

In the present case, Arnold J considered it of "minor significance" that Lilly had not adduced expert evidence in support of its case on added matter.

On the burden of proof, the judge noted that Genentech, as the party seeking to amend the patent in issue, bore the legal burden of showing that the proposed amendments satisfied the applicable statutory requirements. Nevertheless ([330]):

"...the question of added matter is not one which falls to be resolved by reference to the burden of proof since it involves an objective comparison by the court of the two documents."

So nor did an absence of expert evidence directed to added matter count against Genentech; but in fact the judge considered that Genentech had elicited some evidence from Lilly's expert (Dr Tite) as to the disclosure of the patent, which supported Genentech's answers to Lilly's added matter objections.

Arnold J addressed five added matter objections raised by Eli Lilly, concluding that:

- It was not added matter to describe (claims 1 and 14) the claimed antibody as specifically binding to an "IL-17A/F heterodimeric complex" rather than to an IL-17A polypeptide. Example 1 would be appreciated as part of the central core of the disclosure of the application and patent and it used the terms "selectively" and "specifically" synonymously. Lily's Dr Tite (antibody engineering) agreed (more generally). Hence the judge concluded that the generalisation was permissible, contrary to the conclusion of the Opposition Division (and the Comptroller's submissions).
- It was not added matter to require (claims 1 and 14) that the antibody "inhibits the activity of the IL-17A/F heterodimeric complex to induce the production of IL-8 and IL-6". Although Lilly contended that that activity was not disclosed in combination with an antibody, example 1 said that "specific antibodies which bind to the novel heterodimeric complex of IL-17A/F have been identified which may serve to **modulate the activity** of this novel cytokine". The judge noted that Lily's expert (Dr Tite) had agreed that the skilled person would understand that reference to the antibodies modulating the activity of the cytokine was a reference to inhibiting the activity of inducing IL-6 and IL-8 production. Hence the combination was singled out in the application. Context was also provided elsewhere. Again the judge's conclusion conflicted with that of the Opposition Division.
- It was not added matter additionally to combine (i.e. with the features noted in the previous paragraph) the antibody feature of being either human or humanised (claim 1). As Dr Tite accepted, the skilled person would be well aware that, for therapeutic applications, human or humanised antibodies would be used. Further, the antibodies of Example 1 were human. The combination was therefore not a prohibited selection from multiple lists but a narrowing of the claim to a part of the disclosure of the application. Again, the judge's conclusion conflicted with that of the Opposition Division.
- It was not added matter to refer to a Kd of "at least about 10^{-8} , 10^{-9} , 10^{-10} , 10^{-11} or 10^{-12} M" where the application referred to 10^{-4} , 10^{-5} , 10^{-6} and 10^{-7} M. The application disclosed that "specific binding" could be exhibited by a molecule having any of the Kds in the list and Dr Tite accepted that the skilled person would want antibodies with Kds in the range 10^{-8} or better. Each Kd was disclosed individually in a series of narrowing embodiments; they

were independent disclosures. Identifying only some of the disclosed Kds in the claim did not make the claim to an undisclosed subset.

- It was not added matter to refer to RA and psoriasis in claims 12, 20 and 22. Although much longer lists of indications were contained in the patent, there was focus on psoriasis, RA and two others in [0015]. The statement of principle of the Enlarged Board of Appeal in G1/93 *Advanced Semiconductor Products/Limiting feature*¹⁸⁵ was not in doubt but was not applicable in the present case.

Consequently, Genentech's proposed amendments were allowable save for the word "comprises"; the conditional amendment to "consists of" was allowable.

Arnold J also captured the principles quite neatly in ***Conversant v Huawei (4 July 2019)***¹⁸⁶. This was the case noted above in which Huawei succeeded in only one of its twenty challenges at trial – but that one was what counted. On added matter, the judge said ([206]):

"Added matter requires a comparison of the disclosures of the application as filed and the patent, viewed through the eyes of the skilled addressee. The comparison is strict in the sense that subject matter will be added unless such matter is clearly and unambiguously disclosed in the application, but that may be done explicitly or implicitly. For this purpose, the claims form a source of disclosure as well as the specification. As the Defendants emphasise, one type of added matter is intermediate generalisation, which occurs when a feature is taken from a specific embodiment, stripped of its context and then introduced into the claim when it would not be apparent to the skilled person that it was generally applicable to the invention: see *Nokia Corp v IPCOM GmbH & Co KG* [2012] EWCA Civ 567, [2013] RPC 5 at [56]-[60] (Kitchin LJ). As *Conversant* emphasises, it is wrong to equate what a claim discloses with what it covers. **The law does not prohibit the addition of claim features which state in more general terms that which is described in the specification.** What the law prohibits is the disclosure of new information about the invention: see *AP Racing Ltd v Alcon Components Ltd* [2014] EWCA Civ 40, [2014] RPC 27 at [28]-[40] (Floyd LJ)."

On the facts of the case, the judge concluded that the disclosure of claim 1 as granted/amended, of a check to determine whether or not the Medium Access Control (MAC) sub-layer (in UMTS) was transmitting in the *current* transmission time interval (TTI), was new information and therefore added matter. So *Conversant's* patent concerned with autonomous enhanced uplink transmission was invalid.

Interestingly, the defendants complained that the effect of *Conversant's* equivalence argument with respect to this claim integer effectively erased it for the purposes of infringement. The judge's view was that the defendants had "no coherent answer" to *Conversant's* argument that checking the status by reference to the *previous*, rather than the *current*, TTI was an immaterial variant. Side-stepping the squeeze, Arnold J said ([222]):

"In my judgment, however, this argument is misconceived, since it is an argument about the scope of protection, and not about disclosure. Infringement by equivalence cannot give rise to an added matter objection."

¹⁸⁵ G1/93 *Advanced Semiconductor Products/Limiting feature* [1995] EPOR 97

¹⁸⁶ *Conversant Wireless Licensing SARL v Huawei Technologies Co. Limited & Ors* [2019] EWHC 1687 (Pat) (4 July 2019) Arnold J

Finally on added matter, in ***Technetix v Teleste (18 November 2019)***¹⁸⁷, Technetix (the patentee) also did not seek to defend the patent as granted. It sought unconditional and conditional amendments, in particular claim language including an 'LC filter'.

On the principles, HHJ Hacon rejected a submission from Technetix that the Court of Appeal's judgment in *AP Racing v Alcon*¹⁸⁸ was authority for the following ([115]):

"... the law does not prohibit the addition of claim features which state in more general terms that which is described in the specification."

HHJ Hacon said that that statement was **not correct**. He explained ([116]):

"In my view this is too general to be an accurate statement of the law. The circumstance in issue in *AP Racing* was this: a narrow class of products was disclosed in the application as filed, whereas in the patent as granted the patentee had gone for a wider monopoly by drafting claims to a broader class of products within which the narrow class fell. I discussed *AP Racing* in *Edwards Lifesciences LLC v Boston Scientific Scimed, Inc* [2017] EWHC 405 (Pat). Having quoted passages from the judgment of Floyd LJ, I referred to his paragraph 40 and said:

"[231] I interpret this paragraph to mean that if the skilled person reading the application as filed would understand that the narrower class disclosed *exemplifies* a broader class, then a claim in the granted patent to the broader class discloses no new technical information and does not offend the prohibition against added matter. On the other hand, if the skilled person would not have that understanding and the broader class is not otherwise disclosed in the application as filed, the court is liable to conclude that a claim to the broader class in the granted patent constitutes a disclosure of added matter."

After quoting from Kitchin LJ's judgment in *Nokia v IPCoM*¹⁸⁹, on intermediate generalisation, Judge Hacon said that the principle discussed by Kitchin LJ was the same as that discussed in *Edwards Lifesciences*. He continued ([118]):

"If the skilled person would have understood that the particular embodiment of the invention disclosed in the application as filed exemplifies a broader class, in the sense that the invention may be performed without this or that incidental feature of the particular embodiment, there will be no intermediate generalisation if the claims in the patent as granted are not limited by reference to those incidental features. On the other hand, if this would not have been the skilled person's understanding, there will be an intermediate generalisation should those features, not perceived as merely incidental, be excluded from a claim in the patent as granted (or as sought to be amended)."

Turning to the facts, the reasoning was brief. Judge Hacon said he had been given no reason to suppose that the skilled person reading key passages of the application as filed would take an understanding that, provided the LC filter included at least two 1nF capacitors and one 3.3µH coil, there was freedom regarding the other features of the LC filter. In other words, he did not believe that the skilled person would understand that the embodiments disclosed exemplified the broader class of systems as now defined in Conditional Claim 1. Accordingly, the claim disclosed new information to

¹⁸⁷ *Technetix BV & Anr v Teleste Limited* [2019] EWHC 3106 (Pat) (18 November 2019) HHJ Hacon

¹⁸⁸ *AP Racing Limited v Alcon Components Limited* [2014] EWCA Civ 40

¹⁸⁹ *Nokia Corporation v IPCoM GmbH & Co KG* [2012] EWCA Civ 567

the reader, namely the particular significance of those features, and by extension, that other features such as the voltage rating were merely incidental. Conditional Claim 1 was therefore invalid as disclosing matter which extended beyond that disclosed in the application as filed.

The job of reconciling Arnold J's statement of principle in *Conversant v Apple* with Judge Hacon's statement in *Technetix v Teleste* (18 November 2019) may yet reach Lord Justice Arnold!

f) Patentable subject matter

The Patents Act, section 1(2)(d), excludes from patentability "as such" the "presentation of information".

In *Garmin v Philips*¹⁹⁰, Garmin contended that Philips' patent fell foul of s.1(2)(d).

Henry Carr J noted that from the Court of Appeal's judgment in *Aerotel v Telco*¹⁹¹, it was necessary to: properly construe the claim; identify the actual contribution; ask whether it falls solely within the excluded subject matter; and check whether the actual or alleged contribution is actually technical in nature. Subsequent jurisprudence (e.g. *Symbian*¹⁹², *HTC v Apple*¹⁹³, *Gemstar v Virgin*¹⁹⁴) had placed particular emphasis on the requirement that the actual contribution must be technical. Illustrative of these principles, in *HTC v Yozmot*¹⁹⁵, Arnold J had held that a customised call message on a mobile phone which allowed music or a spoken message to be assigned and played for a particular caller involved a "technical solution" to the problem of identifying unknown callers and therefore had technical character. The fact that the invention involved the presentation of audible information did not mean that its contribution lay solely in that area.

Henry Carr J considered also the EPO Guidelines in the area, noting his agreement with the authors of *Terrell on Patents* (18th edition, November 2015) that those current at the time supported the view that there was no reason why a novel and inventive method of presenting information should be excluded from patentability, provided that the information content itself was not claimed.

Henry Carr J concluded that the EPO and UK authorities applied essentially the same test, this being that ([283]):

"If features related to the presentation of information produce a technical effect serving a technical purpose then the contribution made by the invention may not lie solely in the presentation of information."

Turning to Philips' patent in issue, in view of his findings on inventive step, the judge said that the "actual contribution" of the invention was "the feature of audio entertainment and volume dimming during presentation of real time performance information".

Garmin argued, among other things, that the feature of turning down the volume was the audio equivalent of filtering out visual information and so was a purely presentational feature not relating to the operational state of the device, and that the manner of presentation did not assist the user in performing a technical task by means of a continued or guided human machine interaction process.

¹⁹⁰ *Garmin (Europe) Limited v Koninklijke Philips NV* [2019] EWHC 107 (Ch) (29 January 2019) Henry Carr J

¹⁹¹ *Aerotel Ltd v Telco Holdings Ltd & Ors* [2006] EWCA Civ 1371

¹⁹² *Symbian Ltd v Comptroller General of Patents, Designs and Trade Marks* [2009] EWCA Civ 1066

¹⁹³ *HTC Europe Co Ltd v Apple Inc* [2013] EWCA Civ 451

¹⁹⁴ *Gemstar-TV Guide International Inc v Virgin Media Ltd* [2009] EWHC 3068

¹⁹⁵ *HTC Corporation v Yozmot 33 Limited* [2010] EWHC 786 (Pat)

However the judge thought these arguments ignored the technical solution that the patent had provided to the technical problem of how to enable the athlete to simultaneously listen to music from an audio entertainment system and to be provided with aural feedback on his/her performance. The solution was to introduce aural feedback to the personal performance monitor in a manner that enabled the aural signal to be combined with the music, by automatically reducing the music volume when the device presented aural real-time performance information. The judge continued ([291]):

"The skilled person would understand that the system disclosed and claimed in the patent was a single integrated system with a switching mechanism which ensured that the music volume would lower to enable the athlete to hear real-time performance information. Both experts agreed that, having read the Patent, the skilled person would implement such a system by use of a mixer or switching mechanism to ensure that the music volume would lower to enable the athlete to hear real-time performance information. That is a substantive technical contribution, and not presentation of information as such."

Illumina v TDL (17 June 2019)¹⁹⁶ concerned Illumina's patent claiming a fraction of a blood sample having been submitted to a DNA extraction followed by size separation process. TDL contended that the claimed invention was a "discovery" and so excluded from patentability under the Patents Act, section 1(2)(a).

Interestingly, the defendants accepted that as the law presently stood, this contention could not succeed. Nevertheless they asked the court to make appropriate findings of fact (propositions put before the court) to enable the issue to be argued in a higher court if necessary.

The judge declined to take this course, saying it was unsatisfactory for the court to be asked to make findings of fact in a legal vacuum. There was a danger of the court being led into making findings which were freighted with legal value judgments. Further, there was no specific evidence relied upon as establishing the facts propounded.

For example, the defendants' first proposed finding of fact was: "maternal blood and its contents are naturally occurring products". While the claimants accepted that maternal blood was a naturally occurring product, the "contents" part depended on which contents one was referring to, and for what purpose one was asking the question. A sample of plasma, for example, was an artificially created product even though it derived from a naturally occurring one.

g) Amendment

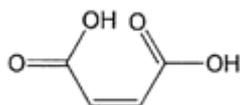
As usual, many cases raised questions of amendment in 2019, and many proposed amendments raised issues concerning added matter, inventive step and insufficiency that are discussed above.

L'Oréal v Liqwd¹⁹⁷ is the case in which Liqwd/Olaplex sought unconditional amendment as follows:

¹⁹⁶ *Illumina, Inc & Anr v TDL Genetics Limited & Ors* [2019] EWHC 1497 (Pat) (17 June 2019) Arnold J

¹⁹⁷ *L'Oréal (UK) Limited & Anr v Liqwd Inc & Anr* [2019] EWCA Civ 1943 (18 November 2019) Davis, McCombe & Arnold LJ

"The use of an active agent which is



~~or a simple salt thereof~~ simultaneously with a bleaching agent to reduce or prevent hair damage due to a treatment to provide bleached hair."

The chemical formula is for 'maleic acid'. On its face, the amendment (which the judge had permitted) deleted the alternative in the claim of "a simple salt" of maleic acid.

However *L'Oréal* argued that "[maleic acid] or a simple salt thereof" was a composite phrase which denoted a single class of compounds, so that deletion of "a simple salt" actually extended the protection conferred.

At first instance, Birss J had explored the argument in quite some detail, before dismissing it. In the Court of Appeal, Arnold LJ and Davies LJ were briefer. Arnold LJ noted that the experts and the parties had agreed that the formula would not have been understood by the skilled team to mean simply the deprotonated acid, but as covering also the singly and doubly unprotonated maleate ions. This was fatal to *L'Oréal's* argument because it meant that the words "or a simple salt thereof" did not limit the meaning of maleic acid/the rest of the claim, and so the removal of those words did not expand the meaning of the claim.

Both Arnold LJ and Davis LJ noted that as a matter of language, it would be counter-intuitive for a deletion of a disjunctive proposition to operate not to narrow the claim but to enlarge it.

h) Technical matters and procedure

Transfer

The patent asserted in *IoT v Haandle*¹⁹⁸ was in the field of on-line child safeguarding and parental control. The second defendant (SafeToNet, the exclusive licensee) and Haandle were small- to medium-sized enterprises that were relatively new start-ups. IoT and SafeToNet sued for patent infringement in the Patents Court. At the first case management conference, which took place after pleadings had closed, Haandle sought a transfer to IPEC.

The judge considered the factors set out in CPR 30PD paragraph 9.1, i.e. ([6]):

"... whether – **(1)** a party can only afford to bring or defend the claim in the [IPEC]; and **(2)** the claim is appropriate to be determined by the [IPEC] having regard in particular to – **(a)** the value of the claim (including the value of an injunction); **(b)** the complexity of the issues; and **(c)** the estimated length of the trial."

On (2)(a), the judge agreed with the claimants that the value of the injunction sought would 'certainly' exceed £0.5m. This was based on the 4 years of patent term left to run and the fact that the parties were competing for contracts whose value ran into millions (at least). This was despite the defendant pointing out that it had only made £80,000 sales to date.

¹⁹⁸ *IoT IP GmbH & Anr v Haandle Limited* [2019] EWHC 534 (Pat) (26 February 2019) Arnold J

On (2)(b), the judge noted that: the defendant had pleaded 5 separate items of prior art as novelty destroying (two of which were also foundations for obviousness attacks too); the claimants' case included a claim for s.60(2) contributory infringement, which would involve consideration of the knowledge of the defendant and/or what was obvious to a reasonable person in the circumstances; and there would have to be a conditional application for amendment of the patent in view of the ongoing appeal of the Opposition Division's decision maintaining the patent in amended form. The experts would need to be cross-examined as to their expertise and the CGK, and they would potentially need to give evidence in respect of infringement too. All these features of the case introduced complexity.

On (2)(c), against this background, the claimants' estimate of 4 days for the trial (excluding reading) was much more realistic than the defendant's position that it should be accommodated within the normal two-day IPEC slot.

Turning to consider (1), Haandle's evidence gave no suggestion that it would be unable to afford to defend the claim if it remained in the Patents Court.

The judge concluded that these factors all pointed against a transfer to IPEC.

Applications to transfer were also considered in related disputes *Kwickbolt v Airbus*¹⁹⁹ and *Centrix v Kwickbolt*²⁰⁰.

Kwickbolt sued Airbus for infringement, commencing proceedings in IPEC. Kwickbolt's patent claimed a device for fastening one workpiece to another, which can be inserted and fixed from just one side of the workpiece. (In contrast, a nut and bolt type fastener requires access from both sides). The patented devices being removable, they can be useful when only temporary fixing is required. Kwickbolt alleged infringement of its patent by Airbus' use, at its manufacturing facility in Wales, of devices from a US company called 'Centrix'.

Airbus applied to transfer the proceedings to the Patents Court. After noting key authorities²⁰¹, HHJ Hacon made some general observations:

1. There are some proceedings which have far too many issues and would plainly take too much time at trial to be heard in IPEC. In such a case, even important matters such as access to justice cannot assist a party who wants the case heard in IPEC.
2. If the proceedings could be heard fairly within 2-3 days, possibly following some focussing of the issues, by far the most important factor is to ensure that parties with limited financial means are afforded access to justice. Where access to justice is likely to be possible only if the proceedings are in IPEC, that is a very powerful factor in favour of having the case heard in IPEC. On this, note in particular HHJ Hacon's comments in *77M*.
3. The value of the claim should not be confused with the IPEC damages cap. It would make no sense for an impecunious claimant never to seek to enforce his right in IPEC solely because the injunction could have a large financial impact. Access to justice

¹⁹⁹ *Kwickbolt Limited v Airbus Operations Limited* [2019] EWHC 2450 (IPEC) (31 July 2019) HHJ Hacon

²⁰⁰ *Centrix Inc. v Kwickbolt Limited* [2019] EWHC 3049 (Pat) (12 November 2019) deputy judge Richard Meade QC

²⁰¹ *77M Ltd v Ordnance Survey Ltd* [2017] EWHC 1501 (IPEC) HHJ Hacon, *ALK-Abello Ltd v Meridian Medical Technologies* [2010] EWPCC 14, *Comic Enterprises Ltd v Twentieth Century Fox Film Corporation* [2012] EWPCC 13, *Environmental Recycling Technologies* [2012] EWHC 2097 Pat and *Destra Software Ltd v Comada (UK) LLP* [2012] EWPCC 39

always remains important. That said, the value of the claim, including the likely financial impact of the injunction, is relevant, and sometimes will be a matter of significance e.g. because a defendant who is facing the possibility of an injunction which could have high financial consequences will have a proportionately greater entitlement to ensure that all reasonable arguments in their defence are taken.

4. The approach to the litigation taken by the parties seeking to have the case heard in IPEC is relevant. As Judge Birss said in *Comic Enterprises*, if the claimant pleads and otherwise approaches a case in a manner more appropriate for a case in a list outside IPEC, that case is liable to be transferred out of IPEC.

In the present case, the Judge Hacon noted that the patent in suit was to a "not at all complex" mechanical invention, with 17 claims, all dependent on claim 1. Kwikbolt alleged infringement on the doctrine of equivalents. Airbus challenged the patent for lack of novelty (over CGK) and obviousness (prior art x3). In the judge's view, this was a case that could easily be heard in IPEC.

There was an overwhelming imbalance of resources as between Airbus and Kwikbolt. Kwikbolt was a "micro-entity", with a turnover of less than £632,000, and a balance sheet total of less than £316,000. It was fair to infer that Patents Court litigation would put it under serious financial strain, and it might be too great a burden for Kwikbolt to bear. A very small enterprise like Kwikbolt was bound to be prejudiced if it had to face the higher costs of the Patents Court, and Airbus' offer to undertake to keep the costs caps in place would not address additional costs Kwikbolt would have to face in running its own case in the Patents Court against such a well-funded opponent.

Airbus' arguments about the potential harm it would face if it were enjoined (i.e. that an injunction would be disproportionate) would only be relevant to the issue of transfer if there was a realistic risk that Airbus' ability to argue its defence to the claim for patent infringement would be significantly limited if the case were heard in the present court. HHJ Hacon said had "no doubt that it would not".

In separate proceedings, *Centrix v Kwikbolt*²⁰², Centrix sued Kwikbolt for patent infringement (of Centrix's patent), commencing proceedings in the Patents Court. Kwikbolt sought a stay pending the outcome the opposition against Centrix' patent in the EPO, alternatively a transfer to IPEC.

On the stay, deputy judge Richard Meade QC applied the guidelines found in *IPCom v HTC*²⁰³. The opposition proceedings were at a relatively early stage: the hearing was unlikely to take place until after the first instance proceedings in the UK, an appeal would likely take more than two and a half years more and there could be ping pong judgments between the different instances of the EPO. The UK trial and appeal would give a lot of certainty and were extremely likely to finish significantly earlier than the EPO proceedings. So the deputy judge refused a stay, noting that the factual picture presented in this case was fairly common.

Turning to the application to transfer to IPEC, Richard Meade QC noted HHJ Hacon's summary of the principles in *Kwikbolt v Airbus*. He also noted that if it was obvious that a party simply could not afford proceedings in the High Court, then that could be decisive on its own.

Although Kwikbolt never said that it simply could not afford High Court proceedings, the deputy judge considered it right to infer that the cost of such proceedings would be a significant strain. There was also an imbalance of size between the parties, for example with Centrix having ten times the number of employees as Kwikbolt.

²⁰² *Centrix Inc. v Kwikbolt Limited* [2019] EWHC 3049 (Pat) (12 November 2019) deputy judge Richard Meade QC

²⁰³ *IPCom & Co. KG v HTC Europe Co Limited* [2013] EWCA Civ 1496

Although Centrix had pleaded commercial success and the invention story (the former in an "extremely thin" way, the latter without any indication of whether the inventor had been aware of the cited prior art), both amounted merely to secondary indicia of obviousness. The deputy judge thought the case could still be managed in IPEC, a three day trial estimate providing a generous safety margin. Further, accrued damages would be very small, Centrix's real case as to value being on the basis that Kwikbolt might win the whole of Airbus' business, but the deputy judge thought it was very unlikely.

Trying to avert a transfer, Douglas Campbell QC, for Centrix, suggested that instead the case could be put into the Shorter Trial Scheme, with a costs cap of £500,000, arguing that this had some justification in its equiparation to the UPC costs cap of €600,000. However, the deputy thought £500,000 was still a lot of money, and noted that Kwikbolt would also incur costs of its own.

These factors, in sum, pointed in favour of allowing a transfer to IPEC.

Before moving to other technical issues, it is perhaps worth noting too the judgment in ***Volumatic Limited v Ideas For Life***²⁰⁴. Volumatic's claim concerned an agreement asserted by Volumatic to have contractual force. Volumatic sought specific performance of a term of the agreement that "all property rights" be assigned to Volumatic. Although no issues of IP law fell to be decided, it was common ground that Volumatic's action had been properly brought in the IPEC because the expression "all property rights" included a number of patents.

Pleadings

Traditionally in patent cases, pleadings have been kept very brief, in order to identify the issues in dispute and therefore the subject matter needing to be addressed in the expert evidence and by way of disclosure. More detailed technical arguments have followed those stages.

In 2013, the Patents County Court became the Intellectual Property Enterprise Court, and with this change a more front-loaded procedure was introduced in IPEC. The changes in IPEC did not impact procedure in the Patents Court. Nevertheless, there have been attempts to blur the distinction between these two distinct courts.

This happened, for example, in ***Emtelle v Hexatronic***²⁰⁵. The directions set following the Case Management Conference had followed the traditional Patents Court approach, with expert evidence following (relatively less specific) particularisation.

Nevertheless, well ahead of expert evidence, Emtelle sought more details of Hexatronic's case, for example, of which of various combinations of possible alternative disclosures in the prior art would be relied upon. Emtelle contended that good and modern case management required this sort of detail in any event.

The judge accepted that patent litigation is not immune from earlier particularisation in a case which merits it, and that it can be ordered. He was sympathetic to the desire to have earlier particularisation of at least certain aspects of patent cases than has traditionally been the case.

²⁰⁴ *Volumatic Limited v Ideas For Life* [2019] EWHC 2273 (IPEC) (29 August 2019) David Stone

²⁰⁵ *Emtelle UK Limited v Hexatronic UK Limited & Ors* [2019] EWHC 2230 (Pat) (1 August 2019) Mann J

However, in the present case, against the background of the directions set and the fact the defendants had not yet finally identified the expert(s) on whom they would rely, Mann J considered that it would be unfair to force the defendants to nail their colours to the mast at the present stage. It would also be likely to lead to contested applications to amend in the future.

Emtelle's application was therefore dismissed. Hexatronic was awarded its costs.

The extent of pleading concerning invalidity and infringement was looked at in some depth in **J.C. Bamford v Manitou**²⁰⁶, a judgment which is very much aligned in its approach with that taken by Mann J in *Emtelle v Hexatronic*. The proceedings concerned five JCB patents relating to control systems and methods intended to prevent load handling machines tipping over.

Manitou had previously been ordered to provide ([7]):

"... a Statement of Case on Invalidity setting out, for each of the Patents and each relevant prior art citation, where each feature of each independently valid claim is said to be disclosed in the cited prior art and identifying the claim features in respect of which the Defendants rely upon in support of their allegation of a lack of inventive step".

Manitou's amended statement of case alleged obviousness and anticipation. The claims alleged to be anticipated were set out in tabular form alongside the features of prior art said to disclose particular integers. For some claim integers, no specific feature of prior art was relied upon as amounting to a disclosure.

When replying to Manitou's amended statement of case, JCB had been ordered to set out "whether for the purpose of these proceedings the Claimant admits, denies or does not admit that each of the claim features are disclosed and/or lack inventive step as alleged". Against the tabularised alleged disclosures, JCB stated "Admitted", "Denied" or "Not admitted". Where Manitou's box had been left blank (i.e. no specific disclosure had been identified by Manitou), the JCB Reply stated "Not alleged to be present".

Manitou made a number of complaints about JCB's pleading, in respect of which deputy judge Nicholas Caddick QC held:

- (Contrary to Manitou's submissions) JCB's approach in responding "Not alleged to be present" had been wholly understandable. Manitou's assertion of invalidity was made "having regard" to the common general knowledge, which had not been particularised. Insofar as the invalidity claim was based on the prior art identified, JCB's response was set out. Further, whilst in very general terms, it was clear that JCB denied the obviousness challenges.
- (Contrary to Manitou's submissions) it was not impossible to tell the difference between JCB's case on 'denied' and 'not admitted'. The deputy judge saw no reason to doubt that both parties were aware of the difference: JCB was drawing a distinction between matters (denied) where it intended to put forward a positive case and those (not admitted) where it was simply putting Manitou to proof.

²⁰⁶ *J.C. Bamford Excavators Limited v Manitou UK Limited & Anr* [2019] EWHC 3071 (Pat) (18 November 2019) deputy judge Nicholas Caddick QC

- (Contrary to Manitou's submissions), JCB should not be ordered to further particularise its case. With respect to the **non-admissions**: CPR rule 16.5 did not say that a party should state its reasons for a non-admission; and so if a party chose not to admit a fact pleaded against it (and, therefore, not to put forward a positive case in relation to the matter pleaded), the Court should not in general require it to give its reasons for so doing. With respect to the **denials**: early particularisation was desirable and as a starting point a claimant defending an invalidity counterclaim should be expected to give some sort of reasons when denying aspects of that counterclaim. However, in the Patents Court, cases have traditionally not become fully particularised until after expert evidence. Although there has been a trend towards earlier particularisation, as reflected in IPEC's procedure, in the present case pleadings had been envisaged as preceding expert evidence, and JCB had adopted the same level of particularity as Manitou. The pleadings as they stood were therefore perfectly sufficient to identify the issues and allow the parties to take appropriate expert advice on them. If there were specific matters on which Manitou thought further particulars were needed, this would more properly be a matter for a request for further information under CPR Pt 18.
- (Contrary to Manitou's submissions) the issue of whether JCB were denying or not admitting "the presence of a raft of very simple features which, on the face of the documents, are clearly disclosed in the prior art" was a matter for trial, not the present hearing.
- (Agreeing with Manitou), JCB's Reply to the Defendant's Amended Statement of Case on Invalidity (a statement of case for the purposes of CPR r.22.1) should be verified with a Statement of Truth.

With respect to infringement, previous case management orders had not required JCB to provide a statement of case. The deputy judge agreed with Manitou that such a pleading should now be provided, but (addressing JCB's concerns), held that Manitou should first "provide a list identifying (i) the configuration which Manitou had used in respect of each model of Manitou telehandler that JCB alleges infringed its patents and (ii) where there had been a change in the configuration used in respect of a model, the date when such change first occurred".

As Manitou had been ordered to provide these lists, it was not appropriate to order further particulars under the PPD at the present stage.

Non-admissions were looked at too in *Mitsubishi v Archos*²⁰⁷. The issue was the extent to which it was permissible for the defendants, in responding to Mitsubishi/Sisvel's Statement of Case on Essentiality, simply to "not admit" matters pleaded against it.

Deputy Judge Nicholas Caddick QC said ([13]):

"A defendant which does not admit a matter pleaded by the claimant is putting the claimant to proof of that fact. It is not asserting any positive case of its own. On this basis, there is no justification for ordering the defendant to give reasons for its non-admission. It is the claimant's case and a defendant is entitled to require the claimant to prove that case."

So the Patents Court is open to adopting a more IPEC style of procedure on a case by case basis. However, if the usual course is followed, with commencement in the Patents Court, pleadings in the

²⁰⁷ *Mitsubishi Electric Corporation & Anr v Archos SA & Ors* [2019] EWHC 3477 (Pat) (19 December 2019) deputy judge Nicholas Caddick QC

usual way and then a case management order setting out the steps to trial in the conventional form, the IPEC style boat will have sailed already. And reasons do not need to be given for non-admissions.

Finally on pleadings, a highly technical legal issue arose in ***Technetix v Teleste (3 April 2019)***²⁰⁸. At the pre-trial review, five weeks before the trial, Technetix wanted to amend its case by abandoning claim 1 and asserting the independent validity of a superficially amended claim 2. Technetix had not previously asserted that claim 2 was independently valid.

Teleste objected, and with a view to identifying the appropriate legal test to resolve the dispute, the judge considered whether an assertion of independent validity counted as an "averment" (i.e. a formal statement by a party of a fact or circumstance which the party offers to prove or substantiate) or an "admission". Whereas the withdrawal of an admission always requires the permission of the court (rule 14.1(5), 14PD7.2), a withdrawal of an averment only requires permission at the appropriate stage of proceedings, the principles being those which govern amendments more generally e.g. on conditions as to costs.

Judge Hacon preferred the view (Technetix's case) that it was an averment. He said that stating which claims have independent validity is generally better characterised as part of a patentee's enforced selection of his best case, not an admission. A similar procedural requirement is imposed on parties seeking to revoke a patent - selecting the short list of prior art to be relied upon at trial does not constitute an admission that the abandoned items of prior art do not invalidate the patent. Accordingly, in the present case at least, the selection of one claim having independent validity did not involve an admission.

However, in case he was wrong on that, the judge considered the consequences if the permission of the court was required under CPR 14.1(5), on the assumption that Technetix did make an admission. This required the court to have regard to all the circumstances of the case, and he concluded that while Technetix's change in direction was unsatisfactory, refusing permission would potentially be tantamount to ruling that Technetix's claim failed, which he was not prepared to do. Permission was therefore given in the alternative position too.

Disclosure and inspection

The Disclosure Pilot has now been running in the Chancery Division, including the Patents Court, for a full year, governed by PD51U. Relatively little case law has emerged in patent cases on its effect.

In ***MSD v Wyeth***²⁰⁹, in the context of MSD's claim for revocation of Wyeth's patent, Arnold J ordered the disclosure of laboratory notebooks, internal reports, emails, meeting minutes and presentations created which provided information as to the vaccine formulation, tests and syringe models which underlay a conclusion in a Wyeth presentation given at a conference. Wyeth had resisted the application on the basis that there was little likelihood of documents existing that would have probative value in supporting or undermining a party's claim or defence (PD51U 6.4(iii)). However, the judge considered that such disclosure was needed as going to Wyeth's pleaded case that, contrary to the solution proposed by the patent for inhibiting silicone induced aggregation of a polysaccharide protein conjugate, in the real world Wyeth had to do something else.

²⁰⁸ *Technetix B.V. & Anr v Teleste Limited* [2019] EWHC 928 (Pat) (3 April 2019) HHJ Hacon

²⁰⁹ *Merck Sharp & Dohme Limited v Wyeth LLC* [2019] EWHC 1692 (Pat) (28 June 2019) Arnold J

On the other hand, in *Akebia v Fibrogen*²¹⁰, deputy judge Nicholas Caddick Q.C. refused an application for extended disclosure on the basis that it was not "reasonable and proportionate" to make the orders sought in the context of the case.

The *Akebia* case is a consolidated action commenced under four claim numbers, about inhibitors of hypoxia inducible factor (HIF) prolyl hydroxylase (HIF-PH), an enzyme that regulates HIF activity. By inhibiting HIF-PH, the products allow an increase in a person's level of HIF and, therefore of erythropoietin (EPO), thereby stimulating production of red blood cells. Such products are used to treat various types of anaemia.

The patents in issue had been challenged for insufficiency. Some disclosure had already been agreed. Akebia additionally sought the following:

"Documents relating to non-specific or "off-target" effects. These are described more specifically as "Results of experiments relating to the off-target effect(s) and/or toxicity of the compounds tested including those relating to: (a) the ability of the compounds to modulate the activity of other enzymes, including (but not limited to) other enzymes of the 2-oxoglutarate dependent dioxygenase family (b) whether the compounds give rise to the modulation of the expression of other target genes of HIF, including (but not limited to) VEGF and GLUT-1 (c) other safety/efficacy issues."

Deputy judge Nicholas Caddick QC noted that the primary evidence on which the court would rely was expert evidence. What Akebia sought was the results of any experiment relating to any off-target effect however trivial and without reference to whether that effect would prevent the use of the compound to fulfil the therapeutic indications of the patent claims. This did not go to a pleaded issue: Akebia's Grounds of Invalidity did not rely on the argument that the patents were invalid because the compounds might have off-target effects.

Akebia's request therefore did not comply with the requirement of the Disclosure Pilot that disclosure should be limited to what is necessary in order for the court to resolve clearly defined issues. Further, the agreed disclosure was adequate for the purposes of the pleaded claim of insufficiency. The extended disclosure sought was therefore not "reasonable and proportionate".

Akebia also sought:

"Any analysis or reporting (including reports to management) of the results referred to in [the various assays and experiments for which disclosure is ordered]"

Akebia argued that despite the primary evidence being that of the experts, evidence as to FibroGen's own assessment of the results of the disclosed assays and experiments would assist the court on the basis that it would be a "real-world" evaluation and would help the court in assessing the evidence of the experts. However, the deputy judge was not satisfied that such material would be of any real assistance to the court or, to the limited extent that it might provide some assistance, that that benefit would justify the cost and effort involved in making such a search. He also observed that the request could have been better targeted at analysis or reporting material that had been considered at an appropriate level of seniority (e.g. at director level).

²¹⁰ *Akebia Therapeutics Inc. & Anr v Fibrogen, Inc* [2019] EWHC 1943 (Pat) (26 July 2019) Nicholas Caddick Q.C.

Application to re-open trial

Finally in this section, in *Regen v Estar*²¹¹, there was a real-life dog-ate-my-homework type of argument.

After the trial hearing but before the judgment had been handed down, the defendants applied to re-open the trial and adduce further evidence. There was a dispute as to whether the application concerned genuinely new evidence or was an attempt to re-argue an old point. The evidence included a witness statement explaining how a package had been found under someone's bed and was further evidence of what had previously been demonstrated by Regen.

After considering the case law in some depth, Judge Hacon found in favour of the defendants on the merits of the case but refused the application, partly for abuse of process and partly under the over-riding objective.

4. Competition law/settlement/licensing

In *Technetix v Teleste (29 January 2019)*²¹², Technetix's patent to a "cable tap unit" was found invalid. The judge nevertheless explored the doctrine of equivalents, a possible *Formstein* defence and a licensing issue.

The licensing issue was whether the second claimant had been an exclusive licensee in the years 2006-2016; in 2016 an exclusive licence in writing had been granted by the proprietor (the first claimant) to the second claimant. The claimants' particulars asserted ([135]):

"During the period 23 May 2006 to 19 December 2016 the Second Claimant was the sole legal entity with the authority of the proprietor of the Patent to manufacture products falling within the scope of the claims of the Patent in the jurisdiction. In the premises the Claimants contend that the Second Claimant was the exclusive licensee of the Patent under an implied licence."

The claimants asserted that because all three claimants were part of the same group, on these facts the judge should infer on the balance of probabilities that an exclusive licence had been granted to the second claimant for the 2016-2016 term. However, Judge Hacon saw two problems with this: first, the assertion was of "sole" not "exclusive"; second, prior to an assignment to the first claimant in August 2016, the proprietor of the patent had been the third claimant, and the terms of the assignment ("the full and exclusive benefit thereof and all rights privileges and advantages appertaining thereto") were inconsistent with an exclusive licence having been granted to the second claimant.

The case of *Ablynx v VHSquared*²¹³ brought into conflict with each other a number of terms of the Recast Brussels Regulation.

²¹¹ *Regen Lab SA v Estar Medical Ltd & Ors* [2019] EWHC 63 (Pat) (18 January 2019) HHJ Hacon

²¹² *Technetix B.V & Ors v Teleste Limited* [2019] EWHC 126 (IPEC) (29 January 2019) HHJ Hacon

²¹³ *Ablynx NV & Anr v VHSquared Limited & Ors* [2019] EWCA Civ 2192 (10 December 2019) Lewison, Newey & Asplin LJ

A dispute seems to have long been afoot regarding the line between the "Reserved Sector" and other uses respectively in parallel exclusive licence agreements granted by the patentee, Vrei Universiteit Brussel. One licence, to Vlaams Instituut voor Biotechnologie vzw (VIB), had since been sub-licensed to Ablynx. The other, essentially to Unilever, had been sub-licensed to VHsquared. The Unilever licence contained an exclusive jurisdiction clause in favour of the courts in Belgium.

The scope of the Unilever licence had already been considered in two rounds of litigation in the Netherlands.

In the present proceedings, Ablynx sued the defendants (VHsquared and Unilever) in the Patents Court for infringement of three related patents. VHsquared challenged the jurisdiction of the court. The validity of the patents had not yet been put in issue, but VHsquared's evidence included the following ([25]):

"Should this application not succeed and the UK Claim continue [VHsquared] would intend to raise a number of defences. These include limitation under the Limitation Act 1980, **invalidity of the patents in suit**, lack of infringement due to activities complained of being experimental and covered by the VUB Licence and in particular because V565 is not an antibody to a "specific pathogen"; and absence of any common design."

VHsquared contended that its activities were covered by its licence and therefore there had been no infringement; and that any question about the scope of the licence was within the exclusive jurisdiction of the Belgian court.

After the English proceedings were commenced, VHsquared issued proceedings in the Brussels Enterprise Court raising two issues: i) Whether Ablynx had standing to sue in respect of VHsquared and Unilever's activities; and ii) a claim that those activities were within the scope of the Unilever licence.

At first instance²¹⁴, Judge Hacon dismissed the defendants' challenge to the jurisdiction of the court. He held that if the present infringement proceedings progressed to trial, they would be concerned with the validity of three EP(UK)s. Article **24(4)** of the **Recast Brussels Reg** was therefore engaged.

VHsquared appealed, leading the Court of Appeal to have a thorough look at the Recast Brussels Regulation (1215/2012) and the jurisprudence. It is perhaps worth noting here a few of the provisions:

Article 24, which states:

"The following courts of a Member State shall have exclusive jurisdiction, regardless of the domicile of the parties...**4.** in proceedings concerned with the registration or validity of patents, trade marks, designs, or other similar rights required to be deposited or registered, irrespective of whether the issue is raised by way of an action or as a defence, the courts of the Member State in which the deposit or registration has been applied for, has taken place or is under the terms of an instrument of the Union or an international convention deemed to have taken place.

Article 25, which states:

"**1.** If the parties, regardless of their domicile, have agreed that a court or the courts of a Member State are to have jurisdiction to settle any disputes which have arisen or which may

²¹⁴ *Ablynx NV & Anr v VHsquared Limited & Ors* [2019] EWHC 792 (Pat) (29 March 2019), HHJ Hacon

arise in connection with a particular legal relationship, that court or those courts shall have jurisdiction, unless the agreement is null and void as to its substantive validity under the law of that Member State. The agreement conferring jurisdiction shall be either:

(a) in writing or evidenced in writing;

(b) in a form which accords with practices which the parties have established between themselves; or

(c) in international trade or commerce, in a form which accords with a usage of which the parties are or ought to have been aware and which in such trade or commerce is widely known to, and regularly observed by, parties to contracts of the type involved in the particular trade or commerce concerned....

4. Agreements ... conferring jurisdiction shall have no legal force ... if the courts whose jurisdiction they purport to exclude have exclusive jurisdiction by virtue of Article 24."

Article 27, which states:

"Where a court of a Member State is seised of a claim which is principally concerned with a matter over which the courts of another Member State have exclusive jurisdiction by virtue of Article 24, it shall declare of its own motion that it has no jurisdiction."

Article 31, which states:

"2. ... where a court of a Member State on which an agreement as referred to in Article 25 confers exclusive jurisdiction is seised, any court of another Member State shall stay the proceedings until such time as the court seised on the basis of the agreement declares that it has no jurisdiction under the agreement.

3. Where the court designated in the agreement has established jurisdiction in accordance with the agreement, any court of another Member State shall decline jurisdiction in favour of that court."

The Unilever licence contained a jurisdiction clause in the following terms:

"9. Applicable law and settlement of disputes

9.1 Belgian law shall govern this Agreement. The Court of Brussels shall alone be competent in case of dispute between the Parties or one of their (sub)licensee(s) concerning this Agreement.

9.2 In exemption from Article 9.1, the Parties hereby also agree that all disputes on the definition of the Reserved Sector, the scope of [the patents] and its delimitation from the Community Patents shall exclusively be settled by arbitral tribunal consisting of one jurist and two scientists, sitting in Brussels, according to the rules of the International Chamber of Commerce."

The Court of Appeal did not think that the judge had erred in concluding (in light of the expert evidence on Belgian law) that there was a *prima facie* case that VHSquared was not barred under Belgian law from relying on art 9.1 of the Unilever licence, assuming that the article had the meaning and effect which the defendants said it had.

However, pursuant to article 25, the mere fact that an agreement contained an exclusive jurisdiction agreement was not enough: the agreement must cover the particular dispute that had arisen. VHSquared contended that it did not. The disagreement between the parties on this issue could only be resolved by the judge if he resolved conflicting evidence of Belgian law. The judge had not erred in concluding that he was not in a position to do so.

This brought the analysis to article 31(2)– which court should decide the jurisdiction issue? The Belgian court, as the one named in the exclusive jurisdiction clause, or the English court, as the one first seized?

Giving the only reasoned judgment, Lewison LJ observed that the judge appeared to have addressed the question of which court actually *had* jurisdiction, not which court *decided* that question. Although article 24 was "at the top" in so far as substantive jurisdiction was concerned, this did not necessarily preclude the Belgian court from deciding which court had substantive jurisdiction. Article 27 was not a jurisdictional rule but a procedural one²¹⁵, and in Lewison LJ's view, the same was true of article 31(2). It followed that the Belgian court was empowered to decide whether the English court had exclusive jurisdiction. That question would involve whether the choice of court agreement was overridden by article 25(4).

Accordingly, it was for the court designated in the exclusive jurisdiction agreement (i.e. the Belgian court) to decide whether (and, if so, to what extent) it was deprived of its jurisdiction as a result of article 25(4).

Nevertheless, Lewison LJ proceeded to consider the question of whether article 25(4) was engaged. He looked at a number of CJEU²¹⁶ and English²¹⁷ authorities.

In *Akçil v Koza*, the UK Supreme Court applied the CJEU's judgment in *BVG*, which said that the question of jurisdiction turned on whether the "principal subject matter" of the action concerned the validity of the German company's actions. This required an evaluation of the *particular claim*, not an overall evaluation of the *proceedings*. The Supreme Court's judgment established that:

- (i) the exclusive jurisdiction provisions of article 24 were to be narrowly interpreted;
- (ii) a claim which fell within the exclusive jurisdiction of one court might be severed from a claim that did not, even if the two claims were linked; and
- (iii) in deciding the scope of exclusive jurisdiction, it was wrong in principle for the court to embark upon a broad evaluative assessment of what was in the claim, taken as a whole.

HHJ Hacon's first instance judgment had preceded the UK Supreme Court's judgment in *Koza*. Applying the Supreme Court's judgment, Lewison LJ noted that there were a number of defences to Ablynx's claim which did not engage 24(4): that it was outside the scope of the licence; experimental use; time barred; and V565 did not exist before the patents expired. So the validity of the patent was

²¹⁵ (Case C-4/03) *Gesellschaft für Antriebstechnik mbH & Co KG v Lamellen und Kupplungsbau Beteiligungs KG* [2006] FSR 45

²¹⁶ (Case C-4/03) *Gesellschaft für Antriebstechnik mbH & Co KG v Lamellen und Kupplungsbau Beteiligungs KG* [2006] FSR 45; *Berliner Verkehrsbetriebe v JP Morgan Chase Bank NA* (Case C-144/10) ("BVG") EU:C:2011:300; *Weber v Weber* (Case- C-438/12) [2015] Ch 140.

²¹⁷ *Berliner Verkehrsbetriebe v JP Morgan Chase Bank NA* [2010] EWCA Civ 390; *Coin Controls Ltd v Suzo International (UK) Ltd* [1999] Ch 33; *Fort Dodge Animal Health Ltd v Akzo Nobel NV* [1998] FSR 222); *Akçil & Ors v Koza Ltd & Anr* [2017] EWCA Civ 1609, [2019] UKSC 40

not the "sole or even the principal" subject matter of the dispute. While the Belgian court did not have jurisdiction to decide definitively the validity of the UK designation of the patents in issue between the parties, this did not mean that the whole of the (infringement) action was pulled into the exclusive jurisdiction of the UK court, or that there was anything objectionable about a Belgian court expressing provisional views about a UK designated patent.

The Court of Appeal's judgment in *Ablynx v VHSquared* strikes me as consistent with the approach taken by the courts in licensing disputes involving both UK and non-UK patents in recent years: in *Chugai v UCB*²¹⁸ and in *Celltech v Medimmune*²¹⁹.

Ignoring for now what will replace the Recast Brussels Regulation upon Brexit, the Court of Appeal's judgment in this case suggests that England and Wales might be a very good place for a patentee to use for exclusive jurisdiction. This is because the doctrine of equivalents seems to reach a conclusion of infringement in almost every case in which it is run in the Patents Court, and the English court's approach to the Recast Brussels regime suggests that issues of validity of non-UK designations could just be bifurcated out.

Finally in this section, a point to note on settlement arose in *Emtelle v Hexatronic*²²⁰. When the dispute about particularisation first reached a hearing, the lawyers managed to reach an oral agreement outside the court room; the hearing was delayed by a few minutes and then vacated. Unfortunately, capturing what had been agreed in wording for a consent order did not prove possible, resulting in another hearing being scheduled.

The side issue of what had been 'agreed' the week before, however, was not pressed. Mann J noted ([6]):

"As I have always understood it, where there is a compromise which is to be embodied in a court order, unless there is some clear binding agreed stage before the court order is made, it is the court order that is eventually the compromise. That of course does not apply to matters such as Tomlin Orders or other orders which are signed, or which might be signed in advance to denote a binding agreement. In this case there was no such signing or comparable agreement. It therefore seemed to me that if one side was going to be insisting that there was a binding compromise, it would not be possible to deal with the matter today, and the matter would have to go off for a rather more elaborate hearing, with all the delay, cost and trouble that entailed."

5. Entitlement / employee inventor compensation

The long-running dispute between the inventive Mr Shanks and his former employer, Unilever, reached the Supreme Court in 2019 (*Shanks v Unilever*²²¹). The issue was whether Mr Shanks was entitled to compensation for the 'outstanding benefit' to Unilever of patents obtained in respect of inventions that he made.

²¹⁸ *Chugai Pharmaceutical Co. Ltd v UCB Pharma S.A. & Ors* [2017] EWHC 1216 (Pat), [2018] EWHC 2264 (Pat) (24 August 2018) Birss J

²¹⁹ *Celltech R & D Limited v Medimmune Inc* [2004] EWHC 1522; [2004] EWCA Civ 1331

²²⁰ *Emtelle UK Limited v Hexatronic UK Limited & Ors* [2019] EWHC 2230 (Pat) (1 August 2019) Mann J

²²¹ *Shanks v Unilever plc & Ors* [2019] UKSC 45 (23 October 2019) Lady Hale, Lords Reed, Hodge, Black and Kitchin

The basis for Mr Shanks' claim was the Patents Act, s.40(1), in the form prior to its amendment in 2005, which stated:

"Where it appears to the court or the comptroller on an application made by an employee within the prescribed period that the employee has made an invention belonging to the employer for which a patent has been granted, that **the patent is (having regard among other things to the size and nature of the employer's undertaking) of outstanding benefit to the employer** and that by reason of those facts it is just that the employee should be awarded compensation to be paid by the employer, the court or the comptroller may award him such compensation of an amount determined under section 41 below." (emphasis added)

At first instance, the Hearing Officer had taken a multifactorial approach to the assessment of s.40(1), noting that the benefit provided by the Shanks patents was a substantial and significant one in money terms - the sort of sum that Unilever would, on the evidence, worry about, and 'stand out' in comparison to the benefit from other patents to Unilever. Nevertheless, taking account of the size and nature of Unilever's business, including for example that Unilever made profits at an order of magnitude greater on other inventions, the Hearing Officer concluded that the benefit fell short of being outstanding. On this conclusion, the Patents Court and Court of Appeal dismissed Mr Shanks' appeals.

The Supreme Court, however, concluded that the Hearing Officer had erred by focusing, in the end, upon the overall turnover and profits generated by Unilever and comparing this with the benefit derived from the Shanks patents alone. Lord Kitchin reasoned, for example, that only a proportion of the sale price of any Unilever product could be attributed to any patent protection, and Unilever's attempts to assess the value of its other patents in this respect had failed; on the other hand, Unilever's income from the licensing and sale of the Shanks patents had entailed only modest costs and insignificant risk.

Lord Kitchin summarised as follows ([85]):

"...Professor Shanks made his invention using his own initiative for his brief was to work in the area of biosensors for process control and process engineering and he was made to understand that he should not stray too far from it. He built the first prototype of his invention in October 1982, some five months after he had joined CRL. This would have been a new product area for Unilever but it was a development which the group did not, in the hearing officer's terminology, get behind and push. It was regarded as far from a key technology and it was one into which Unilever made only a modest investment. It is true that Unilever patented and maintained a patent portfolio which protected it and in due course expended significant effort and skill in the licensing negotiations. But the rewards it enjoyed were substantial and significant, were generated at no significant risk, reflected a very high rate of return, and stood out in comparison with the benefit Unilever derived from other patents. What was more, they could not be attributed to the deployment or application of Unilever's wider business assets or infrastructure; nor were they found to be the consequence of any leverage Unilever could exert because of its size. In short, the benefit Unilever enjoyed from the Shanks patents was outstanding within the meaning of section 40 of the 1977 Act."

On a key issue on the law – the meaning of 'employer' and 'employer's undertaking' - and the consequences for the meaning of 'benefit' and 'outstanding benefit', the Supreme Court took a pragmatic approach. Mr Shanks' 'employer' was clearly the Unilever group company Unilever UK Central Resources Limited ("CRL"), a subsidiary of Unilever plc which at the relevant time employed all of the Unilever group's UK-based researchers. CRL was not a trading company. It assigned its rights in the Shanks patents to other Unilever group entities for £100. The subsequent income derived by the Unilever group from the Shanks patents vested in Unilever group companies other than CRL. In this circumstance, the Supreme Court considered that the 'benefit' and the question of whether

such benefit was 'outstanding' should be assessed by reference to the wider Unilever group, which was deemed to be the 'employer's undertaking, rather than by reference to CRL.

Mr Shanks therefore succeeded in his claim for compensation.

Drawing upon the factual findings made by the Hearing Officer, the Supreme Court then proceeded to make the rulings necessary to dispose of the case. In particular, in the assessment of the level of compensation to be awarded to Mr Shanks, a 'fair share' as required under the Patents Act section 41, the Supreme Court adopted the Hearing Officer's conclusion that Unilever's total earnings from the Shanks patents were approximately £24 million and a fair share of this benefit was 5% (not 3%, which the Patents Court had concluded).

Further, and contrary to conclusions reached in the Patents Court and some of the Court of Appeal's reasoning: the sums Unilever had received as 'benefit' should not be discounted to reflect the payment of corporation tax; and an adjustment should be made to reflect the time value of money – an average annual inflation rate of 2.8% was applied to the 5% of £24 million.

This meant that the award to Mr Shanks of a 'fair share' of the benefit accruing to Unilever, including CRL, was for £2 million.

What does the Supreme Court's judgment mean for companies employing inventors?

Well, it makes clear that a straight comparison between, on the one hand, the benefit in financial terms derived by the employer (and its group companies) from a patent, and on the other hand, the turnover of the company or the income stream on other products protected by inventions, will not provide a simple way for larger companies to avoid compensating employee inventors for outstanding benefit derived from their inventions. The 'too big to pay' defence does not exist.

A more nuanced approach is needed when considering whether there has been outstanding benefit, for example taking account, by way of comparison, of the benefit obtained in respect of other patents and (since 1 January 2005) inventions more generally (which may include patents in jurisdictions beyond the UK).

The 5% royalty rate upheld by the Supreme Court in respect of patents to a platform technology provides a starting benchmark. However, it should not be confused with a 5% royalty on a marketed product. Unilever's 'benefit' was the value of the royalties paid in respect of – and the assignment value of – the Shanks patents, and Mr Shanks' compensation was for 5% of that royalty. The circumstances which led to the Shanks patents having 'outstanding benefit' to the wider Unilever business included the nature of the invention in the context of Unilever's core business, and the fact that all but one of the licences were entered into following initial contact made by the subsequent licensee.

For the overwhelming majority of patents, inventors and employers of inventors, the Supreme Court's judgment in *Shanks v Unilever* will not represent a change to the *status quo* in the UK. In the occasional case, it may make a difference. However since the Supreme Court's guidance indicates that the statutory compensation regime will be engaged in 'stand out' cases only, proactive employer engagement with key inventors – for example appropriate recognition and sensitive reward for technical advancements, enabling a positive relationship to be maintained - may avoid the statutory regime ever being invoked.

6. Summary and conclusions

If anyone has read this document and got this far, well done! I must apologise for the almost Arnoldeque length of this year's so called "summary" of the case law of 2019. The fact is that the courts have been very busy and they have covered a lot of ground.

That in itself directs me to the first of the issues of concern for our patent enforcement system in the UK.

We have prided ourselves over the years that we have the most thorough and rigorous process of patent litigation, backed by highly professional and experienced lawyers and attorneys and safely reliant on truly outstanding judges. We have been able to overcome many disadvantages in terms of costs, disclosure, and complexity to remain a very attractive jurisdiction because of the sheer quality of the judgments delivered. To obtain a strong UK judgment could be worth a great deal around the world in terms of the likelihood that it would be respected and upheld in other jurisdictions.

At the time of writing this we have one technically qualified first instance judge, with every likelihood that he will be on his way to the Court of Appeal before too long. Yes, we have HHJ Hacon in the IPEC, but we are otherwise dependent on judges who have been drafted in from other areas to help out, or deputy judges. Deputies are, more often than not, technically qualified and highly experienced, but they do not conduct enough cases to gain the real experience required to operate at the highest level, and in any event there is a reluctance to pay for deputies emanating from the Lord Chancellor's Department.

In short, we run the risk of losing our reputation as a thorough, accurate and dependable jurisdiction if we do not get on with appointing at least two more highly experienced, technically qualified full-time members of the IP bench.

One of the challenges which high quality judiciary helps us to face is that the UK is a very expensive place to litigate. At the moment we have two extremes – the full-blown High Court procedure and IPEC. The Shorter Trial Scheme is intended to bridge that gap but it does not really do so as its influence on costs is minimal, and the fact that it lifts a case out of the Precedent H discipline means that the level of costs incurred even in preparing for a shorter trial, can still be prodigious and uncontrolled.

Some practices which were introduced with a view to improving case management and reducing costs have had precisely the opposite effect. There now seems to be a whole new layer of pleadings between the actual claim, defence and counterclaim and the expert's reports. There was a time when the issues of CGK and the identity of the skilled person were dealt with in expert's reports. Now we are seeing complex statements of case on validity and infringement which, in effect, add nothing and do not save either cost or time.

I have proposed an interim costs bar whereby Shorter Trial Scheme cases would have a default upper limit of recoverable costs at £500,000, which could only be lifted if there were compelling reasons and it would be incumbent on the party wishing to break the cap to demonstrate why that would be appropriate. That idea is under consideration but, for reasons not fully clear to me, has met significant opposition from some members of the professions. I would invite comments and maybe ideas as well which may prove useful in the discussions which will be taking place over the next few months.

My goal is to ensure that the UK remains the leading patent jurisdiction in the world and to safeguard our position whatever befalls us after the end of January.

As far as the actual cases go, there have been no real howlers this year – we have not had a repeat of the *Warner-Lambert* shambles. I cannot say that there are any judgments which will come to be considered classics – I do not expect many of them to be topping the citation charts in years to come. I do fear, as I have already said, that the judges have embraced the doctrine of equivalents with a little too much glee.

I make absolutely no apology for the largely sentimental award of my "Judge of the Year" accolade for 2019. The IP professions were deeply saddened by the loss of one of our most beloved members, Mr Justice Henry Carr. He worked almost right to the end of his long struggle with pancreatic cancer, and even in 2019 delivered a series of his usual cogent, clearly reasoned and, of course, correct judgments. We were in front of him in one of his last cases – *TQ Delta v ZyXEL* – where he patiently worked his way through numerous interim hearings and some highly demanding lawyers to achieve an outcome which was both just and innovative. He will be very sadly missed, and he is the Judge of the Year for 2019.

2019 was a sad year for our firm and in particular the IP team. Two of the great foundation stones who have under-pinned the development and growth of our team passed away in 2019 – David Barron and Bill Jones. Much has been said and written about my "partnership within a partnership" with David. He was my most trusted and beloved colleague and I miss him every day. Less well known is the influence of Bill Jones, who joined the firm on the same day as me, and worked his way through the ranks with me so we became partners in the firm and the IP team on the same day in 1990. He interviewed David with me, and it was only later that Bill moved across to focus on IT and outsourcing and that our paths diverged. We remained friends and indeed were scheduled to have lunch just a couple of days after he died.

They were both great men and great lawyers and I want to sign off this year's paper simply by paying tribute to their fantastic contribution to the world of IP over the last 30 years.

Gordon Harris and Ailsa Carter

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Gowling WLG, Official Legal Advisers -
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