SWINGS AND ROUNDABOUTS:
A REVIEW OF PATENT CASES IN 2020

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GOWLING WLG

This Paper is dedicated to the memory of

David Gibbins

Aidan Robson

David was our great partner, colleague and friend over so many years. Aidan has been a long term friend of our team and a regular attendee at this annual Patent Seminar. Both are sadly missed.

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Swings and Roundabouts

A Review of Patent Cases in 2020

1. Introduction

No one could describe 2020 as "normal" in almost any way. Even at the time I was preparing and delivering the update for the 2019 cases, this time last year, the dreaded name "Covid-19" was already printing itself on our consciousness. At some point early in the year I thought that preparing this year's talk paper would be a simple task – how could there possibly be many cases to report on?

Well, I was about as wrong as I could be. There were plenty of cases in 2020, and one particular aspect of the stage we are at in the judicial cycle has meant that the judgments are not by any means brief. The last few years have seen a major change in the IP bench. We have a new IP expert in the Supreme Court – Lord Kitchin – who only really started to get going in 2020 as he was conflicted out of cases where he had sat in the Court of Appeal. We have two new IP judges in the Court of Appeal – Lords Justice Arnold and Birss, though the latter has not got started there yet. We have a number of new joiners to the periphery of the IP bench at first instance and IPEC level and, answering the call that I made in my summary last year, a new full time High Court IP judge capable of handling the most complex cases – Mr Justice Meade. Further, hot off the press is the news that yet another appointment has been made with the elevation of James Mellor QC to the bench to join Meade J.

The upshot of all this change, and the period when there was no expert IP judge in the Supreme Court, is that there have been a lot of judges finding their way in IP, and doing what they always do in this situation – revisiting some well-established principles to apply their own touch and their own gloss. There are pros and cons to this. It can get a bit long-winded when you are working your way through these judgments, but it can also provide a welcome recap and revision. They also have a habit of delving into deepest history and aged case-law. There has been a lot of that this year. Again, this can be good or bad. Anyone with a fascination for legal history, like me, finds it massively interesting. Others probably wish they would just get up to date and cut the reflections. So, it's a case of "Swings and Roundabouts". Let us treat this year as an opportunity to have a recap and catch up on some basics.

Adopting the usual structure I will start with construction, infringement, evidence and remedies, then move on to questions of validity and finally the sweep up of technical issues. That last section contains some interesting cases dealing with the "new normal" – remote hearings and how to conduct them. That is not going to be an issue unique to these Covid years. The courts have made it quite clear that the new practices are here to stay so it's worth spending some time on that.

Buckle up, here we go…….

2. Infringement

a. Construction

Interpretation

In 2017, Lord Neuberger's judgment in *Actavis v Eli Lilly*[1] overhauled the law of patent infringement. Questions as to collateral upheaval in other areas of patent law were immediately apparent, not least in respect of construction. We discussed this in some depth in our review of 2018 and 2019 patent

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

judgments. Entering 2020, the position was therefore largely established. Nevertheless there has been useful further clarification this year.

The case law in 2020 has confirmed that, when interpreting or 'construing' the meaning of claim language, the normal/purposive approach (here I use the lower case deliberately) is a contextual interpretation. This is apparent from article 69 of the European Patent Convention, and in English law it has long been apparent in the patent authorities (for example *Kirin-Amgen v Hoechst*[2]), which have drawn upon English legal principles governing the construction of contracts (as Lord Neuberger did when he referred to the Supreme Court's judgment in *Wood v Capita Insurance*[3]).

In 2017, one of the first judgments to consider the impact of *Actavis v Eli Lilly* was *Fisher & Paykel v ResMed*[4], in which case Richard Meade QC sat as a deputy. In 2020, Richard Meade QC became Mr Justice Meade and handed down judgments addressing substantive issues of infringement and/or validity in two cases. The contextual nature of claim interpretation is apparent from both of those judgments.

In ***Fisher & Paykel v Flexicare***[5], a case (aptly for 2020) about ventilator technology, when interpreting the claim language in issue Meade J expressly considered the "ordinary contextual meaning", what made "sense" of the claim language "contextually", and the context of the claim structure.

In ***MSD v Wyeth***[6], a case (also aptly for 2020) about vaccine formulation, Meade J noted that the claim as a whole must be construed in context, including the scientific context. Points of construction in that case concerned the operation of the words "comprised in", "comprising" "comprises" and "are", claim 1 being in the following terms ([249]):

> A. A siliconized container means filled with a formulation which inhibits silicone induced aggregation of a polysaccharide-protein conjugate comprised in a siliconized container means, the formulation **comprising**
> B. (i) a pH buffered saline solution, wherein the buffer has a pKa of about 3.5 to about 7.5,
> C. (ii) an aluminum salt and
> D. (iii) one or more polysaccharide-protein conjugates
> E. wherein the polysaccharide-protein conjugate **comprises** one or more pneumococcal polysaccharides
> F. and wherein the one or more pneumococcal polysaccharides **are** [13 pneumoniae serotypes identified, including 6B and 19A].

Wyeth's case was that the claim would cover formulations containing polysaccharides other than the 13 identified serotypes listed in feature F and would not be limited by requiring the serotypes of feature F. To this end, Wyeth argued that: "comprising" (feature A) meant that other polysaccharides were also allowed; and "comprises" (feature E), taken with the opening words of feature A ("a formulation…conjugate") meant any limitation in feature F to the 13 identified serotypes was avoided.

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[2] *Kirin-Amgen Inc & Ors v Hoechst Marion Roussel Limited & Ors* [2004] UKHL 46 at [32]
[3] *Wood v Capita Insurance Services Ltd* [2017] UKSC 24
[4] *Fisher & Paykel Healthcare Limited & Anr v ResMed Limited* [2020] EWHC 2748 (Ch)
[5] *Fisher & Paykel Healthcare Limited v Flexicare Medical Limited & Anr* [2020] EWHC 3282 (Pat) (8 December 2020) Meade J
[6] *Merck Sharp & Dohme Limited v Wyeth LLC* [2020] EWHC 2636 (Pat) (15 October 2020) Meade J

Meade J stuck with the conventionally understood meanings of the drafter's staples. He noted that conventionally in patent claim drafting, the word "comprises" is used to indicate "includes", meaning that those things that follow must be present, but others are allowed in addition.

This meant that in feature A, "comprising" followed by three components meant all three must be present but other ingredients were allowed. This would permit the inclusion of any other excipient, such as a preservative. In feature E, "comprises" meant that component (iii) allowed other bacterial polysaccharides but required that one or more was pneumococcal. Up to this point, the language was inclusive rather than limiting.

In feature F, however, the ordinary meaning of "are" did not extend to "include". Rather, it specified that the set of pneumococcal polysaccharides required must be exactly the 13 listed. The judge said that if the patentee had intended that other pneumococcal polysaccharides could be included in addition to the 13 listed, it would just have used the word "comprised" again. This meant that the claim was not infringed.

A useful point of principle was captured by Douglas Campbell QC, sitting as a Judge of the Patents Court in *IPCom v Vodafone*[7] ([70]):

> **"…construction is done without reference to the alleged infringement**. At most the nature of the infringement allows the court to concentrate on the important points: see Pumfrey J in *Nokia v Interdigital* [2007] EWHC 3077 (Pat) at [25]."

So in the court's construction of patent claims, reference to both the alleged infringement and the prior art is prohibited. Construction is confined to interpreting the words of the claim in the context of the specification as a whole, as the skilled addressee of the patent would have understood the author of the patent to have meant by using those words.

Further, when considering the context of the specification of the patent, in ***Akebia v Fibrogen***[8] Arnold LJ said ([218]):

> "…there is no principle of law that the skilled team are deemed to read all documents cited in a patent. It is a context- and fact-dependent question, and thus it depends firstly upon the wording of the specification and secondly on the evidence. …"

In *Akebia* the patent specifications in issue referred to other publications. There was a dispute as to whether, and if so to what extent, the skilled team would read those documents. In light of the evidence, the judge concluded that the skilled team would not necessarily follow up any of the cited publications. They would also be more likely to read some than others (because of the ways they were cited). Some of the reasoning appears to blur a little the distinction between claim interpretation (for which expert evidence is strictly admissible only in respect of terms of art) and the assessment of sufficiency (for which expert evidence as to the disclosure of the specification is admissible and usually key), but sympathy is perhaps due to the judge here in view of the complexity of the patents.

[7] *IPCom GmbH & Co KG v Vodafone Group plc & Ors* [2020] EWHC 132 (Pat) (28 January 2020) Recorder Douglas Campbell QC

[8] *Akebia Therapeutics Inc & Anr v Fibrogen Inc* [2020] EWHC 866 (Pat) (20 April 2020) Arnold LJ

Arnold LJ observed ([262]):

> "Counsel for the Claimants reminded me that it is not appropriate to interpret a claim by a process of meticulous verbal analysis; but this claim forces the skilled person to wrap a cold towel round their head when trying to understand it."

Some issues of construction concerned the interpretation of a chemical formula, and so this was to be done through the eyes of the skilled medicinal chemist member of the skilled team. All the expert medicinal chemists agreed in cross-examination that there was no chemical reason why, for groups said to be "optionally substituted" without more, the substitution in question should or should not be permitted. It therefore followed that their opinions as to the correct interpretation of the formula were inadmissible.

A similar point was made by Morgan J in ***Lufthansa v Astronics* (22 July 2020)**[9], a case about voltage supply apparatus for aircraft seating. Lufthansa argued that the disclosure of a publication (Quintel) referred to in the specification of the patent should be considered in the course of construing the claim language. After considering the dicta in *Ultraframe v Eurocell*[10], *ASSIA v BT*[11] and *Akebia v Fibrogen*, the judge said that the authorities showed ([79]):

> "…there is no principle of law which requires a finding that the skilled addressee of the Patent would obtain and consider the full patent specification in Quintel and then take it into account when construing the Patent."

I must say that I find that a surprising assertion. Given that the skilled person is deemed to be capable of reading anything in any language, and having been specifically pointed to a citation by the words of the patent to be construed, it seems unlikely to me that the skilled person would not have that in mind when construing the wording of the patent.

The court's interpretation of claim language being through the eyes of the skilled addressee of the patent, the case law in 2020 has again confirmed that the skilled reader is deemed to have some understanding of patent law.

For example, in ***Edwards v Meril***[12], Birss J noted that the skilled person was taken to know about the pre/post characterising format of claim drafting and to take this into account. In the context of that case, the skilled person would also understand the patent in issue as a whole to have been written on the basis that both embodiments in the specification were embodiments of the invention.

In ***Neurim v Mylan* (4 December 2020)**[13], Marcus Smith J said ([27]):

> "Patents are technical documents, and the skilled person must have sufficient understanding of patent law to appreciate the general nature and function of a patent specification and claims."

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[9] *Lufthansa Technik AG v Astronics Advanced Electronic Systems & Anr* [2020] EWHC 1968 (Pat) (22 July 2020) Morgan J
[10] *Ultraframe (UK) Ltd v Eurocell Building Plastics Ltd* [2005] RPC 7 at [73]
[11] *Adaptive Spectrum and Signal Alignment v British Telecommunications Plc* [2014] EWCA Civ 1462 at [110]
[12] *Edwards Lifesciences Corporation & Anr v Meril GmbH & Anr* [2020] EWHC 2562 (Pat) (29 September 2020) Birss J
[13] *Neurim Pharmaceuticals (1991) Limited & Anr v Generics UK Limited (trading as Mylan) & Anr* [2020] EWHC 3270 (Pat) (4 December 2020) Marcus Smith J

An excellent summary of the principles governing the construction of patent claims was provided by HHJ Melissa Clarke in one of the three IPEC patent judgments handed down near the end of the year. ***Communisis v The Tall Group***[14] concerned Communisis' patent to a security measure for banking cheques. The judge explained the task of the court as follows ([47]-[50]):

> "The task of the court in construing the claims of a patent is to determine what the person skilled in the art would have understood the patentee to intend the language of the claim to mean in the light of his or her common general knowledge. It is impermissible to use the infringement as an aid to construction of the Patent, and it is also impermissible to use cited prior art as an aid to construction except where the prior art is itself in the common general knowledge or is expressly referred to in the patent being construed. Neither party claims that either of those exceptions apply in this case. …
>
> …just as purposive construction does not mean that an integer can be treated as ignored, it also does not permit an additional limitation (or, I would add, an extension) to be implied into the claim, even if connected with the way in which the invention works, if that does not arise from a proper construction of the language of the claim itself."

HHJ Melissa Clarke also addressed how the PSA would approach the patent ([30]):

> "The skilled addressee of the Patent reads the specification with the common general knowledge of persons skilled in the relevant art at the application date of the patent…and knowing that its purpose is to disclose and demarcate an invention."

Further ([66]):

> "…the skilled person understands that, in the claim, the patentee is stating the limits of the monopoly which it claims".

Finally on interpretation, a judgment of David Stone in ***Geofabrics v Fiberweb***[15] is notable for a simple statement of principle. The judge was not bound by the construction reached by Jacob J in a different case (*Milliken v Walk Off Matts* [1996] FSR 292) about very similar claim language, useful though that case might be in demonstrating the proper *approach* to construction (subject to subsequent authorities). Indeed, in 2020 the Court of Appeal confirmed that the court is not bound by earlier findings in respect of the same patent reached in a different case – I will return to this in the obviousness section.

Role of evidence in construction

Several judgments in 2020 have contained hard words on expert evidence. In the context of construction, a theme of the commentary has been on the place and limitations of expert evidence.

[14] *Communisis Plc v The Tall Group of Companies Limited & Ors* [2020] EWHC 3089 (IPEC) (17 November 2020) HHJ Melissa Clarke

[15] *Geofabrics Limited v Fiberweb Geosynthetics Limited* [2020] EWHC 444 (Pat) (5 March 2020) David Stone

Early in the year, in ***IPCom v Vodafone***[16], Douglas Campbell QC succinctly referred to the basic principle ([69]):

> "It was not suggested that any of the terms in the Patent, or any of the claims, were technical terms or terms of art. In those circumstances construction is a matter for the Court, not for witnesses: see eg *STEP v Emson* [1993] RPC 513…."

The Court of Appeal elaborated in ***Conversant v Huawei* (8 October 2020)**[17], in which Floyd LJ said ([101]:

> "Although the meaning of a document is, in the end, a question of law, the correct interpretation of a passage in a patent specification is a matter to which evidence of those skilled in the art can be relevant. This can take a number of forms. Whilst evidence of the meaning of ordinary English words is inadmissible, experts are frequently, and properly, asked to address the consequences of a particular term, on assumptions as to its meaning. They also conventionally address the relevant factual matrix, i.e. the common general knowledge."

In ***Communisis v The Tall Group***[18]**,** HHJ Melissa Clarke's helpful summary of principles also addressed the role of evidence in construction. She said ([49]):

> "Jacob LJ at [182] of *Virgin* makes clear **the task of construction is for the court**. The Claimant submits that expert evidence is admissible on the subject of construction, but the Defendants submit, and I accept, that **expert evidence has only a limited role to play**. As Laddie J (as he then was) put it in *Brugger and Others v Medic-Aid Ltd* [1996] RPC 635 at page 642, "*Construction is a matter for the court unless the claims and specification contain technical expressions which need to be explained by suitable evidence*". That is a limited role, and the court will not generally be assisted by the evidence of experts which goes beyond this."

It is unusual for a patent claim to contain a term of art, but this was found to be the case in ***Neurim v Mylan* (4 December 2020)**[19]. Neurim's patent was to second medical use of melatonin for "improving the restorative quality of sleep in a patient aged 55 years or older". The first paragraph of the specification described the field of the invention as follows ([32]):

> "The present invention relates to a method for treating primary insomnia (as defined by **DSM-IV** or nonorganic insomnia as defined by **ICD-10**) when characterised by non-restorative sleep, and to the use of melatonin in the manufacture of a medicament for this purpose."

"DSM-IV" and "ICD-10" were terms of art, references to the Diagnostic and Statistical Manual of Mental Disorders (4th edition) and the International Classification of Mental and Behavioural Diseases (10th edition) respectively. This had consequences for the meanings of "primary insomnia characterised by non-restorative sleep" in the language of the claims. The judge, Marcus Smith J, had a lot to say about the evidence in that case, as I will return to below.

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[16] *IPCom GmbH & Co KG v Vodafone Group plc & Ors* [2020] EWHC 132 (Pat) (28 January 2020) Recorder Douglas Campbell QC

[17] *Conversant Wireless Licensing SARL v Huawei Technologies Co., Limited* [2020] EWCA Civ 1292 (8 October 2020) Patten, Floyd & Newey LLJ

[18] *Communisis Plc v The Tall Group of Companies Limited & Ors* [2020] EWHC 3089 (IPEC) (17 November 2020) HHJ Melissa Clarke

[19] *Neurim Pharmaceuticals (1991) Limited & Anr v Generics UK Limited (trading as Mylan) & Anr* [2020] EWHC 3270 (Pat) (4 December 2020) Marcus Smith J

b. Infringement

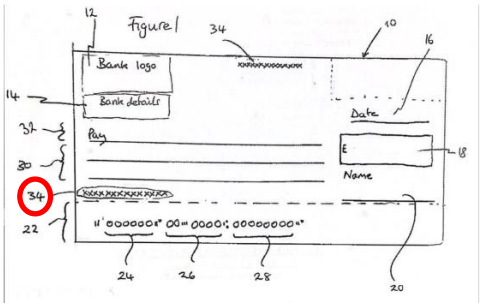
Following *Actavis v Eli Lilly*, in the first stage (limb (i)) of the assessment of infringement, the court considers whether the alleged infringing product or process falls within the scope of the claim of the patent when the claim has been given its "normal interpretation". The second stage (limb (ii)) is the doctrine of equivalents.

In patent disputes that reach the court the answer to the limb (i) test tends to follow, without much further reasoning, from the determination of issues of construction. I will therefore just mention a couple of cases in respect of the limb (i) test, before turning to limb (ii), which has continued to develop in 2020. Finally in this section I capture some technical points about pleading of infringement issues.

Limb (i) of the infringement test: the normal interpretation

Communisis v The Tall Group[20] concerned Communisis' patent, to a security measure for cheques (and other banking instruments) that consisted of converting visible data on the check (sort code, account number, serial number of the cheque) into a higher base and then printing the generated code (or part of it) on at least one place on the cheque as well.

In the example of Figure 1 of the patent, the generated code ("UCN") was shown at 34:



Claim 1 was in the following terms ([29]):

> "1.1. A method of generating a payment/credit instrument comprising:
> 1.2. **Generating a code** based on at least one string of information to be applied to the payment/credit instrument during generation thereof;
> 1.3. Applying at least one string of information to the payment/credit instrument; and
> 1.4. **Applying the generated code** to the payment/credit instrument in at least one location of the payment/credit instrument during generation thereof by a printing technique,
> 1.5. Wherein the or each string of information is converted to a code **by conversion to a higher base**; and
> 1.6. Wherein the payment/credit instrument is a cheque or credit slip, and
> 1.7. Wherein the at least one string of information is one or more of a bank sort code, a payment/credit instrument serial number and an account number for the payment/credit instrument."

[20] *Communisis Plc v The Tall Group of Companies Limited & Ors* [2020] EWHC 3089 (IPEC) (17 November 2020) HHJ Melissa Clarke

An issue of construction was whether "by conversion to a higher base" meant that the code had to be generated *by* that conversion, or whether it covered a process involving encryption by another cryptographic process followed by presentation of the output *in* a higher base. The judge agreed with The Tall Group that it was the former. Her reasoning included that: the latter approach involved ignoring words that were present in the claim and in doing so fundamentally altering its meaning; the patent only taught how to generate a code by base conversion and so that should be the limit of the scope of the monopoly; and a claim that caught every cryptographic function invented or yet to be invented as long as the result was presented in a higher base would exceed "by a very great way" Communisis' contribution to the art.

The Tall Group likened Communisis' claimed invention to a translation of a word from one language to another. (Communisis' own expert described the security it would provide as "frankly pretty awful"). The Tall Group's case was that its product achieved the generation of a code by applying quite a different, much more secure and effective cryptographic process, namely applying a standard secure hash function to the information string, in which the input numerical value and output numerical value were different. The information string was first converted to a lower base (binary), the hash function was applied, and the output in binary was then converted to a higher base for display in hexadecimal (base 16). The judge was satisfied that this meant the claim was not infringed on the normal interpretation.

There now follows the "comic relief". Just think of this as the "Porter's Scene" in Macbeth!

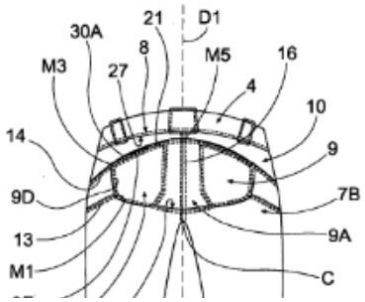
Freddy v Hugz[21] was a case about a patent "for shaping the female buttocks and hips". Claim 1 was crafted in somewhat dry language ([32]):

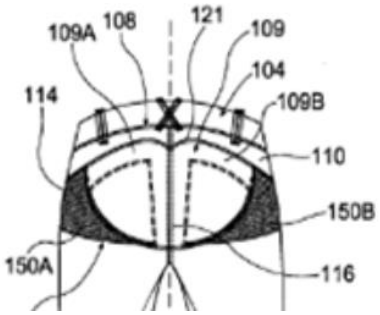
> "- at least one first **element** (7B, 107B, 207B) adapted to cover at least a lower terminal portion (S1) and lateral portion (S2) of the buttocks,
>
> - at least one second **element** (9, 109, 209) adapted to cover at least a central portion (S3) of the buttocks,
>
> - and at least one third **element** (4, 10; 104, 110; 204, 210) adapted to cover at least an upper terminal portion (S5) of the buttocks,
>
> characterised in that
>
> - said first (7B, 107B, 207B), second (9, 109, 209) and third (10, 4, 110, 104, 210, 204) **element** comprise a knitted fabric,
>
> - said first (7B, 107B, 207B) and third (10, 110, 210) **element** define a central aperture (40, 140, 240), the outer edges (9C, 9D, 9E; 109C, 109D, 109E; 209C, 209D, 209E) of said second element (9, 109, 209) being secured to the edges (7H, 10A; 107H, 110A; 207H, 210A) defining said aperture of said first (7B, 107B, 207B) and third element (10, 4, 110, 104, 210, 204) so as to close said aperture,
>
> - and that said second **element** (9, 109, 209) comprises two parts (9A, 9B, 109A, 109B, 209A, 209B), each adapted to cover only one of the two central parts (S3) of the buttocks, said two parts being secured together along respective lateral edges (9F, 109F, 209F)

[21] *Freddy SpA v Hugz Clothing Limited & Ors* [2020] EWHC 3032 (IPEC) (19 November 2020) David Stone

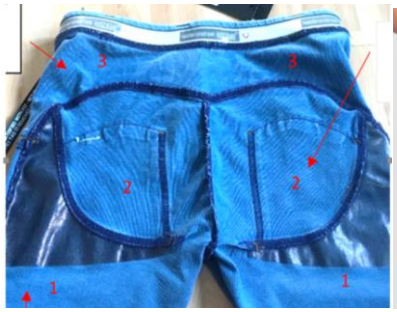
provided at the intergluteal cleft (S4) of the buttocks by a central seam (16) adapted to be positioned at said intergluteal cleft (S4)."

Here are some figures from Freddy's patents, along with a picture of them being worn:





And here is a picture of the inside of the Hugz jeans alleged to infringe, along with a picture of Hugz jeans being worn:



The word 'element' was construed as not meaning a totally separate piece of material. And so the portions labelled 1 and 2 in the Hugz jeans were separate "elements", even with the interconnecting bridge of fabric between the larger first and second elements. The Hugz design infringed.

The judge also concluded that Hugz were liable for passing off and unregistered design right infringement. So the *Freddy* case is an interesting one for the breadth of intellectual property rights that proved useful, as well as providing further confirmation that patents can be a valuable asset in the fashion industry. I also suspect that it holds the record for the judgment with the most frequent use of the word "buttocks". Indeed, I doubt if there is much competition for that title.

Limb (ii) of the infringement test: 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?" In this context Lord Neuberger considered that the old Improver/Protocol questions provided helpful assistance but needed some reformulation. This he proceeded to undertake, 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.

In ***Evalve v Edwards* (substantive)**[22], Birss J, adopting some of the upgrades introduced by other cases since *Actavis,* summarised the questions to be answered as follows ([311]):

> "Question 1: does the variant achieve substantially the same result in substantially the same way as the invention?
>
> Question 2: 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?
>
> Question 3: 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?"

Evalve v Edwards concerned devices to treat mitral valve regurgitation by a transcatheter technique. Evalve/Abbott's '810 patent claimed a "**fixation device** for engaging tissue" (**A**), comprising:

- a pair of fixation elements each having a first **end**, a **free end** opposite the first **end**, and an engagement surface therebetween for engaging the tissue (**B**),
- the first **ends** being movably coupled together such that the fixation elements are moveable between 1) a **closed** position wherein the engagement surfaces face each other, and 2) an **inverted** position where the engagement surfaces face away from each other (**C**); and
- D an actuation mechanism coupled to the fixation elements adapted to move the fixation elements between the **closed** position and the **inverted** position (**D**),
- further comprising a pair of gripping elements, each gripping element moveable with respect to one of the fixation elements and being disposed in opposition to one of the engagement surfaces so as to capture tissue therebetween (**E**), wherein
- the gripping elements are moveable from an undeployed configuration in which each gripping element is separated from an opposing engagement surface, to a deployed configuration in which the gripping element is adjacent to the opposing engagement surface (**F**), and wherein
- each fixation element is at least partially concave and each gripping element is at least partially recessed within the fixation element in the deployed configuration (**G**), or wherein
- the gripping elements are approximately parallel to each other in the undeployed configuration (**H**).

Modified Conditional Amendment F made tweaks to claim 1 as granted. In particular, the tweaks added a requirement for the fixation device to be "for the repair of a valve of the heart" (integer A), added the words "wherein in the inverted position the engagement surfaces provide an atraumatic surface to deflect tissue" (integer C), and deleted optional integer H so that integer G was the only option.

Illustrations of embodiments of the invention of the patent, showing the closed/delivery position, open

[22] *Evalve, Inc & Ors v Edwards LifeSciences Limited* [2020] EWHC 514 (Pat) (12 March 2020) Birss J

position and inverted position, were given ([154], [160]):

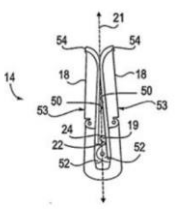


Fig 7A - Closed / Delivery position

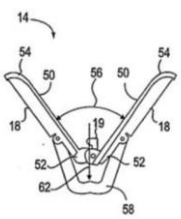


Fig 7B – Open position

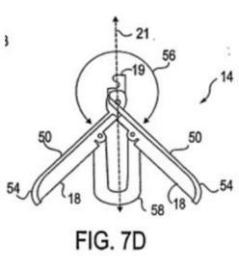


Fig 7D – Inverted position

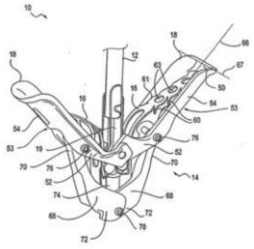


Figure 9

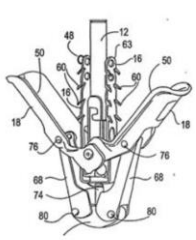
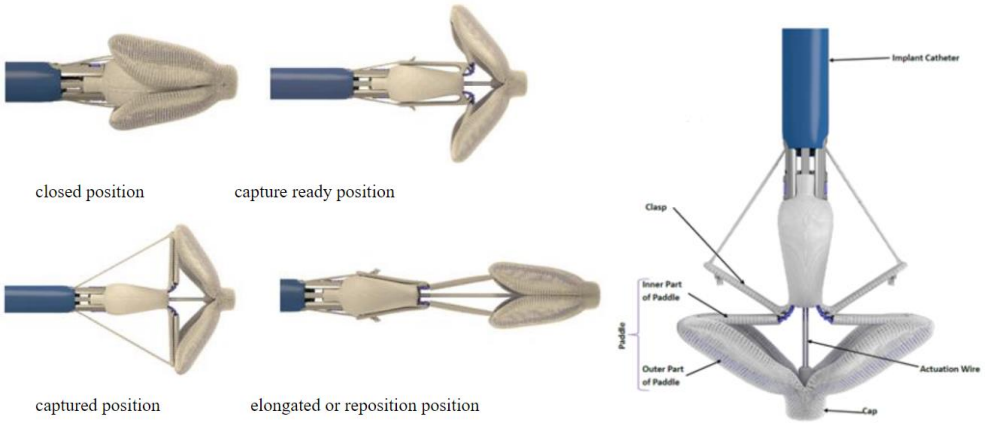


Figure 11B

Edwards' PASCAL device was alleged to infringe. The various operation of the PASCAL is depicted here ([193], [136]):



Abbott's primary case was that the **fixation elements called for by claim 1 were the paddles of the PASCAL device**, and that each integer of claim 1 was met on the normal interpretation.

Edwards' overall case was that the PASCAL device provided a different solution to the same problem. Rather than inverting around a hinge point at the shaft, the bend was in the middle. So rather than invert into a position for withdrawal, PASCAL's paddles flattened and extended into a position for withdrawal (as in prior art Goldfarb), and this was not the invention claimed.

The judge's view was that the dispute on this case concerned the claim integers B, C and G. The **whole paddle** could be regarded as a fixation element as required by claim 1. The two ends of the paddle would then be the end of the inner part close to the actuation wire (X) and the end of the outer part which was also close to the actuation wire (Y). Each fixation element had an engagement surface on the top of the inner part of each paddle. Those engagement surfaces satisfied feature C in that they faced each other in the closed position and faced away from each other in the elongated position. The fact that there was another part of the fixation element which also engaged the leaflet but did not satisfy feature C did not matter. In the closed position, the curved arms on the outer part of the paddle made it concave and the gripping elements were recessed etc. So this fixation element also satisfied feature G.

However, If the relevant ends X and Y of the whole paddle were the ends which had to satisfy the requirements of feature B then the device was outside the claim on a normal construction because neither X nor Y was a free end. (Nor was point 'Z', which comprised a "living hinge" (i.e. a piece of material which bent)). So there was **no infringement on the normal interpretation** on Abbott's primary case.

Abbott's secondary case (apparently made at trial) was that the **fixation element was the inner part of the paddle**. This followed evidence of Abbott's expert that because the inner and outer parts of the paddles were made from a continuous braided structure, the inner part could not be considered to be a separate element attached to the outer part.

Looked at this way, the inner part of the paddle could be regarded as a fixation element with an engagement surface on the top of the inner part. Points X and Z would then be the opposite ends of the fixation element. Point X could satisfy integer C. Point Z would be a free end because it was free to move relative to the first end. But **in the closed position, the fixation element would then not satisfy feature G: the curved arms in the outer part of the paddle were not part of the fixation element. However, alternative claim feature H would be satisfied**.

So on Abbott's secondary case, claim 1 as *granted* would be infringed on the normal interpretation. However, Modified Conditional Amendment F would not be infringed because integer H had been deleted and integer G remained unsatisfied.

So the assessment of infringement moved to limb (ii), the judge focusing on Modified Conditional Amendment F in his consideration of the doctrine of equivalents.

For **Question 1,** Birss J said that the first step must be to identify the variant, and a necessary aspect of the analysis must be to identify the missing feature of the claim.

On Abbott's primary case, this was a free end of the whole paddle fixation element. On Abbott's secondary case, it was Modified Conditional Amendment F claim 1 feature G - the fixation element, being the inner part of the paddle, which was not partially concave and the gripping element was not recessed within it. However, Birss J considered that there was really only one variant represented by PASCAL: the structure of the fixation element and the actuation mechanism had been combined in a manner which was different from the structure in the claim, construed normally ([313]):

> "In effect, the hinged joint 76 between the fixation element 18 and actuation leg 68 has been moved to the tip of element 18 (point Z of PASCAL). Secondly the curved longitudinal edges of fixation element 18 has been taken off element 18 and placed onto leg 68."

Birss J noted that from *Icescape v Ice-World*[23], in the first question one should examine what was the problem underlying the invention and how the patent solved that problem. In this case the problem faced by the skilled team was to produce an effective interventional cardiology based technique to treat mitral regurgitation. The '810 patent solved this problem with a device of Modified Conditional Amendment F. The inventive concept was a fixation device with proximal and distal elements between which the leaflets would be held and in which the distal elements had a closed position and an inverted position, the latter being to mitigate the risk of injury if the device was withdrawn in the closed or open positions. Further, bearing in mind feature G, the proximal elements were partially recessed into a concave structure in the distal elements to help to secure the leaflets.

The judge rejected Edwards' attempts to distinguish the elongated position of PASCAL from the inverted position of the patent. The PASCAL solved the problem in essentially the same way as the claimed invention. In particular ([319]):

> "The hinged joint at point Z is free to move in exactly the same way as the free end referred to in the claim. The upper part of the paddle can be thought of as a fixation element and has a closed position and an inverted position. This inverted position helps mitigate the risk of injury

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

which would arise if the device was withdrawn in the closed position or in an open position (such as capture ready)."

Question 2 asks whether it would 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. Evalve/Abbott contended that the skilled reader would easily understand how the PASCAL worked and that the answer 'yes' to question 2 followed automatically from that understanding. The judge said ([323]):

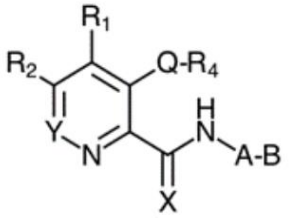
> "In a case about a fairly simple mechanical device like this, I accept that is a legitimate way of dealing with question 2".

Question 3 asks whether the reader of the patent would 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. The judge considered the issue a matter of construction. He did not think there was anything in the patent that would lead the skilled person to think that the relevant features of the variant were intended to be excluded.

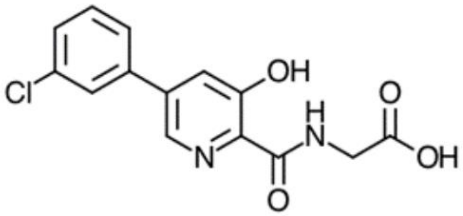
Therefore claim 1 of Modified Conditional Amendment F would be infringed on the doctrine of equivalents.

The operation of the doctrine of equivalents was considered by Arnold LJ in some depth in ***Akebia v Fibrogen***[24]. (At 61,089 words in 639 paragraphs, this was also the longest patents judgment of the year). The case concerned six Fibrogen patents, in two families.

The judge having construed Formula (I) (below left) as permitting the R_2 group to be substituted with halogen, Akebia's vadadustat product (below right) fell within Formula (I). Vadadustat would therefore infringe claim 19A of EP 823 and claim 2 of EP 301 if those claims were valid; but they were not.

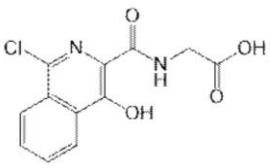


Formula (I)

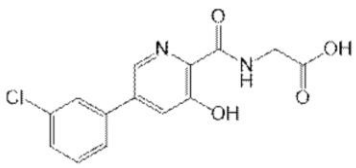


Vadadustat

However, claim 17A of EP 531 survived the invalidity challenges (with amendments). This claim was limited to Compound C (below left). The question therefore became whether vadadustat (below) right infringed on the doctrine of equivalents.



Compound C



Vadadustat

[24] *Akebia Therapeutics Inc & Anr v Fibrogen Inc* [2020] EWHC 866 (Pat) (20 April 2020) Arnold LJ

Arnold LJ noted (from Lord Neuberger in *Actavis v Eli Lilly*) that the reformulated questions were guidelines, not strict rules, and that the language of some or all of the questions may sometimes have to be adapted to apply more aptly to the specific facts of a particular case. Also (from the Court of Appeal in *Icescape v Ice-World*), the questions begin from the normal interpretation[25].

Continuing with the governing principles, Arnold LJ said that question 1 is partly a question of interpretation of the specification (what is the inventive concept revealed by the relevant claim(s) of the patent?) and partly a question of fact (does the variant achieve substantially the same result in substantially the same way?). In so far as it is a question of fact, the burden of proof must lie on the patentee.

Arnold LJ observed that given the way in which question 2 had been formulated by the Supreme Court, there will rarely be scope for a negative answer if the answer to question 1 is “yes”.

For question 3, as the test had been laid down by the Supreme Court, the answer could not be dictated by the fact that the variant did not fall within the wording of the claim on its normal interpretation, because otherwise there would be no point in answering the question. What mattered was the reason why the addressee would think that the claim was limited in the relevant respect.

Additionally, Arnold LJ gave some notable commentary going to the legitimacy of narrowing from very broad claims to save validity while still seeking broader protection. He said ([453]-[454]):

> "As counsel for the Defendants submitted, it is contradictory for the Claimants on the one hand to be amending the claim down to just Compound C, particularly in order to save its validity, and yet at the same time to be asserting that the scope of protection of the amended claim extends well beyond Compound C to a structurally rather different compound, and by implication to a large number of other compounds as well. By amending down to Compound C, the Claimants are disclaiming the other ways of achieving the same effect disclosed in the specification, and in particular everything covered by the broader granted claims.
>
> This is an extreme instance of a principle which is well established in the jurisprudence of the Bundesgerichtshof (German Federal Court of Justice). As the BGH held in Case X ZR 16/09 - *Okklusionsvorrichtung* (Occlusion Device):
>
> > “If the description discloses a plurality of possibilities for achieving a specific technical effect, but only one of those possibilities is catered for in the patent claim, the utilisation of any of the other possibilities properly does not constitute infringement of the patent with equivalent means.” "

Further, from the Bundesgerichtshof's judgment in Case X ZR 69/10 *Diglyzidverbindung* (Diglycid compound) emerges a principle that, where the specification discloses several ways in which a particular technical effect can be achieved but only one way is claimed, the conclusion that use of the other (disclosed but not claimed) ways to achieve the technical effect cannot amount to infringement as an equivalent extends to further undisclosed ways in which the technical effect can be achieved where the further ways operate in a manner more similar to the disclaimed than the claimed methods.

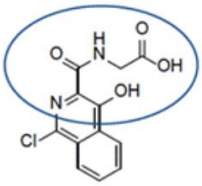
[25] It is worth commenting that Arnold LJ was indeed right that Lord Neuberger's judgment described the use of the questions as 'for guidance' and indicated that their use was therefore optional. Kitchin LJ (as he then was) adopted a different line in *Icescape v Ice-World* and said of the investigation of equivalence that "this is to be determined by asking these three questions". Given where he now sits, we may see that adjustment restated at the highest level at some stage.

Turning to the assessment of the doctrine of equivalents:

On question 1, Arnold LJ accepted that the inventive concept of claim 17A was the use of Compound C (a specific molecule) for treating anaemia associated with kidney disease. However, he said that the inventive concept was not the use of *any* compound that inhibited HIF-PH for treating anaemia associated with kidney disease.

Compound C was different to Compounds D-K of EP 531, both structurally and in terms of the experimental results obtained. There was no teaching in EP 531, or anything in the common general knowledge, that would suggest to the skilled team, and in particular the medicinal chemist, that the bicyclic ring of Compound C and Compounds D-K was not essential to the function of Compound C, or that it could be replaced by a chlorophenyl group with no material effect on binding or specificity. The separation of the second ring in vadadustat might affect the rotational freedom of the molecule. Vadadustat also differed from the commonality between Compounds C-K in other ways. Given the differences, it was likely that vadadustat had a different activity to Compound C in terms of its binding and specificity to HIF-PH – indeed it seemed superior to Compound C, which had not progressed to a phase III trial. Further, it was not known whether vadadustat was a specific inhibitor of HIF-PH or whether (like Compounds C to K) it inhibited both collagen PH and HIF-PH. In these circumstances, it had not been shown that vadadustat achieved the same result in the same way (or even substantially the same way) as Compound C.

Another case on question 1 run by Fibrogen was based on vadadustat and Compounds C-K all having a “common structural motif”, this being the ringed part of the structure shown for compound C here:



Compound C

The judge rejected this case too, for number of reasons. These included that: Claim 17A being to Compound C alone, its inventive concept was not broader than Compound C and it was not right to search for an inventive concept common to compounds C-K; there was no hint in EP 531 of the existence of a "common structural motif" and no such motif would have been apparent to the skilled medicinal chemist; and the alleged common structural motif was in any event not a proper characterisation of the features shared by Compounds C-K but a cherry picking of features.

Question 2 was not independently considered.

On question 3, Arnold LJ gave multiple reasons for answering the question 'YES', and therefore declining on a second count the operation of the doctrine of equivalents to find infringement. The reasons included the following:

- Claim 17A was limited by structure to Compound C and so, on its face, was not intended to cover anything that worked or anything that did so by competing with 2-OG, or anything which shared the "common structural motif";
- Read in context the claim was clearly intended to be narrow, not to define a formula but an individual compound;

- Compound C would be understood to be the most promising and best explored of the exemplified compounds in EP 531, and so it would be understood that a technical choice had been made to limit the claim to that compound;
- It was common ground that the skilled team would be aware that granted claim 1 had been amended down to claim 17A alone because the broader claims were invalid or likely to be invalid, and it was contradictory for the claimants on the one hand to amend down to Compound C to save validity while seeking still to cover a structurally rather different compound;
- As vadadustat was less similar, structurally, to Compound C than Compounds D-K, as D-K had been disclaimed the skilled team would not understand the claim to extend to a product such as vadadustat;
- By narrowing the scope of the claim 1 of EP531 to compounds of Formula (I) in order to preserve novelty in the course of examination, Fibrogren thereby represented that it was not seeking to contend that the patent, if granted, would have a scope extending beyond the confines of Formula 1, yet extending claim 17A in the way now contended for under the d.o.e. would do precisely that. This was therefore an example of a case in which it would be contrary to the public interest for the contents of the prosecution file to be ignored. Fibrogren's statements about deleted subject matter not being abandoned, in correspondence with the examiner, did not prevent this conclusion – Fibrogen could not "have it both ways".

Quite a thorough list! But that was not all.

One of the areas we have been watching since *Actavis v Eli Lilly* is the role that considerations as to validity have in the application of the doctrine of equivalents. A long standing principle of English law is that anyone is entitled to feel secure if they know that that which they are doing differs from that which has been done of old only in non-patentable variations. The principle was expressed by Lord Moulton in *Gillette v Anglo-American*[26] (1913) and re-stated by Lord Hoffmann in *Merrell Dow*[27] (1995). In 2019, in *Technetix v Teleste*[28], HHJ Hacon said one way of reconciling the 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.

Interestingly, in 2020, Arnold LJ did not take up the *Formstein* baton. He did, however, note the relevance of the obviousness questions. I noted above the judge's reference to principles explored in the German cases Case X ZR 16/09 - *Okklusionsvorrichtung* and Case X ZR 69/10 *Diglyzidverbindung* (Diglycid compound). In view of this, it is perhaps unsurprising that Arnold LJ's reasons for answering question 3 to exclude the operation of the doctrine of equivalents also included the following:

- On the claimants' broader approaches to question 1 (at least), claim 17A would extend to compounds shown to be inhibitors of a relevant enzyme (HIF-PHIs) in prior art Epstein. Here the judge said ([457]):

[26] *Gillette Safety Razor Co v Anglo-American Trading Co Ltd* (1913) 30 RPC 465
[27] *Merrell Dow Pharmaceuticals Inc & Ors v H.N. Norton & Co. Limited* [1995] UKHL 14
[28] *Technetix B.V & Ors v Teleste Limited* [2019] EWHC 126 (IPEC) (29 January 2019) HHJ

> "Since the case of obviousness over Epstein has only failed because it did not lead to Compound C, the result would be an invalid claim. This is a good reason to conclude that the scope of claim 17A is not intended to extend beyond Compound C."

- The scope of claim 17A by equivalence would be a claim that was so broad that it would suffer the same problems with insufficiency (both plausibility and undue burden) as the claims of EP 823 and EP 301. Again, that was a good reason to conclude that the scope of claim 17A was not intended to extend beyond Compound C.

Finally, Arnold LJ said ([461]):

> "If…one cross-checks the foregoing conclusion with the Protocol on the Interpretation of Article 69 of the European Patent Convention, I consider that it is manifest that extending the scope of protection of claim 17A in the manner contended for by the Claimants would go well beyond fair protection for the patentee and would not afford a reasonable degree of legal certainty for third parties."

In 2020, Birss J's approach to the assessment of the doctrine of equivalents has also included consideration of obviousness issues. One of the ways in which this has been apparent is the structure of the judge's analysis: in both the cases in which Birss J considered the doctrine of equivalents, he did so after considering construction and infringement on the normal interpretation, then questions of obviousness, and then the doctrine of equivalents. One of those cases was *Evalve v Edwards* (discussed above) which was about technology to mend the mitral valve of the heart. The other case was ***Edwards v Meril***[29] which concerned technology to mend the aortic valve of the heart – this time Edwards was the patentee.

Edwards' '929 patent claimed a delivery system for delivering the prosthetic valve. Birss J held that Meril's 'Navigator' device did not infringe claim 1 on the normal interpretation because the skilled person would regard the outer shaft of that device as a single composite structure, not as comprising two distinct (balloon and guide) catheters as required by the claim.

Turning to the doctrine of equivalents, Birss J began with question 1. He noted Kitchin LJ's explanation in *Icescape v Ice-World*[30] that part of what is required to answer the question is to identify what is the "inventive concept" or "inventive core" of the patent. To this, Birss J added ([223]):

> "In other words one should examine what is the problem underlying the invention and how does the patent solve that problem. Since it will be necessary to deal with the inventive concept when addressing equivalents, I will address equivalents after addressing obviousness."

In *Edwards v Meril*, the inventive concept relevant to claim 1 was an improvement on known systems, being "means to give the operator a visual indication of the amount of flex at the distal end using a flex indicating member and indicia in the proximal handle of the delivery system". In the variant, the fact the pull wire was attached the balloon catheter and there was no need for a separate guide catheter made no difference to the way the invention of claim 1 worked. The variant provided the same advantages as the claimed invention and in the same way. The fact the variant did not take advantage of the two catheter system did not matter because it was not germane to the way the invention worked.

[29] *Edwards Lifesciences Corporation & Anr v Meril GmbH & Anr* [2020] EWHC 2562 (Pat) (29 September 2020) Birss J
[30] *Icescape Limited v Ice-World International BV & Ors* [2018] EWCA Civ 2219

It would have been obvious to the skilled reader that the variant achieved substantially the same result as the invention in substantially the same way as the invention. So question 2 was answered 'YES'.

In the context of question 3, Birss J concluded that the reader would see that the inventor described the invention by reference to what was then a conventional set up, and that off-balloon crimping – which did require both catheters and relative movement – was not an essential feature of the flex indication invention and so claimed the flex indication invention separately from it. Question 3 was answered 'NO'.

The Navigator would therefore infringe claim 1 (if claim 1 was valid) under the doctrine of equivalents. But claim 1 was not valid. Several dependent claims were valid though, and for each of them Birss J considered whether the additional claim features were met in the Navigator on the normal interpretation. For those that were met in this way (claims 4, 5, 8, 9, 13), the judge combined his finding of infringement of claim 1 on the doctrine of equivalents with the finding of infringement of the additional claim features on the normal interpretation, to hold that the claims were infringed.

The additional feature of claim 12 was not met on the normal interpretation but the judge concluded that if claim 1 was infringed (e.g. under the doctrine of equivalents), then claim 12 would also be infringed "via its own equivalents analysis".

However, going forward, I would be wary of relying on double equivalents analysis. The 'variant' would seem more properly to include all of the differences from the claimed product or process, to be considered together when addressing whether the product or process complained of varies from the invention in a way or ways which is or are immaterial.

On the relevance of obviousness considerations in the doctrine of equivalents analysis, ***Communisis v The Tall Group***[31] is also worth a comment. HHJ Melissa Clarke held that there could be no infringement on the doctrine of equivalents because the "essence" of the invention was not inventive over the prior art and because the patent provided no actual contribution to the art. This would seem to rather contradict the approach taken by Birss J in *Edwards v Meril*, but as long as Judge Clarke's findings of invalidity are not overturned, it will make no difference to the outcome between Communisis and The Tall Group.

Pleading infringement

Finally in this section, it is worth capturing some points about pleading infringement (or non-infringement) cases that emerged in 2020.

In ***Geofabrics v Fiberweb***[32], infringement had been pleaded, and Deputy Judge David Stone held that this covered both infringement on the normal interpretation and infringement on the doctrine of equivalents. There was sufficient evidence in the case to make findings about the basis on which the equivalents case was put. Infringement was found on the normal interpretation but in case he was wrong on that, the judge also considered and found infringement on the doctrine of equivalents.

[31] *Communisis Plc v The Tall Group of Compnies Limited & Ors* [2020] EWHC 3089 (IPEC) (17 November 2020) HHJ Melissa Clarke

[32] *Geofabrics Limited v Fiberweb Geosynthetics Limited* [2020] EWHC 444 (Pat) (5 March 2020) David Stone

Geofabrics got away with it in the circumstances of that case but it is much safer practice now to plead both limbs expressly – indeed this is how drafting practice has evolved. Remember too that evidence will need to be directed to equivalents issues; the pleaded case therefore needs to be kept in mind when considering matters for the expert to address.

In ***Viiv v Gilead***[33], Birss J refused to strike out aspects of patentee Viiv's pleading on the doctrine of equivalents going to the knowledge and intent of Gilead when seeking to develop its alleged infringing product. Although the test for infringement is objective, subjective facts may be relevant to the assessment of an objective question. Does this mean that the question of whether a party intends to create an equivalent can be relevant to the issue of whether what they have created is actually equivalent? That would seem to be the implication.

The area remains a developing part of the law.

c. Defences, acts of infringement, stays, evidence

Defences

The patent in issue in ***IPCom v Vodafone***[34] was a divisional in the same family as a patent that had been litigated in *Nokia v IPCom*[35] and *IPCom v HTC*[36]*.* The earlier cases were about 3G standards; the present dispute was about Vodafone's network infrastructure for 4G.

Vodafone relied upon a number of defences to infringement, the most notable of which was the **crown use defence**.

Section 55 of the Patents Act states:

> "(1) Notwithstanding anything in this Act, any government department and any person authorised in writing by a government department may, for the services of the Crown and in accordance with this section, do any of the following acts in the United Kingdom in relation to a patented invention without the consent of the proprietor of the patent, that is to say—…"

There then follows *inter alia* a list of the acts that would otherwise constitute infringement under s.60(1) (the direct infringement provisions). Section 55 then continues:

> "(7) Where any use of an invention is made by or with the authority of a government department under this section, then, unless it appears to the department that it would be contrary to the public interest to do so, **the department shall notify the proprietor of the patent as soon as practicable after the second of the following events**, that is to say, the use is begun and the patent is granted, and furnish him with such information as to the extent of the use as he may from time to time require."

[33] *Viiv Healthcare Company & Ors v Gilead Sciences, Inc & Ors* [2020] EWHC 615 (Pat) Birss J (10 March 2020)
[34] *IPCom GmbH & Co KG v Vodafone Group Plc & Ors* [2020] EWHC 132 (Pat) Douglas Campbell QC
[35] *Nokia OYJ (Nokia Corporation) v IPCom GmbH & Co KG*[2011] EWHC 1470 (Pat); [2012] EWCA Civ 567
[36] *IPCom GmbH & Co KG v HTC Europe Co. Ltd & Ors* [2015] EWHC 1034 (Pat)

Section 56 of the Patents Act states:

> "(2) In this Act, except so far as the context otherwise requires, "the services of the Crown" includes -
>
> (a) the supply of anything for foreign defence purposes;
> (b) the production or supply of specified drugs and medicines; and
> (c) such purposes relating to the production or use of atomic energy or research into matters connected therewith as the Secretary of State thinks necessary or expedient;
>
> and "use for the services of the Crown" shall be construed accordingly."

Section 59 of the Patents Act states:

> "(1) During any period of emergency within the meaning of this section the powers exercisable in relation to an invention by a government department or a person authorised by a government department under section 55 above shall include power to use the invention for any purpose which appears to the department necessary or expedient—
>
> (a) for the efficient prosecution of any war in which Her Majesty may be engaged;
> (b) for the maintenance of supplies and services essential to the life of the community;
> (c) for securing a sufficiency of supplies and services essential to the well-being of the community;
> (d) for promoting the productivity of industry, commerce and agriculture;
> (e) for fostering and directing exports and reducing imports, or imports of any classes, from all or any countries and for redressing the balance of trade;
> (f) generally for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community; or
> (g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any country or territory outside the United Kingdom which is in grave distress as the result of war;
>
> and any reference in this Act to the services of the Crown shall, as respects any period of emergency, include a reference to those purposes.…"

Section 59 also states:

> "(3) In this section "period of emergency" means any period beginning with such date as may be declared by Order in Council to be the commencement, and ending with such date as may be so declared to be the termination, of a period of emergency for the purposes of this section.
>
> (4) A draft of an Order under this section shall not be submitted to Her Majesty unless it has been laid before, and approved by resolution of, each House of Parliament."

The Comptroller made submissions on the interpretation of these provisions, as well as the parties, the upshot of which was that the judge held:

- There has to be evidence of authorisation in writing by a government department[37];

- "For the services of the Crown" does not necessarily mean that the use has to benefit the Crown itself directly. For example, in *Pfizer v Minister of Health*[38] it included use by members of Crown services (such as the armed forces); and the concept of the Crown's own benefit is itself wide;

- Section 56(2) does not provide an exhaustive list of "for the services of the Crown" - the word "include" plainly indicates this; nor does s.59 limit s.56 to the three specific examples given;

- An express written authorisation to do a specific identified act establishes Crown use;

- The authorisation does not need expressly to identify the specific patent in question; and

- The Crown use defence to a claim of infringement of patent X is not limited to circumstances in which it is shown to be necessary to infringe patent X when carrying out that authorised act.

The judge seems to have pretty much ignored article 31 of the TRIPS Agreement, which requires the authorisation to be considered on its individual merits and states that it may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions, and that such efforts have not been successful within a reasonable period of time. (The latter requirement may be waived by the state concerned in a national emergency, "in other circumstances of extreme urgency or in cases of public non-commercial use").

Vodafone asserted the crown use defence in the context of the Mobile Telecommunications Privileged Access Scheme ("MTPAS"). The MTPAS provided privileged access to mobile phone networks to organisations involved in responding to an "Emergency" as defined in the Civil Contingencies Act 1994. When Vodafone activated the MTPAS scheme, it did so at the request of a Police Gold Commander who was acting pursuant to Cabinet Office authority. This was done so that the emergency services could best help the public, as well as helping and protecting the emergency responders themselves.

There was no dispute that, under the MTPAS, Vodafone was authorised in writing by a government department to provide priority access to their network for emergency responders, but the authorisation in question said nothing about any particular patents.

The judge was satisfied that, whatever the precise limits of section 56(2), when Vodafone activated the MTPAS, this constituted use "for the services of the Crown". The defence extended also to Vodafone's testing of the system. It did not matter that MTPAS did not require LTE to be used, merely that relevant emergency services be given privileged access to the relevant mobile phone networks.

In view of the judge's interpretation of the legislation, it did not matter that MTPAS did not grant express permission to infringe the '666 patent or any patent. Also, in case it mattered, Vodafone's use was not "public non-commercial use" for the purposes of article 31 of the TRIPS Agreement, but individual requests from the Police Gold Commander were likely to qualify as "other circumstances of extreme urgency". The Crown use defence was therefore made out.

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[37] *MMI Research Ltd v Cellxion Ltd* [2009] EWHC 1533 (Pat)
[38] *Pfizer Corporation v Minister of Health* [1965] 2 WLR 387 (HL)

Vodafone also invoked a ***de minimis* defence** in respect of testing and some confidential acts.

The jurisprudence on *de minimis* in the context of patent infringement was reviewed by Arnold J in 2016 in *Napp v Dr Reddy's*[39] - the authorities involved disputes about small amounts of infringing by-product during a process which, as a whole, did not infringe. In contrast, the present case involved a process only performed in rare situations. Additionally, the deputy judge noted that in *Sienkiewiecz v Greif*[40], Lord Phillips of Worth Matravers stated ([214]):

> "I doubt whether it is ever possible to define, in quantitative terms, what for the purposes of the application of any principle of law is *de minimis*. This must be a question for the judge on the facts of the particular case."

The deputy judge took the view that the infringer's intention cannot be directly relevant to the operation of the defence, but might negative any suggestion that rare events of infringement were accidental. On the other hand, the infringer's knowledge was not relevant. Further, whether the use was commercially significant was a relevant factor, but not the infringer's profit.

Turning to the facts, the deputy judge said that given access control was not performed in normal operation, but (in general) only in extreme circumstances, the fact the actual volume of acts was small was not surprising. However, the small scale of the acts did not mean they were commercially insignificant, given the context. Vodafone's participation in MTPAS was a small part but a significant part of Vodafone's commercial operations as a network provider. Therefore they were not such that Vodafone must be allowed to use somebody else's invention with impunity.

Vodafone's *de minims* defence was therefore rejected.

Acts of infringement

Aircraft seating technology was in issue (again) in 2020, in ***Lufthansa v Astronics* (22 July 2020)**[41]. The facts underlying this case read like nothing so much as an exam question to me.

Claim 1 of Lufthansa's patent was in the following terms ([45]):

> "A voltage supply apparatus for providing a supply voltage for electric devices (36) in an aeroplane cabin, comprising
>
> a socket (22) to which the device (36) is connectable by means of a plug (38) and to which the supply voltage can be applied, the socket (22) comprising a socket detector (45, 46, 48) detecting the presence of a plug (38) inserted in the socket (22), and a supply device (16) being provided remotely from the socket (22) and being connected to the socket (22) via a signal line (18) and via a supply line (20) for the supply voltage, the supply device (16) applying the supply voltage to the socket (22) when the plug detectors (45, 46, 48) indicate the presence of the plug (38) via the signal line (18) to the supply device (16).
>
> characterized in that

[39] *Napp Pharmaceutical Holdings Ltd v Dr Reddy's Laboratories (UK) Ltd & Anr* [2016] EWHC 1517 (Pat)
[40] *Sienkiewiecz v Greif (UK) Ltd* [2011] UKSC 10
[41] *Lufthansa Technik AG v Astronics Advanced Electronic Systems & Anr* [2020] EWHC 1968 (Pat) (22 July 2020) Morgan J

the plug detector (45, 46) is formed such as to detect the presence of two contact pins (53, 54) of the plug (38) in the socket (22), and

the supply device (16) only applies the supply voltage to the socket (22) if the presence of two contact pins (53, 54) of the plug (38) is detected simultaneously."

The three defendants had each dealt with the components of the system complained of in different ways and questions arose as to whether infringing acts had taken place in respect of apparatus having all the features of claim 1.

The first defendant, Astronics, manufactured the components, advertised them internationally, and supplied in the UK to its UK customers. At the time of Astronics' supply in the UK, the components had yet to be connected together to form the system. However Astronics admitted that it had the required knowledge for s.60(2) contributory infringement.

The second defendant, Safran, was a manufacturer of seats. It used the components of the system by connecting them together into a system in a seat, which it then supplied. Safran accepted that it thereby committed an act of direct infringement.

A further defendant (technically the defendant in a joined case) was Panasonic Avionics. Its alleged infringing system incorporated a bespoke implementation of the claimed system. Panasonic supplied the components with the knowledge and intent that they would be assembled into the completed system in the UK having done some connecting work already, so there was only one way to install the supplied components. Panasonic contended that it was not liable either for direct infringement (because it did not assemble the components into the system) or for s.60(2) infringement (because it did not have the knowledge required for liability under s.60(2).

However, the judge side-stepped the issues about direct and indirect infringement because he concluded that there was infringement on the basis of joint tortfeasorship. After citing the test from *Fish & Fish v Sea Shepherd*[42], the judge noted the earlier patent cases *Rotocrop v Genbourne*[43] and *Virgin v Delta*[44]. In the *Virgin* case at [131], Arnold J said:

> "Furthermore, if the defendant not only supplies a kit of parts to its customer, but also provides instructions for assembly of the kit into the claimed product, then I anticipate that under most systems of law the defendant will be liable as an accessory for the infringement committed by the customer when it assembles the kit. Under English law the defendant would be liable as a joint tortfeasor, as the decision of Graham J. in *Rotocrop* demonstrates."

On the undisputed facts of the present case, Panasonic was therefore liable pursuant to a common design.

An interim judgment in the same case (***Lufthansa v Astronics* (14 January 2020)**[45]) is notable for its comments on the meaning of "supply" in s.60(2) (governing contributory infringement) and "import" in s.60(1) (governing direct infringement).

With reference to *Kalman v PCL*[46], the judge agreed with the defendants that there was at least "a seriously arguable case" that Astronics was not, as a matter of law, liable for supply in circumstances where title passed to the purchaser in the US (as appeared to have happened).

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[42] *Fish & Fish Ltd v Sea Shepherd UK* [2015] UKSC 10

[43] *Rotocrop International Ltd v Genbourne Ltd* [1982] FSR 241

[44] *Virgin Atlantic Airways Ltd v Delta Airways Inc* [2010] EWHC 3094 (Pat)

[45] *Lufthansa Technik AG v Astronics Advanced Electronic Systems & Ors* [2020] EWHC 83 (Pat) (14 January 2020) Nugee J

However, Nugee J said that it was not obvious that "supply" in s.60(2) meant the same as "import" in s.60(1). In circumstances where, pursuant to contractual terms, title passed but delivery did not take place until it had occurred to a destination in the UK, it was not clear that "supply" in s.60(2) meant the same as import in s.60(1).

The resolution of this question will have to wait for another case though, Morgan J having gone on to find infringement against each of the defendants in the *Luftansa* case in other ways.

Questions as to ***quia timet*** **infringement** arose in two life sciences cases in 2020.

In ***Akebia v Fibrogen***[47] the Family B patents (second medical use claims) were to use in treating 'anaemia of chronic disease', 'functional iron deficiency associated with anaemia' and 'anaemia'. The defendants intended to market vadadustat in the UK if and when it was authorised. Phase III trials were ongoing. The defendants' evidence was that they would seek authorisation for "treatment of anaemia associated with chronic kidney disease (CKD) in adults who are non-dialysis-dependent (NDD) and those who are dialysis-dependent (DD)". The Summary of Product Characteristics (SmPC) would include some wording about evaluating serum ferritin "per standard of care", alternatively "prior to and during treatment with vadadustat". On its face this did not include any of the uses claimed in the Family B patents, but only the use taught/claimed by Family A.

Arnold LJ is, of course, the judge whose first instance reasoning on the infringement of Swiss form claims reached the Supreme Court in *Generics v Warner-Lambert*[48]*.* In his judgment in *Akebia* he took the opportunity to clarify some basics:

- Direct infringement of EPC 2000 claims falls to be determined under section 60(1)(a) of the Patents Act 1977, whereas direct infringement of Swiss-form claims falls to be determined under section 60(1)(c).

- Claims for indirect infringement of Swiss-form claims by downstream dealings in the product of the manufacturing step are unsustainable for the reasons explained by Lord Sumption (with whom all the other members of the Supreme Court agreed on in this issue) in *Generics v Warner-Lambert* at [87]-[88]; no such problem arises in the case of EPC 2000 claims.

- The Supreme Court were divided three ways as to the correct approach to the mental element required for direct infringement of a Swiss-form claim.

We would note that the second bullet point, while an accurate reflection of the Supreme Court's reasoning in *Warner-Lambert*, is actually inconsistent with the Supreme Court's reasoning in *Actavis v Eli Lilly*[49] (Lord Neuberger). However Arnold LJ did not address this.

In the *Akebia* case, Arnold LJ side-stepped the problem represented by the last bullet point because Fibrogen's case was pressed only on the basis of indirect infringement (section 60(2) of the Patents Act 1977). Section 60(2) provides that it is an infringement 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

[46] *Kalman & Anr v PCL Packaging (UK) Ltd & Anr* [1982] FSR 406
[47] *Akebia Therapeutics Inc & Anr v Fibrogen Inc* [2020] EWHC 866 (Pat) (20 April 2020) Arnold LJ
[48] *Generics (UK) Ltd & Anr v Warner-Lambert Company LLC* [2018] UKSC 56
[49] *Actavis UK Limited & Ors v Eli Lilly & Company* [2017] UKSC 48

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."

The question was therefore whether the defendants were threatening to market vadadustat in circumstances where they would know, or it would be obvious to a reasonable person in the circumstances, that vadadustat was suitable for putting and intended to put the claimed invention into effect in the UK.

Arnold LJ said that this required the Court to consider both the defendants' state of mind (at least in terms of what would be obvious to a reasonable person in those circumstances) and the state of mind of clinicians prescribing vadadustat (in terms of their intentions) at some indeterminate future point in time.

The evidence was that the scope of marketing authorisation the defendants would seek would not, on its face, include the claimed uses of Family B. On the current state of the clinical evidence it was not foreseeable that clinicians would prescribe vadadustat off-label for the uses claimed by Family B. Accordingly, the defendants were not currently threatening to market vadadustat in circumstances where they would know, or it would be obvious to a reasonable person in the circumstances, that vadadustat was suitable for putting and intended to put the claimed inventions into effect in the United Kingdom. The s.60(2) *quia timet* infringement case therefore failed.

The second case was ***Teva v Chiesi***[50], an interim judgment in litigation in which Teva sought to revoke three Chiesi patents. Chiesi counterclaimed for infringement on a *quia timet* basis. Teva did not yet have a marketing authorisation.

Teva applied to the court to strike out Chiesi's infringement claim. It argued *inter alia* that there was or should be a legal principle in patent cases that a *quia timet* action cannot proceed with no relevant marketing authorisation pleaded: it is a prerequisite.

Birss J rejected Teva's application. He held that a *quia timet* infringement action could proceed (i.e. not be struck out) if, based on the material pleaded, there was a real prospect of the patentee succeeding in establishing *at trial* that the relevant party threatened and intended to commit the act alleged to infringe. **This did not require a relevant marketing authorisation to be pleaded**.

If the party alleged to infringe had commenced a revocation action and not given assurance that it would not launch before patent expiry, a simple, rebuttable inference arose that it intended to launch at risk. So the fact there was no MA in place when the action began was not relevant. It was the existence of a threat and intention to start selling product sometime within the lifetime of the patent which justified a *quia timet* infringement action, even if the material available at the start of the action would not justify an interlocutory injunction at that early stage. (A different question, for another day, was what to do if, at trial, no marketing authorisation had been granted. That might or might not indicate that there would never be a launch in future).

Against this test, Chiesi's case was adequately pleaded, in particular by relying on the issue of the revocation proceedings, the earliest expiry of the patents in suit (2027) and Teva's failure to say that it did not intend to launch unless it succeeded in its revocation claim.

[50] *Teva UK Limited v Chiesi Farmaceutici SpA* [2020] EWHA 1311 (Pat) (2 June 2020) Birss J

This meant that the dispute would proceed through the usual stages of litigation, including disclosure. Additionally, Birss J said that once a claim is properly pleaded, a party to civil proceedings does not have an unfettered right to keep relevant information to itself.

Evidence

A real theme of the reasoning in patent judgments in 2020 has been on the role and adequacy of expert evidence. Expert evidence is critical to the outcome of almost every patent dispute and leads to notable jurisprudence every year. Nevertheless, the guidance emerging in 2020 has probably set the course for the next few years.

I will mention first one short point from the first patent judgment of the year, ***Conversant v Huawei* (8 January 2020)**[51]. In that case Birss J agreed with the defendants that Conversant's expert, Mr Wiffen, had been "prepared to read a very great deal into relatively short passages of text in the patents and the priority document". The judge said ([20]):

> "It is notable that in *RIM v Motorola* ([2010] EWHC 118 (Pat)) Arnold J identified Mr Wiffen as having engaged in detective work in a similar way. It is something I will take into account."

Conversant ended up succeeding in respect of two of its three patents in issue. Nevertheless the judgment serves a reminder to do your homework on a potential expert – read earlier judgments (from within and outside the jurisdiction), and if possible the trial transcripts, of cases in which the potential expert has been involved.

In ***IPCom v Vodafone***[52], Douglas Campbell QC gave a simply phrased reminder that ([14]):

> "…the purpose of expert witnesses is to explain things, and for this purpose it does not matter whether they do or do not approximate to the skilled man".

The deputy judge also noted that reliance on the evidence of an expert with prior knowledge of a closely related patent might introduce an element of hindsight into the analysis of whether a patent is obvious. He indicated that this would be more of a problem for a defendant's witness (i.e. for the party seeking to challenge validity) than for the claimant's witness (for whom the prior knowledge was pertinent before him).

Later in the year, a defendant's expert's evidence became unstuck on exactly such a point in ***Fisher & Paykel v Flexicare***[53]. Meade J was highly critical of Flexicare's expert Dr Dixon for his failure to acknowledge the full extent of his prior knowledge of the patent and the alleged invention. This "lack of care" meant that "he had not really turned his mind to how it might have influenced his thinking on the issue of obviousness" and there was significant hindsight in his approach. I will return to the *Fisher & Paykel* judgment shortly.

In 2011, in *MedImmune v Novartis*[54], Arnold J considered the preparation of expert reports in a passage that has since guided the way in which lawyers have instructed experts, and formed the basis for criticism of expert evidence, in patent cases. Arnold J explained that when asked to prepare an expert report in a patent case, an expert will have to consider such questions as the identity and

[51] *Conversant Wireless Licensing S.à.r.l v Huawei Technologies Co. Ltd & Ors* [2020] EWHC 14 (Pat) (8 January 2020) Birss J
[52] *IPCom GmbH & Co KG v Vodafone Group Plc & Ors* [2020] EWHC 132 (Pat) Douglas Campbell QC
[53] *Fisher & Paykel Healthcare Limited v Flexicare Medical Limited & Anr* [2020] EWHC 3282 (Pat) (8 December 2020) Meade J
[54] *MedImmune v Novartis* [2011] EWHC 1669 (Pat)

attributes of the person skilled in the art to whom the patent is addressed, the common general knowledge of the skilled person, and whether something would or would not be obvious to that person. Therefore experts need considerable assistance from the lawyers in drafting their report, and the instructing lawyers bear a heavy responsibility for ensuring that an expert witness is not put in a position where they could be made to appear to have failed in their duty to the court, including of objectivity.

By way of example, Arnold J noted two "common traps for the unwary": the discussion of the prior art in the report must be a balanced account – an ambiguous passage, for example, should not be ignored because the expert will end up being confronted with it in cross-examination; and any involvement or contribution of the expert with the invention, or a similar invention, in the past should be disclosed and, where appropriate, explained in the report.

In cross-examination, one of the experts in the *MedImmune* case testified that, when he was instructed, he was first asked to consider the prior art, then the priority documents and then the patents. Arnold J said that that was the correct way for those instructing him to proceed, since it was calculated to enable the expert to form and express his opinions on the prior art without knowledge of the invention, and on the priority documents without knowledge of the patents.

Nevertheless, compliance with Arnold J's guidance has not always proved straightforward. For example, in *American Science & Engineering v Rapiscan*[55] both parties appeared to follow the *MedImmune* approach, but in different ways, and both were criticised by the judge (Arnold J again).

In ***Akebia v Fibrogen***[56], Arnold LJ heard the trial in the Patents Court after his promotion to the Court of Appeal. Re-visiting the instruction of expert witnesses and the preparation of reports, he reiterated the responsibility of instructing lawyers not to put experts in a position in which it looks like they have failed in their duty to the court. In particular, he stated that it is the instructing lawyers' responsibility to spot and flag drafting errors, and to make sure the experts disclose their own previous relevant publications and, where appropriate, explain them. It is conventional to instruct experts to exhibit their CV to their report.

On the order in which experts are shown relevant documents (and which in practice can necessitate multiple stages of contact with an expert or potential expert), Arnold LJ said ([36]):

> "… it can be advantageous to try to instruct expert witnesses in sequence, first asking them about the common general knowledge, then showing them the prior art and asking them questions such as what steps would be obvious in the light of it and only then showing them the patent in suit. This is a procedure known as “sequential unmasking” in the psychological literature (see generally on this subject C.T. Robertson and A.S. Kesselheim (eds), *Blinding as a Solution to Bias*, Academic Press, 2016). The point of it is to try to avoid, or at least reduce, hindsight. In my opinion, it is desirable to try to minimise hindsight on the part of expert witnesses where possible. There is no rule or principle that experts must be instructed sequentially, however. Moreover, there are often real practical problems in doing so. To take just one obvious example, any discussion about the common general knowledge must start by identifying the skilled person or team. How is this to be done if the expert cannot be shown the patent? One way is to ask the expert to make an assumption, which they can check later when they see the patent; but that is not necessarily a perfect solution. Other problems can be caused by the pre-existing knowledge of the expert and by amendments to the parties’ cases (such as the introduction of new prior art after the expert has read the patent). Still

[55] *American Science & Engineering Inc v Rapiscan Systems* Limited [2016] EWHC 756 (Pat) at [98]-[114], [118]
[56] *Akebia Therapeutics Inc & Anr v Fibrogen Inc* [2020] EWHC 866 (Pat) (20 April 2020) Arnold LJ

> further, instructing experts in this way can make their task even more burdensome, particularly when it comes to cross-examination, because they may find it difficult to recall what they knew when unless it is clearly documented."

On the cross-examination of experts, Arnold LJ also reiterated some earlier guidance, this time from his 2016 judgment in *MSD v Shionogi*[57]*.* As a general observation, he said that although some cross-examination as to the way in which an expert witness had been instructed was often justified, too much time was being spent by cross-examiners in patent cases on *ad hominem* attacks that were "unfair to the witnesses, unhelpful to the court and waste expensive time". For example, with reference to the trial in the *Akebia* case, Arnold LJ said that it was not proper cross-examination to attempt to get the expert to choose between two possibilities neither of which reflected the evidence that that expert had previously given; nor to mis-characterise an expert witness's evidence, badger them, or ask questions without making any attempt to establish the critical point.

Having extolled his wrath on the lawyers, Arnold LJ let off the expert witnesses more lightly. He said there was a specific, understandable reason why Fibrogen's expert Professor Winearls had had some difficulty in distinguishing between what would have been known by an ordinary clinical nephrologist and what would have been known by a nephrologist with a research interest in renal anaemia. This was that Professor Winearls had been "next door" to a Nobel Prize winner in the area. On another point, Professor Winearls' oral evidence had cleared up some "poor" drafting in his report, which the judge did not regard as significant. Akebia's expert, Professor Haase, had been open about his relationships with Akebia (and his relationship with Fibrogen) and his alleged partiality towards Akebia had not even begun to be demonstrated.

In the *Akebia* case no technical primer had been prepared, which with the benefit of hindsight the judge said had been a mistake. He made clear his expectations for future cases ([48]):

> "In future, the preparation of a technical primer should be regarded as mandatory in Category 4 and 5 cases unless there are good reasons to the contrary."

One of the reasons judges like technical primers is because they can lift lots of the agreed technical background and dump it straight into their judgment. It saves them time while removing scope for complaint about the content.

Later in the year, Meade J conveyed a similar message in ***Fisher & Paykel v Flexicare***[58], a case about a type of expiratory breathing tube for a ventilator device. The parties had not prepared a primer and there was nothing in the nature of a textbook that the court could be directed to as a source of agreed common general knowledge. At the judge's request, the parties collaborated during the trial to prepare a joint summary of the common general knowledge, which the judge said had proved extremely useful and had saved a lot of time in his preparation of the judgment. For future cases he said ([53]):

> "Because this was a relatively simple case the absence of a primer, textbook or agreed CGK summary during my reading and the oral evidence was not too much of a problem (although I was in an unnecessary state of uncertainty about some details when the evidence began) but in a more complex case it would have been. It is to be hoped parties will ensure that at least one of these is available by trial in future cases."

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[57] *Merck Sharp and Dohme Limited v Shionogi & Co Limited* [2016] EWHC 2989 (Pat)

[58] *Fisher & Paykel Healthcare Limited v Flexicare Medical Limited & Anr* [2020] EWHC 3282 (Pat) (8 December 2020) Meade J

Meade J also had some comments on the sequential approach to the instruction of experts following *MedImmune*. He noted that the main driver behind the approach is that if experts are shown the patent in suit before they have said what the common general knowledge is or (more importantly) before they have said what they consider to be obvious over the prior art, then there is a risk of hindsight. He continued ([20]):

> "It is therefore preferable for experts to be asked about the CGK, then shown the prior art, and only then shown the patent in suit (*MedImmune*). But this is a counsel of perfection since the expert may well already know what the invention of the patent in suit is, for example from the patentee's commercial embodiment of it (*HTC, Akebia*)."

Where the expert already knows the invention, Meade J said "there may yet be value in sequencing the documents that he or she reviews to focus the mind on avoiding hindsight", but the opportunity to give a completely untainted view of the prior art then does not exist. In such a situation it is important for the expert to identify how they knew about the invention and when, and to reflect carefully on how that might influence them. Nevertheless, the judge acknowledged that the sequencing of an expert's involvement can cause problems.

In the *Fisher & Paykel* case, Meade J was easier on the lawyers than Arnold LJ had been in *Akebia*. He criticised Flexicare's expert, Dr Dixon, for his failure to acknowledge the full extent of his prior knowledge of the patent and the alleged invention, which indicated that he had not turned his mind to how his previous knowledge might have influenced his thinking on the issue of obviousness. Dr Dixon had also approached each piece of prior art with an expectation that it might contain a solution to the problem addressed in the patent: this was hindsight.

Meade J also had some cautionary words about cross-examining based on an assumption of focus on a particular problem, abandoning known solutions and reading prior art with the mindset that an alternative or better solution might be found in the prior art.

More fundamental criticisms were made of an expert in ***MSD v Wyeth***[59], the case about Wyeth's vaccine formulation patent (which was found invalid for obviousness and not infringed). In particular, Wyeth's formulator expert, Dr Vanden Bossche, was "argumentative", unable to see or consider the opposing view point and unwilling to qualify his evidence even where it was apparent that that was needed. As a result, the judge said he came to doubt Dr Vanden Bossche's real experience in the formation aspects of the case (in particular surfactants). Additionally, Dr Vanden Bossche failed to support his opinions with citations, and without such supporting material he intransigently put forward and maintained "extreme" and "implausible" views, and ideas that the judge considered speculative.

Choosing an individual who is not confrontational is an important part of finding and instructing an expert for your case. Supporting assertions with appropriate references is a basic when drafting/assisting an expert to draft their report(s). So is the need to put forward a positive case, not just to attack your opponent's case.

However, Meade J did note a possible contributory factor for the expert concerned, in the form of a possible mis-match between Dr Vanden Bossche's personal area of expertise and the subject matter of the dispute. Meade J said this may have arisen because of the way the case developed. Before the proposed amendment to claim 1, the focus of the patent was more on the aluminium adjuvant, which was where Dr Vanden Bossche's real experience seemed mainly to lie.

[59] *Merck Sharp & Dohme Limited v Wyeth LLC* [2020] EWHC 2636 (Pat) (15 October 2020) Meade J

So keep in mind that if amendments are sought, it is wise to step back and reconsider whether your expert (and their evidence) is still fit for purpose. This is not Meade J going out on a limb; it is consistent with the approach taken by Birss J in 2019 in *Conversant v Apple*[60]. In that case there was a dispute about the identity of the person skilled in the art. Apple's case was that the way to identify the skilled person as a matter of law was to look at the field the patent located the invention in and posit a person in that field as the relevant person. Rejecting this, Birss J explained that from *Catnic v Hill & Smith*[61], a patent is taken to be directed to those with a practical interest in its subject matter, and its subject matter is the invention, which is what is defined in the claims. So claim amendments may well impact the most suitable expert(s) and the focus of their evidence.

In ***Neurim v Mylan***[62], Neurim's expert, Professor Roth, was described by the judge, Marcus Smith J, as a "colossus in his field" and an extremely impressive witness. The judge said his evidence reflected this – Professor Roth was able to answer any question within his expertise with precision, clarity and confidence. He was also "obviously familiar with patents and the concepts and issues underlying patent litigation". The judge said he had no doubt that Professor Roth was, when giving evidence, doing his absolute best to assist the court.

In contrast, Mylan's expert, Professor Morgan, was heavily criticised for the evidence he gave, which the judge described as, in critical respects, "disingenuous". His reports were written in a manner that seemed calculated "not to assist, but to mislead" the court. In particular, paragraphs were written in ways that wove in points from other areas, which took meticulous unpicking to expose. Also citations were given in support of points which did not, in fact, support the points, and this was particularly the case for Professor Morgan's evidence in respect of the common general knowledge.

Additionally, Professor Morgan's evidence in relation to both the prior art and the teaching of the patent was substantially undermined by his failure to appreciate the essential "nuts and bolts" of patent law, the judge saying that it was evident at times that Professor Morgan was reading the patent in a way that the person skilled in the art would not.

Marcus Smith J laid the blame for Professor Morgan's failings with the expert himself, noting that an expert is responsible for his or her evidence, including the precise wording of any report submitted to the court in their name.

It is certainly important that experts step back from their draft evidence and carefully consider whether the overall picture presented reflects their objective, unbiased opinion, and is not merely justifiable at a carefully-crafted-sentence-by-carefully-crafted-sentence level. However, other judges may also have been critical of the instructing lawyers: it is a little harsh to blame an expert for their failure to understand relevant principles of patent law.

A similar point arose in ***Communisis v The Tall Group***[63], the case about Communisis' patent to a security measure for banking cheques (which was found invalid). HHJ Melissa Clarke was satisfied that Communisis' expert, Dr Brewer, gave fair and independent oral evidence. However, in his written evidence, he had taken an incorrect approach to some legal tests.

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[60] *Conversant Wireless Licensing s.a.r.l. v Apple Retail UK Limited & Ors* [2019] EWHC 3266 (Pat) (29 November 2019) Birss J
[61] *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183
[62] *Neurim Pharmaceuticals (1991) Limited & Anr v Generics UK Limited* (trading as Mylan) & Anr [2020] EWHC 3270 (Pat) (4 December 2020) Marcus Smith J
[63] *Communisis Plc v The Tall Group of Companies Limited & Ors* [2020] EWHC 3089 (IPEC) (17 November 2020) HHJ Melissa Clarke

In particular: Dr Brewer approached the identity of the person skilled in the art and what they did from the perspective of the end consumer of the security product rather than on the principles set out in *Hospira v Cubist*[64]; he stated that he believed the common general knowledge was what the person skilled in the art needed to compare the patent with The Tall Group's product and process description (PPD); his evidence on claim interpretation (the admissibility of which is another point) was given on the basis of his understanding of what the terms meant in the context of both the patent and the PPD and in a manner which sought to distinguish between the prior art and the claims of the patent; and he did not attempt to give evidence on *Pozzoli* step 3 but instead made comparisons of the whole of the prior art documents with the patent at a general level in a way which did not assist the court.

Additionally, Mr Brewer's written evidence, in places, was mismatched with the pleaded issues and did not support the pleaded case.

The judge therefore gave more weight to Mr Brewer's oral evidence than to his written evidence. For our purposes though, as was explained by Arnold J in *MedImmune v Novartis*, the responsibility for getting such points right must lie with the instructing lawyers. Such points are a part of why expert evidence in patent actions requires such a high level of instruction by the lawyers, usually entailing an iterative drafting process. However much we would all like to forget 2020, it is important that this aspect of the year's case law is remembered.

d. Remedies and costs

Public interest defence to injunctive relief

2020 produced a couple of important judgments on injunctions. One of these was the Supreme Court's judgment in the *Unwired Planet* case, which I will discuss in subsection (f) below on FRAND. The other was the judgment of Birss J in ***Evalve v Edwards*** **(public interest)**[65].

On 12 March 2020 Birss J handed down two judgments in the *Evalve v Edwards* case. One, the 'substantive' judgment, followed a trial that took place in December 2019 concerning two patents claiming devices for treating mitral valve regurgitation by a transcatheter technique. The judge found both patents valid and infringed. The other judgment, the 'public interest' judgment, followed a trial that took place in January 2020 on the question of whether, if the patents were found valid and infringed, injunctive relief should be awarded.

Edwards submitted that even if its PASCAL device was found to infringe a valid claim, no final injunction should be ordered because to do so would be contrary to the public interest. In his public interest judgment, Birss J took the opportunity to have thorough look at this area of patent law, beginning with the basics.

Birss J began by setting out the statutory framework.

The Patents Act 1977 provides that a patent is personal property (s.30(1)). A patentee's right to remedy for infringement is set out in s.60(1) – this includes injunctive relief and damages. The public interest plays a role in a number of aspects of the Patents Act. For present purposes, this included: the specific exclusions from patentability for methods of treatment and diagnosis; defences to

[64] *Hospira UK Limited v Cubist Pharmaceuticals LLC* [2016] EWHC 1285 (Pat)
[65] *Evalve Inc v Edwards LifeSciences Inc* [2020] EWHC 513 (Pat) (12 March 2020) Birss J

infringement, in particular for extemporaneous preparation of a medicine for an individual, use in clinical trials, and activity for the purpose of obtaining medicinal product marketing authorisations; the compulsory licensing regime; and the Crown use scheme.

The IP Enforcement Directive (2004/48/EC (the "Directive") imposes a general obligation on Member States to provide for "measures, procedures and remedies necessary to ensure the enforcement of the intellectual property rights covered" by the Directive, which must "be effective, proportionate and dissuasive". Proportionality is therefore a relevant factor[66]. In *Virgin v Premium*[67] the test for whether or not a permanent injunction should be withheld was "whether enforcement would be 'grossly disproportionate'".

The TRIPS Agreement (article 28) provides that a patent shall confer upon its owner certain exclusive rights, to which "limited exceptions" may be provided, "provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".

The Senior Courts Act 1981 (SCA) (section 37) sets out the power to grant an injunction, where it is just and convenient to do so (1), and provides that an injunction may be made unconditionally or on such terms and conditions as the Court thinks just. The SCA (section 50) also expresses the power of the court to award damages "in addition to or in substitution for" an injunction.

For a long time, the leading authority governing when damages could be awarded in lieu of an injunction was *Shelfer v City of London Electric Lighting Co*[68]*.* In 2014 the application of s.50 SCA was considered by the Supreme Court in *Coventry v Lawrence*[69], a nuisance case. The Supreme Court concluded that a more flexible approach should be taken to determining whether an order for damages would be appropriate than was laid down in *Shelfer*.

Birss J agreed with Evalve/Abbott that while *Coventry* and *Shelfer* might be instructive, patent rights are different from the right in land protected by nuisance, have a distinct rationale and are governed by a separate scheme.

In *Chiron v Organon No 10*[70] Aldous J gave detailed consideration to the protection of the public interest in the context of patents, in particular when an infringer is seeking to invoke that public interest as a reason to withhold an injunction. He noted that the opportunity to acquire monopoly rights in an invention stimulates technical progress in at least four ways ([52]):

> "First it encourages research and invention; secondly, it induces an inventor to disclose his discoveries instead of keeping them a secret; thirdly, it offers a reward for the expense of developing inventions to the state at which they are commercially practical and, fourthly, it provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embarked on them simultaneously. Those are particularly relevant to the development of medicinal products."

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[66] *Cartier International AG & Ors v British Sky Broadcasting & Ors* [2016] EWCA Civ 658, Case C-2/10 *Azienda Agro-Zootecnica Franchini Sarl v Regione Puglia* (2011)
[67] *Virgin Atlantic v Premium Aircraft* [2009] EWCA Civ 1513
[68] *Shelfer v City of London Electric Lighting Co* [1895] 1 Ch 287
[69] *Coventry & Ors v Lawrence & Anr* [2014] UKSC 13
[70] *Chiron Corporation & Ors v Organon Teknika Ltd No 10* [1995] FSR 325

To this, Birss J added ([53]):

> "…the incentives Aldous J refers to, in particular in the investment of capital, need to operate many years before the inventor is likely to be asking the court to enforce the patent by an injunction and thereby safeguard that investment. Accordingly **long term certainty about the principles on which such relief is to be determined is an important end in itself**."

In *Chiron*, Aldous J concluded that any attempt to dissuade the court from granting an unqualified injunction was effectively seeking to obtain a compulsory licence without having established the grounds set out in the PA. (This aspect of *Chiron* was followed by Neuberger J in *Kirin-Amgen (No. 3)*. Aldous J continued then to address the presence in the Patents Act of the various provisions reflecting the public interest in limiting patent rights, before saying ([54]):

> "Thus it is a good working rule that an injunction will be granted to prevent continued infringement of a patent, even though that would have the effect of enforcing a monopoly, thereby restricting competition and maintain prices. Something more should be established before the Court will depart from the good working rule suggested in the *Shelfer* case."

On this, Birss J said ([55]):

> "Although Aldous J there expressed himself by reference to *Shelfer*, in my judgment the point remains a good one under the modern approach. When the court is considering withholding an injunction on public interest grounds, it is relevant to have regard to the fact that the patent legislation itself already places limits on patent rights in order to safeguard the public interest. That includes a power to make life saving treatments available to the public without the permission of the patentee."

Birss J noted that recent IP authorities in the area had not conducted such a comprehensive analysis. He thought the reason for this in *HTC v Nokia*[71] (Arnold J) was that the public interest as a ground to award damages in lieu was not the basis of the argument in that case. In *Edwards v Boston*[72] (also Arnold J), the existence of an injunction and the idea of a carve out of some kind had already been agreed between the parties. However Birss J noted his agreement with the following statement of the law by in *HTC* ([56]):

> "32. Conclusion. Drawing these threads together, I consider that Article 3(2) of the Enforcement Directive permits and requires the court to refuse to grant an injunction where it would be disproportionate to grant one even having regard to the requirements of efficacy and dissuasiveness. Where the right sought to be enforced by the injunction is a patent, however, the court must be very cautious before making an order which is tantamount to a compulsory licence in circumstances where no compulsory licence would be available. It follows that, where no other countervailing right is in play, the burden on the party seeking to show that the injunction would be disproportionate is a heavy one. I suspect that the practical effect of this approach is little different to Pumfrey J's test [in *Navitaire v EasyJet* [2005] EWHC 282 (Ch)] of "grossly disproportionate"."

[71] *HTC Corporation v Nokia Corporation* [2013] EWHC 3778 (Pat)
[72] *Edwards Lifesciences LLC & Ors v Boston Scientific Scimed Inc* [2018] EWHC 1256 (Pat)

To this, Birss J added ([58]):

> "In my judgment when the court is considering the public interest relating to a medical device or treatment as a ground for refusal of a patent injunction, it is also relevant to have in mind the factors identified by Aldous J in Chiron. I believe that applies when considering the wide discretion following *Coventry v Lawrence* and/or under the Enforcement Directive's requirement that remedies be "just and equitable" and "effective, proportionate and dissuasive". In terms of the Enforcement Directive it bears pointing out that the provisions in Art 3 are general and are applicable to all intellectual property rights. The balancing of public interest factors for copyright and trade marks will differ from the balance relating to patents because their public interest justifications are different. That is why it is relevant to highlight the particular way the public interest operates in the patent system as a whole when exercising this discretion."

Birss J then turned to the adequacy of damages in lieu as a remedy, which is one factor to be considered when assessing whether to award injunctive relief. He thought the following observations of Aldous J in *Chiron* remained applicable ([59]):

> "…the court must have sufficient information before it to be able to estimate the compensation and decide whether the defendant can pay it. The suggestion that the court should refuse the injunction and order that there be an inquiry as to the amount of compensation should not be accepted. To do so, would mean that the court would refuse the injunction without being able to conclude that the compensation was adequate and small. Further at the inquiry, which might not take place for many months, the court might conclude that the compensation could not be properly estimated or that the amount was not adequate or was large. Determination of the amount and sufficiency of the compensation is part of the decision whether to refuse the injunction and needs to be undertaken at the same time."

In light of this, Birss J thought the footing on which the issue of relief had reached trial in the present case had been wrong. The footing had been that an inquiry as to the damages in lieu would be ordered if an injunction was refused or qualified; but Birss J said that while it may not have been necessary to examine the finances in sufficient detail to settle the amounts to be paid, an indication of the level of profitability of the products relative to their prices was needed.

This was because if it was asserted that it was in the public interest that a defendant's product came onto the market, in order to ensure the product did indeed come on the market, the damages in lieu might have to be a royalty (rather than an account of profits or compensatory damages) even though that could necessarily cause substantial, quantifiable and uncompensated economic harm to the patentee. The patentee would then just have to bear those losses, in the public interest.

In the present case, the absence of such evidence arose from decisions both parties made so the judge did not think it fair to penalise Edwards for its absence. He continued with his assessment on other grounds. But for future cases, such basic financial information could be expected to be needed at an earlier stage of proceedings than quantum.

Drawing together all of the above, the judge summarised the applicable legal principles as follows ([73]):

> "i) A general injunction to restrain future infringements is the normal remedy for the patentee.

ii) The burden is on the defendant to give reasons why such an injunction should not be granted.

iii) All the circumstances should be considered. The public interest, such as the impact on third parties, is a relevant consideration. This applies under domestic law (*Coventry v Lawrence*) and under Art 3 of the Enforcement Directive.

iv) In a proper case the public interest may justify refusal of or carve out from injunction, and an award of damages in lieu. Smallness of the damages in lieu is not determinative. Even if the damages were a large sum of money and/or one which was difficult to calculate, it might still be in the public interest to refuse an injunction or carve scope out of it.

v) The starting point of any consideration of the public interest in relation to a remedy after a patent trial is that the patent system as a whole is already criss-crossed with provisions which strike balances between different public interests.

vi) The availability of an exclusionary injunction is an important manifestation of the monopolistic nature of a patent right. While monopolies in general are against the public interest, once a patent has been found valid and infringed, the patent monopoly is something which it is in the public interest to protect by an injunction in order to further the purposes of the system as a whole, such as to promote investment in innovation.

vii) Therefore when, as here, various public interests are engaged and pull in different directions, one should have in mind that the legislator is better equipped than the courts to examine these issues and draw the appropriate broad balance. The jurisdiction to refuse or qualify a patent injunction on public interest grounds is not there to redraw the broad balance of public interests set by Parliament in the patent system. The power should be used sparingly and in limited circumstances."

The judge then proceeded to apply these principles in a clinical setting. He noted that patent law places restrictions on a doctor's clinical judgment by limiting the available options – in the form of patents for drugs and devices. So the fact that reasonable doctors would choose the defendant's drug or device in preference to the patentee's product cannot on its own be sufficient to invoke the public interest as a ground for refusing or putting a carve out into a patent injunction. For this kind of public interest to begin to be relevant, it must be concerned with treatments for serious medical conditions, and perhaps only for life saving treatments.

A relevant factor may be the nature of the competitive product. A generic would not usually engage the public interest in this way. For medical devices (and biosimilars), the existence of clinically tangible differences between the patentee's product and the infringing product will inevitably mean that some doctors are likely, non-negligently, to prefer to employ one product in preference to the other if they are presented with a choice. In doing so they will be acting in the best interests of their patients.

However, the judge noted experience with two of Abbott's MitraClip products, for which clinical trials had eventually shown that reasonable opinions held by clinicians were not correct. This illustrated why a reasonable clinical preference unsupported by objective evidence "does not engage a relevant public interest, not least because it does not necessarily carry with it the idea that if the choice had not

been available, all the patients could not have been treated adequately with the patentee's product". Birss J continued ([85]-[87]):

> "In my judgment in order to engage the public interest in these circumstances it will be necessary to examine the evidential basis for the clinical judgments relied on. What is required is **sufficient objective evidence to find that there are in fact patients who ought not to be treated using the available product from the patentee but who could, in the reasonable opinion of a body of doctors, be treated using the rival's product. …**
>
> …the relevant public interest sufficient to justify a refusal, at least in part, of a patent injunction, is the need to protect the lives of patients for whom **the defendant's product is the only suitable treatment, when that fact is established by objective evidence**."

Birss J explained that if the public interest in allowing doctors to exercise their clinical judgments in the best interests of their patients was sufficient to justify the refusal or carving out from a patent injunction, this would be a wide exception. It would mean that throughout the field of inventions of life saving products, just because the defendant's embodiment of the patentee's invention happened to have some clinically tangible differences from the patentee's own commercial embodiment of their invention, there would be no exclusionary monopoly.

Birss J's view was that balancing the public interests to reach that result would be a matter for Parliament and should not be created by the courts. The patent system had been set up in such a way that it did restrict the choice open to doctors by restricting the products available to them. That restriction was in the public interest overall because it promoted innovation.

In the present case, Edwards had not attempted to prove that PASCAL was objectively better, and nor had such a conclusion emerged yet in the clinical literature. So the "most" Edwards had set out to prove was not enough to justify refusal or carve out from the patent injunction. Edwards' submission that no final injunction should be ordered because to do so would be contrary to the public interest therefore failed. Injunctive relief would be ordered with a carve out limited to the case when a MitraClip implantation had already been unsuccessful.

In view of the reasoning of the Court of Appeal and the Supreme Court in the *Warner-Lambert* case, we can expect the public interest defence to injunctive relief to be re-visited in the context of second medical use patents. For standards essential patent disputes the Supreme Court has confirmed a slightly different course in the *Unwired Planet* case. But outside those two contexts, Birss J's reasoning in *Evalve v Edwards* (public interest) indicates that despite the discretion of the court and the consideration afforded to the principle of proportionality, the courts in England and Wales will be as likely to award an injunction following a finding of infringement as the courts in any other European jurisdiction, and may be more likely to do so than the courts in the USA. This is a helpful message.

Stay of injunctive relief pending appeal

A few weeks later, Birss J was called upon to give another judgment in the *Evalve* case, this time on the form of order following his public interest judgment (***Evalve v Edwards* (form of order)**[73]). The issue was whether injunctive relief should granted or stayed pending appeal. Birss J noted that the

[73] *Evalve Inc & Ors v Edwards Lifesciences Limited* [2020] EWHC 1524 (Pat) (18 June 2020) Birss J

principles to be applied in such a context were set out by the by Buckley LJ in the Court of Appeal in *3M v J&J*[74] ([16]):

> "Briefly put the test is the balance of justice. The court considering the terms of any stay pending appeal will endeavour to arrange matters so that the Court of Appeal is best able to do justice between the parties once the appeal is heard."

Birss J continued the terms of the interim order, permitting limited use in two hospitals but not a full commercial launch.

Interim injunctive relief

The ***Neurim v Mylan*** case produced several judgments in 2020, including two and a half stages of reasoning on Neurim's application an interim injunction to restrain launch of generic melatonin pending first instance judgment[75]. Of course, this engaged the *American Cyanamid*[76] test, which has governed the assessment of an application for an interim injunction since 1975.

The *American Cyanamid* principles have been phrased slightly differently by different judges in subsequent cases, but in essence they address the following questions:

1. Is there a serious question to be tried?
2. Would damages be an adequate remedy to the claimant?
3. Would damages be an adequate remedy to the defendant?
4. If damages are not an adequate remedy for either side, where does the balance of convenience lie?

Back in 2015 in the *Warner-Lambert* case, interim injunctive relief in the context of a Swiss form claim was keenly contested but refused in the Court of Appeal[77] at the 'balance of justice' stage of the *American Cyanamid* test. In the Patents Court[78], Arnold J also rejected Warner-Lambert's application at the first stage of the test, which requires the patentee to establish a serious issue to be tried. The point turned on the construction of Swiss form claim language, in particular the question of the mental element – knowledge or intent about subsequent use. In the substantive case, the Supreme Court was subsequently split three ways in *obiter* judgments on the interpretation and requirements for infringement of such claims[79].

Neurim's patent was also in Swiss form, to a prolonged release formulation comprising 2mg melatonin in unit dosage form for improving the restorative quality of sleep. However the points arising in *Warner-Lambert* about the test for infringement were not engaged and in the Patents Court[80] Mylan accepted there was a serious issue to be tried. Marcus Smith J said that in view of the evidence in the case Mylan had been right to do so.

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[74] *Minnesota Mining and Manufacturing Co v Johnson & Johnson Ltd* [1976] RPC 671 at 676

[75] *Neurim Pharmaceuticals (1991) Limited & Anr v Generics UK Limited (trading as Mylan) & Anr* [2020] EWHC 1362 (Pat) (3 June 2020) Marcus Smith J; *Neurim Pharmaceuticals (1991) Limited & Anr v Generics UK Limited (t/a Mylan) & Anr* [2020] EWCA Civ 793 (24 June 2020) Floyd, Males & Arnold LLJ; *Neurim Pharmaceuticals (1991) Limited & Anr v Generics UK Limited (t/a Mylan) & Anr* – Reasons for the UKSC refusing permission to appeal, 29 June 2020

[76] *American Cyanamid Co v Ethicon Ltd* [1975] AC 396 (HL)

[77] *Warner-Lambert Company LLC v Actavis Group PTC EHF & Ors* [2015] EWCA Civ 556

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

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

[80] *Neurim Pharmaceuticals (1991) Limited & Anr v Generics UK Limited (trading as Mylan) & Anr* [2020] EWHC 1362 (Pat) (3 June 2020) Marcus Smith J

The judge also said that the question of serious issue to be tried must be considered through the prism of the proceedings being tried in *this* jurisdiction. The fact an interim injunction was refused in other jurisdictions was of "no moment". Additionally, from *Buehler v Chronos*[81] an Opposition Division decision (dismissing an opposition) was not a final judicial decision as to the validity of a patent and so was no bar on revocation proceedings under s.72 of the Patents Act. This meant that in the present (converse) case, a decision of the Opposition Division finding the patent to be invalid was likewise not binding, and so arguments about what might happen on appeal were irrelevant.

However, Marcus Smith J considered that damages *would* be an adequate remedy for the patentee in the event of launch by Mylan, even in the event of additional generic entrants and a price spiral, despite accepting that it would be very difficult for Neurim to raise its prices following success at first instance. Considerable evidence from Neurim on the negative consequences of the *status quo* not being maintained failed to impress the judge, who therefore refused to award an interim injunction.

The judgment went against a well-established line of patent cases[82] in which interim injunctions have been granted largely on the basis that generic launch would lead to a downwards spiral in the price of the patentee's product which could not subsequently be restored to previous levels.

Nevertheless, the Court of Appeal rejected Neurim's appeal, and agreed with the judge that damages would be an adequate remedy for Neurim and its registered exclusive licensee, Flynn Pharma, in the event they succeeded at trial.

In the Court of Appeal, Floyd LJ gave the only reasoned judgment. On the second stage of the *American Cyanamid* test, he said that when Lord Diplock spoke of damages being an "adequate" remedy, he was not suggesting that damages must provide a perfect remedy. The boundary between the adequate and the inadequate was not a precise one. It was a matter for judicial evaluation on the evidence in any given case whether or not the boundary was crossed, but if it was not crossed in relation to the claimant's loss then normally an injunction will not be granted.

Floyd LJ said that the judge had erred in his approach to the assessment of the second stage of *American Cyanamid* because he approached it from the standard of there being a serious issue to be tried (as for stage 1). It was possible though for both parties to meet a serious issue test on the same point, and so the second (and third and fourth) stage of the *American Cyanamid* test needed to be decided on the balance. However, as all the evidence was in writing, the Court of Appeal was in as good a position as the judge to come to a conclusion.

Floyd LJ disagreed with Neurim's submission that Lord Diplock's judgment indicated that a court should normally accept that damages are not an adequate remedy for the parties and should instead move on to the consider the balance of convenience.

Floyd LJ also rejected Neurim's arguments that the judge had been wrong to put the consequential loss out of account. Neurim's evidence had been prepared on the basis of trial taking 1-2 years to reach rather than (as had now been ordered) taking place in the autumn. At least half the market was presently protected by branded prescription writing. Teva were prohibited from launching pending trial under the terms of a settlement agreement. And despite Neurim's assertions, the evidence did not

[81] *Buehler AG v Chronos Richardson Ltd* [1998] RPC 609 at 616

[82] *SmithKline Beecham v Generics UK Limited* (unreported, 23 October 2001); *SmithKline Beecham Plc & Anr v Apotex Europe Limited & Ors* [2003] EWCA Civ 137; *Wyeth Holdings Corporation & Ors v Alpharma Limited* [2003] EWHC 3196 (Pat); *Warner-Lambert Company LLC v Sandoz GmbH & Ors* [2015] EWHC 3153 (Pat)

indicate that it was *likely* that another company had a product ready to launch in that timeframe. A short period (until trial) of generic competition could not be equated with Neurim's product "becoming generic". Loss of exclusivity of "4 months" would not cause the loss to Neurim's research and investment, or necessitate the "drastic steps" referred to by Neurim and Flynn. So such consequential loss could be put aside when considering the adequacy of damages. And the case should not be treated as one of multiple generic entrants and a downward price spiral.

Against this background, Floyd LJ's view was that the judge had in fact over-estimated the complications of the assessment of damages, which must be "assessed liberally" without going so far as to punish the infringer[83]. Floyd LJ therefore agreed with the judge that damages would provide an adequate remedy for the loss in both the period leading to trial and the period from that point until patent expiry. Neurim's appeal was dismissed.

On 29 June 2020, the Supreme Court rejected Neurim's application for permission to appeal, providing the following reasoning:

> "The panel considered that there is a point of law of public general importance touching on the question whether the four-stage test outlined by Lord Diplock in *American Cyanamid v Ethicon* [1975] AC 396 should be applied in a rigid and strictly sequential manner or whether a more overarching and flexible approach to the issues adumbrated by Lord Diplock would be appropriate – cf the observations of Lord Goff in *R. v Secretary of State for Transport Ex p. Factortame Ltd* (No. 2) [1991] 1 A.C. 603.
>
> The panel decided, however, that permission should not be given in this case. Prominent among the reasons for this decision was the imminence of the trial in the action. (It is scheduled to begin in October 2020).
>
> The parties and those considering the refusal of permission are reminded that the decision not to give permission should not be taken as indicating the views of the panel as to the correctness of the judgments of the Court of Appeal and the High Court – see Practice Direction 3.3.3: "The reasons given for refusing permission to appeal should not be regarded as having any value as precedent".

So in a suitable case, the Supreme Court might well be interested in revisiting the *American Cyanamid* principles.

Amazon complaint as an alternative to an interim injunction

In view of the challenges represented by the reasoning in *Neurim,* patentees may be a little heartened by a judgment highlighting the power of Amazon's complaints procedure.

In ***Shenzhen Carku Technology Co v The Noco Company***[84], Carku was a designer and manufacturer of car battery jump start devices and The Noco Company was the proprietor of a relevant patent. In January 2020, The Noco Company complained to Amazon about Carku products sold by distributors, using Amazon's complaints procedure. As a result, Amazon de-listed a number of Carku products. The effect was equivalent to an injunction keeping Carku out of 40% or so of the UK market, but without Noco having to succeed on *American Cyanamid* or give a cross undertaking.

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[83] *Pneumatic Tyre Co Ltd v Puncture Proof Pneumatic Tyre Co Ltd* (1899) 16 R.P.C. 209 at 215

[84] *Shenzhen Carku Technology Co, Ltd v The Noco Company* [2020] EWHC 2104 (Pat) (24 July 2020) Douglas Campbell QC

Amazon told Carku that it would only revisit the delisting if Carku provided Amazon with a "judicial decision declaring that Car-ku's products do not infringe NOCO's patent…". So Carku commenced proceedings for a declaration of non-infringement and threats, and applied for summary judgment. It also sought an interim declaration.

In order to defeat Carku's application for summary judgment, Noco had to establish that it had a 'realistic' (as opposed to 'fanciful') prospect of success. A 'realistic' claim is one that carries some degree of conviction; that is more than merely arguable. Noco was successful on this.

The Civil Procedure Rules Part 25.1(1)(b) provide that the court can grant an interim declaration in any proceedings. In view of the principles[85], there were two issues in the *Carku* case:

i) whether it could be appropriate for the court to grant a declaration where the question only permitted of a final rather than a temporary answer; and

ii) if the first question was wrong or too absolute a position, the court had to be satisfied to the high degree of assurance which should permit a mandatory injunction to be granted; his latter test was not markedly different from the question of summary judgment.

Douglas Campbell QC concluded that the answer to issue i) was that it was not appropriate for the court to grant an interim declaration on the issue of infringement, which is a yes/no question that only permits a final answer, not a temporary one. Products either infringe or they do not. And in view of the outcome of the summary judgment application, Carku also would have failed at issue ii).

Douglas Campbell QC observed that the Amazon complaints procedure is more suitable for obvious counterfeits than for trying to resolve patent validity and infringement issues. Nevertheless, in the Carku case it proved rather useful to the patentee.

Disclosure

Finally on remedies, there is a short judgment to note on disclosure, in ***ADD2 v Dspace***[86]*.* In English procedure, disclosure is not a remedy but a part of the litigation process. Nevertheless it is covered by the IP Enforcement Directive and similar types of procedure are very much considered a form of remedy in some other jurisdictions, and so I mention it here.

ADD2 sought disclosure and inspection of manuals supplied by the defendants to their customers, before the PPD had been served. ADD2 argued that access to the material was proportionate and relevant because it would assist them in addressing infringement and might reduce the cost of preparing a PPD. The claimants complained that despite extensive engagement pre-action, the material sought had not been provided.

The judge gave some (rare) observations on the Pre-action protocol. In particular she noted that the obligations under the Practice Direction on Pre-Action Conduct and Protocols needed to be considered in the context of its objectives. This was to encourage the reasonable and proportionate

[85] *Amalgamated Metal Trading Ltd v City of London Police Financial Investigation Unit* [2003] 1 WLR 2711; *The National Crime Agency v N and Royal Bank of Scotland plc* [2017] EWCA Civ 253; *British Airline Pilots' Association & Anr v British Airways CityFlyer Ltd* [2018] EWHC 1889 (QB)

[86] *ADD2 Research and Development Limited v Dspace Digital Signal Processing & Control Engineering GmbH & Anr* [2020] EWHC 912 (Pat) (18 March 2020) Ms Pat Treacy

exchange of information before litigation with a view, broadly, to averting proceedings or at least to encouraging more efficient resolution of proceedings. The Practice Direction provided general guidance to the parties as to the sort of conduct to be expected but there was no specific pre-action protocol for the type of action envisaged (a patent action) and so, unsurprisingly, it was not prescriptive. While parties were obliged to have regard to it, the expectations were drafted in broad terms and similarly the court would consider whether the parties had complied "in substance" with the pre-action protocol.

In particular, paragraph 3 addressed the exchange of information. While the appropriate steps might include the disclosure of key documents relevant to the dispute (such as, for example, in the case of a patent action, prior art), the protocol did not give parties a right to receive any and all material that they might speculate would be useful. It required parties to think carefully about supplying sufficient key information (including documents) which was both relevant to the issues and went to the objectives of the Practice Direction. The obligation was to act proportionately.

What was required to comply therefore depended on the nature of the dispute. The Patents Court takes a particular approach to technical disclosure for the purpose of assessing infringement. It would not be appropriate to require steps in pre-action conduct which were likely to undermine the approach generally adopted for the efficient management of such actions. Therefore the defendants' failure to provide ADD2 with the particular documents requested did not mean that the defendants had failed to comply, in substance, with the Practice Direction.

ADD2's application for specific disclosure needed to be considered under the usual rules governing disclosure, which gave the defendant the option to serve a PPD in lieu of standard disclosure on infringement. Any court considering the specific disclosure of documents must be alert not to undermine the careful balance struck by the Patents Court over many years. The defendants intended to serve a PPD in the present case. The award of specific disclosure at this earlier stage would likely increase costs. The appropriate course was therefore to refuse the application for disclosure, and the secondary application for inspection. Both were premature.

Confirmation that the Pre-Action Protocol is not a back door key for early disclosure.

Costs

Unusually, the costs impact of a certificate of contested validity was considered in 2020, in ***Optis v Apple*** **(23 November 2020)**[87]*.*

A few weeks earlier, Birss J had concluded that the patent in issue was valid, essential and infringed (***Optis v Apple*** **(16 October 2020**)[88]). The findings were consistent with those reached in the *Unwired Planet* case about the same patent[89], and as a consequence of which the certificate existed.

The Patents Act, section 65, states:

> "(2) Where a certificate is granted under this section, then, if in any subsequent proceedings before the court or the comptroller for infringement of the patent concerned or for revocation of the patent a final order or judgment or interlocutor is made or given in favour of the party relying on the validity of the patent as found in the earlier proceedings, that party shall, unless

[87] *Optis Cellular Technology LLC & Ors v Apple Retail UK Limited & Ors* [2020] EWHC 3248 (Pat) (23 November 2020) Birss J
[88] *Optis Cellular Technology LLC & Ors v Apple Retail UK Ltd & Anr* [2020] EWHC 2746 (Pat) (16 October 2020) Birss J
[89] *Unwired Planet International Limited v Huawei Technologies Co., Limited & Ors* [2016] EWHC 576 (Pat)

the court or the comptroller otherwise directs, be entitled to his costs or expenses as between solicitor and own client (other than the costs or expenses of any appeal in the subsequent proceedings)."

In view of this, it was common ground that Optis' costs should be assessed on the "solicitor and own client basis". Governed by CPR rule 46.9, this was different to standard assessment and indemnity assessment.

CPR r.46.9(3) provides:

> "Subject to paragraph (2), costs are to be assessed on the indemnity basis but are to be presumed –
>
> "(a) to have been reasonably incurred if they were incurred with the express or implied approval of the client;
>
> (b) to be reasonable in amount if their amount was expressly or impliedly approved by the client;
>
> (c) to have been unreasonably incurred if –
>
> (i) they are of an unusual nature or amount; and
>
> (ii) the solicitor did not tell the client that as a result the costs might not be recovered from the other party."

Accordingly, the presumptions that would operate in the normal indemnity basis operate in a different way – they are more favourable to the receiving party, but not entirely so, paragraph (c) being a different kind of presumption.

In order that the effect of s.65(2) PA and r.46.9(3) CPR would not be overridden by s.44.3(4)(b) CPR (which states that costs will be standard basis if the court makes an order without indicating the basis, or indicating a basis other than standard or indemnity), the judge proposed that his form of order recite that "the costs will be assessed as between solicitor and own client in accordance with" s.65 and r.46.9(3)".

e. Threats

Little case law has emerged concerning threats in 2020. However there was a judgment in the long-running *Warner-Lambert* litigation (***Warner-Lambert v Dr Reddy's***[90]) about the timing of proceedings to resolve claims for damages on cross-undertakings and in the threats actions. Noting that the Pre-Action Protocols should be "servants and not masters" and that the dispute was going to be difficult to resolve until all the claimants who intended to come to court were before the court, Birss J directed for service of the initial pleadings, a CMC to be fixed for July, and for W-L, in the meantime, to write to the various potential parties to invite them to attend that CMC.

So we may yet see more of the *Warner-Lambert* dispute.

[90] *Warner-Lambert Company LLC v Dr Reddy's Laboratories (UK) Limited & Anr* [2020] EWHC 628 (Pat) (16 March 2020) Birss J

f. FRAND?

FRAND injunctions

Probably the most significant judgment of 2020 is the Supreme Court's affirmation of the lower courts' judgments in ***Unwired Planet v Huawei***[91]. Beginning with some background -

In the *Unwired Planet v Huawei* case, following a finding of essentiality, infringement and validity of two standards essential patents (SEPs), Birss J awarded a new form of injunctive relief[92], which he called a "FRAND injunction". This was an injunction to restrain infringement of the UK patent, which would be enforceable unless the implementer elected to rely on the patentee's undertaking to the SSO to be prepared to grant a FRAND licence and enter into that licence. The terms of the FRAND licence fell to the Court to determine because the parties had failed to agree the same despite many years of negotiations.

The parties brought fact and expert evidence before the Court concerning licensing practices in their industry for SEP licences which proved that such licences were global in scope (as opposed to country-by-country or region-by-region). The settled licence included provision for payment of royalties at differing rates worldwide depending on the size of the portfolio of patents in different jurisdictions. It also included an "adjustment mechanism" enabling the rate to be adjusted to reflect change in the size of the portfolio in any territory (for example following findings of invalidity). The rates settled were higher than had been agreed in one of the comparables licences before the Court between Unwired Planet and Samsung, but neither the 'ND' arm of FRAND nor competition law had the effect of requiring the royalty rate to be set at the same level as the lowest rate granted to another implementer to date. Birss J stayed the FRAND injunction pending appeal of the FRAND judgment but imposed an ongoing interim payment obligation on Huawei on account of licence fees it would otherwise be paying under the global licence.

The Court of Appeal upheld Birss J on almost all points of his judgment[93]. Among other points, it dismissed Huawei's arguments that the award of injunctive relief contravened the CJEU's judgment in *Huawei v ZTE*[94], a case in which Huawei (as a SEP owner) had sought an injunction from the German court concerning ZTE's infringement of its SEPs.

Meanwhile, Conversant sued Huawei and ZTE for infringement of UK patents asserted to be SEPs and sought a FRAND injunction by way of relief. The defendants challenged the jurisdiction of the court to grant such relief, at all and to settle extra-territorial terms in the licence. The defendants also contended that, alternatively, the court should decline to exercise its jurisdiction for *forum non conveniens*, the defendants' case being that China was the natural forum on the basis of the defendants' commercial activity, place of manufacture and so on.

The defendants' challenges were rejected by Henry Carr J in 2018[95]. The appeals were dismissed by the Court of Appeal in 2019[96]. The Court of Appeal considered that the defendants' justiciability

[91] *Unwired Planet International Limited & Anr v Huawei Technologies Co Ltd & Anr* [2020] UKSC 37 (26 August 2020) Lords Reed, Hodge, Black, Briggs & Sales
[92] *Unwired Planet International Ltd v Huawei Technology Co. Ltd & Ors [*2017] EWHC 711 (Pat); [2017] EWHC 1304 (Pat); [2020] EWHC 2988 (Pat); [2017] EWHC 3083 (Pat)
[93] *Unwired Planet International Limited & Anr v Huawei Technologies Co. Limited & Anr* [2018] EWCA Civ 2344
[94] *Huawei Technologies Co. Ltd v ZTE Corp. & Anr* (Case C-170/13) EU:C:2015:477; [2015] 5 CMLR 14; [2016] RPC 4
[95] *Conversant Wireless Licensing S.A.R.L. v Huawei Technologies Co Ltd & Ors* [2018] EWHC 808 (Pat)
[96] *Huawei Technologies Co., Ltd & Ors v Conversant Wireless Licensing S.A.R.L.* [2019] EWCA Civ 38

challenge was foreclosed by the Court of Appeal's judgment in *Unwired Planet*, and so its reasoning addressed only the *forum non conveniens* challenge. The Court of Appeal agreed with Conversant and the judge that the proper characterisation of the case was that it was a dispute concerning UK patent infringements. The UK was therefore not just the most appropriate forum but also the only possible forum for the whole dispute which included the defendants' counterclaim for invalidity. The fact the UK Huawei and ZTE defendants were domiciled in the jurisdiction meant that the court could not decline jurisdiction as against them, and this was an appropriate consideration in the assessment of *forum non conveniens* with respect to the Chinese Huawei and ZTE defendants. Further, it remained unknown at that time whether the Chinese courts would conduct a global royalty-setting exercise without the consent of the parties. (This uncertainty has since been clarified in recent disputes before the Shenzhen and Wuhan courts which have now accepted cases seeking global rate-setting determinations).

In October 2019, the UK Supreme Court heard the joined appeals in the *Unwired Planet* and *Conversant* cases. The SEP owners, Unwired Planet and Conversant, emphasised the cause of action as 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" recognises the FRAND defence relied on by the defendants and instead gave them 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 nor were they forced off the market if they would rather be licensed.

The implementers, Huawei and ZTE, 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 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 the SSO (in this case ETSI) to offer licences on FRAND terms was to mean that injunctive relief should not be awarded to restrain infringement of a SEP (but nor did they offer to take the FRAND licence). 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. At most they acknowledged that the UK court could settle terms for a UK-only licence to the patents in suit or potentially the UK portfolio.

The Supreme Court's 2020 judgment in the joined cases *(**Unwired Planet v Huawei**)* was unanimous and dismissed the implementers' appeals in their entirety.

In short, the Supreme Court ruled that the UK courts do have jurisdiction to grant a FRAND injunction in cases where the patent in suit is held to be infringed, essential and valid and a FRAND defence has been relied upon by the defendants. The FRAND injunction is an injunction to restrain infringement but it provides the implementer with the opportunity to avoid the injunction by taking a FRAND licence on terms to be settled by the Court based on the evidence to be put before it by the parties, if not agreed. This is a choice for the implementer to take: the patentee cannot decide the outcome. It is a choice that is only open to the defendant due to the standards essential nature of the patent. The terms of such a FRAND licence will reflect the evidence before the court of what is FRAND in the circumstances.

The ability of the implementer to rely on the patentee's undertaking to the standards setting organisation to grant a FRAND licence to any person with regard to the patentee's SEPs was characterised by the Supreme Court as a *"contractual defence to the enforcement of an English patent by injunction"*. However, while the implementer may rely on the undertaking (contract) given by

the patentee to the standards setting organisation (SSO) as a third party beneficiary under French contract law principles (it being noted that the ETSI IPR Policy under which the undertaking is given is expressed to be governed by French law), the patentee has no ability to assert any form of breach of contract argument against an implementer who is trading in standards essential goods without paying a licence. The patentee must sue for patent infringement. If the implementer elects an injunction and comes off the market, the patentee has no ability to insist on a FRAND licence being imposed.

At each instance, a part of the dispute was whether the 'ND' (standing for 'Non-Discriminatory') requirement of the ETSI FRAND undertaking is "hard-edged" or "soft-edged". Hard-edged means that the patentee must offer the lowest price it has previously agreed with any other party to any new licensee irrespective of any other factors. Soft-edged recognises that other factors will affect price. The Supreme Court confirmed that ND is soft-edged and that competition law does not require the lowest rate previously agreed to bind future terms. For example, a patentee might charge lower rates for a first licence.

The Supreme Court also considered the approach taken by the lower courts to be consistent with the CJEU's reasoning in *Huawei v ZTE.* The Supreme Court noted that although in some EU Member States (such as Germany, from where the reference in *Huawei v ZTE* was made), it was possible for a SEP owner to obtain an injunction before validity has been determined by the court, this is not the practice of the courts in the UK. The scheme set up by the CJEU prevents an organisation that is unwittingly using a SEP without a licence from being ambushed by injunction proceedings without any prior notification of the problem; it provides the SEP owner with a route map which, if followed, will ensure it can seek an injunction without risking infringing competition law; and it otherwise provides a number of points of reference to assist in assessing the question of whether each of the parties is willing to enter into a licence on FRAND terms. Interpreted in this way, *Huawei v ZTE* has sufficient flexibility to cater for the inevitable variations that will occur from case to case, and from country to country. There is no mandatory requirement that the patentee itself make an offer of terms that coincide with those that are ultimately determined by the court to be FRAND. On the facts of the *Unwired Planet* case, what mattered was that Unwired Planet had shown itself willing to license Huawei on whatever terms the court determined were FRAND, whereas Huawei had only been prepared to take a licence with a scope determined by Huawei.

The issue of *forum non conveniens* arose in the Conversant appeals. The first element was, on the assumption that (as the Supreme Court did find) the English court had jurisdiction to settle a global licence on FRAND terms for a multinational SEP portfolio, the High Court should have set aside service out of the jurisdiction on the two Chinese defendants (Huawei (China) and ZTE (China)). The implementers' case was that the real dispute between the parties was as to the terms of a FRAND licence, and that the claim to enforce English patents by injunction was no more than a convenient peg upon which to hang the dispute so as to attract English jurisdiction.

In this context a key issue was how the dispute should be properly defined. Was it a dispute in substance about the terms of a global FRAND licence (as the implementers/defendants contended) or about the vindication of the rights inherent in English patents, with FRAND issues arising only as an aspect of an alleged contractual defence (as the patentees contended)?

The Supreme Court indicated that, like the lower courts, it preferred the patentees' characterisation, but it side-stepped this part of the dispute because, even on the implementers' characterisation a challenge to jurisdiction on *forum non conveniens* grounds required the challenger to identify some other forum which did have jurisdiction to determine the dispute. In the present case, China was the

only candidate put forward but after hearing extensive expert evidence, the judge had found that the Chinese courts did not, at present, have jurisdiction to determine the terms of a global FRAND licence, at least in the absence of agreement by all parties that they should do so. The prospect that the Chinese courts would embark upon the exercise was therefore no more than speculative. And after considering fresh evidence, the Court of Appeal confirmed this. Therefore the *forum non conveniens* challenge failed.

The second element was, on the same assumption, whether the claim for injunctive relief in the English proceedings should be temporarily stayed or otherwise case managed to enable relevant matters in dispute first to be litigated to a final conclusion in pending proceedings in the Chinese courts. However, no application for a stay had thus far been made in the *Conversant* case and the Court of Appeal's reasoning for refusing to schedule the hearing of the FRAND trial to facilitate the outcome of the Chinese proceedings being factored in could not be faulted. (The Court of Appeal's reasons included that the Chinese FRAND proceedings were only for Conversant's Chinese patents; noting also the age of Conversant's portfolio).

Finally, in the Supreme Court a further point was argued that had not been argued in the courts below. Huawei contended that even if it infringed the relevant SEPs, and even if the SEP owners were willing to offer a licence on terms found by the court to be FRAND, nevertheless an injunction to prevent continuing infringement should not be awarded because it would not be appropriate or proportionate.

Interestingly, in this context Huawei drew upon the Senior Courts Act 1981 (section 50), recent Supreme Court judgments in *One Step v Morris-Garner*[97] and *Lawrence v Fen Tigers*[98] and reasoning of the US Supreme Court in *eBay Inc v Mercexchange LLC* 547 US 388 (2006), each of which was considered by Birss J in *Evalve v Edwards* (public interest) (discussed in section 2d. above).

The Supreme Court dismissed the concern expressed by Kennedy J in the *eBay* case that an injunction could be employed by a patent assertion entity (ie a SEP owner) as a bargaining tool to charge exorbitant fees, explaining that a SEP owner cannot enforce their rights unless they have offered to license their patents on terms which the court is satisfied are fair, reasonable and non-discriminatory.

Further, the Supreme Court noted that in a case of the present kind an award of damages is unlikely to be an adequate substitute for what would be lost by the withholding of an injunction. Such an approach would incentivise infringing implementers to continue infringing until, patent by patent, and country by country, they were compelled to pay royalties (or more likely the patentee ran out of the wherewithal to chase the infringer around the globe) – a point that had been recognised by the Court of Appeal. This was the central reason why an injunction was necessary in order to do justice, and why damages in lieu would not be an adequate substitute.

So the Supreme Court has confirmed the process for resolution of SEP/FRAND disputes in the UK courts, in a well-reasoned and digestible judgment. Looking forward, a question now is how the courts will handle situations in which differing parties seek resolution of FRAND disputes in different jurisdictions. What happens if the FRAND terms settled in litigation in the UK are global and differ from the terms settled by a court in another jurisdiction? Will it be enough for the patentee to offer one

[97] *One Step (Support) Ltd v Morris-Garner* [2018] UKSC 20
[98] *Coventry & Ors v Lawrence & Anr* [2014] UKSC 13

of the sets of terms as both have been adjudicated to be FRAND therefore fulfilling its obligation to be prepared to offer a licence on FRAND terms?

This is a question for resolution in another case, but concurrent litigation has already arisen in another judgment in 2020, as discussed below.

FRAND trial scheduling

In the *Unwired Planet* case, three technical trials (i.e. to address questions of validity, infringement and essentiality of the asserted patents) took place, and for which judgments were handed down, before the parties postponed the remaining technical trials and moved to the FRAND trial.

Consistent with that process, in ***Interdigital v Lenovo***[99] Birss J ordered the FRAND trial in the case to be listed after the first two of five scheduled technical trials. Dismissing the alternative options of putting off the listing decision, or listing the FRAND trial after all five technical trials, he said the realistic likelihood was that if the FRAND trial was scheduled after two technical trials, it would go ahead. If the patentee lost both technical trials then matters would have to be revisited but this was the most appropriate course.

Birss J also dismissed an argument by Lenovo that the proceedings should be managed such that the FRAND trial took place after the proceedings filed by it in Delaware and China some 8 months after the commencement of the English proceedings. He said ([13]):

> "The courts will manage cases in accordance with the conventional case management principles, applying the overriding objective and taking into account the possibility that a decision elsewhere may produce a useful result, but it is not a trump card. … The court will take into account foreign decisions if it reasonably can, but in this case that would involve an enormous delay to these proceedings which I am not prepared to countenance."

Jurisdictional issues in FRAND cases

In *Unwired Planet v Huawei*, Huawei contended that if a national court were prepared to determine that a worldwide licence was FRAND and that entering into such a licence was a precondition for the refusal of an injunction to prohibit patent infringement, there was a risk of forum shopping, conflicting judgments, and applications for anti-suit injunctions.

The Supreme Court dismissed Huawei's argument, saying that so far as that was so, it was the result of the policies of the SSOs, which limit the national rights of a SEP owner if an implementer agrees to take a licence but do not provide for any international tribunal or forum to determine the terms of such a licence. Absent such a tribunal it fell to the national courts, before which the infringement of a national patent was asserted, to determine the terms of a FRAND licence.

The proceedings in ***Philips v Tinno & TCL***[100] were commenced by Philips for patent infringement in October 2018. The TCL defendants initially challenged the English court's jurisdiction, then commenced proceedings in France against Philips and ETSI (the relevant SSO) seeking a declaration of FRAND terms. Two months later, TCL changed its position in the English proceedings and filed an

[99] *Interdigital Technology Corporation & Ors v Lenovo Group Limited & Ors* [2020] EWHC 1318 (Pat) (20 May 2020) Birss J
[100] *Koninklijke Philips NV v Tinno Mobile Technology Corporation & Ors* [2020] EWHC 2553 (Ch) (25 September 2020) Mann J

acknowledgement of service and defence and counterclaim. Birss J disposed of the jurisdiction application, declaring that *"The court has jurisdiction to try the claim"*.

Technical trials were scheduled for July and October 2020, but the parties reached a "compromise" after the Court of Appeal upheld the validity of the patents in issue in December 2019 in *Philips v Asustek*[101]. The FRAND trial continued to be scheduled for November 2020.

In the meantime, in the French proceedings, Philips challenged the jurisdiction of the French court under articles 29 and 30 of the Recast Brussels Regulation ((EU) 1215/2012). ETSI submitted "for its own reasons" that those articles were not fulfilled. The TCL parties argued that there was no identity of parties, cause or object. Before the first instance judge they succeeded, in a judgment of 6 February 2020. Philips filed an appeal.

Following the French court's judgment, TCL applied to the English court to stay the proceedings pursuant to articles 29/30 of the Recast Brussels Regulation, including a vacation of the November 2020 FRAND trial, in favour of the French proceedings.

Article 29 requires any court other than the one first seised to decline jurisdiction in favour of the court first seised where "proceedings involving the same cause of action and between the same parties are brought in the courts of different Member States". TCL's position appeared to depend on establishing that Philips' submission before the French court was that the English court was first seised of the FRAND issue, and that in rejecting all Philips' procedural challenges the French court was inevitably determining that the English court was not seised of that issue and that the French court was.

However, Mann J concluded that in fact what the French court rejected was Philips' case that the commitment to grant a FRAND licence, and the determination of its terms, was what the English proceedings were about. Instead the French court decided that the English proceedings were in tort for infringement; the French proceedings could not be characterised in that way, and so for the purposes of article 29 they did not have the same subject matter. The French court's reasoning did not involve an implicit finding that the English court was not seised of FRAND issues, or that the French court was first seised of FRAND proceedings. In the English proceedings, argument that Philiips' terms were FRAND had been in the case from the beginning even though Philips only sought a declaration as to FRAND terms at a later point and so the presence (or not) of the claim for a declaration did not make any difference. TCL's article 29 case was rejected.

Article 30 states that any court other than the one first seised *may* stay its proceedings in favour of the court first seised where "related actions are pending in the courts of different Member States". TCL's case was that the English and French actions were related, and they became related when the FRAND statement was served in the English proceedings (and so the FRAND claim was raised for the first time in England), so the English court could and should exercise its article 30 jurisdiction to stay.

However, Mann J again thought TCL was wrong on the time at which the FRAND issues were raised in the English proceedings. As they were raised at the outset, the English court was first seised for the purposes of article 30 and so the English court had no jurisdiction to stay its action. TCL's article 30 case was therefore rejected too.

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

Damages for infringement of standards essential patents

In *Unwired Planet v Huawei*, the Supreme Court said that the exercises performed by the court in (i) awarding damages and (ii) determining the terms of a licence including the royalties to be paid, were different and could not be equated. It was therefore not anomalous that an implementer that chose to withdraw from the UK was liable to the SEP owner only in respect of losses incurred through infringement of the SEP, whereas an implementer that wished to remain in the UK had to pay global royalties (on the facts of the *Unwired Planet* case). The point being that damages are financial compensation for past acts of infringement of the patent in suit; the determination of the terms of the FRAND licence is an assessment of the terms of the contract arising from a defence which relies on enforcing the patentee's undertaking to the SSO to be prepared to offer FRAND licences.

Nevertheless, SEP owners have been challenging the principles governing the assessment of damages in FRAND cases, and in particular whether damages for past infringements should be calculated by reference to a hypothetical FRAND licence fee.

In ***Philips v Asustek***[102], after being found liable for infringement of two of Philips' SEPs, the 'ASUS' defendants sought to extricate themselves from the scheduled FRAND trial, saying they would take an injunction. Philips, however, contended that ASUS had to remain as a defendant in the FRAND trial because the amount of damages (for past infringements) remained at large, and Marcus Smith J agreed.

An issue was the extent to which the FRAND terms as declared by the court (the Declared Licence) were to be read across into the assessment of appropriate compensatory damages. Marcus Smith J noted the "critical distinction" between the two, which meant that any claim for automatic linkage between the terms of the Declared Licence and the terms of the counterfactual licence (for the purposes of the damages assessment) was wrong in principle and should be struck out. Nevertheless, the process for assessing damages is heavily fact based and the extent to which the terms of the Declared Licence were relevant was a question of fact to be determined at trial, in no way susceptible of summary determination. The issue therefore must be determined as part of the FRAND trial.

In ***Philips v Tinno***[103] technical trials were scheduled for July and October 2020, but the parties reached a compromise after the Court of Appeal upheld the validity of the patents in issue in December 2019 in *Philips v Asustek*[104]*.* The FRAND trial continued to be scheduled for November 2020.

Philips claimed for damages *inter alia* on the basis of the sum to which it would have been entitled under a licence had the sales been licensed, that the appropriate licence for these purposes would be a worldwide licence because that was the only licence which Philips would have granted, and that it would have extended back to before the limitation period appropriate to the infringements. In this context, Philips sought disclosure of the annual number of devices that implemented the various mobile telephony technologies, broken down by product name, broken down into UK sales figures

[102] *Koninklijke Philips NV v Asustek Computer Incorporation & Ors* [2020] EWHC 29 (Ch) (17 January 2020) Marcus Smith J
[103] *Koninklijke Philips NV v Tinno Mobile Technology Corporation & Ors* [2020] EWHC 2553 (Ch) (25 September 2020) Mann J
[104] *Koninklijke Philips N.V. v Asustek Computer Incorporation & Ors* [2019] EWCA Civ 2230 (17 December 2019) Patten, Floyd & Henderson LLJ

and worldwide figures, and not limited to sales within the limitation period which would be applicable to the infringement action.

TCL contended that worldwide sales were not relevant to an inquiry as to damages for infringement of UK patents. Mann J said that the way TCL's point was put required determination that the way in which the claimants put this part of their case was hopeless. This was akin to a striking out or summary judgment application. But while Philips' case "might fairly be described as ambitious", it was arguable, and in *Philips v Asustek* Marcus Smith J had declined to hold that the terms of a worldwide licence were sufficiently irrelevant to a damages assessment as to justify striking out a claim which seemed to involve an averment of relevance. In that case the judge considered that the correct measure of damages and how one got there was a matter for trial in his case. The same was true of the present case. Mann J also noted that in *Unwired Planet* the Supreme Court had said (at [87]) (140]):

> "If the court awards damages it does so on proof of the loss which the SEP owner has suffered through the infringement of its patent or patents. It may be that the measure of damages which a court would award for past infringement of patents would equate to the royalties that would have been due under a FRAND licence."

This meant that it could not simply be said that the terms and effect of a potential FRAND worldwide licence, and the moneys which would flow from it, were irrelevant to a damages assessment.

Later in the year though, SEP/FRAND veteran Birss J reined things in a bit, in ***IPCom v HTC***[105].

In 2011, IPCom succeeded in establishing essentiality (3G), infringement and validity of its patent. HTC represented that it would not infringe any more in the UK because it would only sell workaround phones (the case was unusual in that it was possible to make a phone that worked with the standard but did not use the invention). It later transpired that HTC had continued, in fact, to sell phones in the UK that infringed the patent. IPCom applied for a final injunction. HTC declined to elect to pursue its entitlement to a FRAND licence, and so the injunction sought by IPCom was ordered by Sir Geoffrey Vos on 17 December 2019. The order also dismissed the FRAND inquiry and directed an inquiry as to damages. IPCom sought damages in respect of ([8]):

> "i) A big number (more than a million) of phones which were sold in the UK and infringed the patent.
> ii) An enormous number (over a hundred million) of phones which fall into one of three groups:
>
> a) Workaround phones – i.e. phones sold as 3G phones but which did not infringe the patent;
> b) 2G only phones, which necessarily never infringed the patent; and
> c) Phones which were never imported into the UK and therefore never infringed the patent."

Category (ii), and in particular category ii(c), was critical to whether the damages inquiry was worth hundreds of millions of dollars or about 100 times less than that. HTC applied to strike out category (ii).

[105] *IPCom GmbH & Co KG v HTC Europe Co Ltd & Ors* [2020] EWHC 2941 (Pat) (4 November 2020) Birss J

Birss J was not prepared to allow IPCom's claim to proceed in respect of phones sold outside the UK. He explained that the only acts of infringement relied upon were acts committed within the UK relating to products which fell within the relevant claims of the UK patent in suit, but under the notional licence relied upon by IPCom the implementers would be paying so as to receive a licence in states other than the UK. The extra-territorial sales of phones were not in any sense convoyed goods or caused by the infringement of the UK patent.

IPCom's equivalent patents had been found invalid or not infringed in Italy, Japan and the USA, yet IPCom's approach to damages would involve awards for those countries. Birss J said that in such a case the argument that a licence with a scope wider than the UK would be agreed was fanciful. Here the judge distinguished the issues in the *Unwired Planet* case, in which the global licence derived not from national law but from the interaction between national patent law and the internationally effective ETSI FRAND undertaking.

Birss J also noted a "small" difference between the factual circumstances of the present case and *Philips v Asustek*, in that *Philips* was about FRAND obligations whereas the present case was not – but Birss J said that he did not believe that really made a difference.

Some of category (ii) survived though, to the extent non-infringing phones sold in the UK were covered. This was because in the *Unwired Planet* case, Birss J had approached damages for UK patent infringement on a UK portfolio basis rather than on the basis only of the individual patents found valid and infringed (although he said that might have been following a concession in that case). Birss J expressed the view that absent a concession or agreement, the court could only award damages for infringement of the individual UK patents found valid and infringed but given what seemed to have happened in *UP*, the fair thing to do was to allow this part of the case to go to trial. If a UK portfolio approach was legitimate, it might (or might not, depending on the facts) justify a claim for damages based on the workaround phones.

Birss J's approach seems entirely appropriate, and probably mandated by, the Supreme Court's *Unwired Planet* judgment, which (as noted above) explained the very different basis for, and therefore the lack of alignment between, a damages claim for UK patent infringement and the contractual defence to an injunction claim that arises from the FRAND undertaking. It is easy to see how a damages award in respect of worldwide sales of phones manufactured and sold outside the UK, following a finding of infringement in the UK, could be seen as overreach. Nevertheless we will have to wait and see what becomes of the wider damages arguments in *Philips v Asustek* and *Philips v Tinno*.

3. Validity

a. The skilled person and the common general knowledge

The person skilled in the art

The concept of the skilled addressee of the patent, also called the 'person skilled in the art' is a stable part of patent law, although frequently illustrative judicial comments emerge re-explaining the principles. In 2020 the most notable comments of this nature were in judgments handed down relatively late in the year.

In ***Communisis v The Tall Group***[106] (the case about a security measure for banking cheques), HHJ Melissa Clarke said ([30]):

> "There is no dispute about the correct approach to the skilled person, the principles applicable to which were summarised by Henry Carr J in *Hospira UK Limited v Cubist Pharmaceuticals LLC* [2016] EWHC 1285 (Pat). It is common ground that 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); such persons are those with practical knowledge and experience of the field in which the invention is intended to be used. The skilled addressee of the Patent reads the specification with the common general knowledge of persons skilled in the relevant art at the application date of the patent (here, 1 February 2013), and knowing that its purpose is to disclose and demarcate an invention. The skilled person reads prior art documents with interest but is unimaginative and has no inventive capacity. He may be a team of persons with differing expertise, or a single person with all the practical knowledge and experience needed. Although the skilled person is a hypothetical construct, his or her composition and mind-set is founded in reality."

By trial, the dispute as to the identity of the PSA was the extent to which the skilled person/team had cryptography expertise. In cross-examination, Communisis' expert, Mr Brewer, confirmed that he was approaching the skilled person as being someone who was assessing competing solutions to see which one of them adequately fit the requirements. The judge said that this disclosed an incorrect approach ([37]):

> "Taking Mr Brewer's own example, the skilled addressee of a patent for a fuel injection system for a car is not the purchaser of the car, but a notional person who fulfils the *Hospira* principles: this is likely to be an engine management specialist, or perhaps a team comprising an engine management specialist and a software engineer if that injection system is computer-controlled."

The judge accepted The Tall Group's submission that the patent postulated the use of a re-ordering algorithm which would need to be chosen and assessed by a cryptographer in order to make and use the invention. Further, in the field of data security, the banking industry had been working with cryptographers for decades, including in the area of concern to the inventors of the patent. Therefore, as The Tall Group contended, the patent would be read by those with both financial/banking and cryptographic expertise (at the level described by the defendants' expert in his oral evidence). This expertise could reside in the same person.

In ***Neurim v Generics* (4 December 2020)** [107] Marcus Smith J addressed the territorial nature of the person skilled in the art. He noted Lord Neuberger's statement in *Actavis v Eli Lilly*[108] that a patent is interpreted on the basis that it is addressed to a person/group who is/are likely to have a practical interest in the subject matter of the claimed invention (i.e. through the eyes of the person skilled in the art). He also noted Arnold J's comment in *Generics v Warner-Lambert*[109] that at a minimum it must be shown that the matter in question was common general knowledge in the UK because a UK patent

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[106] *Communisis Plc v The Tall Group of Companies Limited & Ors* [2020] EWHC 3089 (IPEC) (17 November 2020) HHJ Melissa Clarke

[107] *Neurim Pharmaceuticals (1991) Limited & Anr v Generics UK Limited (trading as Mylan) & Anr* [2020] EWHC 3270 (Pat) (4 December 2020) Marcus Smith J

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

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

(GB or EP(UK)) is concerned with a right in respect of the UK – reasoning that has been followed in a number of cases since. To this Marcus Smith J added ([24]-[26]):

> "The skilled person will be looking at an invention that is claimed within the United Kingdom and whose territorial ambit is defined by the United Kingdom, and that must be the starting point for determining the nature of the skilled person. A United Kingdom designation of a European patent confers no rights outside the territorial scope of the United Kingdom….
>
> Of course, that does not mean that the skilled person will not have an international outlook, and will not consider prior art published anywhere in the world."

Neurim's expert was from the US, while Mylan's expert was from the UK. They described rather different clinical pictures in the two countries in 2001. However the judge said he declined to accept that at that time the UK could not offer up as a skilled person someone having the combination of research and clinical experienced described by Neurim's expert.

Marcus Smith J made two further observations that are worth capturing on the person skilled in the art. First, with reference to the House of Lords' judgment in *Kirin-Amgen v Hoechst*[110] and *Terrell's* commentary in on the Court of Appeal's judgment in *Virgin v Premium*[111], he said ([27]):

> "Patents are technical documents, and the skilled person must have sufficient understanding of patent law to appreciate the general nature and function of a patent specification and claims."

Secondly, the judge made an astute observation of his own ([30]):

> "In reality, the patent in issue, the skilled person and the skilled person's common general knowledge are three mutually supporting pillars in terms of determining what is required to understand the Patent."

In ***Fisher & Paykel v Flexicare***[112], Meade J observed that Flexicare's approach to some of the argument appeared to proceed on the assumption that the person skilled in the art was focused on solving a particular problem, this being the problem addressed in the patent. This was not the right approach and was "symptomatic of hindsight".

More generally, the judge said ([44]):

> "…it is often possible to deduce the attributes which the skilled addressee must possess from the assumptions that the patent in suit makes about his abilities (*Horne v. Reliance* [2000] FSR 90 at [11]). So, for example, the fact that the Patent expects its skilled addressee to be able to make a co-extruded tube with breathable material with very little guidance implies that the skilled addressee could undertake the same or a similar task starting from the prior art.

While it is common for aspects of the person skilled in the art (and their common general knowledge) to be agreed between the parties, it is also common for there to be disagreement too. In ***Geofabrics***

[110] *Kirin-Amgen Inc & Ors v. Hoechst Marion Roussel Limited & Ors* [2004] UKHL 46
[111] *Virgin Atlantic Airways Limited v. Premium Aircraft Interiors UK Limited* [2009] EWCA Civ 1062
[112] *Fisher & Paykel Healthcare Limited v Flexicare Medical Limited & Anr* [2020] EWHC 3282 (Pat) (8 December 2020) Meade J

v Fiberweb[113] Deputy Judge David Stone reiterated that "there is limited utility in parties saying they are agreed on the skilled addressee/CGK without saying, in words, who the skilled addressee is and what the CGK is". He explained ([51]):

> "Judges need to write judgments – this involves setting out who the skilled addressee is, and what the CGK is. It is no good for the parties simply to say that they agree: it is incumbent on them to express, in terms, what that agreement is, preferably before the trial. If it cannot be done before the trial, it should be done shortly after the conclusion of the evidence. Importantly, where minor differences subsist after the evidence, it will be of significant help to the court if they are summarised, along with why it makes a difference. The court can then rule on the differences based on the evidence. If the lack of agreement on a minor aspect makes no difference, then it should be ignored. What is important is that where the skilled addressee and/or the CGK are agreed, the court has a clear statement of who the agreed skilled addressee is, and what the agreed CGK is."

The common general knowledge

In ***Fisher & Paykel v Flexicare*****,** Meade J gave a pithy description of the 'common general knowledge' (CGK) ([50]):

> "CGK is that which is generally known and generally regarded as a good basis for further action by the bulk of those in the particular art."

In ***Conversant v Huawei*** **(8 January 2020)**[114] Birss J said that even if thinking of a particular problem followed readily from the application of the common general knowledge to a particular situation, this did not make the problem itself part of the common general knowledge. Further, the fact a document (technical paper 3GPP TSG-RAN WG1 #43) showed a problem was known to some, even those working on the standard, did not mean it was common general knowledge. Nor did the fact that lead engineers in one group at the forefront of the technology had considered the problem mean that the legal standard for common general knowledge had been reached.

The consequence of this was that while Birss J accepted that with 'Voice Over IP' (referring to techniques such as Skype whereby voice signals are sent over an internet protocol network), the significant amount of control data sent in each data packet took substantial resources relative to the low amount of data being sent, he held that this "VOIP problem" did not constitute common general knowledge.

Later in the year, in ***Optis v Apple*** **(16 October 2020**)[115], which concerned handover between different Radio Access Technologies (i.e. GSM (2G) and UMTS (3G), Birss J made some notable observations on the common general knowledge on the facts of that case for telecommunications standards cases. For example ([28]):

> "In my judgment the skilled person would be well aware of the standardisation work which was being actively pursued at the time (Nov 1999) but they would not be immersed in the detail, following closely every document presented to the various meetings and tracing the relationship between them. Their knowledge would be of the broad outline of what was going

[113] *Geofabrics Limited v Fiberweb Geosynthetics Limited* [2020] EWHC 444 (Pat) (5 March 2020) David Stone
[114] *Conversant Wireless Licensing S.à.r.l v Huawei Technologies Co. Ltd & Ors* [2020] EWHC 14 (Pat) (8 January 2020) Birss J
[115] *Optis Cellular Technology LLC & Ors v Apple Retail UK Ltd & Anr* [2020] EWHC 2746 (Pat) (16 October 2020) Birss J

> on. If they wanted to delve into the detail of how an aspect of the standard was developing, they would know who to ask (or how to do it themselves) but the skilled person would need a reason to embark on that exercise before undertaking it."

By 1999 a textbook (published in 1992) would be regarded as a good introductory text which might be given to a new engineer joining a group, but that was all. The standards themselves would be the primary source.

In ***Rockwool v Knauf***[116], Marcus Smith J confirmed the Hearing Officer's dismissal of Rockwool's application for revocation of two patents owned by Knauf. The patents concerned the manufacture of binders, that is, substances for binding non- or loosely- assembled matter, for example mineral wool to form a useful material for the insulation of houses and other buildings.

The skilled person's identity was not in issue in the appeal. The HO had found the patents to be addressed to someone interested in the development of binders in the field of mineral wool insulation manufacture. Such a person would have knowledge of chemistry and detailed knowledge of binders used in mineral wool insulation. Marcus Smith J concluded that the HO had not erred in his identification of the skilled person's level of knowledge of the Maillard reaction. (This is a chemical reaction between an amino acid and a sugar to give melanoidins – brown, high molecular weight polymers – which give browned food (like seared steak) its distinctive flavour). The skilled person's knowledge would not be detailed because literature on the Maillard reaction had largely been confined to the field of food chemistry. This meant the patent was not obvious over the pleaded prior art.

In ***MSD v Wyeth***[117] (the case about vaccine formulation) Meade J observed that, as per Aldous LJ in *Beloit v Valmet*[118], it is difficult to appreciate how the use of something which has never been used in a particular art can ever be held to be common general knowledge in the art. However Meade J said that the applicability of the principle depended upon what the "something" that had not been done before was, and how it was characterised ([83]):

> "It is not real to say that something phrased very narrowly has not been done before, when it would be, from the skilled team's perspective, merely a specific instance of doing something that was well known as expressed in broader terms."

As to proof of common general knowledge, the judge noted that this is often achieved by means of textbooks ([85]):

> "These have the advantage that their contents, scope and intended audience are readily ascertainable. Not all textbooks are well known and widely accepted, and that has to be proved by evidence, but frequently is not disputed."

However, this did not limit what could be common general knowledge ([86]):

> "Individual publications in the scientific literature and patent specifications could represent CGK, for example, but it depends on evidence that they had sufficient reach, impact and acceptance. In general, they may be less likely than textbooks to represent CGK. Repeated

[116] *Rockwool International A/A v Knauf Insulation Limited* [2020] EWHC 1068 (Pat) (7 May 2020) Marcus Smith J
[117] *Merck Sharp & Dohme Limited v Wyeth LLC* [2020] EWHC 2636 (Pat) (15 October 2020) Meade J
[118] *Beloit Technologies Inc & Anr v Valmet Paper Machinery Inc. & Anr* [1997] EWCA Civ 993

individual publications of the same information (and as Floyd LJ has repeatedly said, it is information that one is focused on) may, with the right evidence, show that it was CGK, even if each of the publications on its own would not."

b. Priority and anticipation

Priority

***Conversant v Huawei* (8 January 2020)**[119] concerned three Conversant patents addressing semi persistent scheduling (SPS) in LTE/4G, two of them being divisionals of the third. Huawei challenged the claimed priority of one of the divisionals (the '206 patent).

On the principles governing the assessment of a question of priority, Birss J referred to Kitchin LJ's summary in *Medimmune v Novartis*[120]. The requirement of the Patents Act, section 5, that the invention claimed is supported by the priority document has the same effect as article 87 EPC, which requires that priority is given to the "same invention". Birss J continued ([59]):

> "Therefore the test is not only an enablement test although enablement is required and it is not only an added matter test, although adding matter is likely to lead to a loss of priority. A granted claim which is wider in scope than any claim or disclosure in the priority document may still be entitled to priority but to do that it must be supported by the priority document."

Birss J said that the priority document in question in the *Conversant v Huawei* case really disclosed a single inventive concept, which was that as long as the mobile phone knew when to expect data and what the transport format was, control information need not be sent for each fixed allocation data packet and so control overhead (data) could be reduced. Two ways of doing this were disclosed: re-use of stored HS-SCCH control information from previous fixed allocation packets (alternative 1); and default values based on higher layer signalling (alternative 2).

Claim 1 of '206 differed from the inventive concept disclosed in the priority document in that it covered a case in which timing was not fixed. This was materially wider than the disclosure of the priority document and related to a different concept. What would be required to implement it was different and its effects would be different too. Therefore the claimed invention was not the same invention as that disclosed in the priority document and so it was not entitled to priority. Conversant conceded that, if priority was lost, the '206 patent was invalid in light of intervening prior art.

Anticipation

I have often said that, given my emphasis over the years on mechanical engineering cases, my career in patents could be summarised as one of "planes, trains and automobiles". In truth, the "trains" element has been a little thin on the ground, so imagine my delight……..

Geofabrics v Fiberweb[121] was a case about railway trackbed technology. By way of background Deputy Judge David Stone explained that, with reference to the diagram below left, a railway track is

[119] *Conversant Wireless Licensing S.à.r.l v Huawei Technologies Co. Ltd & Ors* [2020] EWHC 14 (Pat) (8 January 2020) Birss J
[120] *MedImmune Limited v Novartis Pharmaceuticals UK Limited & Anr* [2012] EWCA Civ 1234
[121] *Geofabrics Limited v Fiberweb Geosynthetics Limited* [2020] EWHC 444 (Pat) (5 March 2020) David Stone

constructed in layers, very basically being (from the bottom up) the soil/ground/subgrade (22), then a 300-500mm deep layer of ballast made from graded, crushed rock aggregate (20), then the sleepers, then the rails.

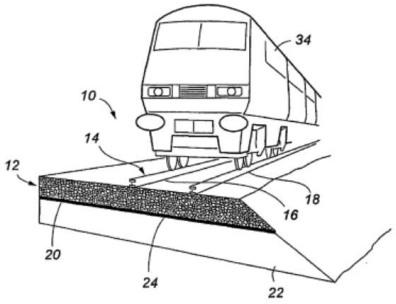


Fig. 1

Where the subgrade has a high clay content, the pressure of the train passing over causes water to be squeezed from the clay. The water carries with it fine particles of clay and silt. Over time, it forms a liquid slurry on the upper surface of the subgrade. The removal of particles from the subgrade causes erosion to the track bed and settling of the track. The slurry can even migrate up through the ballast (see the picture above right).

The problem of pumping erosion has long been well known. Traditionally it was addressed by building the trackbed with a layer of sand between the subgrade and the ballast. The sand would act as a filter, slowing the passage of water and trapping the fine clay and silt particles. However sand is expensive and difficult to lay and so a replacement was desirable. Various synthetic liners had been tried. Geofabric's patent, the alleged infringement and the prior art in the case all concerned synthetic liners.

Geofabric's patent was directed to a liner made of a "filtration layer" sandwiched between two "support layers", claim 1 being in the following terms:

> "A trackbed liner comprising:
> 1.1 an upper support layer;
> 1.2 a lower support layer; and
> 1.3 at least one filtration layer of a material having a plurality of pores
> 1.4 and which is **normally** impermeable to liquid water, that is in the absence of the load of a vehicle acting on the trackbed,
> 1.5 the filtration layer located between the upper and lower support layers;
> 1.6 in which the pores of the filtration layer are dimensioned so that, in use and under load of a vehicle acting on the trackbed, the filtration layer
> 1.6.1 permits passage of liquid water upwardly therethrough but
> 1.6.2 restricts the passage of solids materials, so as to restrict pumping erosion of material located beneath the liner."

Subsequent claims limited to pores with a maximum dimension of "no more than about 2µm" (claim 3), or 2nm (claim 4), and to the normally impermeable filtration layer becoming permeable on the application of a pressure of at least about 10kN/m^2.

The deputy judge concluded that "normal" conditions included the weight of the ballast, sleepers and rails (but not a train) and the presence of rain water (but not a flood). Capered laying of the geotextile

would mean rain water would drain from the top of the geotextile to the sides and so would not form stands under normal conditions. The skilled addressee, being aware of the rugged circumstance of use, would not care if small amounts of water passed through – 'impermeable' did not have to be absolute.

The deputy judge rejected Fiberweb's case that there was an implicit limitation in claim 1 to a pore size of 2µm or less because there was nothing that implied a specific pore size in claim 1. What was important was that there was a filter substantially preventing the passage of solids, including clay fines.

Fiberweb contended that the patent was invalid over prior art 'Hoare', a patent application published in 1995, more than 15 years before the priority date of the patent in suit. Hoare referred to geotextiles as a potential solution to prevent pumping erosion in some circumstances. It taught the use of a multi-layer structure at the interface between the ballast and the subgrade: an upper layer described as water permeable; an intermediate load-spreading layer having gaps that liquid could pass through; and a lower layer of three possible types. Only one type of lower layer was relied upon by Fiberweb, this type being "water vapour permeable but substantially impermeable to liquid water". In this context, express cross-reference to another publication (Gore) meant that Gore was to be taken as a part of the disclosure of Hoare. Gore was a patent relating to the well-known GORE-TEX material, example 10 being impermeable at lower pressures (below 5PSI/35kPA) and permeable above 10PSI/70kPA.

There was no dispute on the principles governing the assessment of novelty, on which the Deputy Judge cited *General Tire v Firestone*[122], *Lundbeck v Generics*[123], *Synthon v SKB*[124] and *Takeda v Roche*[125]. He agreed with Geofabrics that Hoare (even with Gore) did not read onto the structure described in the patent. It did not describe the use of a filter layer, nor the use of a normally impermeable layer that allowed the upward passage of water under the load of a train. Therefore it did not provide clear instructions to do or make something that would infringe the patent, and so Fiberweb's anticipation challenge failed.

Evalve v Edwards **(substantive)**[126] concerned devices to treat mitral valve regurgitation by a transcatheter technique. Two Evalve patents were in issue. The '850 patent had a priority date in June 2001 and claimed a device adapted for repairing a cardiac valve. The '810 patent had a priority date in May 2004 and claimed a fixation device for engaging tissue.

Prior art 'Deem' was an Evalve application published before the priority date of '850 and sharing some inventors. It focussed on interventional devices for treating mitral regurgitation and contained a large number of proposals, many of them based on the idea of using some kind of temporary grasping device and then a suture or clip to make the permanent fixing.

The evidence in the case established that each of Edwards (in respect of its 'MOBIUS' project), Columbia University and St Jude's (a medical device company) did work based on such an approach

[122] *General Tire & Rubber Co v Firestone Tyre and Rubber Co Ltd* [1972] RPC 457
[123] *H. Lundbeck A/S v Generics (UK) Ltd & Ors* [2008] EWCA Civ 311
[124] *Synthon BV v SmithKline Beecham Plc* [2005] UKHL 59
[125] *Takeda UK Ltd v F. Hoffmann-La Roche AG* [2019] EWHC 1911 (Pat)
[126] *Evalve, Inc & Ors v Edwards LifeSciences Limited* [2020] EWHC 514 (Pat) (12 March 2020) Birss J

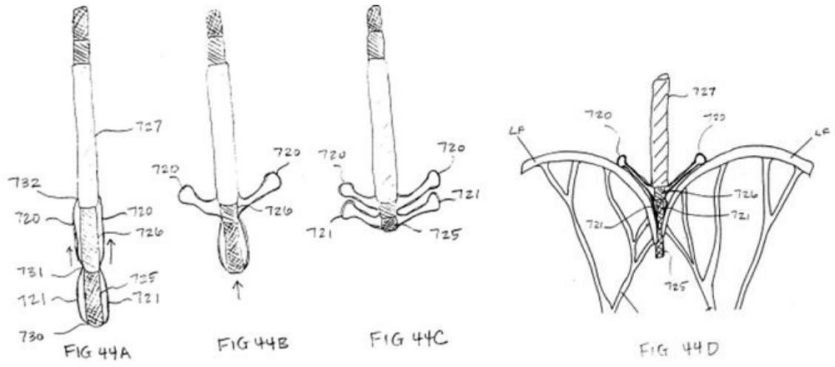
but none had led to a successful commercial product. In light of this, Birss J said ([94]):

> "…it is a reasonable inference, on the balance of probabilities, that trying to use a transcatheter approach to treat mitral regurgitation using a device which relies on piercing the leaflets and leaves behind a suture or rivet type structure, is a blind alley and does not work."

Deem did not form the basis of an anticipation challenge against either '850 or '810, but Edwards contended that '850 was obvious in light of Deem, in particular the disclosure of figure 44. Dismissing the challenge, Birss J said ([106]-[108]):

> "The interventional cardiologist at that time did not know of a working interventional technique to treat mitral regurgitation. As a matter of common general knowledge the most obvious way forward was to try to replicate the successful surgical techniques. They were based on suturing….
>
> Moreover if a team did wish to follow up the idea of a combined fixation/capture device, they would not focus on fig 44 because that is not what it is. It is a temporary grasper. Such a team would follow up figure 46 or fig 87.
>
> In my judgment it is only with hindsight that it might be obvious to set about trying to convert the fig 44 device in Deem into a detachable fixation implant."

A later Evalve patent application ('Goldfarb') formed the basis of lack of novelty and obviousness challenges against '810. In both cases, Edwards' case was based on the figure 18 embodiment of Goldfarb, which contained the same hand-drawn depictions as in figure 44 of Deem:



The main text in Goldfarb describing how the figure 18 embodiment worked and what to do with it (paragraph [0100]) was the same as the corresponding teaching in Deem. As noted above, Deem had been held not to disclose the idea of making the embodiment detachable. However, in Goldfarb, further text (paragraph [0104]) expressly disclosed the idea that any of the captured devices "described above" (i.e. including fig 18) might be detachable and left in place as fixation devices.

Birss J said that the fact that the numerals used in figure 18 for the distal and proximal loops (721 and 720) were different from the ones used in figure 17 would not lead the reader to conclude that the patentee meant that the general teaching at the start of paragraph [0104] did not apply to figure 18. Goldfarb left it to the reader to work out how to apply that teaching to Goldfarb figure 18, but as a matter of disclosure, it was taught.

So *Evalve v Edwards (*substantive) is an interesting example of how fact sensitive the interpretation of prior art can be.

Claim 1 of '810 is set out in section 2b. above, in the context of infringement, in respect of which Evalve/Abbott ran a primary case and a secondary case. When tracking the disclosure of Goldfarb to the language of claim 1, the judge aligned his approach. Evalve/Abbott's 'primary' approach to normal infringement of claim 1 (which led to a finding of non-infringement because integers B & C were not met), when applied to prior art Goldfarb in the context of anticipation, led to a finding of non-anticipation.

Abbott's 'secondary' approach to the normal infringement of claim 1 as granted (which led to a finding of **infringement**), when applied to prior art Goldfarb, still led to a finding of non-anticipation. This was because, on this approach, the requirement of integer C for "a **closed** position wherein the engagement surfaces face each other" was not met. Fig 18C showed the position of Goldfarb's fixation elements when the proximal elements could be said to have closed against them to hold the leaflets, but this was not the closed position of the fixation elements as claimed by the claim. Edwards argued, relying on fig 18D and cross-exam, that in fact Goldfarb disclosed that when the loops gripped the leaflets, the angle which the loops would be set to adopt relative to the shaft would be more acute than shown in fig 18C. But the judge understood the same evidence to be that fig 18D was an illustration and if the mitral valve looked like it then you would have to set the loops to an acute angle of that kind. So the judge was not satisfied that Goldfarb disclosed the idea of setting the loops at an acute angle any smaller than the one shown in figure 18D – it was not taught. (Nor was alternative integer G satisfied).

Birss J then proceeded to consider a number of the dependent claims. In particular, claim 14 required a coupling member for detachably coupling the fixation device to the delivery device. The judge had found this was disclosed in Goldfarb, and in his assessment of novelty he considered whether it had also been enabled by Goldfarb, concluding that it had not been. He explained that the clear and unmistakable directions to make the figure 18 device detachable could be carried out in a variety of ways but this disclosure would only deprive a later claim of novelty if all of those ways necessarily fell within the claim. The figure 18 device could not be made detachable without changing what was shown in figure 18 but the evidence in the case had not examined this question in any depth. It would be necessary to establish that the variety of ways forward would all produce materially the same result. Without working through a particular avenue all the way to the end, one could not say what exactly would be produced. Claim 14 therefore had independent novelty.

Finally, in ***MSD v Wyeth***[127], Meade J had some useful comments on the conceptual difference between anticipation and obviousness. Wyeth's patent concerned the formulation of a 13-valent pneumococcal vaccine and an aluminium salt (as an adjuvant) in order to address aggregation of protein components of the vaccine.

The lack of novelty challenge was over WO 2006/110381 ("Hausdorff 381"), a novelty-only citation. Wyeth did not resist the conclusion that the disclosure of Hausdorff anticipated product claim 1, but it defended the challenge against use claim 6. This led to issues as to the *MOBIL* (G02/88)[128] line of case law.

[127] *Merck Sharp & Dohme Limited v Wyeth LLC* [2020] EWHC 2636 (Pat) (15 October 2020) Meade J
[128] MOBIL/Friction reducing additives (G02/88) [1990] EPOR 73

From the Enlarged Board of Appeal's decision in *MOBIL* the use of an old product for a new use is not anticipated by prior art which does not disclose the new use, even if performance of the prior art would inevitably have the technical result supporting the new use. The parties were agreed that the overall standard for assessing novelty was clear and unambiguous disclosure, and the judge concluded that Hausdorff did not to disclose two features: that the container means (syringe) was siliconized; and the use was to inhibit silicone induced aggregation.

As to the first of these features, MSD argued that common general knowledge syringes were routinely siliconized, or otherwise they would not work. But the judge said ([314]):

> "This would quite clearly be overwhelmingly strong evidence if the issue were one of obviousness, but there is a conceptual difference between anticipation and obviousness, not a difference of a degree. Strong obviousness does not lead seamlessly into anticipation; the tests are different. There is no disclosure of a siliconized container in Hausdorff 381 and so the novelty attack fails for this reason alone."

As to the second of the features, MSD relied on the teaching in two different passages of Hausdorff being combined, but the judge said there was no disclosure that the passages were talking about the same thing. Again, a strong case could be made for obviousness, but that was not enough. Further, although aluminium adjuvants were known as a matter of common general knowledge to be capable, in some circumstances, of reducing aggregation, that did not mean that there was disclosure in Hausdorff. There was no disclosure that were it not for the adjuvant, aggregation would occur. (Wyeth's patent did not, however, survive an obviousness challenge based on different prior art).

c. Obviousness

Historical observations on obviousness

Delving into patent law history can be an enlightening experience. Sometimes it can indicate where senior judges might re-set a path (as Lord Neuberger did in *Actavis v Eli Lilly*[129]). More frequently it can provide helpful support when trying to persuade a judge to follow and develop a particular line of authority. Often the technology in issue decades ago is easier to understand, and sometimes the technology involved or a judge's wit just makes for enjoyable reading.

Geofabrics v Fiberweb[130] (the case about railway trackbed technology) provides an opportunity for a bit of historical delving. In the context of obviousness, Deputy Judge David Stone noted that ([93]):

> "… *Non-Drip v Strangers* [1943] 60 RPC 135 and *British Westinghouse v Braulik* (1910) 27 RPC 209 remain good law: *Technip France SA's Patent* [2004] RPC 46".

In *Non-Drip v Strangers*[131], the House of Lords overturned the Court of Appeal to hold the patent in suit valid (not obvious). Lord Russell of Killowen's judgment in particular is worth revisiting; the principles governing the assessment of obviousness appear to have changed remarkably little in the

[129] *Actavis UK Limited & Ors v Eli Lilly and Company* [2017] UKSC 48
[130] *Geofabrics Limited v Fiberweb Geosynthetics Limited* [2020] EWHC 444 (Pat) (5 March 2020) David Stone
[131] *Non-Drip Measure Coy Ltd v Stranger's Ltd & Ors* [1943] RPC 135

intervening 70 years. *Geofabrics v Fiberweb* was also not the only judgment in 2020 to draw upon it. Lord Russell said ([at 138]):

> "The Plaintiff's patent, which was granted in the year 1936, is for a device for delivering measured quantities of liquid and has for its object (to quote from the specification) 'to provide an improved construction and arrangement capable of adaptation to any liquid container and enabling an exact predetermined quantity of liquid to be supplied to a receptacle at each operation of the device'. Of previous devices used or proposed for this purpose, only two need be mentioned; they are the only ones in any way relevant for our consideration. One was a device, known as an 'Optic', which was the subject of Letters Patent No 298589, granted in the year 1928. It was essentially different from the Plaintiff's patent, being operated by rotating forward and backward what was called a vertical rotatable plug valve, the rotation being effected by manually moving a handle in a plane at right angles to the vertical. Its only importance in the present case lies in the evidence that it was apparently the instrument best known and mostly in use before the Plaintiff's patent, and that in operation it had the following disadvantages, namely, it took up time, it leaked, it was difficult to clean, and at times gave faulty measure.…
>
> Whether there has or has not been an inventive step in constructing a device for giving effect to an idea which when given effect to seems a simple idea which ought to or might have occurred to anyone, is often matter of dispute. More especially is this the case when many integers of the new device are already known. Nothing is easier than to say, after the event, that the thing was obvious and involved no invention. The words of Moulton LJ (*British Westinghouse Coy v Braulik*, 27 RPC 209 at page 230) may well be called to mind in this connection:— 'I confess' (he said) 'that I view with suspicion arguments to the effect that a new combination, bringing with it new and important consequences in the shape of practical machines, is not an invention, because, when it has once been established, it is easy to show how it might be arrived at by starting from something known, and taking a series of apparently easy steps. This ex post facto analysis of invention is unfair to the inventors, and in my opinion it is not countenanced by English Patent Law.'
>
> My Lords, it is always pertinent to ask, as to the article which is alleged to have been a mere workshop improvement, and to have involved no inventive step, has it been a commercial success? Has it supplied a want? Some language used by Tomlin J in the case of *Samuel Parkes & Coy Ld v Cocker Bros Ld*, 46 RPC 241 at page 248 may be cited as apposite: 'Nobody, however, has told me, and I do not suppose that anybody ever will tell me, what is the precise characteristic or quality the presence of which distinguishes invention from workshop improvement. … The truth is that when once it has been found, as I find here, that the problem had waited solution for many years, and that the device is in fact novel and superior to what had gone before, and has been widely used, and used in preference to alternative devices, it is, I think, practically impossible to say that there is not present that scintilla of invention necessary to support the Patent.' As to the commercial success of the Plaintiff's patent there can, in my opinion, be no doubt. In 1935, 430 measures were sold; in 1936, 7996; in 1937, 16700 and in 1938, 18400. In the war years the sales naturally fell off, but the success of the machine was immediate and great. That there was a need for such a machine was clear from the defects in those already on the market. Nor should it be forgotten that as far back as the year 1908 Newland was trying to solve the problem of producing a machine which would deliver measured quantities of liquid without requiring one hand of the operator to be left free to operate the valve. He failed to produce a practical or marketable

machine. It is not until some 27 years have elapsed that the successful machine is forthcoming which achieves the object at which Newland aimed. My Lords, if during that long period it only required a workman to be told to adapt Newland to upward pressure, for him to produce a machine as claimed in the Plaintiff's patent, it is hard to understand why the production was so long delayed. There can, I think, be only one explanation, and it is that before such a machine could be produced an inventive step had to be taken, and that those who took out the Plaintiff's patent were the first to take it."

In the *Geofabrics v Fiberweb* case, the Deputy Judge rejected Fiberweb's challenge of obviousness based on prior art Hoare. Geofabric's expert had maintained under cross-examination that Hoare required a membrane impermeable to water. In order to reach the invention of the patent the person skilled in the art would therefore need to:

- reject the teaching in Hoare that the liner should be substantially impermeable, and instead choose a layer which was permeable under the load of a train;
- use a liner capable of filtering clay fines, contrary to the teaching of Hoare; and
- select a material with pore sizes which made it impermeable to liquid water in the absence of a load, but which permitted upward passage under the load of a train.

The Deputy Judge held that these steps were too significant for the skilled addressee to take without invention; Hoare proposed a very different solution to the patent to the problem of pumping erosion.

Geofabric's patent was also not obvious over prior art 'Jay', a GB patent that described the known use of an impermeable geomembrane sandwiched between two layers of sand, "to prevent water from moving upwardly or downwardly through the geocomposite", and so to prevent hydraulic pumping of underlying water into the ballast. Fiberweb argued that the person skilled in the art reading Jay would know that it would not prevent pumping erosion – slurry would pass laterally through the lower support layer because it could not pass upwards through the impermeable membrane – but that on reading Jay it would be obvious to consider whether lateral loss of water could be prevented. Jay taught (by the wording noted above) that a permeable layer could be used to remove water vertically, and Fiberweb argued that combined with the common general knowledge that geotextiles could be modified to prevent soil particles being washed out of the soil, this made the invention of the patent obvious.

The Deputy Judge noted that this case also required the skilled addressee to ignore the key requirements and teachings of the prior art, in particular to use an impermeable layer. It was "by no means clear" that the skilled addressee would take the steps needed to get to the invention, including of choosing a geomembrane that operated under the load of a train.

The general approach to the assessment of obviousness

In 2019 the Supreme Court affirmed the use of the *Pozzoli* approach in *Actavis v ICOS*[132]. By way of reminder, here is the *Pozzoli* approach as set out by Lord Hodge in *Actavis v ICOS* ([60]):

"(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;

[132] *Actavis Group PTC EHF v ICOS Corporation & Anr* [2019] UKSC 15 at [60]

(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?"

In the last substantive judgment of 2020, ***Fisher & Paykel v Flexicare***[133], Meade J provided a pithy summary of the principles governing the assessment of obviousness in light of *Actavis v ICOS* ([151]):

> "i) There is a single statutory question: whether the invention is obvious, having regard to the state of the art at the priority date.
>
> ii) In some cases the *Pozzoli* [2007] EWCA Civ 588 approach is helpful, and subject to a point I address below, both parties argued their positions by reference to it.
>
> iii) The Supreme Court endorsed the statement of Kitchin J (as he then was) in *Generics (UK) Ltd v H Lundbeck A/S* [2007] EWHC 1040 (Pat) at [72]…"
>
> > "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."

Meade J also noted that the identification of the inventive concept can be difficult and is not mandatory[134].

The rest of the patent case law from 2020 elaborates upon this basic position without changing it. Yet leaving the discussion of obviousness at this point would fail to do justice to the useful contributions made by many different judges. In particular, discussion of the year's case law would be lacking without a decent look at the Court of Appeal's judgment in ***Emson v Hozelock***[135], in which Arnold LJ and Floyd LJ could not agree on how the principles applied.

In April 2019, Nugee J handed down the first instance judgment in the case[136], which concerned a new type of garden hose. He concluded that Emson's two patents in issue were invalid for obviousness over prior art 'McDonald'. This differed from the conclusion reached by Birss J and the Court of Appeal in earlier litigation (*Blue Gentian v Tristar*[137]) involving the same patents and an obviousness challenge based on McDonald. So it is probably no surprise that the *Emson* case went to the Court of Appeal. Arnold LJ gave the leading judgment, confirming the conclusion of obviousness; Floyd LJ dissented.

McDonald was a US patent application that described a way of providing oxygen to crew on an aircraft.

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[133] *Fisher & Paykel Healthcare Limited v Flexicare Medical Limited & Anr* [2020] EWHC 3282 (Pat) (8 December 2020) Meade J
[134] *MedImmune v Novartis* [2012] EWCA Civ 1234 at [86]; *Conor v Angiotech* [2008] UKHL 49 at [19] ([153])
[135] *E. Mishan & Sons, Inc v Hozelock Limited & Ors* [2020] EWCA Civ 871 (8 July 2020) Floyd, Henderson & Arnold LLJ
[136] *E. Mishan & Sons, Inc t/a Emson v Hozelock Limited* [2019] EWHC 991 (Pat)
[137] *Blue Gentian LLC v Tristar Products (UK) Ltd* [2013] EWHC 4098 (Pat); [2015] EWCA Civ 746.

Emson's new type of garden hose comprised 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 expanded but the outer tube constrained the extent of the expansion, both the longitudinally and radially. As the outer tube expanded, its ruffles unfurled; and the ruffles reformed when the pressure was released and the hose assembly contracted.

Arnold LJ and Floyd LJ were agreed that the commercial success of Emson's invention did not assist Emson in defeating the obviousness attack based on McDonald. The commercial success was due to the "breathtaking ingenuity" of the invention, bringing with it real practical advantages, over what was available and the common general knowledge. However, the relevant consideration was how commercial success forebore on the particular allegation of obviousness. McDonald was neither common general knowledge nor shown to have been known to some in the field in question.

On the question of obviousness over McDonald, **Floyd LJ** considered that the judge had made "a fundamental error of principle" in treating the document as a real, practical machine (i.e. something that had been made and tested), as opposed to a mere paper proposal, that this was hindsight, and that it had infected the judge's reasoning and his treatment of the evidence.

Stepping back to overarching principles, Floyd LJ said ([87]):

> "It is undoubtedly the law that an invention may have been published in, or rendered obvious by, a document which no person skilled in the art would ever be likely to have seen. The award of a monopoly is not available if such a document exists and the person skilled in the art could have access to it, whether or not in the real world anybody would ever have taken that opportunity, or read it. The policy justification for the rule, which is in essence a "deeming provision", is that once the possibility exists that a skilled person could obtain the document and consider what to do in the light of it, a subsequent patent should not interfere with his freedom to take it forward, either as precisely directed by the document or in ways which are rendered obvious by it. The policy justification does, however, lose its force in the situation, of which this case is an example, where the evidence establishes positively that the person skilled in the art would not even look for the document. The net result of the application of the rule to such a case is that the person who delivers the benefit of the invention to the consuming public is deprived of his monopoly in order to protect a right which would never in fact be exercised."

Floyd LJ said that judges had in the past bridled at the harshness of this rule and found ways of mitigating its penal nature. For example, in *Inhale v Quadrant*[138], Laddie J said that the more distant a prior art document was from the field of technology covered by the patent, the greater the chance that an intelligent but uninventive person skilled in the art would fail to make the jump to the solution found by the patentee and would simply dismiss the prior art as irrelevant. To this, Floyd LJ added ([90]):

> "If the art is facing a particular unsolved problem, then a reading of a prior document from a wholly different field which suggests a specific solution to that problem may indeed cause the skilled person to seize on it. But the same is not true merely because the remote document discusses a design consideration which is also a design consideration for his own field. The skilled person may have common general knowledge ways of satisfying the design consideration in his field, so that achieving it is no longer a problem that he faces."

[138] *Inhale Therapeutic Systems Inc v Quadrant Healthcare Plc* [2002] RPC 21 at [47]

Floyd LJ said that a second factor which can in many cases mitigate the unfairness of the rule is that **documents which have not resulted in practical application have less force in an obviousness argument than those which have been implemented or are well known**, citing dicta from Jacob LJ in *Grimme v Scott*[139] and *Ferag v Muller Martini*[140], which Floyd LJ said was "obviously right". He continued ([93]):

> "Unless the difference between the document and the invention is entirely trivial, it is not right to assume that a paper proposal could be successfully implemented when there is no evidence that it has in fact been implemented over a substantial period. It is no answer to say that the document says that it works: most documents describing apparatus will say that. Without a degree of assurance that a proposal is a practical one, there is little if any basis for a skilled person to consider adapting it in any way."

Floyd LJ thought that Arnold LJ (as Arnold J) had made a similar point in the context of the value of confidential information to be attributed to a mere paper proposal in *Vestergaard v Bestnet*[141]. He continued ([94]):

> "Particular care is needed with unworked proposals in patent specifications. A patent specification is not a declaration of what a patentee has done: it is a description of an idea."

Additionally, Floyd LJ said that the case law contained many well-known warnings about the dangers of hindsight and of being mis-led by apparent simplicity, for example in *Siddell v Vickers*[142]; *Non-Drip v Strangers*[143] and *Technip France SA's Patent*[144].

Floyd LJ considered that the judge had made a number of "fundamental errors of principle" in arriving at his conclusion of obviousness in light of McDonald. As well as treating McDonald as a real, practical machine, as opposed to a mere paper proposal, although there was no evidence it had been made in the 8 years from its publication to the priority date, the judge's analysis of the evidence assumed that the skilled person read McDonald's untested proposal completely uncritically and took as read the statement that the hose self-retracted, even though he could not understand properly how this could be so. Floyd LJ questioned why the person skilled in the art would start to contemplate the application of McDonald's untested idea to a different application if unpersuaded that it would work for its own purpose. He said there was "all the difference" between transposing a hose structure shown to have worked well in the different field, and transposing a mere paper proposal from that field. Overall, Floyd LJ's view was that the judge had been "misled" into treating a paper proposal as if it were something which had been made and tested. This was redolent of the use of hindsight.

Floyd LJ thought that the judge's focus on the space saving advantages of McDonald was also infected by hindsight. Further, the judge had been wrong in principle not to attach any weight to the fact that the design of garden hoses had not changed in many decades ([115]):

> "Just as the judge was astute to clothe the skilled person with real world characteristics (namely exposure to technical hoses), so also the judge ought to have recognised that the skilled person's interest was in an industry where there had been no innovation in the design

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[139] *Grimme Maschinenfabrik GmbH v Scott (t/a Scotts Potato Machinery)* [2010] EWCA Civ 1110
[140] *Ferag AG v Muller Martini Ltd* [2007] EWCA Civ 15
[141] *Vestergaard Frandsen A/S & Ors v Bestnet Europe Ltd & Ors* [2009] EWHC 657 (Ch)
[142] *Siddell v Vickers, Sons & Co. Ltd* (1890) 7 RPC 292 at 304 (HL)
[143] *Non-Drip Measure Co Ltd v Stranger's Ltd & Ors* [1943] RPC 135 at 142
[144] *Technip France SA's Patent* [2004] RPC 46

> of the hosepipe itself (as opposed to its fittings) for decades. Although the judge found that the skilled person was used to adapting a hose found useful in one application to another application, this is obviously not something which had happened in garden hoses, at least for a very long time. It was at least material to ask the question why this was, rather than to dismiss it as irrelevant. The idea that the notional, unimaginative skilled person with an interest in this industry would seize on an untested proposal from a "very particular and very distant field" has the air of unreality when no ideas (even practical ones) appear to have been so transposed for so long."

Nugee J had concluded that there was nothing to put the skilled person off "seeing that this new type of hose might have wider application". However Floyd LJ considered this not to be the correct question. Rather, the correct question was whether there was anything to cause him to make the connection. Floyd LJ's view was that this was not merely a linguistic error on the part of the judge.

Arnold LJ took what might be considered a more clinical approach to his review of Nugee J's reasoning. He began by confirming the judge's view that, strictly speaking, the previous decisions were not admissible evidence on any question of fact arising in the present case. The function of the judge was to decide the case before him on the evidence adduced by parties. The evidence in the present case was materially different to that in the previous case. Arnold LJ also noted that since obviousness involves a multi-factorial evaluation, the Court of Appeal is not justified in intervening in the absence of an error of law or principle on the part of the judge (*Actavis v ICOS*[145]).

The judge had adopted the *Pozzoli* approach and in this context Arnold LJ noted:

Pozzoli Step 2 (identify the inventive concept): the judge's finding was not challenged - it was an expandable garden water hosepipe comprising of a non-elastic outer and an elastic inner, that were joined together at their ends and that between the ends were unattached.

Pozzoli Step 3 (the differences between McDonald and the inventive concept): the judge's finding was not challenged – the differences were: that McDonald was not a garden water hose assembly and so did not expand by the operation of water pressure; and that McDonald did not have a water-flow restrictor.

Pozzoli Step 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?): this was where the challenge was.

The judge had accepted the evidence of Hozelock's expert, Mr Doosterlink, that the general hose designer would be well used to designing hoses for both liquids and gases, and would have no difficulty in appreciating that the way in which the McDonald hose worked, by being pressure-actuated, did not depend on the type of fluid used.

Emson's first ground of appeal was that the judge had erred in principle because he conducted an *ex post facto* hindsight-based analysis, and moreover one based upon the evidence of Mr Doosterlinck, which was tainted by hindsight. (The second ground was that the judge had erred in principle in failing to take commercial success into account when assessing obviousness – as noted above, the Court of Appeal unanimously dismissed this ground).

[145] *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15

Arnold LJ observed that the judge was clearly conscious of the need to avoid hindsight as he had expressly noted it. Emson argued that the judge's reasoning nevertheless did involve hindsight despite his attempt to avoid it – an argument that Arnold LJ said required the Court of Appeal to consider every step of that reasoning in detail. It was therefore important to keep in mind throughout that the question for the Court of Appeal was not what its evaluation of the issue would have been had the Court of Appeal been in the judge's position, but whether the judge had fallen into error.

Emson had submitted that McDonald was addressing issues that did not arise with garden hoses, and in particular the need for aircrew to don gas masks in 5 seconds or less; so there was only a small overlap between the problem addressed by McDonald and those addressed by the patent. But the fact remained that the problem addressed by McDonald's hose was saving space and that was also the first problem addressed by the patents. If an invention was obvious for one reason, the fact that it also had other, non-obvious, benefits was immaterial[146].

Emson had submitted that in view of the mindset of the person skilled in the art, they would be unlikely to make the leap to a garden hose; and the judge's reasoning here also amounted to hindsight. The judge had said ([180] of [2019] EWHC 991 (Pat)):

> "Whatever his mindset as to how garden hoses were usually constructed, I do not see that this would put him off seeing that this new type of hose might have wider application, including to garden hoses."

Arnold LJ said that Emson's complaint that the words "put off" betrayed hindsight was purely a linguistic point: if the judge had used instead 'prevent', it would not have altered his reasoning. So there was no error in the judge's approach, whether of hindsight or otherwise, and the conclusion was open to him. There was no evidence of blindness or prejudice in the present case, or that the industry was resistant to innovation. (This, of course, was a key point on which Floyd LJ disagreed).

The judge had also dismissed Emson's submissions that a number of features of McDonald were confusing. In particular, that the skilled person would not see the teaching of McDonald as being tied to any particular diameter or gas pressure, or as disclosing how the gas flow was initiated, or as disclosing details as to how the hose retracted; and the skilled person would be required to work with unfamiliar materials. However Arnold LJ's view was that there had been no error in the judge's approach when concluding that the skilled person would readily be able to make the necessary adaptions to turn McDonald into a garden hose. In particular, the judge had been well aware of the principle that the prior art must be read properly and in that sense with interest (*Asahi*[147]) and had not cherry-picked the parts supporting obviousness while ignoring all the inconvenient difficulties with the details; and as a matter of principle, if hindsight could not be demonstrated by examining the judge's reasoning in his judgment, then it was not legitimate to compare his reasoning with that of another judge based on different evidence in another case (the *Blue Gentian* case and the EPO opposition).

Arnold LJ then turned to consider three points relied upon by Floyd LJ but which "did not form part of counsel's submissions".

First, Arnold LJ said that it was a relevant consideration that McDonald had not been commercialised, but the force of this consideration depended crucially on two factors. If the prior art had been "long

[146] *Hallen Co & Anr v Brabantia (UK) Ltd* [1989] RPC 307, [1991] RPC 195
[147] *Asahi Medical Co Ltd v Macopharma (UK) Ltd* [2002] EWCA Civ 466

disregarded", this invited the question as to why. Drawing on *Grimme*, Arnold LJ said ([72]):

> "…the age of the prior art is a relevant consideration in considering obviousness: other things being equal, the older the prior art, the less likely it is to contain teaching which assists in solving current problems. This is reinforced if the prior art is known to those in the field, because it makes it more likely that skilled persons have not found it to be of assistance. In *Grimme* the prior art in question (Spatz) had been published as long ago as 1960 and was acknowledged in the patent. In the present case McDonald was only eight years old at the priority dates of the Patents; and the evidence was not that McDonald had been disregarded, but that, as discussed in more detail below, it was unknown to those in the hose industry."

If the prior art had been "unused", that invited the question as to why, which could cast doubt on its teaching and/or the applicability of that teaching to the problem at hand ([73]):

> "In *Grimme* not only had Spatz not been commercialised, but also the patent began by identifying problems with Spatz. In the present case it is a matter for speculation as to why McDonald was not commercialised, but the evidence did not establish that the reason for this was because the hose did not work."

Second, Arnold LJ rejected a point that the problem of providing a compact space-saving hose had already been solved. *Inter alia* there was no evidence to this, Emson's patents stated it as a problem to be solved, and Emson's own case was that the commercial success of its Xhose was attributable, at least in part, to its space-saving properties.

Third, Arnold LJ rejected the suggestion that the allegation of obviousness involved a step-by-step analysis of the kind deprecated by Fletcher Moulton LJ in *British Westinghouse v Braulik*[148] (subsequently approved in *Non-Drip v Strangers* and *Technograph v Rockley*[149]), saying ([75]):

> "Where getting from the prior art to the claimed invention involves a number of steps, the dangers of hindsight are particularly acute even if each step is simple in itself. In the present case, however, it only requires a single step to get from McDonald to the claimed invention. Moreover, McDonald's hose is as simple in conception as the hose described and claimed in the Patents."

Stepping back, Arnold LJ expressed sympathy with the inventor of the patents but explained the balances (and need for balance) in the patent system ([76]):

> "…the patent system aims to incentivise technical innovation, and investment in and disclosure of such innovation, by conferring limited monopolies. Monopolies are generally contrary to the public interest, however, because they prevent competition. Patent law contains a number of mechanisms which are designed to strike a balance between these conflicting considerations. Amongst these mechanisms are the requirements of novelty and inventive step (i.e. non-obviousness): in order not to fetter competition unduly, the public is deemed to have the right to do anything which is disclosed by, or obvious in the light of, any item of prior art, no matter how obscure, which was made available to the public anywhere in the world before the relevant date, without infringing a patent. For that reason, when attacking the validity of a patent, the party doing so is allowed to select the prior art used as the

[148] *British Westinghouse Electric and Manufacturing Co v Braulik* (1910) RPC 209
[149] *Technograph Printed Circuits Ltd v Mills and Rockley (Electronics) Ltd* [1972] RPC 346

> foundation for the argument with 20/20 hindsight. To that extent (but only to that extent), hindsight is not merely permitted, but an inherent feature of the current design of the European patent system (and indeed, of most patent systems worldwide). It inevitably follows that some patents turn out to be invalid because, unbeknownst to the inventor, or indeed other persons skilled in the relevant art, prior art emerges when sufficient searches are carried out which anticipates or renders obvious the claimed invention."

Arnold LJ therefore concluded that he could not see any error in the judge's approach, whether of hindsight or otherwise, and the judge's conclusion had been one that was open to him. He was supported in that decision by Henderson LJ and so prevailed against Floyd LJ in the battle of the IP giants. For my part, had I been sitting the score would have been 2-2 and penalties would have been required. I think that Floyd LJ got it right and Arnold LJ was far too strict in his interpretation. Floyd LJ cited the case of *Dyson v Hoover*[150] in support of his position and I must say that was the first case which sprung to my mind by way of relevant analogy. Whilst fact-matching is a dangerous game, there were clear parallels between the potential relevance of large scale cyclonic dust extractors found in mines, and the McDonald hose designed for use in the aviation industry – not someone's back garden.

Note that it is not only inexperienced judges who invoke aged case law – Floyd LJ wheeled out authorities from 1890 and 1943 to support his contentions.

***Pozzoli* step 2 – identify the inventive concept**

In ***Optis v Apple* (16 October 2020)**[151]*,* the case about handover between different radio access technologies (i.e. GSM (2G) and UMTS (3G)), Birss J addressed the second *Pozzoli* step, saying ([152]):

> "Identifying the inventive concept involves the same kinds of considerations as identifying the technical contribution made by an invention and as identifying the problem to be solved in a problem/solution analysis. These three things relate to one another although they are not necessarily the same thing."

In the Court of Appeal's judgment in *Pozzoli*[152] Jacob LJ said that in the end what matters is/are the difference(s) between what is claimed and the prior art. In *Actavis v ICOS*, the Supreme Court rejected a submission (made in reliance upon *Conor v Angiotech*[153]) that in all circumstances, obviousness must be assessed by reference to the precise wording of the claim. Also, in 2019, in *Takeda v Roche*[154], Birss J said that if '*AgrEvo'l*'lack of technical contribution' obviousness is in issue, the question for the expert is what, if anything, does the patent make by way of a technical contribution over the state of the art.

There would seem also to be a conceptual overlap between the identification of the inventive concept for the purposes of *Pozzoli* step 2 and the assessment of infringement under the doctrine of equivalents, in particular the first of the 'reformulated questions' described by Lord Neuberger in *Actavis v Eli Lilly*[155]*.* Lord Neuberger focused on the inventive concept of **the patent** – and so on the

[150] *Dyson Appliances v Hoover* [2001] RPC 27 and on appeal at [2001]EWCA Civ 1440
[151] *Optis Cellular Technology LLC & Ors v Apple Retail UK Ltd & Anr* [2020] EWHC 2746 (Pat) (16 October 2020) Birss J
[152] *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588 at [19]
[153] *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] UKHL 49
[154] *Takeda UK Ltd v F.Hoffmann La-Roche AG* [2019] EWHC 1911 (Pat)
[155] *Actavis v Eli Lilly* [2017] UKSC 48 at [66]

facts of that case the inventive concept was pemetrexed + vitamin B12, although the claim language was to pemetrexed disodium + vitamin B12. The *Actavis v Eli Lilly* case only addressed infringement, not validity. In 2020 in ***Akebia v Fibrogen***[156], Arnold LJ paraphrased the first reformulating question as addressing the inventive concept of the relevant **claim(s)** of the patent.

2020 also saw Birss J introduce a new structure to his analysis of questions of infringement and validity, which highlights the conceptual overlap between the second question of the *Pozzoli* approach and the assessment of infringement on the doctrine of equivalents. In ***Evalve v Edwards* (substantive)**[157]and ***Edwards v Meril***[158]**,** Birss J considered issues of construction and infringement on the normal interpretation, then the invalidity challenges based on the prior art, and then questions of infringement on the doctrine of equivalents. In his equivalents analysis (reformulated question 1), he then drew upon the inventive concept he had settled upon for the purposes of the *Pozzoli* analysis.

***Pozzoli* step 3 – the differences between the state of the art and the inventive concept**

Later in the year, in ***Communisis v The Tall Group***[159], HHJ Melissa Clarke continued her run of helpful revision of basic principles with some words on obviousness in the case about a security measure for cheques. She started with the basics, explaining that it is convenient to assess inventive step using the *Pozzoli* approach but that it is also important to remember the statutory question, which still applies. Underpinning *Pozzoli* step 3 is the interpreting of the disclosure of the prior art. As to how the person skilled in the art approaches prior art documents, HHJ Melissa Clarke said ([30]):

> "The skilled person reads prior art documents with interest but is unimaginative and has no inventive capacity. He may be a team of persons with differing expertise, or a single person with all the practical knowledge and experience needed."

Further ([92]):

> "The skilled reader is reliably careful, reading prior art assiduously (per Jacob LJ in *Rockwater v Technip* [2004] RPC 46 at [79]) with interest and understanding (per Lord Reid in *Technograph Printed Circuits Ltd v Mills & Rockley (Electronics) Ltd* [1972] R.P.C. 346 at p.355), and what is important is what the prior art says. What it says is what it discloses, and the skilled person can be taken to have understood it in the absence of obvious error and subject to the Court determining any ambiguities in the wording."

HHJ Melissa Clarke agreed with The Tall Group that Communisis' expert, Mr Brewer, had not attempted *Pozzoli* step 3. Instead he had made comparisons of the whole of the prior art documents with the patent at a general level in a way which did not assist the court. His evidence had not accorded with Communisis' pleaded case. He had also resiled from aspects of it. (Not a good start – and another reminder of the need to keep in mind the correct legal test when preparing expert evidence).

There were three challenges of obviousness over prior art. Prior art 'Martens' was also concerned with

[156] *Akebia v Fibrogen* [2020] EWHC 866 (Pat) at [419]
[157] *Evalve, Inc & Ors v Edwards LifeSciences Limited* [2020] EWHC 514 (Pat) (12 March 2020) Birss J
[158] *Edwards Lifesciences Corporation & Anr v Meril GmbH & Anr* [2020] EWHC 2562 (Pat) (29 September 2020) Birss J
[159] *Communisis Plc v The Tall Group of Companies Limited & Ors* [2020] EWHC 3089 (IPEC) (17 November 2020) HHJ Melissa Clarke

cheque technology. It stated ([87]):

> "The checks [meaning cheques] are specially designed to prevent fraud such as alterations of the payee, amount and multiple deposits. **In addition to the encryptions imprinted on the check, a secret key and a plurality of digital signatures are generated based on the concatenated branch number, account number and check number.** Furthermore the new kind of checks described in this invention will also make fraud much harder when traditional methods of depositing are used."

The only issue was whether generation of the code by conversion to a higher base (integer 1.5) was obvious in light of Martens' disclosure – the other claim integers were agreed to be disclosed by Martens. Communisis argued that the purposes of the patent and Martens were different: the purpose of the patent was to ensure the integrity of the Personalisation Data and so to validate the origin of the cheque; whereas the purpose of Martens was of ensuring *inter alia* that the amount of the cheque was part of the validation, improving the security of the Drawer Data. The judge disagreed, saying ([92]):

> "As I think I made apparent to Counsel before this submission was made, I had identified the two parts to the invention in Martens when carrying out my own pre-trial reading of that patent: it is in no way hidden or ambiguous, and I have no doubt the notional skilled person would understand that is what it discloses."

Interestingly, the defendants' expert, Professor Landrock did not "pick up" this point or "realise that it was important" when preparing his evidence on the subject. But the judge did not agree with Communisis that this meant the second part of the invention was not something a skilled person would understand or focus on.

Turning to the question of whether it was obvious that a code could be generated by converting the Personalisation Data into a higher base, Communisis' case was that such conversion provided poor security from a cryptographic point of view and would not be considered as a practical method of fraud prevention by the person skilled in the art, therefore it was not obvious to the person skilled in the art. On this, the judge said ([95]):

> "It seems to conflate two questions posed to the skilled person: (i) "is it obvious?" and (ii) "would you use it?". It is only the former which is relevant to the question of inventive step."

The judge concluded that the step was obvious. Conversion to a higher base would produce a code in more compact form. So as the skilled person would understand that there was limited space in the cheque, it would have been obvious to do this.

Continuing on the relevance of "would" in the test for obviousness, HHJ Melissa Clarke said ([97]):

> "However, if you asked the skilled reader whether he **would** generate the code by conversion to a higher base, I expect he would respond, as these experts have suggested, "Well, you could, but that wouldn't produce very good security and I wouldn't do it. I would use better cryptography." As I have stated, that doesn't detract from my finding of obviousness."

The Tall Group's other challenges of obviousness succeeded too, for similar reasons.

Continuing with the skilled person's approach to the prior art in the context of *Pozzoli* step 3, the nature of the prior art was particularly pertinent in ***Neurim v Generics* (4 December 2020)**[160]. This was the case about Neurim's patent to second medical use of melatonin for improving the restorative quality of sleep. One of the obviousness challenges made was based on information made on a webpage for 'Melatonex'. Melatonex was a dietary supplement containing melatonin and the webpage stated ([90]):

> "…MELATONEX supplementation can help to restore the melatonin we need for a restful, natural sleep…"

The webpage included a disclaimer, saying that the statements contained had not been evaluated by the Food and Drug Administration (FDA) and the product was not intended to diagnose, treat, cure or prevent any disease.

The experts appeared to agree that the Melatonex webpage amounted to no more than advertising copy. Nevertheless, Mylan's expert opined that it would motivate the person skilled in the art to conduct further research, and they would conduct a trial of melatonin doses with a reasonable expectation of showing an improvement in the subject's experience of getting to sleep, maintaining sleep and non-restorative sleep.

Neurim's expert's evidence was that the skilled person would not consider the Melatonex webpage to provide any legitimate information relevant to their clinical practice, including to treating a patient suffering from primary insomnia. It provided no scientific data or any other form of support for the claims made, and at the priority date, the expert said that he would have been highly sceptical of the claims and information provided and would not have given the document any weight.

The judge said that it had to be taken into account that the Webpage "emphatically was not a respected publication: it was an advertisement for a non-medicament". There was no suggestion in the webpage that the product would be of benefit to those suffering from primary insomnia, and there was no reference whatsoever to non-restorative sleep. Mylan's expert's suggestions that the advertising "puff" could be construed as having technical meaning, and that it would motivate the skilled person to conduct further research, were "fanciful" and the patent was "plainly not obvious" over it.

The skilled person's approach to the prior art was considered in some depth by Birss J in ***Evalve v Edwards* (substantive)**[161], in particular on the approach to the assessment of an obviousness challenge based on a selected embodiment of a prior art patent document.

The outcome for the obviousness challenge based on figure 18 of prior art Goldfarb is discussed above (in section 3b.) immediately following the discussion of the lack of novelty challenge based upon the same embodiment. Edwards contended that the legal question was what was obvious in light of the embodiment relied upon when read in the context of the whole document and the common general knowledge. Birss J disagreed ([254]-[255]):

> "In my judgment Edwards' submission about the law is wrong. There is nothing in the legislation which requires that the context in which a discrete piece of information has been

[160] *Neurim Pharmaceuticals (1991) Limited & Anr v Generics UK Limited (trading as Mylan) & Anr* [2020] EWHC 3270 (Pat) (4 December 2020) Marcus Smith J

[161] *Evalve, Inc & Ors v Edwards LifeSciences Limited* [2020] EWHC 514 (Pat) (12 March 2020) Birss J

disclosed should be ignored, as a matter of law, when considering it as a starting point for an obviousness analysis. As a matter of fact a piece of information disclosed in isolation may well be regarded differently by skilled people from the same piece of information disclosed as part of a larger work. Although the obviousness analysis is necessarily artificial in a number of ways and the skilled person is a legal construct, there is nothing in the law which precludes that result or renders it necessarily irrelevant. Both sides must take the prior art as they find it.

The skilled person is presented with the prior art and reads it with interest. As a matter of law they read it all and they never tire when doing this. That satisfies the policy identified by Edwards because it means that all the words, pictures, paragraphs and embodiments in a document, even those buried a long way inside, are part of the state of the art and are available as potential starting points, in principle. This is so even if in the real world actual skilled people would never have read the document or would have started skimming after the first page. However once the notional skilled person has read the whole document, including what is (with hindsight) the important paragraph, what they do then will be a question of fact. They may put the whole thing down and walk away. There may be a number of obvious avenues to take forward. The obvious avenues may include the one the defendant wants or it may not. The perceived qualities of one route may or may not have an effect on the attractiveness of another route as a place to start. The fact one route is a very attractive and obvious place to start does not, either as a matter of law or in fact, mean that other routes may not be obvious places to start too."

Birss J then reiterated comments he made in 2016 in *Unwired Planet v Huawei*[162] that while "the mere existence of alternatives is not in itself an argument against obviousness" (from *Brugger v Medicaid*[163]), the correct proposition about alternatives is the statement of Kitchin J in *Lundbeck v Generics*[164] (noted above). Birss J continued ([258]):

"Kitchin J's words were approved by Lord Hodge in *Actavis v ICOS* [2019] UKSC 15 at paragraph 63 as illustrative of the kinds of factors which could be taken into account, and not exhaustive. Lord Hodge went on at paragraph 69 to expressly approve the point from *Brugger* that "if a particular route is an obvious one to take or try, it is not rendered any less obvious from a technical point of view merely because there are a number, and perhaps a large number, of other obvious routes as well". In other words the legal principle is the one identified and approved by Lord Hodge but that principle does not mean that the existence and attractiveness of alternative routes, in other words the context in which a disclosure is made, is by law irrelevant. Quite the contrary."

And so when assessing obviousness over the cited prior art, the notional skilled person reads the whole document, including the parts/embodiments relied upon by the party contending invalidity. It is not permissible to pre-empt the question of what the skilled person would then do by focusing the challenge on a particular part/embodiment of the disclosure of the prior art document. Embodiments to not offer a leap-frog over the general approach.

[162] *Unwired Planet International Ltd v Huawei Technologies Co., Ltd & Ors* [2016] EWHC 576 (Pat)
[163] *Brugger & Ors v Medic-Aid Ltd* [1996] RPC 635 at 661
[164] *Generics (UK) Limited & Ors v H. Lundbeck A/S* [2007] EWHC 1040 (Pat)

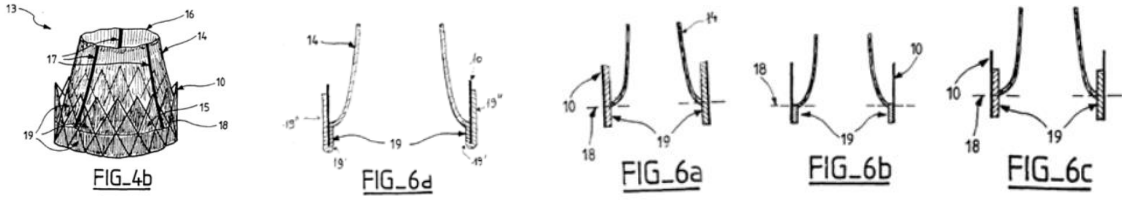
Mosaicing

Another point relevant to *Pozzoli* step 3 is the permissibility of mosaics, and this was addressed in ***Edwards v Meril***[165]***.*** The case concerned technology to mend the aortic valve of the heart. Edwards' '753 patent was to a prosthetic heart valve; Edwards '929 patent was to a delivery system for delivering such a valve.

Against the '753 patent, Meril's obviousness challenge was based on a PCT application ('Cribier'). Cribier cited (only) 'Andersen US', which it also discussed. The aspects of Andersen relied upon were central to Cribier; Andersen was also common general knowledge.

The judge said that the combination challenge was therefore permissible. But (for the future) if the argument had involved trying to put together passages buried in the Andersen patent (and not common general knowledge) with other less than central parts of Cribier, then there might have been a significant mosaicing problem.

Cribier disclosed an implantable valve comprising an occluder set in a stent frame, the valve structure of which was described as a collapsible continuous structure which included guiding means for stiffness. A number of examples were given as to how to configure the lower part of the device and attach the valvular structure to the frame ([118]-[120]):



Cribier also critiqued features of the Andersen US design.

Birss J noted that the '753 patent was directed generally to expandable heart valves and identified two specific embodiments. The first, assembled prior to storage, was depicted as follows:

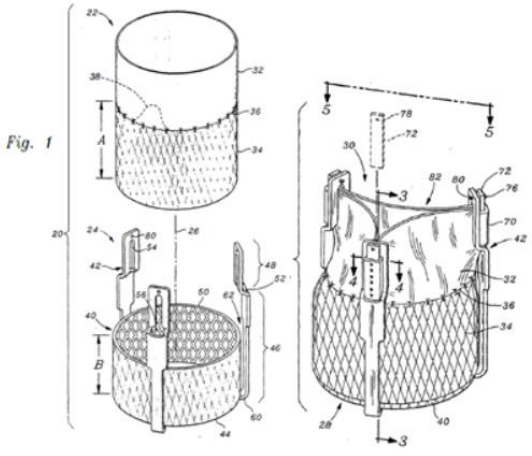


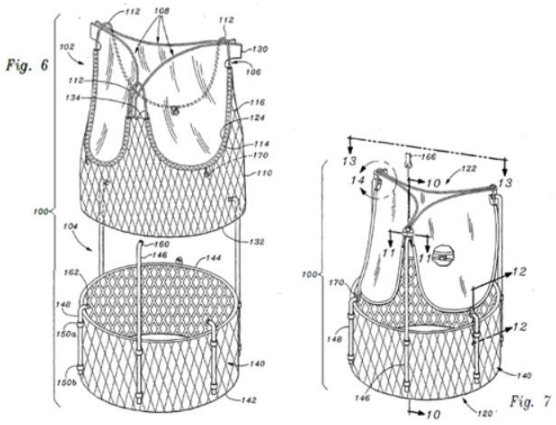
Figure 1 Figure 2

Tubular member 22 had a leaflet section 32 attached to a fabric section 34. The tubular member 22 was fitted to the support stent 24 between the support stent's tubular base 40 and the three

[165] *Edwards Lifesciences Corporation & Anr v Meril GmbH & Anr* [2020] EWHC 2562 (Pat) (29 September 2020) Birss J

commissure posts 42. Assembled this way, the leaflet section was attached to the commissure posts. The axial length of the fabric section 34 of the tubular member was a bit more than the axial length of the tubular base. The leaflet section 32 was not in contact with the base 40, thus increasing the life of the valve. The plurality of leaflets were defined between the commissure posts. The leaflets formed a continuous tube.

The second embodiment was depicted as follows ([79]):



The two parts were stored separately for assembly just prior to delivery. The tissue engaging base 104 had commissure posts 146 (as well as cusp posts 148) on the exterior of a tubular member 140. The leaflet sub-assembly 102 comprised a wireform 106 supporting a plurality of prosthetic leaflets 108 and a fabric skirt 110. Each leaflet was attached to the commissures and along the entire arcuate cusp. When assembled, the bottom of the leaflets was higher than the top of the tubular member 140. The fabric skirt was on the outside of the tissue engaging base 104. The leaflets in this embodiment were separate.

With reference to *Pozzoli*, Birss J noted the differences from Cribier to claim 1 as being:

i) Cribier did not disclose commissure posts. Birss J said this was because the truncated hyperboloidal valvular structure did not need them for attachment to the frame. For that reason only, features B and D of claim 1 were not disclosed by Cribier.

ii) Cribier did not disclose the use of fabric for the internal cover. It only disclosed the internal cover, and not the rest of the valvular structure, contacting the tubular base, and the internal cover was not described as made of fabric.

The judge dismissed any inventiveness as residing in the use of fabric. In view of the evidence, the idea of using fabric was obvious given that the structure would need to be crimped and expanded. Further, with an internal cover made of fabric, the skilled person would make it in such a way that the fabric was attached to the frame and the leaflet material was attached to the fabric, as per figure 6d of Cribier.

Essentially, Cribier disclosed feature E of claim 1, which was the characterising feature that distinguished it from Andersen. Both Andersen and Cribier disclosed a different combination of features and claim 1 was yet a further combination of "more or less the same features".

Stepping back, the judge said ([130]):

> "New combinations of known features can most certainly amount to subject matter which involves an inventive step, but they may not. It depends on the facts and detailed circumstances."

Meril argued that using the three leaflet designs as in standard (known) surgical valves, the leaflet commissures would be attached to the stent frame with the commissure posts. With an internal cover as well, the device would fall within claim 1 and so the patent would be invalid for obviousness.

Edwards argued that Meril's approach was tainted with hindsight; and that it failed to face up to Cribier's criticisms of the Andersen design. These included that the Andersen design was inherently fragile, both in the frame and the valve structure, with a number of consequences, including a risk of "massive regurgitation" through the spaces between the wire frames which made it impossible to use in practice.

However, analysing these criticisms, Birss J concluded that they actually made the solution of claim 1 more obvious. Birss J also referred to a number of other factors relied upon by Edwards but addressed only two, dismissing both:

This was not a case in which it could be said that the teaching/contribution of the patent was the solution to a particular technical problem which was, itself, the reason the successful treatment of aortic stenosis on humans had not been achieved at the priority date. Therefore, the fact no one had achieved a successful treatment of aortic stenosis at the priority date was not sufficient enough to make a difference, even though *(inter alia)* the invention was something the art wanted and was in use today.

It was legitimate in this case for Meril to argue that the skilled team would add a cover to Andersen, rather than adding an Andersen type valve to Cribier *inter alia* because Andersen was common general knowledge, Cribier was written based on a critique of Andersen, and the truncated hyperboloid and the internal cover (of Cribier) would be understood by the skilled team as distinct things.

Standing back, the judge concluded that claim 1 lacked inventive step and summed up Meril's infringement/inventive step squeeze as follows ([156]):

> "If, contrary to Edwards case, claim 1 had been limited to the continuous tube in the first embodiment of the 753 patent then it might well not have been obvious, but it would not be infringed by the Meril device. However given the width of claim 1 as I have construed it, the Meril structure falls within it, but the claim is invalid."

Dependent claims

Turning to Edwards' '929 patent, Birss J noted that what claim 1 really amounted to was an improvement on what was then a well known steerable transcatheter delivery system for prosthetic aortic valves. The improvement was means to give the operator a visual indication of the amount of flex at the distal end using a flex indicating member and indicia in the proximal handle of the delivery system.

Meril challenged inventive step over two different published patent applications (Marchland and Falwell) and over prior used 'Rotoflex' devices. Marchand described what was, at the priority date of the '929 patent, the common general knowledge Rotoflex system. The device depicted in figure 1 of Marchland provided tactile feedback on flex by the limits on turning the knob but not visual indicia. An 'alternative embodiment' showed an adjustment lever connected to the handle portion which could be pivoted distally and proximally to adjust the curvature of the shaft 22 (i.e. the guide catheter).

Birss J concluded that claim 1 of '929 was obvious over Marchland. Claim 2 additionally required using numbers as visual marking; this was obvious too.

However, Birss J otherwise rejected Meril's generalised challenge that the additional features of the further dependant claims related to trivial engineering and had no inventive subject matter. Meril's case was focused on making changes to the Rotoflex system. But over the starting point of the alternative embodiment of Marchland, Meril had not really advanced a detailed case, and so the claims to a different kind of rotatable member, a side arm, and a different internal arrangement in the handle did not fall with claim 1 in light of Marchland.

Meril's obviousness challenges based on Falwell and the Rotoflex devices all failed. The consequence was that the dependent claims that survived the Marchland challenge became key to the outcome of the case; several were found infringed.

Edwards v Meril therefore serves as a reminder for litigators about dependent claims. If a defendant's device falls within dependent claims of the patent, attention must be paid to knocking out the additional features of all relevant claims, including of course any amended claims sought.

Long felt want, commercial success and technical merit

Birss J's judgment in ***Evalve v Edwards*** **(substantive)**[166] is notable for its guidance on arguments of long felt want, commercial success and technical merit.

Based on the technical evidence in the case about the common general knowledge, Birss J said ([44):

> "…I am sure that there was a *need* for an effective interventional cardiology based technique to treat mitral regurgitation, and it was *felt* by real skilled teams including interventional cardiologists. … there was a reasonably long felt want at the first priority date (June 2001) and a longer one at the second priority date (May 2003).

Nevertheless, Birss J pointed out that a long felt want may have little relevance to an obviousness case based on prior art that was unknown to the real teams at or which emerged close to the priority date.

In the *Evalve* case, the arguments of long felt want did not end up playing much of a role in the judge's assessment of obviousness because the prior art relied upon was published only 8 months and 16 months, respectively, before the priority dates of the patents in issue. However Birss J made some notable observations on the potential for overlap between arguments about long felt want and the success of the commercialised product. His judgment flags that this is an area in which patentees

[166] *Evalve, Inc & Ors v Edwards LifeSciences Limited* [2020] EWHC 514 (Pat) (12 March 2020) Birss J

need to take care about the way their cases are pleaded and structured. In particular, Birss J said ([46]):

> "Edwards detected that Abbott was seeking to rely on an unpleaded commercial success argument. It is convenient to address this now as part of common general knowledge although it also fits into obviousness generally. Abbott did not comply with the clear and mandatory rules on that (PD63 para 4.6 and 6.3) and so if commercial success is what Abbott relies on then it may not do so without permission (which was never sought). Thus to the extent Abbott is seeking to use the commercial success of MitraClip as a way of proving elements of the long felt want or anything else, it is not entitled to do so. I did not take that into account above. It is possible to establish a long felt want directly from the technical evidence, and that is what has happened in this case."

Evalve/Abbott contended that their argument was one of *technical* success (or "technical merit") rather than *commercial* success. The judge said he believed the distinction had been drawn in other cases, but one needed to take care with such an approach. The main purpose of the submissions was prejudicial, because no judge wanted to revoke a patent for a breakthrough. The legal relevance could be to support a finding of long felt want. Provided such evidence was kept in its place there was no problem.

Technical merit, however, was a different point from long felt want ([50]-[51]):

> "…In my judgment "technical merit" is capable of being relevant in a case where the skilled person is presented by a number of possible routes forward, one of which leads to the invention. The others may be equally obvious ways to reach a meritorious result in which case their existence does not help the patentee (*Brugger v Medicaid*), but they may not be. The latter could be because another route indeed seems to be an obvious way forward but once followed in fact does not lead to a meritorious result. The technical merit of the invention could shed some light on that.
>
> However there are pitfalls in these efforts to use evidence of the technical and/or commercial performance of the commercially sold embodiments of an invention. That is why these things are best identified early in the proceedings. Save in single chemical compound cases, the patent claim almost always covers more scope than just the commercial embodiment. That difference may matter. The success may be due to features not claimed at all. The success will most likely be influenced by advertising and marketing to some degree. What is in issue in this way may not just be sales revenue, but also statements made by third parties…but the truth is that many scientists and doctors have been influenced by hype in the past."

Birss J noted that for commercial success arguments, CPR PD 63 paragraphs 4.6 and 6.3 regulate the disclosure of financial information, and it remains the law, from *John Deks v Aztec*[167], that this requires the provision of information setting out ([52]):

> "…what is the defect [in the prior art], if there be one, how it was overcome and whether long-felt want is being sought to be established and, if so, how the plaintiffs are going to say they are going to establish it."

[167] *John Deks v Aztec Washer* [1989] RPC 413

Birss J said that if this information ought to be provided at the pleadings stage in a commercial success case, then he could not see why it ought not to be provided (except for the financial information) in a case in which the patentee wishes to rely on the technical success or technical merit of its own product. He also indicated that the rules need to catch up with this ([53]):

> "The current terms of Part 63 do not expressly apply to such a case, but that does not prevent the defendant who is challenging validity from asking the patentee if they intend to rely on technical success, and if they do, asking for this information. The right place to find out should not be in the skeleton arguments for trial."

As noted above, in ***Emson v Hozelock***[168], Emson's appeal based on commercial success was not successful. On the principles, Arnold LJ noted the "classic exposition of the law" as that of Laddie J in *Haberman v Jackel*[169] ([77]):

> "As he explained, commercial success of a patented invention can only demonstrate that the invention was not obvious over the prior art if it provides an insight into the thinking of the skilled person when considering that prior art. Accordingly, one of the considerations identified by Laddie J was the following at sub-paragraph (e):
>
> > "What prior art would have been likely to be known to all or most of those who would have been expected to be involved in finding a solution? A development may be obvious over a piece of esoteric prior art of which most in the trade would have been ignorant. If that is so, commercial success over other, less relevant, prior art will have much reduced significance.""

Since it was Emson that relied on commercial success, the burden lay on Emson to establish the necessary factual basis for the contention, but there was no evidence that McDonald was known to anyone in the hose industry (and such evidence as there was pointed the other way). In those circumstances the commercial success of Emzon's hose could not, as a matter of logic, help to show that the invention of its patents was not obvious over McDonald.

In the last substantive judgment of the year, ***Fisher & Paykel v Flexicare***[170], long felt want was found to count.

This is the case about Fisher & Paykel's patent to a type of expiratory breathing tube for a ventilator device. The patent claimed priority from May 2011. Flexicare's obviousness challenges included two based on older prior art: 'Psaros', a European patent application published in 1993; and Kertzman, an international patent application published in 1988. For each, the judge rejected the obviousness challenge after following the *Pozzoli* approach but also noted support in Fisher & Paykel's long felt want case.

In particular, Meade J noted that the kind of tubes described in *Kertzman* were common general

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[168] *E. Mishan & Sons, Inc v Hozelock Limited & Ors* [2020] EWCA Civ 871 (8 July 2020) Floyd, Henderson & Arnold LLJ
[169] *Haberman v Jackel International Ltd* [1999] FSR 683 at [32]
[170] *Fisher & Paykel Healthcare Limited v Flexicare Medical Limited & Anr* [2020] EWHC 3282 (Pat) (8 December 2020) Meade J

knowledge from the late 1980s, as were the appreciation of the relevant problems ([184]):

> "It is therefore a powerful real-world point against obviousness that despite this, no one actually thought to make the expiratory limb of a breathing circuit out of breathable materials so as to dry the exhaled gases prior to the Patent. The point cannot be answered by suggesting that Kertzman was obscure, since it was essentially the CGK. Nor was I impressed by Flexicare's reliance on there being concrete data in Kertzman since, as I have said, it just demonstrated that the sampling tubes disclosed, of the generally known construction, would work well as sampling tubes."

Confidentiality issues

The Janger v Tesco[171], the last substantive patent judgment of 2020, concerned a patent to a "hangable garment hook". A dispute arose as to whether a prior disclosure had been made under conditions of confidence.

It was common ground that the approach to determining whether the information was communicated in circumstances importing an obligation of confidence was an objective one which depended on the circumstances. With reference to the principles, the judge quoted from Arnold LJ's judgment in *Racing Partnership v Sports Information Services*[172] ([88]):

> "So far as the law is concerned, neither side took issue with the test that I derived from the authorities in *Primary Group (UK) Ltd v Royal Bank of Scotland plc* [2014] EWHC 1082 (Ch), [2014] RPC 26 at [223], which was approved by this Court in *Matalia v Warwickshire County Council* [2017] EWCA Civ 991, [2017] ECC 25 at [46] and referred to by the judge at [135]:
>
> > "It follows from the statements of principle I have quoted above that an equitable obligation of confidence will arise not only where confidential information is disclosed in breach of an obligation of confidence (which may itself be contractual or equitable) and the recipient knows, or has notice, that that is the case, but also where confidential information is acquired or received without having been disclosed in breach of confidence and the acquirer or recipient knows, or has notice, that the information is confidential. Either way, whether a person has notice is to be objectively assessed by reference to a reasonable person standing in the position of the recipient." …"

The alleged disclosure in *The Janger v Tesco* had been made in a meeting between M&S (not a party to the litigation) and one of their suppliers, in 2013. On the evidence before the court, the judge concluded that it had been made under conditions of confidence. Nevertheless the patent was invalid (anticipated and obvious) in light of another piece of prior art.

Iterative filing can have consequences for obviousness

There is a short take home point on obviousness to be extracted from Arnold LJ's judgment in ***Akebia v Fibrogen***[173]. In that case the priority document for Fibrogen's Family A patents (WO '997) was prior art for the Family B patents. The suggestion in WO '997 that the methods of its invention increased

[171] *The Janger Limited v Tesco Plc* [2020] EWHC 3450(IPEC) (16 December 2020) Recorder Douglas Campell QC

[172] *Racing Partnership Ltd v Sports Information Services Ltd* [2020] EWCA Civ 1300 at [79]

[173] *Akebia Therapeutics Inc & Anr v Fibrogen Inc* [2020] EWHC 866 (Pat) (20 April 2020) Arnold LJ

iron transport, processing and utilisation was not supported by data, and the judge concluded that, with the exception of an amended claim narrowed to 'Compound C', the Family A patents lacked plausibility and were insufficient. Nevertheless, WO '997 rendered the claims of the Family B patents obvious. No other obviousness challenge against the Family B patents was considered in the judgment.

So the case serves as a reminder of the need for real care when deciding upon the point(s) in research at which patent applications should be filed, particularly in pharmaceutical and biotech fields. Filing too soon, with disclosures at too high a level of generality/without supporting data, may not just result in any patent granted for the work to that point being found invalid (insufficient); it may also prevent patent protection for subsequent stages of the research. Yet waiting for more substantial supporting data may result in invalidating prior art being published (or filed).

Internal invalidity

Finally on obviousness, it is common for judges to draw analogies in their analysis between some insufficiency issues (particularly *Biogen* insufficiency and excessive claim breadth insufficiency) and *AgrEvo* obviousness. In 2020 in ***Optis v Apple* (16 October 2020)**[174] Birss J grouped arguments of insufficiency (*Biogen* and uncertainty), *AgrEvo* obviousness and added matter as "internal invalidity" challenges, considering them after the prior art challenges and drawing analogies. (In *Evalve v Edwards* (substantive)***[175]*** and *Edwards v Meril****[176]*** Birss J's approach was consistent with this; and he considered such challenges before questions of infringement on the doctrine of equivalents).

In the *Optis* case, Birss J said that he agreed with Floyd J in *Samsung v Apple*[177] that there was no reason why *Agrevo* obviousness cannot apply in the telecommunications field or in any other field. The principle is a general one but care needs to be taken when stating what that principle is ([207]-[208]):

> "The principle is not that a claim which contains an arbitrary feature is invalid. Merely having an arbitrary feature in a claim is not a ground of invalidity. The point of *Agrevo* obviousness is that if a claim is found to contain an arbitrary limitation in it, then that limitation cannot assist the patentee in defending an obviousness case. The claim still does have to be obvious over something in the state of the art –perhaps common general knowledge or some cited prior art.
>
> In terms of analogies, a claim to a 9 ½ inch plate is often mentioned as an example of arbitrary uninventive claims. Such a claim would be *Agrevo* obvious but the reason why that is so is not just because the 9 ½ inch diameter is arbitrary and irrelevant, it also depends on the often unspoken proposition that plates are obvious. A different issue again, sometimes equated with *Agrevo*, is the submission that a claim which makes no technical contribution at all is invalid on that ground. It is not necessary to address that in this case."

In the *Optis* case, Apple contended that the claim term 'conversion' was arbitrary and therefore the claim was *Agrevo* obvious. Birss J agreed that if the feature was arbitrary then the claim would be obvious because the process left, couched at its level of generality, would be obvious to the person skilled in the art at the priority date.

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[174] *Optis Cellular Technology LLC & Ors v Apple Retail UK Ltd & Anr* [2020] EWHC 2746 (Pat) (16 October 2020) Birss J
[175] *Evalve, Inc & Ors v Edwards LifeSciences Limited* [2020] EWHC 514 (Pat) (12 March 2020) Birss J
[176] *Edwards Lifesciences Corporation & Anr v Meril GmbH & Anr* [2020] EWHC 2562 (Pat) (29 September 2020) Birss J
[177] *Samsung Electronics Co. Ltd v Apple Retail UK Ltd & Anr* [2013] EWHC 468 (Pat)

However, as construed, the term 'conversion' was not arbitrary, and it had the result that the converted values had two beneficial properties that were shared by everything within the claim. Further ([211]):

> "In a case in which the beneficial properties exist across the full width of the claim, there is no reason based on *Agrevo* or anything else why the inventors should have limited their claim to particular instances of the taking advantage of those benefits."

d. Insufficiency

The case law on sufficiency has been a little turbulent in recent years, particularly in respect of the role of 'plausibility' in the assessment of sufficiency and the standard against which the concept should be assessed. Disagreement between the Patents Court (particularly Arnold J) and the Court of Appeal emerged in the *Warner-Lambert*[178] and *Idenix*[179] cases as to whether plausibility was merely a "low, threshold test" (the Court of Appeal's approach) or a higher standard. In the *Warner-Lambert*[180] case, the Supreme Court rejected the Court of Appeal's approach but in reasoning that could only sensibly be read onto second medical use claims in the pharmaceutical and biotechnological sectors. The Supreme Court also failed to address its own previous reasoning on plausibility, in *Eli Lilly v HGS*[181], even though that reasoning was drawn upon by the Court of Appeal in reasoning that the Supreme Court rejected.

This left uncertainty as to how the principles governing the assessment of sufficiency should be defined, particularly in cases concerning arguments about excessive claim breadth.

In April 2020, in ***Akebia v Fibrogen***[182]***,*** Arnold LJ (sitting in the Patents Court) did a neat job of straightening out the mess…for a few weeks.

In that case it was common ground that the claims of Fibrogen's Family A patents required the therapeutic effects mentioned to be achieved. The criteria for efficacy for this purpose were indicated by the examples in the specification, namely "that the compound in question must inhibit HIF-PH in an appropriate biochemical (in vitro) assay and induce the production of endogenous Epo *in vivo* in a suitable animal model (such as a mouse or rat)…" The claims "obviously" covered using the compounds for the treatment of human patients, but neither side suggested that they required efficacy in humans to be demonstrated even to the level of a Phase II clinical trial.

An issue of construction was the meaning of the expression “structural mimetic of 2-OG” in claim 24A of EP 823 and claim 4 of EP 301. Arnold LJ concluded that the skilled medicinal chemist would be uncertain as to its meaning and unable to determine either from the specification or from the cited papers what criterion to apply to distinguish a compound which met this term and one which did not. (This of course gives a flavour of what was to come on the facts of the case).

On the principles regarding sufficiency, Arnold LJ noted that although insufficiency is a single ground

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[178] *Warner-Lambert Company LLC v Generics (UK) Ltd t/a/ Mylan & Ors* [2015] EWHC 2548 (Pat); [2016] EWCA Civ 1006
[179] *Idenix Pharmaceuticals Inc v Gilead Sciences Inc & Ors* [2016] EWCA Civ 1089
[180] *Warner-Lambert Company LLC v Generics (UK) Ltd t/a/ Mylan & Anr* [2018] UKSC 56
[181] *Human Genome Sciences Inc v Eli Lilly & Company* [2011] UKSC 51
[182] *Akebia Therapeutics Inc & Anr v Fibrogen Inc* [2020] EWHC 866 (Pat) (20 April 2020) Arnold LJ

of invalidity, it embraces three distinct types of objection:

- where the invention cannot be performed at all without undue burden (sometimes called “classical" insufficiency);
- where the invention cannot be performed across the breadth of the claim without undue burden (sometimes called “Biogen" insufficiency and also referred to as “excessive claim breadth”); and
- where the claim does not enable the skilled person to know whether they are within the claim or outside (previously called “ambiguity” and recently re-named “uncertainty”).

Biogen insufficiency/excessive claim breadth insufficiency and the role of plausibility

On the principles regarding **excessive claim breadth insufficiency**, Arnold LJ cited Kitchin J's summary in *Eli Lilly v HGS*[183], which was cited with approval by the Court of Appeal in *Eli Lilly v HGS*[184] and in *Idenix v Gilead*[185]:

> “The specification must disclose the invention clearly and completely enough for it to be performed by a person skilled in the art. The key elements of this requirement which bear on the present case are these:
>
> i) the first step is to identify the invention and that is to be done by reading and construing the claims;
>
> ii) in the case of a product claim that means making or otherwise obtaining the product;
>
> iii) in the case of a process claim, it means working the process;
>
> iv) sufficiency of the disclosure must be assessed on the basis of the specification as a whole including the description and the claims;
>
> v) the disclosure is aimed at the skilled person who may use his common general knowledge to supplement the information contained in the specification;
>
> vi) the specification must be sufficient to allow the invention to be performed over the whole scope of the claim;
>
> vii) the specification must be sufficient to allow the invention to be so performed without undue burden.”

Arnold LJ noted too that in *Idenix*, Kitchin LJ also said ([350]):

> “The extent of the disclosure necessary to make the patent sufficient depends on the nature of the invention, the scope of the claims and the art in which the invention is made …”.

Arnold LJ explained that **the objection of excessive claim breadth concerns the requirement that the invention must be capable of being performed over the whole scope of the claim without**

[183] *Eli Lilly and Company v Human Genome Sciences, Inc* [2008] EWHC 1903 (Pat)
[184] *Eli Lilly and Company v Human Genome Sciences, Inc* [2012] EWCA Civ 1185
[185] *Idenix Pharmaceuticals Inc v Gilead Sciences Inc & Ors* [2016] EWCA Civ 1089

undue burden (points (vi) and (vii) in Kitchin J's summary quoted above). But the requirement must not be taken too far. It is well established that it is permissible for a claim to describe an invention in general terms provided it is plausible in the light of the disclosure and the common general knowledge that the invention will work with anything falling within the scope of those terms.

Arnold LJ then quoted an extract from Kitchin LJ in *Regeneron v Genentech*[186], leading up to and including two key paragraphs ([100]-[101]), which have been quoted extensively since ([352]):

> "100. It must therefore be possible to make a reasonable prediction the invention will work with substantially everything falling within the scope of the claim or, put another way, the assertion that the invention will work across the scope of the claim must be plausible or credible. The products and methods within the claim are then tied together by a unifying characteristic or a common principle. If it is possible to make such a prediction then it cannot be said the claim is insufficient simply because the patentee has not demonstrated the invention works in every case.
>
> 101. On the other hand, if it is not possible to make such a prediction or if it is shown the prediction is wrong and the invention does not work with substantially all the products or methods falling within the scope of the claim then the scope of the monopoly will exceed the technical contribution the patentee has made to the art and the claim will be insufficient. It may also be invalid for obviousness, there being no invention in simply providing a class of products or methods which have no technically useful properties or purpose."

These are paragraphs of reasoning that emerged unscathed from the Supreme Court's judgment in *Warner-Lambert*. They underpinned much of the discussion about excessive claim breadth insufficiency (and plausibility more broadly) in the years that led up to *Warner-Lambert* i.e. in the years 2013-2018. Arnold LJ ignored the jurisprudence from those years (much of which seems not to have survived *Warner-Lambert*) and instead he made the following statement on the law ([353]):

> "Accordingly, the authorities establish that the court must undertake a **two-stage enquiry**. The first stage is to determine whether the disclosure of the patent, read in the light of the common general knowledge of the skilled team, makes it **plausible** that the invention will work across the scope of the claim. At this stage, it is not permissible for either the patentee or the party attacking the patent to rely upon evidence which post-dates the patent. If the disclosure does make it plausible, the second stage is to consider whether the evidence establishes that in fact the invention cannot be performed across the scope of the claim without **undue burden**. At this stage, evidence which post-dates the patent is admissible."

Arnold LJ then noted that the present case was concerned with a first medical use of (largely) known compounds (although there were claims framed as second medical use claims in both forms). While there was no dispute that the guidance given by Lord Sumption in *Warner-Lambert* was applicable, the Claimants contended that it was not the whole story. Lord Sumption said too that plausibility is not a term of art, and it is inevitably influenced by the legal context. The legal context in the *Warner-Lambert* case was that of a second medical use invention.

So Arnold LJ proceeded to look at the story. He noted that, consistently with Kitchen LJ's statement of the law, it had been held in a number of cases that a patent will be insufficient if the specification

[186] *Regeneron Pharmaceuticals Inc & Anr v Genentech Inc* [2013] EWCA Civ 93

requires the skilled person to undertake a substantial research project in order to perform the invention.

More recently, in *Regeneron v Kymab*[187], after reviewing a number of decisions of the EPO's Boards of Appeal, Kitchin LJ made some further points ([364]):

- it is not the law that a specification must necessarily enable the skilled person to make or perform all of the embodiments of a claimed invention;
- the assessment of insufficiency must be sensitive to the nature of the invention and the facts of the particular case;
- it is a general principle that the protection afforded by the claims must correspond to the technical contribution to the art made by the disclosure of the invention; and
- the exposition of the law in *Regeneron v Genentech* (at [173]) was entirely consistent with those principles.

The *Akebia v Fibrogen* case concerned the sufficiency of claims which combined both broad structural and functional features. Fibrogen submitted that such a claim was valid if the skilled person could identify, without undue burden, some compounds having the claimed structural features which also fulfilled the claimed functional requirements.

Arnold LJ did not agree. With reference to the Case Law of the Boards of Appeal of the European Patent Office (9th edition, 2019) at page 368, he said

> "Rather, what is required is that the skilled person or team must be able to identify substantially all compounds covered by the claim without undue burden."

Stepping back, Arnold LJ's reasoning in *Akebia v Fibrogen* seems to provide a workable statement of the principles governing insufficiency for excessive claim breadth/lack of plausibility. The last quote, however, seems likely to present real difficulties for patents claiming broad classes of products with functional features, unless all such functionality applies to the broad class rather than just some as yet unidentified members of it.

The judge then turned to apply these principles to the facts.

It was common ground that the specification adequately demonstrated efficacy for compounds C, E, F, J and K. The issue concerned the sufficiency of broader claims, and the judge approached his assessment by considering those for which Formula (I) was in its widest form. The number of compounds covered by Formula I was "staggeringly large", with in the region of 10^{183} possibilities.

Akebia relied upon unchallenged expert evidence that the skilled medicinal chemist would have no real reason for supposing that substantially all the Formula I compounds would be effective in inhibiting HIF-PH or increasing Epo or otherwise treating anaemia, nor would they be able to make a reasonable prediction that substantially all the compounds would be effective; in fact there were good reasons for believing that a significant number of such compounds would not be effective.

Fibrogen contended that this did not matter because the claims were limited to compounds having both the defined structural features and the functional limitations. In short, the claims were limited to

[187] *Regeneron Pharmaceuticals Inc v Kymab Ltd* [2018] EWCA Civ 671, [2018] RPC 14

those compounds that worked, so it necessarily followed that it was plausible that the invention would work across the scope of those claims.

Unsurprisingly, Arnold LJ did not accept this argument. He noted that in respect of a similar sort of claim in *Idenix v Gilead*, the "very experienced team of specialist counsel" who represented the patentee did not make that submission. Nor did Kitchin LJ or Floyd LJ consider it an answer to the objection of lack of plausibility in that case. Arnold LJ said it was "not hard to see why" ([376]):

> "…the patent is implicitly promising that substantially all compounds which satisfy the structural definitions in the claims in issue will have the claimed therapeutic efficacy. Otherwise, the skilled team would be faced with a situation where the structural definition covers around 10^{183} compounds (or a little less or even more), but the specification only demonstrates that five compounds, namely Compounds C, E, F, J and K, satisfy the criteria for therapeutic efficacy. That would amount to no more than an invitation to the skilled team to find the other compounds covered by the claim which work. It would not involve an inventive step, because it would not solve the technical problem of identifying compounds which have the desired activity, and it would not sufficiently disclose the invention, because it would leave most of the work to the reader."

Arnold LJ noted that, as Lord Sumption pointed out in *Warner-Lambert*, the underlying consideration in both contexts was the same: what actual technical contribution has the patentee made to the art which justifies the scope of the monopoly claimed?

Fibrogen did not contend that it was plausible that substantially all the compounds covered by the structural definition in the claims in issue did have the claimed therapeutic efficacy. But they argued that the claims were commensurate with the technical contribution that “heterocyclic carboxamides, being prolyl hydroxylase inhibitors, can be used to treat anaemia associated with kidney disease by inhibiting HIF-PH”.

However the judge said that what the Claimants actually meant by this was that some heterocyclic carboxamides could be used in this way – not all or substantially all. The actual technical contribution to the art (in light of the Epstein prior art) was no more than the identification of Compounds C, E, F, J and K as having therapeutic efficacy for anaemia associated with chronic kidney disease. While that might justify a claim to "a wider group of compounds that could plausibly be predicted to have similar efficacy for given structure-activity reasons", it did not begin to justify the claims in issue.

Further (and in case he was wrong on his conclusion regarding the limited scope of the actual technical contribution), the judge held that a finding that some such compounds could be used to treat anaemia did not justify a claim to “whichever ones out of 10^{183} compounds in addition to those five that you the reader are able to find that work through your own researches”. To put the same point another way, that finding was not a principle of general application across the breadth of the claims because the evidence showed that a large number of heterocyclic carboxamides were not likely to work.

Accordingly, all the claims in issue were insufficient for want of plausibility.

Further, on 'undue burden' (the second part of Arnold LJ's test for the Biogen/excessive claim breadth ground set out in [353]) Arnold LJ then considered the evidence in the case regarding the

identification of compounds and their functionality, before concluding that this part of the test was not met either. This was because ([399]):

> "It would require a substantial research project to identify any compounds other than those specifically identified in the specification which met the criteria for efficacy, and success would not be guaranteed. While it is probable that, if sufficient resources were thrown at the project, the skilled medicinal chemist would be able to identify some compounds falling within Formula (I) (and more which constituted Carboxamides) which were effective, they would not be able even in many lifetimes of sustained effort to make and test more than a tiny fraction of such compounds, and a substantial proportion either could not be made or would not work. This is not only setting the skilled team a research project and claiming the results, it is a never-ending one. Accordingly, on this ground also I conclude that the claims in issue are insufficient."

Insufficiency for uncertainty

Finally in *Akebia v Fibrogen*, Arnold LJ considered a challenge on the ground of insufficiency for uncertainty. On the principles, he noted (from *Generics v Yeda*[188]) the need to distinguish between claims that are difficult to construe or have a 'fuzzy boundary' on the one hand from those that are 'truly ambiguous' (such that it is unclear what is the correct test to determine whether or not a product or process infringes) on the other. Also, that in *Anan Kasei v Neo*[189] the Court of Appeal renamed this type of insufficiency "uncertainty"; and held that this type insufficiency was not only available where it was impossible to tell in any case whether a product infringed - it applies too if there is "a large territory (more than a fuzzy boundary) where the claim is uncertain".

Akebia's challenge of insufficiency for uncertainty concerned claim 24A of EP 823 and claim 4 of EP 301, which included the expression "structural mimetic of 2-oxoglutarate", and on the facts it succeeded.

The date at which sufficiency is assessed

In *Akebia v Fibrogen*, Arnold LJ did not spell out the date at which he conducted his assessment of insufficiency. But the point very definitely raised its head in two other cases. The distinction can matter a lot because the assessment of whether a patent is sufficient is from the perspective of the person skilled in the art, who is imbued with the common general knowledge. The later the assessment date, the more that may count as common general knowledge, assisting the patentee in establishing the sufficiency of the specification.

In March 2019, in *Eli Lilly v Genentech*[190], Arnold LJ found a Genentech patent ('822) concerned with anti-interleukin 17A/F antibodies, as proposed to be amended, to be invalid. The product claims and claims to use in rheumatoid arthritis were obvious; the claims to use in psoriasis were insufficient for lack of plausibility. Arnold J assessed sufficiency at the priority date, as pleaded by Eli Lilly. Genentech had sought to amend its case to plead sufficiency at the filing date, but only shortly before trial and the judge had refused permission to amend on case management grounds.

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[188] *Generics (UK) Ltd v Yeda Research & Developments Co Ltd* [2012] EWHC 1848 (Pat)
[189] *Anan Kasei Co. Ltd & Anr v Neo Chemicals and Oxides Ltd & Anr* [2019] EWCA Civ 1646
[190] *Eli Lilly and Company & Ors v Genentech, Inc* [2019] EWHC 387 (Pat)

In the meantime, Genentech obtained a divisional patent ('084) which essentially claimed the same subject matter but in a way that cured an added matter problem. Eli Lilly sought revocation of the divisional and applied for summary judgment, based on issue estoppel and abuse of process.

In February 2020, in *Eli Lilly v Genentech*[191], Deputy Judge Roger Wyand QC concluded that Genentech were estopped from arguing that the antibody product claims were valid. The really interesting part of the judgment though concerned Genentech's proposed amended claims (of '804) addressed to use in the treatment of psoriasis. Genentech's defence in respect of such claims was that the patent was sufficient at the filing date, rather than the priority date considered in the earlier action. So the question arose as to how the principles of issue estoppel and abuse of process should be applied in this context.

After considering *Henderson v Henderson*[192] and *Johnson v Gore Wood*[193], the Deputy Judge said ([71]):

> "…the role of the court, when a party seeks to contend that another party cannot raise a point that could have been raised in earlier proceedings, is to make a broad merits-based judgment which takes into account all of the facts, and ask whether, in the light of that, the party alleging abuse has satisfied the court that the other party is misusing or abusing the process of the court by seeking to raise an issue which could have been raised before. Such a finding will be rare unless the later proceedings can properly be characterised as "unjust harassment"."

The Deputy Judge found it arguable that the effect of the finding of lack of plausibility at the priority date would only result in a loss of priority if plausibility could be established at the filing date. He also found that expert evidence submitted by Genentech, and which he allowed in, established an arguable case that there was a change in the common general knowledge between the priority date and the date of filing such that plausibility could be established at the filing date. Genentech therefore had a real prospect of defending the case of insufficiency against the psoriasis claims, on the basis of the common general knowledge developed between the priority date of the patent and the filing date, and so was not estopped from arguing this. Summary judgment was refused in respect of those claims.

And so it was looking like the second case would proceed to trial on the limited question of developments to the common general knowledge in the priority year and whether this impacted the assessment of plausibility (and so sufficiency and validity) of the claims to use in psoriasis.

But then came the Supreme Court's judgment in ***Regeneron v Kymab***[194].

Regeneron's patents concerned transgenic mice that could be used as platforms for antibody discovery. By the priority date of the patents (in February 2001) it was known that in order to avoid an immune response (in the human) against the therapeutic antibody, it would be preferable for the antibody to be a human antibody, as opposed to a murine (i.e. mouse) antibody or a 'chimeric' antibody with mouse variable regions and human constant regions. Humanised antibodies, where the

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[191] *Eli Lilly and Company v Genentech, Inc* [2020] EWHC 261 (Pat) (14 February 2020) Roger Wyand QC
[192] *Henderson v Henderson* 3 Hare 100
[193] *Johnson v Gore Wood & Co* [2000] UKHL 65
[194] *Regeneron Pharmaceuticals Inc v Kymab Ltd* [2020] UKSC 27 (24 June 2020) Lords Reed, Hodge, Briggs and Sales & Lady Black

complementary determining regions of a murine antibody had been grafted onto a human antibody, were better than chimeric antibodies, but there were problems with the mice engineered to produce such antibodies being ‘immunologically sick’.

Regeneron's patents concerned the 'replacement' of mouse antibody variable region genes with human antibody variable region genes to produce immunoglobulin loci that would produce hybrid antibodies. The hybrid antibodies comprised a combination of human variable region gene segments and endogenous mouse constant region gene segments and as such were "reverse chimeric antibodies". The mice were healthier and therefore a more useful research tool.

Two Regeneron patents were in issue in the litigation. Claim 1 of the '287 patent was a process claim, in the following terms:

> "A method of modifying an endogenous immunoglobulin heavy chain variable region gene locus in an isolated mouse embryonic stem cell by an in situ replacement of V, D and J gene segments of the endogenous locus with othologous human V, D and J gene segments, to create a modified immunoglobulin locus that produces hybrid antibodies containing human variable regions and mouse constant regions, said method comprising…"

Claim 1 of Regeneron’s '163 patent was a product claim, in the following terms:

> "A transgenic mouse that produces hybrid antibodies containing human variable regions and mouse constant regions, wherein said mouse comprises an in situ replacement of mouse VDJ regions with human VDJ regions at a murine chromosomal immunoglobulin heavy chain locus and an in situ replacement of mouse VJ regions with human VJ regions at a murine chromosomal immunoglobulin light chain locus."

In the Patents Court and the Court of Appeal, there was an issue of construction. Kymab contended that 'in situ replacement' required deletion of the murine variable region gene segments and insertion of the human variable region segments in the same place. Regeneron contended that it simply meant replacing "in the position of" and did not require deletion of the endogenous mouse gene.

Henry Carr J held that the skilled person would appreciate that the language was being used to distinguish targeted replacement from random insertion into the genome. This included where the relevant murine sequence was deleted and also where it was moved to a different location and inactivated. The Court of Appeal agreed. Accordingly, Kymab's transgenic mouse infringed Regeneron's patents, if they were valid.

Henry Carr J concluded that the patents were not anticipated or obvious. On sufficiency, the judge focused in his reasoning upon the method claim of the '287 patent, concluding that in situ replacements covered by claim 1 of 287 "could not be performed without undue burden in 2001/2"; the likelihood was that none of the replacements attempted by the skilled person would have worked. As the Supreme Court subsequently put it ([3]):

> "The judge held that the teaching in the patent did not enable any type of mouse within the range to be made, let alone mice across the whole of the relevant range."

In the Court of Appeal, Regeneron argued that in view of Kymab's evidence on obviousness, the use of "mini-genes" would have been common general knowledge, and by employing this method the

skilled person could have made an in situ replacement. Focusing on the product claim of '163, Kitchin LJ ruled that it was not the law that the specification must necessarily enable the skilled person to make or perform all of the embodiments of a claimed invention: in appropriate cases, a claim may embrace variants which may be provided or invented in the future and which achieve the same effect in a manner which could not have been envisaged without the invention.

Kitchin LJ noted that the technical contribution of the patent was the concept of a reverse chimera, to avoid immunologically sick mice. He held that this was a principle of general application that worked across the scope of what was claimed and so the claim was justified.

Kitchin LJ having given the judgment in the Court of Appeal, when the case reached the Supreme Court, the newly appointed IP specialist, Lord Kitchin, could not hear it again. The bench comprised Lords Reed, Hodge, Briggs and Sales, and Lady Black. The first three were alumni of the *Warner-Lambert* case.

Lord Briggs (with whom Lords Reed, Hodge and Sales agreed) began his reasoning by stating that the date for the assessment of a question of sufficiency is the *priority* date.

The correct date for assessment was not actually in issue before the Supreme Court. However, with reference to the House of Lords' judgment in *Biogen v Medeva*[195], Lord Briggs said ([2]):

> "It is a general requirement of patent law both in this country and under the European Patent Convention ("EPC") that, in order to patent an inventive product, the patentee must be able to demonstrate (if challenged) that a skilled person can make the product by the use of the teaching disclosed in the patent coupled with the common general knowledge which is already available at the time of the priority date, without having to undertake an undue experimental burden or apply any inventiveness of their own. This requirement is labelled sufficiency. It is said that the invention must be enabled by the teaching in the patent."

Throughout its judgment, the Supreme Court continued to emphasise that the date for the assessment of insufficiency is priority date of a patent.

A rumour seems to have been building in recent years in the patent professions in England and Wales that the House of Lords' judgment in *Biogen v Medeva* is authority for this point. It is fake news.

In *Biogen* at first instance[196], counsel had been unable to find any case where the court had decided what the appropriate date was for deciding sufficiency under s.72 of the Patents Act 1977. Biogen (the patentee) submitted, and **Aldous J** held, that it should be the **date of publication** of the application. Dismissing Medeva's submission that it should be the date of the application for the patent, Aldous J said that the court under s.72(1)(c) is concerned with the specification of the patent and whether that is sufficient. It is not concerned with the application as filed, which may have been amended during the period of examination. Neither party submitted that it should be the priority date if this was different from the date of the application. Aldous J also held that the patent in suit was entitled to its claimed priority and so was not obvious.

[195] *Biogen Inc v Medeva Plc* [1996] UKHL 18
[196] *Biogen Inc v Medeva Plc* [1995] RPC 25

In the **Court of Appeal**[197], Hobhouse LJ noted that s.72 is concerned only with the revocation of patents, not with the adequacy of documentary support for applications for patents. Nevertheless, the Court of Appeal overturned the judge on the date for the assessment of insufficiency, saying it should be the **date of filing of the application for the patent**. Neither party had contended that the right date was the priority date; both had "sought to give the Act a construction which looked to the scheme of the regulation and sought to find a more specific statutory intention". The Court of Appeal described the consequence of its approach (i.e. the filing date, even if different from the priority date), in terms of the interplay with the requirements for priority, in the following way:

> "…If, as is illustrated by the present case, section 5(2) is relied upon to obtain an earlier priority date, then the requirement of support in an earlier document carries with it the question whether the earlier document contained a sufficient and enabling description of the invention (*Asahi*). There is therefore a statutory consistency, on the construction we prefer, between the date of the application and the priority date. The question of sufficiency is determined as at the date of the application; the parallel question of support has to be determined as at the alleged earlier priority date. Whatever priority date is contended for substantially the same test of sufficiency has to be satisfied.
>
> On the approach we adopt, the statutory scheme is also consistent in that the substantive matters have consistently to be decided not later than as at the date of the application. Textual matters are decided at the date of the relevant document but taking into account the rules which govern amendments and added matter."

The Court of Appeal went on to disagree with the judge on entitlement to priority, on obviousness when assessed at the priority date, and on insufficiency – the patent was invalid. In its reasoning on the date for assessment of sufficiency, the Court of Appeal clearly contemplated the possibility of it being the priority date and rejected this.

The House of Lords dismissed Biogen's appeal on the priority issue and on insufficiency. The Law Lords also agreed with the Court of Appeal on the date for the assessment of insufficiency being the filing date rather than the date of publication – and in this context they made no reference to the possibility of it being the priority date (if earlier). After discussing the impact of changes from the 1949 to 1977 Acts, in particular the removal of the 'lack of fair basis' ground for revocation, and how this did not mean that the principle underpinning the ground had been abandoned, Lord Hoffmann said ([81]):

> "Section 72(1)(c) [of the Patents Act 1977] can only give effect to this principle if the relevant date for compliance is the date of application. It would be illogical if a patent which ought to have been rejected under section 14(3) is rendered immune from revocation under section 72(1)(c) by advances in the art between the date of application and the publication of the specification."

Terrell (19th edn) confirms this. It states (13-17):

> **"On what date is the sufficiency of a specification to be judged?**
> The House of Lords in *Biogen Inc v Medeva Plc* held that the correct date for assessing sufficiency for the purposes of the 1977 Act was the date of application, because matter may not be added and an insufficient application should not become sufficient because of general developments in the state of the art after the filing date. It had previously been considered

[197] *Biogen Inc v Medeva Plc* [1995] RPC 25

> that the relevant date was the date of publication of the complete specification (under the 1949 Act)."

And in 2019, in *Regen v Estar*[198] HHJ Hacon said ([185]):

> "There was no discussion of the law on insufficiency. After the trial I noticed that cross-examination and argument was based on the relevant date for assessing sufficiency of disclosure being the priority date, 21 August 2006. It is in fact the date on which the application was filed, 21 August 2007, see *Biogen Inc v Medeva plc* [1997] RPC 1 at pp.53-54."

Lord Hoffmann noted that on the facts of the *Biogen* case, the conclusion that the patent was not entitled to priority from 'Biogen I' meant that it was also insufficient.

But this does not turn *Biogen* into authority for the date of assessment of insufficiency being the priority date. Such an interpretation can only come from an incomplete reading of the judgments in the case with a particular view in mind.

Stepping back, generally in the case law of England and Wales, the requirement for an enabling disclosure is assessed from the perspective of the person skilled in the art interpreting the relevant document at its date (as alluded to in the quote above from the Court of Appeal in *Biogen*). So, for example, for the assessment of novelty, the correct date for the interpretation of documentary prior art is the date of the publication of that prior art, not the priority date of the patent. For the assessment of priority, it is the disclosure of the priority document at the priority date that is considered. The same logic must require that the disclosure of the application as filed be interpreted as at the date of its filing (if not its publication). In all these contexts, when interpreting the relevant document, the skilled person has the benefit of the common general knowledge as it stands at the particular date. If the common general knowledge evolves, it can alter the skilled person's interpretation of a document; the relevant common general knowledge is therefore taken as at the date at which the relevant document is interpreted.

If the date for the assessment of insufficiency really is the priority date (as the Supreme Court stated in *Regeneron v Kymab)*, the tests for entitlement to priority and insufficiency have been conflated. This is because a patent will be invalid for insufficiency if the priority document (combined with the common general knowledge at the priority date) does not provide the skilled person with an enabling disclosure of the claimed invention of the patent (as eventually granted) – any additional material contained in the application for the patent, or which formed part of the common general knowledge at that date, would not be of assistance. This obliterates, in the UK, one of the two rationales upon which the international system of priority filings is founded.

On the other hand if, as has long been understood to be the case, the date for the assessment of insufficiency is the *filing* date of the patent, the lack of an enabling disclosure in the priority document would mean only that information made available to the public in the priority year could become prior art for the purposes of the assessment of novelty and inventive step. In the assessment of sufficiency, additional supporting information included in the application as filed (for example, data from experiments demonstrating support for the claimed invention) would form part of the disclosure of the patent; the assessment of sufficiency addresses whether *this* disclosure enables the skilled person

[198] *Regen Lab SA v Estar Medical Limited & Ors* [2019] EWHC 63 (IPEC)

(with the benefit of the common general knowledge at the same date, the filing date) to perform the subject matter of the claim without undue burden.

The long understood approach is also the foundation upon which patents have been drafted for decades.

So why has the UKSC (unilaterally) got this so wrong?

Well, as the point was not in issue between the parties in *Regeneron v Kymab*, the non-IP specialists hearing the *Regeneron* case would not have been brought up to speed on the authorities in respect of this point. Much of the House of Lords' reasoning in *Biogen* that would have been relied upon before the Supreme (in the context of the principles governing the assessment of sufficiency) would have been drawn from earlier parts of the *Biogen* judgment, in which the House of Lords was considering the concepts of disclosure and enablement in the context of the challenge in *Biogen* to the claimed priority date of Biogen's patent. In *that* context, the House of Lords' reasoning was by reference to the priority date of the patent in issue. The Supreme Court seems to have missed this point entirely in its reasoning in the *Regeneron v Kymab* case.

In fact, the Supreme Court's statement in paragraph 2 of its *Regeneron v Kymab* judgment is also internally illogical: it refers to what is "disclosed in the patent". The patent is the document filed at the *filing* date, which may be up to a year *after* the priority date.

Unfortunately patent litigators need another trip to the Supreme Court to straighten this out.

Classical insufficiency

In *Regeneron v Kymab,* the Supreme Court considered a number of EPO and UK authorities for the principles governing the assessment of sufficiency. These included its own/the House of Lords' judgments in *Actavis v ICOS*[199] (a case on obviousness), *Kirin-Amgen v Hoechst*[200], and *Biogen v Medeva*[201], and *Generics v Lundbeck*[202] and the Court of Appeal's judgment in *Rockwater v Technip*[203] .

A little puzzlingly, the Supreme Court did not refer to its most recent judgment on sufficiency, *Warner-Lambert v Generics*[204], or to *HGS v Eli Lilly*[205], which addressed the concept of plausibility in the context of industrial application.

With reference to *Actavis v ICOS,* Lord Briggs introduced his discussion of the basic principle of sufficiency with the following words ([23]):

> "Sufficiency is one of the established tools by which is measured the correspondence, or lack of it, between the protection afforded by the claim and the technical contribution to the art made by the disclosure of the invention in the patent. The other main tools are novelty, inventive step and industrial application".

[199] *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15
[200] *Kirin-Amgen Inc & Ors v Hoechst Marion Roussel Ltd & Ors* [2004] UKHL 46
[201] *Biogen Inc v Medeva Plc* [1995] RPC 25; [1996] UKHL 18
[202] *H. Lundbeck A/S v Generics* (UK) Ltd & Ors[2008] EWCA Civ 311; [2019] UKHL 12
[203] *Rockwater Ltd v Technip France SA & Anr* [2004] EWCA Civ 381
[204] *Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) & Anr* [2018] UKSC 56
[205] *Human Genome Sciences Inc v Eli Lilly and Company* [2011] UKSC 51

After reflecting upon the EPO and UK authorities, Lord Briggs said they yielded the following principles ([56]):

i) "The requirement of sufficiency imposed by article 83 of the EPC exists to ensure that the extent of the monopoly conferred by the patent corresponds with the extent of the contribution which it makes to the art.

ii) In the case of a product claim, the contribution to the art is the ability of the skilled person to make the product itself, rather than (if different) the invention.

iii) Patentees are free to choose how widely to frame the range of products for which they claim protection. But they need to ensure that they make no broader claim than is enabled by their disclosure.

iv) The disclosure required of the patentee is such as will, coupled with the common general knowledge existing as at the priority date, be sufficient to enable the skilled person to make substantially all the types or embodiments of products within the scope of the claim. That is what, in the context of a product claim, enablement means.

v) A claim which seeks to protect products which cannot be made by the skilled person using the disclosure in the patent will, subject to *de minimis* or wholly irrelevant exceptions, be bound to exceed the contribution to the art made by the patent, measured as it must be at the priority date.

vi) This does not mean that the patentee has to demonstrate in the disclosure that every embodiment within the scope of the claim has been tried, tested and proved to have been enabled to be made. Patentees may rely, if they can, upon a principle of general application if it would appear reasonably likely to enable the whole range of products within the scope of the claim to be made. But they take the risk, if challenged, that the supposed general principle will be proved at trial not in fact to enable a significant, relevant, part of the claimed range to be made, as at the priority date.

vii) Nor will a claim which in substance passes the sufficiency test be defeated by dividing the product claim into a range denominated by some wholly irrelevant factor, such as the length of a mouse's tail. The requirement to show enablement across the whole scope of the claim applies only across a relevant range. Put broadly, the range will be relevant if it is denominated by reference to a variable which significantly affects the value or utility of the product in achieving the purpose for which it is to be made.

viii) Enablement across the scope of a product claim is not established merely by showing that all products within the relevant range will, if and when they can be made, deliver the same general benefit intended to be generated by the invention, regardless how valuable and ground-breaking that invention may prove to be."

Lord Briggs gave as an example a patent claim to products which include five types (A to E), all of which are disclosed to be more efficient or useful than their predecessors by the application to their manufacture of the same new invention. He indicated that the claim will only be sufficient if the disclosure of the specification, coupled with the common general knowledge, enables the skilled

person to make substantially all the types or embodiments of products within the scope of the claim – A to E, not just A and B.

In the Supreme Court it was common ground that the outcome for validity turned upon the validity of claim 1 of the '163 patent (to the transgenic mouse). (This was the claim that the Court of Appeal had focused upon). Lord Briggs said that applying the principles to the facts showed "clearly" that the claim failed for insufficiency ([57]):

> "At the priority date the disclosure of the two patents, coupled with the common general knowledge, did not enable transgenic mice to be “made” with a Reverse Chimeric Locus containing more than a very small part of the human variable region gene locus. The extent to which that variable region of the human antibody gene structure could be included in the hybrid antibody gene structure was, at that date, understood to be a very important factor affecting the diversity of useful antibodies capable of being “discovered” by the use of transgenic mice, so that the range thus denominated was a relevant range for sufficiency purposes, even though it did not affect the immunological health of the transgenic mouse. Thus the claim to a monopoly over the whole of that range went far beyond the contribution which the product made to the art at the priority date, precisely because mice at the more valuable end of the range could not be made, using the disclosure in the patents."

Lord Briggs explained that in the case of a product claim, the contribution to the art is the product which is enabled to be made by the disclosure, not the invention itself. Patents are about products and processes, not pure ideas. In the assessment of sufficiency it is not enough that the benefits which the invention unlocked (in terms of preventing murine immunological sickness) would in due course be realised over the whole range, if and when all embodiments within the range could be made. This did not mean that the patentee had to demonstrate in the disclosure of the patent that every embodiment within the scope of the claim has been tried, tested and proved to have been enabled to be made. But sufficiency required that the disclosure in the patent should enable substantially all products within the scope of a product claim to be made by the skilled person as at the priority date.

Dissenting, Lady Black thought there was "little" between the Court of Appeal and the majority in the Supreme Court on the legal principles, but that the case turned on how the particular claims were characterised. The approach of the majority was to focus on the quantum of replaced material in the reverse chimeric locus, rather than on the reverse chimeric locus as a general principle. She concluded that she would not have interfered with the Court of Appeal's conclusion that the claim related to a principle of general application. Seen in that way, she thought it was enabled, being deployed in each mouse across the range, irrespective of the quantum of human material incorporated. Furthermore, protection across the range coincided with the technical contribution of the patents, which was to solve the problem of immunological sickness, or putting it (loosely) another way, to facilitate the making of immunologically efficient mice.

Accordingly, following the Supreme Court's judgment in *Regeneron v Kymab*, for a patent claim to a range of products to be sufficient, it must be possible for the skilled addressee of the patent to make substantially all the types or embodiments of such products (ie to make products across the scope of the claimed range) at the relevant date.

The law relating to insufficiency has been somewhat mangled by two Supreme Court panels, both comprising only non-IP specialist judges. *Warner Lambert* and now *Regeneron* have both gone 15

rounds with the established law and left it battered and bleeding on the canvass. This is not just because the reasoning was difficult to follow and hard to condense into principles of general application, but because in some respects they were simply wrong. It is very much to be hoped that Lord Kitchin will get an early opportunity to put things right with a comprehensive review and revisiting of the basic law.

He could do a lot worse than to read an excellent article published by Professor Sir Robin Jacob in Bio-Science Review in 2020[206]. Although Sir Robin focuses on the issue of plausibility, the overall consideration of the how the law of insufficiency developed and evolved is very useful and leads in a completely different direction to that adopted by the judiciary in recent years. A "back to basics" consideration of the actual law, and the complete absence of the word "plausibility", is a good starting point for a general reconsideration. Another important aspect which is conceptually important, is the rarely noted point that sufficiency itself is not a requirement of patentability. For grant the requirements are novelty, inventiveness and capability of industrial application. The latter is not the same thing as sufficiency, as the most cursory review of case law reveals. Lack of sufficiency is not a requirement for grant, it is a ground for revocation. It is an "after the event" consideration, which begs the question why other "after the event" considerations may not be taken into account when assessing it? I find the old cases cited by Sir Robin compelling here. If the nature of "the deal" is that the inventor gets a monopoly in return for making public something which contributes to the field of human knowledge and endeavour, why does it matter at all if that contribution was plausible before grant, if it actually does make a contribution? Sir Robin cites *Electric Lamp v Marples*[207], where the patent actually contained a fundamental error of scientific principle. However, the invention it described worked to achieve the desired benefit. Looked at from the perspective of scientific understanding at the priority date or the date of application, the invention was clearly implausible. However, it worked in practice. A patent was granted and maintained.

I particularly enjoy the quote from Pumfrey J which Sir Robin deploys in support of his argument:

> "It has to be remembered that a perfectly valid patent may be written by a person who does not stir from his armchair, thinks it is all obvious, and does no experiment to prove his hunch"[208]

The difference between Lord Sumption's leading judgment in *Warner-Lambert*, and Lord Briggs' leading judgment in Regeneron is that the former is one of a confusing mixed bag of inconsistent judgments, which Kitchin LJ managed to side-step in the Court of Appeal in *Regeneron v Kymab* (facilitating a way forward for Arnold LJ in *Akebia v Fibrogen*), whereas the latter more definitively overturns the Court of Appeal's handling of this area (at least for product claims) without explaining the general principles applicable to all claim types. And of course there is also the priority date issue. So there is a clear need for another outing, to Lord Kitchin, to straighten this all out.

Insufficiency squeezes

The case law that has emerged in 2020 indicates that the extent to which an infringement/insufficiency squeeze may be side-stepped by the application of the doctrine of equivalents remains a developing area.

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[206] Plausibility and Policy – Bio-Science Law Review – Vol 17 Issue 6.- by The Right Honourable Professor Sir Robin Jacob

[207] (1910) 27 RPC 737 CA

[208] [2004] *Cipla v Glaxo* EWHC 477 (Pat) at [116]

As noted in section 2b. above, in ***Akebia v Fibrogen***[209] part of Arnold LJ's reasoning for refusing to apply the doctrine of equivalents to find infringement of a claim to 'Compound C', was that the scope of the claim, by equivalents, would then be so broad that it would suffer from the same problems of insufficiency (both plausibility and undue burden) as the much wider claims, which were found invalid.

However, in ***Edwards v Meril***[210], which concerned technology to mend the aortic valve of the heart, Meade J indicated that the question remained open. Having found the '753 patent invalid for obviousness, he rejected the insufficiency challenges very briefly. However he noted that the Meril device, while covered by the claims of '753 (on the normal interpretation) was not disclosed by the patent because it was not clearly and unambiguously derivable from the specification. With a possible nod to a side-step around such a squeeze, Birss J said ([158]):

> "Whether, given the Meril structure, the team might regard it as equivalent is another different point."

An insufficiency/obviousness squeeze was run in ***MSD v Wyeth***[211], the vaccine formulation patent case. MSD contended that if the 13v combination was not obvious, there was nothing in the teaching of the patent to make it plausible that such a combination would be efficacious or safe.

With reference to *Generics v Yeda*[212] and *Warner-Lambert v Generics*[213], Meade J said that these cases established that squeezes of this kind could work in principle. However, it depended on the facts. They work better the less that the patent under attack provides that is new over the prior art, and best when it provides nothing. On the facts of the *MSD v Wyeth* case, the squeeze failed ([363]-[364]):

> "In the present case it simply was not supported by evidence that the 13v combination of the claims was not plausible. MSD's positive case was that it was. Wyeth's position was that it was plausible once thought of, and that is part of the reason why I have found the Patent obvious over de la Pena (which identifies it specifically) and not over Chiron (which does not identify it at all). It was not inconsistent for Wyeth to say that without it being pointed to, and a case for it made, it would not be obvious to think of it and then pursue it.
>
> So far as the Patent's teaching is concerned, it is true that there is no experimental proof of the protective effect of the 13v combination, but the law does not require it. The combination is clearly identified in the specification and although the concrete work disclosed is about formulating the combination and protecting it from aggregation, that is not immaterial to the achievement of the claims, because as I have explained above, part of the challenge in this field is to balance the multiple serotype antigens that would be desirable with the practical challenges of making the vaccine."

[209] *Akebia Therapeutics Inc & Anr v Fibrogen Inc* [2020] EWHC 866 (Pat) (20 April 2020) Arnold LJ
[210] *Edwards Lifesciences Corporation & Anr v Meril GmbH & Anr* [2020] EWHC 2562 (Pat) (29 September 2020) Birss J
[211] *Merck Sharp & Dohme Limited v Wyeth LLC* [2020] EWHC 2636 (Pat) (15 October 2020) Meade J
[212] *Generics (U.K.) Ltd v Yeda Research and Development Company Ltd* [2017] EWHC 2629 (Pat) at [191]
[213] *Warner-Lambert Company LLC v Generics (UK) Ltd t/a Mylan & Anr* [2018] UKSC 56 at [36]-[37]

e. Added matter

In the first patent judgment of the year, ***Conversant v Huawei* (8 January 2020)**[214], Birss J gave a pithy statement of what constitutes added matter ([194]):

> "…added matter relates to information disclosed by the granted patent (or as a result of a post grant amendment) which was not disclosed in the patent application as filed. However a claim which is wider in scope but does not disclose any new information does not add matter and is not invalid on that ground."

The Court of Appeal had a fairly thorough look at added matter in a different case between the same parties: ***Conversant v Huawei* (8 October 2020)[215]**. This was the case in which, in 2019[216], Huawei had relied on 20 separate points to contend that the patent was invalid or not infringed; and succeeded only on the added matter point. The added matter point went to appeal.

Interestingly, Floyd LJ's approach did not refer to an appellate court's role as being limited to review or dependent upon the identification of an error of principle – a distinction from the clear limitation in the context of obviousness appeals expressed in *Emson v Hozelock*[217] and *Actavis v ICOS*[218], which follow a judge's "multi-factorial evaluation". Floyd LJ assessed the issue of added matter afresh, reaching the same conclusion as the judge: Conversant's patent added matter.

The added matter objection in the *Conversant v Huawei* (8 October 2020) case arose out of amendments made to the claims, partly in the course of prosecution and partly in the litigation. No change was made, though, to the technical disclosure in the body of the specification. So if there was added matter, it was because the amendments to the claim, when considered as a whole, used language which *disclosed* something further about the invention. This meant that the issues as to 'construction' concerned what the claim language *disclosed* rather than the limits of the *scope* of the claim. It was irrelevant how the claim came to be written in that form.

On the role of evidence in the interpretation of the specification in this context, Floyd LJ said ([110]):

> "Although the meaning of a document is, in the end, a question of law, the correct interpretation of a passage in a patent specification is a matter to which evidence of those skilled in the art can be relevant. This can take a number of forms. Whilst evidence of the meaning of ordinary English words is inadmissible, experts are frequently, and properly, asked to address the consequences of a particular term, on assumptions as to its meaning. They also conventionally address the relevant factual matrix, i.e. the common general knowledge."

Turning to the principles governing the assessment of added matter, Floyd LJ said that the first question for the court to determine is what, of relevance, the skilled person would learn from the application as filed. For this purpose the claims form part of the disclosure (although not everything that falls within the scope of the claims is necessarily disclosed). The court must carry out the

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[214] *Conversant Wireless Licensing S.à.r.l v Huawei Technologies Co. Ltd & Ors* [2020] EWHC 14 (Pat) (8 January 2020) Birss J
[215] *Conversant Wireless Licensing SARL v Huawei Technologies Co., Limited* [2020] EWCA Civ 1292 (8 October 2020) Patten, Floyd & Newey LLJ
[216] *Conversant Wireless Licensing SARL v Huawei Technologies Co. Limited & Ors* [2019] EWHC 1687 (Pat) (4 July 2019) Arnold J
[217] *E. Mishan & Sons, Inc v Hozelock Ltd* [2020] EWCA Civ 871
[218] *Actavis Group PTC EHF v ICOS Corporation* [2019] UKSC 15

exercise through the eyes of the skilled addressee, who will approach the documents with the benefit of the common general knowledge. Disclosure may be express or implied, but matter that would merely be obvious in light of the disclosure (rather than an implicit part of the disclosure) is not 'disclosed'.

Next, Floyd LJ said that it is necessary to ask what is disclosed by the challenged specification (i.e. the granted specification or the specification as sought to be amended). Again, the claims form part of the disclosure and the exercise is through the eyes of the skilled addressee.

The two disclosures must then be compared to see whether any subject matter relevant to the invention has been added. The comparison is a strict one: subject matter will be added unless it is clearly and unambiguously disclosed in the application as filed. The mere fact that the language used in the challenged specification does not appear *expressis verbis* in the application as filed does not itself give rise to added matter. However, an applicant should not be allowed to improve their position by adding subject matter not disclosed in the application as filed which would give him an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application. If the challenged specification provided a contribution to the subject matter of the claimed invention then it would give an unwarranted advantage to the patentee. On the other hand, a mere exclusion of protection for part of the subject matter of the claimed invention as covered by the application as filed could not reasonably be considered to give any unwarranted advantage to the applicant.

When amendment of a granted patent is being considered, the comparison to be made is between the application for the patent (rather than the granted patent) and the proposed amendment. The form of the granted patent before amendment does not come into the comparison (*Nokia v IPCom*[219]).

A week after the Court of Appeal's judgment in *Conversant v Huawei* (8 October 2020), in the vaccine formulation case ***MSD v Wyeth***[220] Meade J considered the concept called 'intermediate generalisation'. He said ([280]):

> "…the key principle (again, *Nokia v. IPCom*, ibid.) is that “it is not permissible to introduce into a claim a feature taken from a specific embodiment unless the skilled person would understand that the other features of the embodiment are not necessary to carry out the claimed invention. Put another way, it must be apparent to the skilled person that the selected feature is generally applicable to the claimed invention absent the other features of that embodiment.”

To this, Meade J added a helpful observation for practitioners ([296]):

> "I do not suggest that there is any strict rule differentiating sections of specifications in terms of added matter, but the reader may well, depending on the context, expect that the more general sections prior to the Examples, will contain principles that may be more widely applicable than the individual details of the experiments in the Examples. I think this is reflected in the references in cases such as *Nokia v. IPCom* to taking features from specific embodiments out of context. Nonetheless, it could be added matter to combine parts of the general teaching in a way not taught in the application – it depends on the facts."

[219] *Nokia OYJ v IPCom GmbH & Co KG* [2012] EWCA Civ 567
[220] *Merck Sharp & Dohme Limited v Wyeth LLC* [2020] EWHC 2636 (Pat) (15 October 2020) Meade J

Meade J agreed with MSD that there was no specific disclosure in one paragraph of Wyeth's application of the combination of all the features of claim 1 (or 16) with a surfactant generally, but he dismissed the added matter challenge ([299]-[300]):

> "I consider that MSD's attack takes the parts of the application referred to above too atomically and does not engage with the teaching as a whole. As is clear from the authorities cited above, the application must be considered overall, and if part of its teaching is general, so that would be clearly understood to apply generally, it is not necessarily added matter to take it in conjunction with another part of the general teaching.
>
> In particular, although it is true that the passage at page 7 lines 26-29 refers to polysorbate 80 only, the reader would clearly understand that that was the example given at that stage, and not limiting, and would clearly appreciate that the patentee envisaged other surfactants, indeed a wide range of them, as equally applicable, given the teaching at page 17."

So there was no added matter.

Squeeze arguments with the doctrine of equivalents

In the *Conversant v Huawei* (8 October 2020) case at first instance[221], Arnold J stated that infringement by equivalence cannot give rise to an added matter objection. In 2020, in ***IPCom v Vodafone***[222], Deputy Judge Douglas Campbell QC agreed, explaining ([169]):

> "It muddles up the strict novelty-type test for added matter with the different legal test for infringement. It was also difficult, if not impossible, to reconcile this argument with the law that "An amendment of a specification of a patent … shall have effect and be deemed always to have had effect from the grant of the patent": see s 27(2) of the 1977 Act."

f. Patentable subject matter

Two judgments in 2020 addressed an issue of patentability of subject matter.

Lenovo v Comproller[223] is interesting for its review of the *Aerotel v Telco*[224] approach. The *Lenovo* case concerned Lenovo's application for a patent about avoiding 'card clash' in contactless payment. The Comptroller concluded that the 'invention' was excluded from patentability by section 1(2) of the Patents Act because it related to a computer programme and a business method as such; Birss J heard Lenovo's appeal.

Section 1(2) of the Patents Act states:

> "It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of -

[221] *Conversant Wireless Licensing SARL v Huawei Technologies Co., Ltd* [2019] EWHC 1687 (Pat)
[222] *IPCom GmbH & Co KG v Vodafone Group plc & Ors* [2020] EWHC 132 (Pat) (28 January 2020) Recorder Douglas Campbell QC
[223] *Lenovo (Singapore) Pte Ltd v Comptroller General of Patents* [2020] EWHC 1706 (Pat) 9 July 2020) Birss J
[224] *Aerotel Ltd v Telco Holdings Ltd & Ors* [2006] EWCA Civ 1371

a) a discovery, scientific theory or mathematical method;
b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;
c) a scheme, **rule or method for** performing a mental act, playing a game or **doing business**, or a **program for a computer**;
d) the presentation of information;

but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such."

It was common ground that the court's approach to the assessment of s.1(2) should be governed by *Aerotel v Telco*, which set out a four-step test ([8]):

"(1) Properly construe the claim;
(2) identify the actual contribution;
(3) ask whether it falls solely within the excluded subject matter;
(4) check whether the actual or alleged contribution is actually technical in nature."

Also relevant were the signposts identified by Lewison J in *AT&T v Comproller*[225], reformulated by Lewison LJ in *HTC v Apple*[226], although these were not intended to be prescriptive ([10]):

i) "whether the claimed technical effect has a technical effect on a process which is carried on outside the computer
ii) whether the claimed technical effect operates at the level of the architecture of the computer; that is to say whether the effect is produced irrespective of the data being processed or the applications being run
iii) whether the claimed technical effect results in the computer being made to operate in a new way
iv) whether the program makes the computer a better computer in the sense of running more efficiently and effectively as a computer
v) whether the perceived problem is overcome by the claimed invention as opposed to merely being circumvented."

Computer programs

In respect of *Aerotel* step 2, Birss J expressed the view that it was not formally necessary to conduct a prior art search, although it would not be wrong for the Comptroller to do so.

From a relevant item of prior art that had been identified, the Deputy Director had concluded that the idea of a card reader reading multiple cards at the same time was known; the inventor's contribution lay in the subsequent step to allow the payment to be made automatically across more than one account. The invention would be implemented on a computer system using standard hardware and data transmission means, and was characterised by the Comptroller as ([18]):

"a computer-implemented method of automatically selecting multiple contactless payment identifiers based on user preferences to enable a purchase to be split across multiple

[225] *AT&T Knowledge Ventures LP v Comptroller General of Patents* [2009] EWHC 343 (Pat)
[226] *HTC Europe Co Ltd v Apple Inc* [2013] EWCA Civ 451

payment accounts, and allow the user to benefit from different account payment incentives and limits."

The Deputy Director then considered *Aerotel* steps 3 and 4 together, an approach that Birss J expressed agreement with ([20]):

> "The third and fourth steps of the *Aerotel* test involve considering whether the contribution falls solely within excluded categories, and then checking whether the contribution is technical in nature. It is appropriate to consider these two steps together because whether the contribution is technical in nature will have a direct impact on whether it falls solely within excluded matter."

Birss J said that the *AT&T* signposts (ii), (iii) and (iv) "are really focussed on what one might call the better computer cases". This was not such a case and Birss J agreed with the Deputy Director that those signposts did not advance Lenovo's case. Signposts (i) and (v) had most relevance.

For signpost (i), Birss J agreed with the Deputy Director that making a physical interaction obsolete is capable of giving rise to a technical effect but said that it was important to examine the detail. In the present case, reading multiple cards at the same time was not part of the contribution, because that was known. The invention lay instead in receiving user preferences and automatically deciding which payment accounts should be used for the transaction from those retrieved to make the best use of incentives and account balances.

The Deputy Director had concluded that the "final step of actually selecting an account by pressing a button once those to be used have been chosen is rather straightforward; implementing a manual button press to select a user preference was well-known at the priority date of the invention" and so concluded that Lenovo's invention was excluded under s.1(2).

Disagreeing with this conclusion, Birss J said that the Deputy Director's reasoning was written as if the technical effect relied upon was the step of having the user press a button, which was dismissed because it was well known. But this reasoning was the wrong way round: the alleged technical effect did not involve implementing a button press but getting rid of it. Lenovo's appeal on the computer program exclusion therefore succeeded.

Method of doing business

So too did Lenovo's appeal on the business method exclusion. Birss J reasoned ([36]):

> "The key question in this case is whether the invention involves a different physical interaction with the world outside the computer, as compared to what had gone before. … in US 438 … the user has to press a button to choose which card to use or to split the payment between two cards. In the Lenovo invention, this is handled automatically at the point of sale because the user's preferences have already been acquired and stored elsewhere. … As a result of this automatic feature, the card clash problem experienced with contactless payment cards is solved without the user having to take any extra physical step at the point they use their contactless cards. In my judgment that difference is an effect of the invention which is neither a computer program as such nor a method of doing business as such nor a combination of the two. That difference is technical in character and, in the context of the invention as a whole, it is not just one of the normal incidents of a conventional computer system. The

claimed invention may or may not be obvious over US 438, or any other prior art, but what would count for s1(2) of the 1977 Act / Art 52 EPC is that the invention does have an effect which is of the right character to satisfy the law."

Mathematical method

In ***Communisis v The Tall Group***[227], The Tall Group challenged Communisis' patent under the mathematical method exclusion of s.1(2)(a) Patents Act. The patent was to a security measure for banking cheques.

Applying *Aerotel,* the dispute was as to the identification of the contribution of the invention. Communisis sought to rely on its assertions to the UK IPO, the substance of which the judge rejected. Stripping away the information taught by the prior art, she said that all that was left was encryption by the mathematical method of converting to a higher base. On this ([114]):

> "…It is no party's case that this was inventive at the priority date of the Patent. Accordingly, I cannot identify an actual contribution to human knowledge for the purposes of the second step, and for the third/fourth step, I am satisfied that the alleged contribution is excluded as a mathematical method under section 1(2)(a) of the Patents Act."

Communisis' patent was therefore invalid for excluded subject matter (as well as obviousness).

g. Amendment

IPCom v Vodafone[228] was the case about IPCom's asserted SEP and Vodafone's network infrastructure for 4G. IPCom sought unconditional amendment of the claims as granted, which Vodafone objected to on the basis that they would extend the protection conferred by the patent (section 76(3) Patents Act).

Deputy Judge Douglas Campbell QC held that for the objection to succeed, it only needed to be shown that there had been such an extension by reference to a hypothetical example, but the example had to be a possible one.

Vodafone's argument was that unconditional claim 1 provided an exhaustive list of those who had to do the lottery (for access) whereas conditional claim 1 now provided a non-exhaustive list, and hence the scope of the claim had been extended. The judge disagreed, saying ([121]-[122]):

> "There only ever were 2 types of non-privileged users, namely the normally privileged users and users with no class. That is still the position after amendment. Vodafone did not identify any other possible classes.
>
> Vodafone did put forward a fictional example which they said showed that the scope of protection had been extended. This was a notional class 16 user "that is not Privileged and

[227] *Communisis Plc v The Tall Group of Companies Limited & Ors* [2020] EWHC 3089 (IPEC) (17 November 2020) HHJ Melissa Clarke

[228] *IPCom GmbH & Co KG v Vodafone Group plc & Ors* [2020] EWHC 132 (Pat) (28 January 2020) Recorder Douglas Campbell QC

not required to do the lottery". But no reason was given as to why the user in the fictional example was not required to do the lottery and I do not consider the example to be a possible one. I reject this argument too."

On this, the judge reached the same conclusion as the EPO and the UK IPO.

In ***Evalve v Edwards*** **(substantive)**[229], the case about devices used to treat mitral valve regurgitation by a transcatheter technique, amendment issues arose in respect of the '810 patent.

Evalve proposed tweaks to claim 1 as granted (in the form of 'Modified Conditional Amendment F') which included adding a requirement for the fixation device to be "for the repair of a valve of the heart" (integer A), and adding the words "wherein in the inverted position the engagement surfaces provide an atraumatic surface to deflect tissue" (integer C).

The UK IPO pointed out that the proposed amendment to integer A must refer to a device suitable for performing that function (i.e. of repair to a valve of the heart). The judge agreed, and on that basis held that amendment to be allowable.

The UK IPO was concerned the proposed amendment to integer C lacked clarity (contrary to s14(5) Patents Act) because it defined the invention by a result without specifying the technical means to do so. Interestingly, Birss J disagreed. He explained that having had the "benefit of much more evidence and argument than would ever be available to the Office", including a substantial body of evidence allowing the court to understand the common general knowledge of the skilled team, there was no material lack of clarity ([329]):

> "The inverted position and its purpose are explained in the patent at paragraphs [0052], [0062] and [0063]. The latter specifically explains the ability of the engagement surfaces to deflect tissue allowing the device to be withdrawn upwards and out through the valve. Although it is not spelled out fully in the passage, the skilled reader knows that in doing this there would be a risk of entanglement with tissue such as the chordae."

Evalve's proposed amendments were therefore allowable.

4. Technical matters and procedure

Every year the courts hand down a plethora of interesting judgments on unusual points and 2020 is no exception. In 2020, the courts also had to grapple with a new point: the conduct of remote / hybrid hearings in a new world of lockdowns.

Covid litigation

The challenges of 2020 have forced evolution in court operation, procedural rules and litigation practice that might have taken decades in times formerly known as 'normal'.

[229] *Evalve, Inc & Ors v Edwards LifeSciences Limited* [2020] EWHC 514 (Pat) (12 March 2020) Birss J

On 23 March 2020, the Prime Minister told the country that people must stay at home and certain businesses must close. Particularly in London, people were already working from home where they could, but 23 March is probably when we would say Lockdown 1 began.

The Lord Chancellor was ready. On 19 March, contingency arrangements for tribunals were published, and on 20 March a protocol regarding remote hearings. Within days, new practice directions were pushed out using the Part 51 pilot schemes mechanism. Options for conduct of hearings and trials were supplemented by Practice Direction 51Y on video hearings. Flexibility in procedural time limits was increased by Practice Direction 51ZA.

On the ground, the Rolls Building Courts remained physically open but a notable early casualty of the uncertainty was the FRAND trial scheduled in the *Conversant v Huawei* dispute. At the pre-trial review held on 20 March 2020, Judge Hacon adjourned the trial. A few days later, in ***Conversant v Huawei* (25 March 2020)**[230], he dismissed Conversant's proposal that the judge deal with the issues largely on paper. With reference to the need for trials to be conducted, and judgments given, in public, and the principle of natural justice that parties should be given an opportunity to call their own witnesses and cross-examine opposing witnesses, Judge Hacon concluded that, as things stood on 25 March 2020, the court guidance and rules issued so far did not make it appropriate to conduct the trial in the FRAND dispute on paper. The FRAND trial was subsequently relisted to begin in late January 2021[231].

On 27 March 2020, in the ***MSD v Wyeth*** case about Wyeth's vaccine formulation patent, Birss J permitted Wyeth/Pfizer additional time for service of the expert evidence. Wyeth/Pfizer's expert was an expert on the formulation of vaccines and had been called upon to participate in the emergency Covid-19 task force in Belgium.[232] The following week, in the ***Fisher & Paykel v Flexicare*** case about a patent for ventilator breathing tubes, Morgan J agreed to postpone the trial from September 2020 until not before 2nd November 2020, in order to give Flexicare time to find a new expert and obtain an expert report. Fexicare's existing expert on medical device design, a consultant anaesthetist at Alder Hey, had become unable to proceed to act because of demands in respect of the COVID-19 pandemic.[233]

In the second week of April though, signs of adaption to the 'new normal' began to emerge. In ***Heineken v Anheuser-Besch*[234]** Deputy Judge Daniel Alexander QC rejected an application from Anheuser-Busch for a two week extension for service of reply evidence. The proposal would have resulted in reply evidence being served on 23 April 2020 (instead of 8/9 April), ahead of a trial proposed to start on 29 April 2020. A more modest extension was permitted, to Friday 17 April, to take account of the general disruption and distractions caused to some as a result of the coronavirus crisis and the unavailability of one of the solicitors at Anheuser-Busch's lawyers. The deputy judge said ([13]):

> "…it is desirable where cases have been listed, that attempts are made to keep to the directions timetable where it is realistically possible to do so, without prejudicing safety or

[230] *Conversant Wireless Licensing S.A.R.L. v Huawei Technologies Co., Limited & Ors* [2020] EWHC 741 (Pat) (25 March 2020) HHJ Hacon
[231] *Conversant Wireless Licensing S.À.R.L. v Huawei Technologies (UK) Co., Limited & Ors* [2020] EWHC 989 (Pat) (8 April 2020) HHJ Hacon
[232] *Merck Sharp and Dohme Limited v Wyeth LLC* [2020] EWHC 742 (Pat) (27 March 2020) Birss J
[233] *Fisher & Paykel Healthcare Limited v Flexicare Medical Limited* [2020] EWHC 1094 (Pat) (3 April 2020) Morgan J
[234] *Heineken Supply Chain B.V. v Anheuser-Busch Inbev S.A.* [2020] EWHC 892 (Pat) (9 April 2020) Daniel Alexander QC

risking injustice as a result. It is against that background that paragraph 4 of PD 51ZA should be approached. That provides:

> "In so far as compatible with the proper administration of justice, the court will take into account the impact of the COVID-19 pandemic when considering applications for the extension of time, for compliance with directions, the adjournment of hearings and applications for relief from sanctions." "

Further, the deputy judge said that the guidance that had emerged from the Lord Chief Justice strongly suggested that where it could be safely done and without risks to the integrity of the legal process, "the wheels of justice should keep running at their pre-crisis rate". He continued ([28]):

> "It is not unreasonable to expect that lawyers concerned in keeping cases on track may need on occasion to push a little harder to enable that to be achieved. I also bear in mind that the nature of the proposed expert evidence is such that what may be lost in polish as a result of having fewer hours devoted to it by lawyers may be gained in raw authenticity, as well as the fact that a more limited time encourages confining the evidence to that which is truly essential."

This pretty much set the scene for the rest of 2020. Old dogs had to learn new tricks with videoconferencing platforms. And giving credit where credit is due, the ~~older~~ more senior patent specialists in the judiciary had already led the way.

In ***Regen v Estar***[235], Floyd LJ heard a telephone hearing on 19 March 2020 ahead of a trial scheduled to commence on 1 April 2020. The hearing was to determine a number of applications which had been made by both sides. Since the 2019 first instance judgment in the case[236], in which Regen's patent was found anticipated by prior use, the EPO had found the patent invalid too. In the English proceedings, Regen had ignored every procedural step in its appeal, failed to pay its solicitors (or its costs bills), and at a very late notice had asked for a stay of the appeal pending the outcome of appeal proceedings in the EPO.

Floyd LJ had had enough. Giving the Court of Appeal's 24 March 2020 judgment, he considered (and dismissed) Regen's application for a stay. He considered an adjournment. But he decided instead to strike out the appeal for failure to lodge the appeal bundles. The strike out was of the Court of Appeal's own motion, rather than pursuant to an application made by Estar.

On 26 March 2020, the Court of Appeal heard a highly expedited appeal remotely, handing down its judgment five days later, in ***Master Data v Comptroller*** **(appeal)**[237]. On the conduct of the hearing and management of the bundles, Floyd LJ said ([2]-[3]):

> "A remote hearing of the appeals was held by video conferencing on 26 March 2020 pursuant to Practice Direction 51Y- Video or Audio Hearings during Coronavirus Pandemic, signed by the Lord Chancellor and the Master of the Rolls on 24 March 2020. This avoided the need for any member of the court, party or legal representative to attend court. A media representative

[235] *Genentech, Inc (and Master Data Center, Inc) v The Comptroller General of Patents* [2020] EWCA Civ 475 (31 March 2020) Floyd, Davies, Arnold LLJ
[236] *Regen Lab SA v Estar Medical Limited & Ors* [2019] EWHC 63 (IPEC)
[237] *Master Data Center, Inc & Anr v The Comptroller General of Patents* [2020] EWCA Civ 475 (31 March 2020) Floyd, Davies, Arnold LLJ

was able to access the proceedings remotely, by joining the video conference, and accordingly the proceedings were held in public, pursuant to paragraph 3 of that Practice Direction.

At the hearing of the appeal, as they were below, MDC was represented by Miss Charlotte May QC, Genentech by Mr Andrew Lykiardopoulos QC and the Comptroller by Mr Michael Silverleaf QC. The court was provided with efficient access to electronic bundles via a Dropbox link. The parties and their representatives deserve the court's praise for their ability to adapt at extremely short notice to these new arrangements."

The Court of Appeal confirmed Douglas Campbell QC's 11 March 2020 judgment (*Master Data v Comptroller* (11 March 2020)[238]), with the result that it was not possible to correct Master Data's payment error in respect of, and therefore the early expiry of, Genentech's SPC for Lucentis.

The Court of Appeal was up and running. The challenge then became how to manage a complex patent trial, including cross-examination of experts, without having everyone in the court room. By the end of June the Patents Court had adapted.

In ***Edwards v Meril***[239] Birss J detailed how the trial of that case was heard over six days in July 2020 in a hybrid format, in which the judge and a small number of other participants were physically present in the court room and everyone else was connected by videolink. The judge elaborated ([9]-[10]):

"Following a triage hearing a few weeks beforehand and with the court's permission, the trial was conducted as a "hybrid" hearing using an audio/video system provided privately by the parties by a company called Sparq. For most of the time, present physically in court were up to six participants from each party, the usher, two staff from Sparq and me. All the other participants, including at various stages some junior counsel, solicitors, the transcriber, witnesses, individuals from the client companies and foreign lawyers instructed by the parties, attended by video conferencing, using a secure video link provided to them individually based on a list prepared in advance. Two witnesses attended in person to be cross-examined and the other four attended by the video conference system. Some participants were physically situated in England and Wales and others were overseas, including in the USA. The four remote witnesses were all in the USA. The remote witnesses were able to watch their counterparts give evidence. In addition, a small number of identified members of the public contacted the court and asked to attend, one by video and two in person. Since the court room was full, I permitted all three of them to be sent a video link which permitted them to watch and listen but not to speak. I made clear to those watching online, in a direction given at the outset of the trial, that recording or photographing the proceedings was prohibited. There was no broadcasting or livestreaming of the proceedings to unidentified persons. No breaches of the arrangements for the hearing took place.

I believe what took place was appropriate for the following brief reasons. Everything that took place was carried out only with the court's permission and under the court's control. No participant was provided with a video link without specific permission. Although the number of remote participants is different, the way in which this case was conducted is not different in principle from cases which have been carried out in the intellectual property courts for a long time, well before the pandemic. For example, international video conferencing was used in

[238] *Master Data Center, Inc v Comptroller General of Patents* [2020] EWHC 601 (Ch) (11 March 2020) Douglas Campbell QC
[239] *Edwards Lifesciences Corporation & Anr v Meril GmbH & Anr* [2020] EWHC 2562 (Pat) (29 September 2020) Birss J

> the Patents Court in 1999 in *Nutrinova v Scanchem* [2001] FSR 42 with witnesses in China. There are numerous other examples. The practice is well established. As part and parcel of this the remote participants, such as witnesses and lawyers, are able to see and hear what is taking place in the court room. This is a necessary part of their participation. It has always been something which requires the court's express permission and is under the court's control. It promotes access to justice and is often necessary for a fair trial since the physical attendance by overseas participants may otherwise have been impossible."

In ***Neurim v Generics* (4 December 2020)**[240] Marcus Smith J explained that the trial in that case had been conducted in a hybrid format too (([16]):

> "…all of the central participants in the trial - counsel, key persons in the litigation teams of the solicitors, representatives of the clients and witnesses - were present in court. However, although I had the use of the one of the Rolls Building's "super-courts", due to social distancing compelled by the COVID-19 pandemic, there was not enough room for all of the parties' legal teams (broadly understood), and no room for the public."

Additional participants were therefore connected via videolink (Skype for Business). The videolinks were deemed an extension of the physical courtroom, accordingly the rules that apply in the ordinary course to court proceedings applied in the remote locations. In particular the judge spelled out that no recording or photographing of images on the screen was permitted. The trial was also conducted in public. Although there were elements of the documents before the court that were confidential, it was possible to hold the proceedings without referring, in open court, to these confidential materials.

One of the experts in the case, Professor Roth, gave evidence remotely from the United States of America. The judge pointed out that this, itself, did not make the hearing hybrid; the courts have for many years taken evidence remotely by way of video-link, and Professor Roth's manner of giving evidence was no more than an example of this established practice.

For reference, the Marcus Smith J reproduced the terms of his order making the arrangements for the hybrid trial.

In ***Fisher & Paykel v Flexicare***[241], the trial was heard in November 2020, during Lockdown 2. It was entirely remote. One of the witnesses was located in California. The court accommodated this by conducting the oral evidence starting at 2pm each day and continuing until 6.30 or 7.30pm. Commending the parties and witnesses for their flexibility, Meade J noted special thanks to the Court staff "for dealing with this on top of everything else".

Daily cause lists continue to include a notice providing details of whom members of the public and representatives of the media should contact if they wish to witness a remote or hybrid hearing.

[240] *Neurim Pharmaceuticals (1991) Limited & Anr v Generics UK Limited (trading as Mylan) & Anr* [2020] EWHC 3270 (Pat) (4 December 2020) Marcus Smith J

[241] *Fisher & Paykel Healthcare Limited v Flexicare Medical Limited & Anr* [2020] EWHC 3282 (Pat) (8 December 2020) Meade J

Confidentiality clubs

The availability of 'external eyes only' confidentiality regimes, excluding in-house lawyers with management of the litigation from access to some documents in the case, has been a developing area in recent years. Some notable judgments emerged in the Autumn.

Anan Kasei v Neo[242] is a case discussed last year for the Court of Appeal's renaming of insufficiency for 'ambiguity' as insufficiency for 'uncertainty'. The outcome was that Rhodia/Anan Kasei succeeded in establishing infringement and validity of its patent to "a ceric oxide consisting essentially of a ceric oxide…" (for a catalyst for purifying vehicle exhaust gases). Following pre-election disclosure, Rhodia/Anan Kasei claimed for damages for loss of profits. As this required Rhodia/Anan Kasei to establish its loss, it entailed disclosure by Rhodia/Anan Kasei.

Rhodia/Anan Kasei were prepared to allow, and had allowed, Neo's lawyers and accounting experts to consider certain confidential material, albeit subject to the terms of a confidentiality ring. However they were not prepared to allow anyone within Neo to see or consider the material.

Neo applied to the court for an order that a specified individual at Neo be permitted to have disclosed to him a confidential witness statement. At least by the time of the hearing, Neo had accepted that the relevant confidential material was highly confidential to Rhodia/Anan Kasei and the judge proceeded on the basis that it would be damaging to Rhodia were its confidentiality to be breached.

On the principles, Marcus Smith J noted that the methods of protecting confidential information long permitted by the courts – redaction of irrelevant material, conducting hearings without reference to a particular document or in private, and the use of confidentiality rings for relevant documents that are particularly sensitive - constitute derogations from the normal regime. The normal regime is that disclosure takes place, and the party receiving another's disclosed document receives those documents, subject to the express undertaking contained in CPR 31.22 of the Civil Procedure Rules to use a disclosed document only for the purpose of the proceedings in which that document has been disclosed.

Therefore, before ordering a confidentiality ring, even with the consent of the parties to the proceedings, a judge "is well advised to consider carefully the need for such protection" because they form a "closed material" procedure of the sort warned against by the Supreme Court in *Al Rawi v. The Security Service*[243] and *Bank Mellat v. HM Treasury (No 2)*[244]*.* Even where the terms of a confidentiality ring are agreed between the parties, the court must be satisfied that the creation of a confidentiality ring is appropriate.

In the present case, the judge was satisfied that the creation of a ring was appropriate; the issue was whether it was justified not to include anyone from Neo. With reference to *TQ Delta v ZyXEL*[245] and *Infederation v Google*[246], Marcus Smith J indicated that exceptional circumstances need to be demonstrated for such an order to be appropriate.

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[242] *Anan Kasei Co., Limited & Anr v Neo Chemicals & Oxides* (Europe) Limited & Anr [2020] EWHC 2503 (Pat) (16 September 2020) Marcus Smith J
[243] *Al-Rawi & Ors v The Security Service & Ors* [2011] UKSC 34
[244] *Bank Mellat v. HM Treasury* (No 2) [2013] UKSC 39
[245] *TQ Delta LLC v ZyXEL Communications UK Ltd & Anr* [2018] EWHC 1515 (Ch)
[246] *Infederation Ltd v Google LLC & Ors* [2020] EWHC 657 (Ch) (Roth J)

As the party seeking an external eyes only ring, the burden of the argument rested on Rhodia/Anan. Rhodia/Anan's arguments were put on the basis of the very small number of documents concerned and the timing of the application, points that the judge did not consider sufficient to justify limiting the confidentiality ring to external eyes only. Neo therefore succeeded in its application.

A week later, Sir Alastair Norris heard dispute about disclosure terms in ***Mitsubishi v Archos***[247]. SEP owner Mitsubishi was suing twelve defendant implementers. Four of them were in the 'Oppo' group and four were in the 'Xiaomi' group.

In the procedure leading to the FRAND trial, Mann J ordered the defendants to provide an amended FRAND statement of case particularising any positive case they intended to make. If this was to include a positive case based on comparable agreements, the defendants were to identify and disclose any licences relied upon on their side and to give full particulars of any reliance placed on documents disclosed to them by Mitsubishi.

Mitsubishi was ordered provide disclosure and inspection of copies of licences where the rights licensed included any of the patents in the 'MCP Pool' and copies of agreements entered into by Mitsubishi or its affiliates to which patents/applications comprised in the MCP Pool (or rights or interests therein) were assigned.

This was a broad disclosure order, made (and necessary) because the defendants were being required to formulate a positive case on FRAND. However, the disclosure was to be subject to a confidentiality regime established by Mann J also. Under the regime, parties could designate documents to three levels of confidentiality: (i) external eyes only ('AEO'); (ii) 'Highly Confidential Material' (HCM) – the confidentiality club for which could include up to two agreed representatives of each party as well as external lawyers and experts; and (iii) ordinary disclosure materials.

Mitsubishi disclosed documents including licences with third parties and assignments. It designated 35 documents as AEO and 115 documents as HCM. After the defendants' external lawyers and experts within the AEO club had had the opportunity to review all the materials, the Oppo and Xiaomi defendants applied to the court to expand the availability of disclosure material to in-house representatives, in three different ways. Xiaomi applied for wholesale re-designation of all AEO documents as HCM. Oppo sought re-designation of 6 specific AEO documents as HCM. Oppo also sought the inclusion of three named representatives in the HCM club to which the claimants had not agreed.

Sir Alastair Norris refused the wholesale re-designation of material but agreed to the re-designation of the six specific documents. He refused to include the individuals requested by Oppo in the AEO club.

Six weeks after Norris J's judgment was handed down, the Court of Appeal confirmed it in ***OnePlus v Mitsubishi***[248], a judgment providing well-needed guidance on the principles in this area.

Floyd LJ began his reasoning with the basics of disclosure under the CPR ([1]):

> "Documents disclosed in the course of litigation under the CPR to an opposing party may only be used by that party for the purposes of that litigation unless they are read to or by the court,

[247] *Mitsubishi Electric Corporation & Anr v Archos SA & Ors* [2020] EWHC 2641 (Pat) (9 October 2020) Sir Alastair Norris
[248] *Oneplus Technology (Shenshen) Co., Ltd & Ors v Mitsubishi Corporation & Anr* [2020] EWCA Civ 1562 (19 November 2020) Floyd, Males & Lewis LLJ

or referred to, at a hearing which has been held in public, the court gives permission or the party who disclosed the document and the person to whom the document belongs agree: CPR 31.22(1). In the vast majority of cases, this rule gives adequate protection against misuse of disclosure documents."

However, he noted that it is not uncommon in intellectual property (and other types of) litigation for highly confidential documents to be subject to more restrictive measures designed to prevent documents from entering the public domain or being used for collateral purposes. On the principles governing the use of such regimes, Floyd LJ considered the case law in this area in some depth, in particular *Warner-Lambert v Glaxo*[249], *Roussel Uclaf v ICI*[250], *Al-Rawi v Security Service*[251], and more recent first instance judgments in patent and competition cases illustrating the application of the principles (*IPCom1*[252]*, IPCom 2*[253], *TQ Delta v ZyXel*[254]; *Infederation v Google* [255] and *Anan Kasei v Neo*[256]).

From *Warner-Lambert,* Floyd LJ noted that if policing of a misuse of information would be virtually impossible, this was a factor which should make the court particularly careful not to expose the disclosing party to any unnecessary risk of their trade secrets leaking to any competitors. This was particularly so where those to whom the process was disclosed might not be resident within the jurisdiction of the court. If the case were of such an esoterically technical character that if, even with the help of expert advisers, the party could not really form a view of their own upon the matter in question but would be bound act upon advice on the technical aspects, a court might well be justified in directing disclosure of allegedly secret material only to expert or professional agents, at least at the interlocutory stages.

From *Roussel*, the object to be achieved is that the applicant should have as full a degree of disclosure as will be consistent with adequate protection of the secret. In doing so, the court will be careful not to expose a party to any unnecessary risk of its trade secrets leaking to or being used by competitors. However, it would be exceptional to prevent a party from access to information which would play a substantial part in the case as this would mean the party would be unable to (i) hear a substantial part of the case, (ii) understand the reasons for advice given to him, and (iii) understand the reasons for the judgment.

In *Al-Rawi*, Lord Dyson said that he was not aware of a case in which a court had approved a trial proceeding in circumstances where one party was denied access to evidence which was being relied on at the trial by the other party.

Floyd LJ said that in FRAND cases, the approach to setting licence terms on the basis of other licences dealing with the same or similar subject matter is called the "comparables basis". The terms of any licence ordered to be disclosed are likely to be different in many respects from the notional FRAND licence and from any licence that the recipient would likely be negotiating in the future. Nevertheless, information contained in disclosed licences is of a kind that, once learned, cannot be unlearned, and could be used to direct negotiations with parties to the licences disclosed. Therefore

[249] *Warner-Lambert Co v Glaxo Laboratories Ltd* [1975] RPC 354
[250] *Roussel Uclaf v Imperial Chemical Industries Plc* [1990] RPC 45
[251] *Al-Rawi & Ors v The Security Service & Ors* [2011] UKSC 34
[252] *IPCom GmbH & Co KG v HTC Europe Co. Ltd & Ors* [2013] EWHC 52 (Pat)
[253] *IPCom GmbH & Co KG v HTC Europe Co. Ltd & Ors* [2013] EWHC 2880 (Ch)
[254] TQ *Delta LLC v ZyXel Communications UK Ltd & Anr* [2018] EWHC 1515 (Ch)
[255] *Infederation Ltd v Google LLC & Ors* [2020] EWHC 657 (Ch)
[256] *Anan Kasei Co., Ltd & Anr v Neo Chemicals & Oxides (Europe) Limited & Anr* [2020] EWHC 2503 (Pat)

the court should not facilitate the granting of a competitive advantage, and accordingly inflict a competitive disadvantage, unless justice required such a course to be taken.

Additionally, it may be relevant at what stage of a case the applicable terms are considered, as might the structure and organisation of the receiving party.

In *TQ Delta,* Henry Carr J declined to establish an external eyes only confidentiality regime. Floyd LJ expressed agreement with Henry Carr J on a number of points, in particular: that an external eyes only regime is exceptional; that it is wrong to place the onus for establishing that a document is non-confidential on a receiving party; and that the result of any such regime should not be to exclude the access by one of the parties to the relevant parts of key documents.

However, Floyd LJ expressly disagreed with other aspects of Henry Carr J's reasoning. In particular, Floyd LJ made clear that:

- An approach where *prima facie* highly confidential documents were first disclosed on an external eyes only basis was not wrong in principle; and
- There was no difference in substance between the following two approaches, neither of which was outlawed by Henry Carr J:
    - all documents that a party contended should be external eyes only should be individually examined by the court (with submissions and evidence from each side) before being so designated;
    - initial designation of documents as external eyes only subject to the receiving party's ability to challenge the designation (provided the disclosing party did not unfairly seek to take advantage of the opportunity).

From *Infederation*, confidentiality rings were sometimes established in competition cases to prevent leakage in both directions of confidential information. Sharing of pricing information could contravene competition law, and the court ought not to facilitate it by means of the disclosure process unless impossible to do so.

Additionally, Floyd LJ noted ([40]-[41]):

> "…the court must be alert to the misuse of the opportunity to designate documents as confidential. It remains the case that parties should not designate such material as AEO, even initially, unless they have satisfied themselves that there are solid grounds for establishing that restricting them in that way is necessary to protect their confidential content.
>
> … the exercise of deciding what measure of restriction is justified involves the first instance judge in a judgment of the kind which an appellate court will not interfere with "unless the judge took into account anything which he ought not to have taken into account or that he left out of account anything which he ought to have taken into account, or that he erred in principle … [or that he was] plainly wrong": see *Roussel*".

Turning to the merits of **Xiaomi's appeal**: this was against the judge's refusal to re-designate all the AEO documents HCM.

Xiaomi seem to have contended that the High Court had become a global licensing tribunal, in effect settling what was to be paid by the industry as a whole for the rights in issue and not just what was to

be paid by the implementers involved in the particular litigation. Transparency therefore required the re-designation. Floyd LJ rejected this point. He said that 'transparency', in the sense of helping third parties to understand the reasons for arriving at a particular set of licensing terms, was not what was sought by Xiaomi. Rather, Xiaomi sought re-designation into a private confidentiality regime to which their representatives had access.

Comparable licences were the core documents in the case, at least in a case where that method of valuation was adopted. It was therefore inevitable that some licences were going to take centre stage at the trial, while others would be more peripheral. However, the importance of a sub-set of documents did not justify wholesale re-designation.

Unlike Oppo, Xiaomi had not explained what documents it actually needed to see as a result of initial filtering by its lawyers and experts. The judge was therefore faced with doing significant, unnecessary and lasting damage to the interests of third parties, without assisting the objective of doing justice at proportionate cost. There was no reason why highly valuable confidential information belonging to third parties should be released more widely in circumstances where it was unlikely to be of importance to Xiaomi's case.

Further, following Oppo's success in re-designating six documents, Xiaomi's representatives would have access to them upon giving an undertaking to the relevant counterparties. The undertaking would confirm that the individuals were not involved in cellular SEP licensing but this would be time-limited and the individuals would leave the club if they did become so involved during the pendency of the action; it would permit the representatives to be involved in FRAND litigation including settlement; and for this purpose, Mitsubishi had agreed to release the names of the counter parties. Some of the limitations to the undertaking required were reached following concession by Mitsubishi and some by the Court of Appeal allowing Xiaomi's appeal to a limited extent.

Oppo had succeeded before the judge in getting six AEO documents re-designated HCM. This was not appealed by Mitsubishi. Oppo had been unsuccessful, however, in its application to include three individuals as party representatives. Oppo's grounds of appeal were against: 1) the restriction that members of the HCM club must not be involved in licensing with Mitsubishi and other members of the MCP Pool; and 2) the restriction that the members of the HCM club must not be involved in licensing negotiations with third parties i.e. the counterparties to the HCM licences. In both cases, Oppo contended that the restrictions unjustifiably interfered with Oppo's right to natural justice, and therefore represented an error of law.

Floyd LJ noted that in the Court of Appeal, Oppo had contended that the application was for the purpose of enabling access to the six re-designated documents. However, with reference to the transcript of the first hearing, Floyd LJ made clear that actually the request had been to enable those individuals to have access to all the HCM documents. This was significantly different, and once that was understood, Oppo's criticisms of the judge's reasoning seemed to fall away in their entirety. As the judge had not been presented with Oppo's case as it presently stood, he could not be criticised for dealing with it on the footing that the entire HCM category was in play.

In subsequent correspondence, Mitsubishi had accepted some alterations to arrangements. Floyd LJ said that it would be wrong for the Court of Appeal to rule definitively on whether or not the respondents were entitled to insist on the proposals, but if differences remained the Patents Court could resolve them. Oppo's appeal on the identity of its representatives for the HCM club was therefore dismissed too.

This is really helpful guidance from the Court of Appeal. In cases involving highly sensitive material the misuse of which would confer a competitive advantage on the recipient or a competitive disadvantage on others, the court will be sympathetic to the use of external eyes only arrangements, at least in order to facilitate the filtering of broad disclosure material. Party representatives can be expected to be shown key documents, but the recipient party is expected to propose individuals with a view to minimising the risks and consequences of inadvertent misuse of confidential material.

Disclosure

Turning to more general technical and procedural points, further helpful guidance has emerged in 2020 on the operation of the Disclosure Pilot under Practice Direction PD51U.

Conversant v Huawei **(10 February 2020)**[257] considered an application for disclosure made in the FRAND case after HHJ Hacon[258] had already refused disclosure of the defendants' third party licences on a number of grounds.

Birss J noted that under the old disclosure rules (CPR Pt 31) if a party applied to the court for a second time for an order for disclosure of essentially the same class of documents, the relevant question was that of CPR rule 3.1(7). This is an 'omnibus provision' on the general jurisdiction of the court to revoke or vary its own orders and was designed to deal with orders which, in the ordinary course, would not be revisited.

In contrast, the Disclosure Pilot expressly contemplates the potential for orders for Extended Disclosure to be varied. It sets out the requirements that a party making such an application must satisfy. CPR 3.1(7) therefore gives way to the specific requirements of paragraph 18 of the Disclosure Pilot (PDU51), which expressly sets out a different test:

> "18.1 The court may at any stage make an order that varies an order for Extended Disclosure. This includes making an additional order for disclosure of specific documents or narrow classes of documents relating to a particular Issue of Disclosure.
>
> 18.2 The party applying for an order under paragraph 18.1 must satisfy the court that varying the original order for Extended Disclosure is necessary for the just disposal of the proceedings and is reasonable and proportionate (as defined in paragraph 6.4)."

Before Birss J, Conversant sought an order that Huawei and ZTE produce lists of all of the licences to which they were parties, which related to SEPs between 2011 and 2017 in 2G, 3G and 4G, and then from those lists the parties would each select a number.

Huawei and ZTE submitted that third party licences in which companies in a defendant's (i.e. an implementer's) group were licensees in principle ought never to be disclosed in FRAND cases and/or were not capable of having evidential value. Birss J disagreed. Such licences were capable of having evidential value. It was secondary to the value of licences of the portfolio in issue or a larger portfolio from which that portfolio was taken, but depending on the pleaded cases and the nature of the evidence available to the court, it may be that a measure of such disclosure would be appropriate.

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[257] *Conversant Wireless Licensing S.à.r.l. v Huawei Technologies Co., Limited & Ors* [2020] EWHC 256 (Pat) (10 February 2020) Birss J

[258] [2019] EWHC 1982 (Pat)

In the present case there was a dispute about how the FRAND royalty rate should be calculated: the *Unwired Planet* approach, top down and comparables were variously being argued by the parties. Trial was scheduled for 27 April 2020. Having regard to this timetable, Birss J's view was that it would not be reasonable or proportionate now to award the disclosure sought, even if it was restricted down to, say, six licences. It would add significant extra evidence and would massively disrupt the timetable and holding on to the trial date was something he intended to do his utmost to achieve. (Of course Covid did not listen to that bit).

The judge expressed doubt that the disclosure of 16 third party licences would ever be reasonable or proportionate.

In ***ADD2 v Dspace***[259], Ms Pat Treacy, sitting as a judge of the Patents Court, refused an attempt by a claimant to get early disclosure on infringement in reliance upon the pre-action protocol.

Before Dspace had served its product and process description (PPD), which usually replaces disclosure on issues of infringement, ADD2 sought disclosure and inspection of manuals supplied by the defendants to their customers. ADD2 argued that access to the material was proportionate and relevant because it would assist them in addressing infringement and might reduce the cost of preparing a PPD. ADD2 complained that despite extensive engagement pre-action, the material sought had not been provided.

The judge noted that the obligations under the Practice Direction on Pre-Action Conduct and Protocols needed to be considered in the context of the objectives of that practice direction. This was to encourage the reasonable and proportionate exchange of information before litigation with a view, broadly, to averting proceedings or at least to encouraging more efficient resolution of proceedings. The practice direction provided general guidance to the parties as to the sort of conduct to be expected but there was no specific pre-action protocol for the type of action envisaged. And so, unsurprisingly, it was not prescriptive. While parties were obliged to have regard to it, the expectations were drafted in broad terms and similarly the court would consider whether the parties had complied "in substance" with the pre-action protocol.

In particular, paragraph 3 addressed the exchange of information. While the appropriate steps might include the disclosure of key documents relevant to the dispute (such as, for example, in the case of a patent action, prior art), the protocol did not give parties a right to receive any and all material that they might speculate would be useful. It required parties to think carefully about supplying sufficient key information (including documents) which was relevant to the issues and went to the objectives of the practice direction. The obligation was to act proportionately.

What was required to comply with the practice direction therefore depended on the nature of the dispute. The Patents Court takes a particular approach to technical disclosure for the purpose of assessing infringement and it would not be appropriate to require steps in pre-action conduct which were likely to undermine that approach. Therefore the defendants' failure to provide the claimant with the particular documents requested did not mean that the defendants had failed to comply, in substance, with the practice direction.

The claimant's application for specific disclosure needed to be considered under PD51U, CPR 31.13 and CPR 63PD 6.1, the last of which provides the defendant the option to serve a PPD in lieu of

[259] *ADD2 Research and Development Limited v Dspace Digital Signal Processing & Control Engineering GmbH & Anr* [2020] EWHC 912 (Pat) (18 March 2020) Ms Pat Treacy

standard disclosure on infringement. The defendants intended to serve a PPD in the present case and the award of specific disclosure at the present stage would be likely to increase costs. ADD2's application would therefore be refused; it was premature. The preferable course was to have the PPD first and any further applications after that.

Teva v Janssen[260] is also notable, in the lifesciences context, for the extent of disclosure ordered in respect of non-public material that had been submitted to the European Medicines Agency.

The case was an SPC dispute concerning the correct characterisation of 'active ingredient' in the SPC Regulation. Teva alleged that the active ingredient of Janssen's SPC '044 for 'Xeplion' was 'paliperidone', rather than 'paliperidone palmitate', and therefore the first authorisation to place the active ingredient on the market was not the marketing authorisation granted for Xeplion in March 2011 but that granted for 'Invega' in June 2007. Both Xeplion and Invega were anti-psychotics marketed by Janssen.

If the dispute reaches trial, the court will be asked to determine whether a salt ester prodrug of an active ingredient of an existing approved product is the same or a different active ingredient.

In this context, Teva contended that an issue for disclosure was whether paliperidone or paliperidone palmitate was the active ingredient of Xeplion. Teva sought broad Model C disclosure, alternatively Model D disclosure. Model D would involve Janssen having to assess, against the generality of the Teva's pleaded case, whether a document that related to an active ingredient would be capable of assisting the claimant's case or harming its own test.

The judge agreed with Teva that the issue it had identified was properly an issue for disclosure for the purposes of CPR PD51U. However, he was not persuaded that anything Janssen might itself have said to the EMA was information or a statement likely to be of any assistance to Teva or material at trial in deciding the issues that needed to be decided. Those were issues that would be decided based, essentially, on the contents of the public documents and the expert opinion evidence that the court would hear. Janssen's assertions in documents would carry little, if any, weight against the expert evidence and the public statements.

Accordingly, as requested, the extended disclosure sought was not appropriate or necessary. A few days before the hearing, Janssen had offered to provide non-privileged documents containing the data and/or results underlying the Xeplion European Public Assessment Report (EPAR) tests and/or studies (that would be) identified by Teva as relevant to Teva's Issue for Disclosure. The proposal was that the materials would be "suitably redacted" and disclosed under the terms of an agreed confidentiality club. The judge thought this was the more appropriate way forward, saying there was no reason to think that Janssen would have said anything material to the EMA that was not reflected in some way in the European Public Assessment Report.

The order made was therefore for Model B disclosure for both sides, which required disclosure - to the extent not already complied with in initial disclosure – of the key documents relied upon in support of the pleaded cases and the key documents that were necessary to enable each side to understand the case that they had to meet. Fancourt J said that in due course, a more focused application for specific documents might be justified, but it would need to be preceded by a proper request and explanation in correspondence between solicitors.

[260] *Teva UK Limited v Janssen Pharmaceutica N.A.* [2020] EWHC 3157 (Pat) (16 November 2020) Fancourt J

Withdrawal of admissions

Lufthansa v Astronics **(14 January 2020)**[261], serves as a warning of the importance of each and every word of patent pleadings, and in particular the need for representatives to understand the relevant factual background, legal tests and legal consequences of the words used when drafting statements of case.

The question that arose was whether it was possible for Astronics to withdraw an admission. The admission was that Astronics was liable for acts of importing. At the time it was made, Astronics' legal team had not clocked the point that it was not, in fact, Astronics but 16 other entities that had title in the relevant goods at the point at which they were imported into the UK.

Nugee J considered the defendants' application to amend according to the test set out in CPR Pt 14.7, which provides that an admission made under Part 14 may be withdrawn with the court's permission. In deciding whether to give permission for an admission to be withdrawn, the court will have regard to all the circumstances of the case.

Nugee J said that the assessment of the "prejudice that may be caused to any person if the admission is withdrawn" required a comparison between the position Lufthansa was presently in and the position it would be in if the admission was withdrawn. The comparison was **not** between the position Lufthansa ought to be in or would have been in if the admission had not been made and the position they would be in if the admission were now withdrawn. On the facts, withdrawal of the admission would put some acts of the 16 relevant parties outside the limitation period and would mean that Lufthansa could only recover damages for acts within the limitation period by suing the 16 entities.

Although Astronics had a seriously arguable point that, as a matter of law, it was not liable for supply in circumstances where title had passed in the US, if Astronics felt commercially obliged to stand behind those parties there would be a good prospect of Lufthansa establishing liability as a joint tortfeasor for importation.

With these factors in mind, and having regard to the overriding objective, Nugee J refused Astronics permission to withdraw its admission.

The importance of complying with procedural rules when making interim applications

In 2020 the Court of Appeal had strong words on the importance of complying with procedural rules when making interim applications, in ***Price v Flitcraft***[262].

In 2019[263], Douglas Campbell QC awarded summary judgment finding patent infringement, following an application made by the claimants (Price *et al*). Allowing Flitcraft's appeal, Floyd LJ made clear that Flitcraft's failure to provide documentary support for their case had to be kept in the context of Price's failure to comply with procedural requirements.

On the relevant legal principles, Floyd LJ noted the important function of ensuring fairness in the summary judgment procedure served by the Civil Procedure Rules and *Easyair v Opal*[264] (which

[261] *Lufthansa Technik AG v Astronics Advanced Electronic Systems & Ors* [2020] EWHC 83 (Pat) (14 January 2020) Nugee J
[262] *Price & Ors v Flitfcraft Limited & Ors* [2020] EWCA Civ 850 (9 July 2020) Patten, Floyd, David Richards LLJ
[263] *Price & Ors v Flitcraft Ltd & Ors* [2019] EWHC 1965 (Pat)
[264] *Easyair Ltd v Opal Telecom Ltd* [2009] EWHC 339 (Ch)at [15]

although is stated in terms of an application to strike out a claim, applies mutatis mutandis to an application for summary judgment by a claimant).

Floyd LJ set out the provisions of CPR 24.4(3), which requires the respondent to be given at least 14 days' notice of the date fixed for the hearing and the issues which it is proposed the court will decide at the hearing. He noted the practice direction supplementing Part 24, which requires "the application notice or the evidence contained or referred to in it or served with it" to meet the standard set out in paragraph 2 thereof. He also noted that rule 24.5(1) requires a respondent who wishes to rely on written evidence at the hearing, to file that written evidence and serve copies on every other party to the application at least 7 days before the summary judgment hearing. Floyd LJ then said ([43]):

> "Thus in an idealised case, a claimant can issue and serve an application for summary judgment to be heard in 14 days' time. The defendant must serve his evidence 7 days before the hearing, and the claimant must serve any evidence in reply at least 3 days before the hearing. If all this is done, the hearing can go ahead on the appointed day. The overall object of the rules and practice direction taken together is to ensure a fair hearing of the summary judgment application within a short time scale. **The procedural safeguards**, such as requiring notice of the rule under which the application is brought, identification of issues and/or a statement in the application notice or the evidence referred to in it that the applicant believes that the respondent has no real prospect of successfully defending the claim or issue **are important protections aimed at ensuring that the overall procedure is fair**."

Floyd LJ also addressed the principles governing the admission of further evidence. He permitted the defendants to adduce further evidence and to amend their defence, which he considered (now) to have a real prospect of success.

Trial listing

In July 2020, in ***Facebook v Voxer***[265], the claimant (Facebook) managed to get a trial window listed from 1 March 2021, **before** the expected infringement hearing in Germany (April/May 2021), by employing the Shorter Trial Scheme (STS) and applying to list the trial window before the case management conference took place (which was scheduled for October 2020). The English proceedings were commenced in May 2020.

Birss J noted that when the court is considering an application for an expedited trial date, various judgments of the Patents Court have made it clear that arranging for a trial in London of a validity dispute prior to a hearing on infringement of the same European Patent in Germany is not, on its own, a ground for expedition; although it is a factor which the court can take into account, it is not necessarily a particularly strong factor.

However in the present application it was the principles governing the STS that applied, not those governing expedition. The terms of the STS (PD57AB para 2.38) make clear that parties can apply for a trial date before the CMC. At the CMC, if a trial date has not already been fixed, the date fixed "should be not more than 8 months after the CMC and with a trial length of not more than 4 days (including reading time)". Birss J said that this provision is "intended to accommodate circumstances in which one or both parties seek to have the trial date set at an earlier stage prior to the case management conference". Early certainty about when a trial will take place can be useful; early fixing of a date being not necessarily the same thing as the fixing of an early date. The STS itself arranges

[265] *Facebook Ireland Limited v Voxer IP LLC* [2020] EWHC 1806 (Pat) (7 July 2020) Birss J

for a relatively late date for the case management conference as compared to the timing of the CMC in other cases outside the scheme, such as many patent actions.

Further, it remains the case (as stated at the outset of the scheme) that the STS offers dispute resolution on a commercial timescale, with cases managed by docketed judges with the aim of reaching trial within approximately 10 months of the issue of proceedings and judgment within six weeks thereafter. A trial date within the window sought by Facebook would not be materially earlier than contemplated by the guidance and the terms of the STS, and so it involved the normal application of the STS. It was not a matter of expedition.

As presently constituted, the case was eminently suitable for a 3-4 day trial under the STS. It concerned a telecommunications patent, had a category 4 rating, and involved two items of prior art. In view of the arguments as they presently stood, the case could readily be done in the STS.

The STS provides that a letter before action ought to be sent unless there is a good reason not to; and the defendant should normally respond within 14 days. No letter before action had been sent in the present case. However this was not a new dispute between the parties. Therefore the absence of such a letter had two (and only two) consequences. One was that the claim was started about 14 days earlier than it might otherwise have done. The other was that the claim had not been commenced in the STS with Voxer's agreement.

For Voxer, Dr Nicholson submitted that his clients might take steps that would mean the case was not suitable for the STS. However, Birss J decided to make the order for listing of the trial without prejudice to the ability of Voxer at the CMC to apply to transfer it out. And he was unimpressed by Voxer's point on the availability of its counsel, saying that Counsel's convenience was not a matter of great weight "when addressing issues of this kind at this stage".

Litigants in person

In ***Freddy v Hugz***[266], the case about the bum-lifting jeans, the defendants' (Hugz') solicitors came off the record in June 2020; and the defendants did not turn up to the (remote) trial in October 2020.

This meant that Freddy's expert evidence was uncontested. The case being in IPEC, it also meant that the defendants' Amended Defence stood as their evidence in chief.

The Deputy Judge, David Stone, was asked to, and did, strike out the defendants' counterclaim for (i) invalidity of the patent and (ii) declaration that letters sent by the claimant amounted to threats: the test set out in CPR 39.3(1)(c) was made out. The Deputy Judge said that had he been asked to do so, he also would have struck out the Amended Defence on the basis of the defendants' non-attendance (*Scott v J4K*[267]). However Freddy wanted a reasoned judgment on infringement.

The Deputy Judge said that he had checked with the registry and was confident that that the key individual of the defendants had been made aware of the date of the trial and how to access it, and also how to contact the court again, should he have wished to. He also noted gratitude to Freddy's representatives "for the fair-handed way in which they approached the trial, and, from the correspondence, appear to have approached the matter more generally, including since the

[266] *Freddy SpA v Hugz Clothing Limited & Ors* [2020] EWHC 3032 (IPEC) (19 November 2020) David Stone
[267] *Scott Tynan v J4K Sports Limited* [2018] EWHC 3519 (Ch)

Defendants have been unrepresented". Substantial efforts had been made to inform Mr Kavanagh of and engage with him regarding the conduct of the proceedings.

Having considered the procedural aspects, the judge said he had no concerns about Freddy's evidence, and he proceeded to consider the issues of infringement and to give a reasoned judgment finding infringement.

Finally for this section, the need for legal teams to take particular care when litigating against a litigant in person was flagged by HHJ Hacon also, in ***Permavent v Makin***[268]. Following a settlement of patent litigation that came to further dispute, Mr Makin filed a (counter)claim for payments due and sought disclosure.

The judge reached the view that there had been a misunderstanding between the parties as to what exactly was meant by the terms of the draft confidentiality undertaking that the claimants requested of Mr Makin's auditor. Understanding Permavent's proposal to be that Mr Makin's auditor would be provided access to unredacted copies of documents, but if anything was to be shown to Mr Makin, the claimants proposed to redact irrelevant material, Judge Hacon proposed wording for an order reflecting this but said that if the position had been misunderstood it might be necessary to reconsider the judgment.

Mr Makin's application for disclosure was refused. The auditing arrangements provided in a settlement agreement were sufficient for Mr Markin's right to verify the payments owed to him, and to the extent the disclosure sought went beyond what was provided under the settlement agreement, it would cause unnecessary cost to the claimants and provide Mr Makin with no further information to which he was entitled.

Wrapping up his reasoning, Judge Hacon said that when the opposing party is a litigant in person, a legal team must take particular care to avoid any misunderstandings. It would have been better for Permavent's solicitors to have answered an email sent by Mr Makin in order to clarify their clients' position on confidentiality.

5. Competition law / settlement / licensing

Competition law and patent litigation

Birss J's judgment in ***Teva v Chiesi***[269] is noted in section 2c. above: the judge held that a *quia timet* infringement action can proceed if there is a real prospect of the patentee succeeding in establishing *at trial* that the relevant party threatens and intends to commit the act alleged to infringe. Against this test Chiesi's case was adequately pleaded.

Teva also submitted that if Chiesi's infringement action was permitted to proceed, then it should be stayed pending resolution of the validity dispute: Teva argued that if it had to provide confidential information about its plans to Chiesi, it feared a serious risk of liability under article 101(1) of the Treaty on the Functioning of the EU (TFEU). Teva relied in particular upon the January 2020

[268] *Permavent Limited & Anr v Makin* [2020] EWHC 3495 (Pat) (17 December 2020) HHJ Hacon
[269] *Teva UK Limited v Chiesi Farmaceutici SpA* [2020] EWHA 1311 (Pat) (2 June 2020) Birss J

judgment of the CJEU in the *Paroxetine*[270] case, on a reference from the Competition Appeal Tribunal relating to "pay for delay".

The judge agreed with Teva that the parties to the case could be regarded as potential competitors for the purposes of article 101. Article 101 concerns restrictions which arise from some sort of collusion between undertakings. It was clear from the first sentence of the Commission's Horizontal Cooperation Guidelines that information exchange can engage article 101 if it "establishes" a concerted practice. However this did not mean that the provision of information which, on the relevant hypothesis, would be ordered in the present case must necessarily amount to a form of collusion: it would only engage article 101 if it was an example of practical cooperation between the parties being substituted for the risks of competition, knowingly or not.

However, Birss J said that the necessary disclosure in properly constituted patent litigation would not be an instance of practical cooperation between the parties working as a substitute for the risks of competition. The provision of such information is part and parcel of such litigation, as recognised in EU law (e.g. article 6(1) of the IP Enforcement Directive 2004/48/EC). Article 101 therefore did not justify a stay of the infringement claim pending the resolution of the validity dispute.

Birss J also expressed agreement with the CAT's unanimous judgment in the *Paroxetine* case[271] (which had led to the reference in *Paroxetine*) and which stated ([53]):

> "(3) In our view, an outcome of the litigation whereby the patent was upheld and the generic company found to infringe is not to be regarded as less competitive than an outcome the other way, since the purpose of the patent system is to stimulate innovation, which promotes dynamic competition. A court determination that a patent is valid and infringed therefore cannot properly be regarded as a "negative" result for consumers even if it means that they will continue to pay higher prices or the patented goods. Such determinations are a necessary means of ensuring that patent-holders receive the proper rewards for their innovations."

Competition law featured also in the implementers' arguments before the Supreme Court in ***Unwired Planet v Huawei***[272], in particular on the meaning of 'non-discriminatory' in FRAND and whether the English courts' approach was compliant with the CJEU's judgment in *Huawei v ZTE*[273]. As noted in section 2(f) above, in neither context were the implementers successful.

The meaning of 'exclusive licence'

In ***Neurim v Generics***[274], the meaning of 'exclusive licence' for the purposes of the Patents Act 1977 was considered. The Act provides, in section 130:

> ""**exclusive licence**" means a licence from the proprietor of or applicant for a patent conferring on the licensee, or on him and persons authorised by him, to the exclusion of all other persons (including the proprietor or applicant), any right in respect of the invention to

[270] Case C-307/18 *Generics (UK) & Ors (Paroxetine)* ECLI:EU:C:2020:52; January 2020
[271] *Generics UK Ltd v Competition and Markets Authority* [2018] CAT 4
[272] *Unwired Planet International Limited & Anr v Huawei Technologies Co Ltd & Anr* [2020] UKSC 37 (26 August 2020) Lords Reed, Hodge, Black, Briggs & Sales
[273] *Huawei Technologies Co. Ltd v ZTE Corp. & Anr* (Case C-170/13) EU:C:2015:477; [2015] 5 CMLR 14; [2016] RPC 4
[274] *Neurim Pharmaceuticals (1991) Limited & Anr v Generics UK Limited (trading as Mylan) & Anr* [2020] EWHC 3270 (Pat) (4 December 2020) Marcus Smith J

which the patent or application relates, and “exclusive licensee” and “non-exclusive licence” shall be construed accordingly"

Additionally, section 67(1) provides:

> "(1) Subject to the provisions of this section, the holder of an **exclusive licence** under a patent shall have the same right as the proprietor of the patent to bring proceedings in respect of any infringement of the patent committed after the date of the licence; and references to the proprietor of the patent in the provisions of this Act relating to infringement shall be construed accordingly."

Standing as an exclusive licensee can be important in patent litigation, because it enables damages to be calculated by reference to the exclusive licensee's loss, as well as that of the patentee. The issue in the *Neurim* case was whether the licence granted by Neurim to second claimant Flynn met the statutory requirement.

The judge noted that there may be several exclusive licensees, each having an exclusive licence in their own field. It is for the exclusive licensee to establish the status of exclusivity, where it is disputed. On the meaning of 'exclusive licensee', the judge said ([140(3)(f)]):

> "The critical language in section 130(1) is “conferring…any right in respect of the invention”. Provided that right is exclusive, even if it is only a sliver of a claim of a patent, it seems that the requirements of section 130(1) are met."

Marcus Smith J noted that whether the licence granted by Neurim to Flynn was exclusive or not was, essentially, a question of construction. Applying the principles set out in *Oxford Nanopore v Pacific Biosciences of California*[275] he was satisfied that the requirements of s.130(1) were met.

However, Marcus Smith J held that certain restrictions contained in the contractual instruments as to Flynn's ability to enforce the patent (in particular, that Flynn had no right to bring a claim independent of Neurim, Neurim would take the lead in litigation and Flynn had no right to have a say in respect of settlement) essentially took away Flynn's ability to enforce the patent and therefore rendered the licence non-exclusive.

Flynn therefore did not have standing.

It is difficult to see how this reasoning can be correct. The definition of 'exclusive licence' in section 130(1) is not defined by reference to section 67. Section 67 provides that the holder of an exclusive licence shall have the same right as the proprietor of the patent to bring proceedings: and there is nothing to stop the registered proprietor of a patent from agreeing with a third party anything about the way in which litigation will be handled. So why should there be a restriction of such a nature on the exclusive licensee? It is entirely sensible for a patentee, which may need to be coordinating litigation in multiple jurisdictions, to keep hold of the reigns in the litigation while also enabling its exclusive licensee to be compensated in damages for the infringements.

[275] *Oxford Nanopore Technologies Limited & Anr v Pacific Biosciences of California, Inc & Anr* [2017] EWHC 2930 (Pat) at [44]

While much of the judge's reasoning in his substantive judgment finding infringement and validity is to be commended, his backwards analysis of standing seems unlikely to remain as the last word for long.

6. Entitlement / employee inventor compensation

Patent judgments usually reveal some eccentric characters, as another judgment of Marcus Smith J did in 2020 – ***Thaler v Comptroller***[276]. The question was whether a patent could be granted where the "inventor" named by the applicant (Mr Thaler) was an AI machine.

In the IPO, the Examiner held that the requirements of the Patents Act were not met by the naming of a machine ("DABUS") as an inventor. Nor was the Examiner satisfied as to the manner in which Mr Thaler had acquired rights that would otherwise vest in the inventor. Mr Thaler's appeal was dismissed by the Comptroller; his second appeal reached the Patents Court.

Marcus Smith J began his reasoning by noting that it is the function of the IPO and the courts to construe, not to re-write, the Patents Act. The question of what the law should be is a complex policy issue whose resolution must engage issues of law and policy beyond the remit of intellectual property, but the wider debate was not properly germane to determining the present appeal.

The judge then walked through the relevant sections of the Patents Act (1, 7, 13), considering and dismissing Dr Thaker's arguments on their interpretation. In particular, section 7 provides:

> "(1) Any **person** may make an **application** for a patent either alone or jointly with another.
>
> (2) A patent for an invention may be granted -
>
> > (a) **primarily to the inventor** or joint inventors;
> >
> > (b) **in preference to the foregoing, to any person or persons** who, by virtue of any enactment or rule of law, or any foreign law or treaty or international convention, or by virtue of an enforceable term of any agreement entered into with the inventor before the making of the invention, was or were at the time of the making of the invention entitled to the whole of the property in it (other than equitable interests) in the United Kingdom;
> >
> > (c) in any event, to the successor or successors in title of any person or persons mentioned in paragraph (a) or (b) above or any person so mentioned and the successor or successors in title of another person so mentioned; and to no other person.
>
> (3) In this Act “inventor” in relation to an invention means the actual deviser of the invention and “joint inventor” shall be construed accordingly.

[276] *Thaler v The Comptroller-General of Patents, Designs and Trade Marks* [2020] EWHC 2412 (Pat) (21 September 2020) Marcus Smith J

> (4) Except so far as the contrary is established, a person who makes an application for a patent shall be taken to be the person who is entitled under subsection (2) above to be granted a patent and two or more persons who make such an application jointly shall be taken to be the persons so entitled."

Marcus Smith J interpreted section 7(1) as providing that patent can only be granted to a person (legal or natural). Turning to section 7(2) he held that it provides that the right to be granted a patent is primarily given to the inventor, but the presumption can be overridden in the situations provided for by ss.7(2)(a)-(c). By ss.7(2)(a) the act of creation gives the inventor the primary right to apply; by ss.(2)(b)-(c) the right to apply may be transferred after the invention is created – a right that is derivative – therefore persons falling within classes (b) and (c) can only derive their rights (whether directly or indirectly) from an inventor, who must be capable of holding and transferring property, viz the invention and the right to apply for a patent. This means that either the inventor must be a person or ss.7(2)(a) must be read as "primarily to the person(s) who are the inventors or joint inventors". But when the notion of an inventive step is factored in, the restriction of the term "inventor" to a natural person becomes inevitable. Therefore the term "inventor" does not extend to things: an inventor must be a natural person. On the other hand, the members of classes (b) and (c) are/must be natural or legal "persons".

The applicant for the patent was Dr Thaler. He was a person and so the requirements of s.7(1) were met.

However, for the purposes of s.7(2), Dr Thaler expressly did not assert that he was the inventor. His case was that DABUS was the inventor. However, DABUS was not a person (for ss.7(2)(a)). Nor could DABUS hold or transfer property, and therefore rights could not pass to Dr Thaler for the purposes of ss.7(2)(b) or (c).

The judge said that while he was "quite prepared to accept" that there is a general rule that the owner of a thing is the owner of the fruits of that thing e.g. the owner of a fruit tree will generally own the fruit produced by that tree, no such rule had been framed in the Patents Act. Moreover, merely inventing something does not result in a patent being granted to the inventor – further steps are needed. With a nod to the way in which arguments might be run in a future case, or how adjustments to the legislation could be framed, he said ([49]):

> "(d) It would be far easier to contend that Dr Thaler was entitled to the grant of a patent pursuant to section 7(2)(a) of the Patents Act 1977, on the ground that he (Dr Thaler) owned the machine that did the inventing. That would actually be a much closer analogy to the general proposition advanced by Dr Thaler that "if you own the machine, you own the output of that machine". However, as I have noted, this was not a contention advanced by Dr Thaler: indeed, it was positively not advanced."

The question of whether the owner/controller of an artificially intelligent machine that "invents" something can be said, him- or herself, to be the inventor (the "actual deviser of the invention") was not a matter that was argued before him. It remains a question for another day. Dr Thaler declined to adopt this course, saying that in moral terms by doing so he would illegitimately be taking credit for an invention that was not his.

Nor did the judge lose sight of the bigger picture ([23]):

> "…It may very well be that the common law or a scheme laid down in statute does – when appropriately construed or understood – cater for future developments, including developments that were – until they surfaced in litigation – unforeseen. To take a somewhat extreme example, were an alien from outside the galaxy to present itself before the courts of England and Wales, I would like to think that it would not be denied legal personality simply on the grounds of unforeseen extraterritoriality. The courts are well able to differentiate between an alien artefact (say a meteorite, a thing) and an alien (which if capable of interacting as a natural person, is or ought to be a person). The courts of England and Wales have long taken their own view as to the status of a person appearing before them. Thus, the fact that a foreign law regards a person as a slave cuts little ice for "by the laws of England one man cannot have an absolute property in the person of another man" [*Chamberline v. Harvey*, (1700) 5 Mod 182, 87 ER 598]."

7. Summary and conclusions

In the words of Frank Sinatra, "And now, the end is near"….. I am certainly not claiming that "I did it my way", for this paper involves the help of many people, but most particularly Ailsa Carter whose assiduous observations of cases as they arise through the year enables us to assemble this compendious review of the outpourings of our judiciary.

I ended last year's review in a slightly downbeat and grumpy tone. I was not impressed by some of the "little England" thinking which seemed to be creeping in, and I was gravely concerned that the lack of experienced IP judges was compromising the quality and consistency of the UK bench, for which a well-deserved and longstanding reputation has been gained, and must be retained if the UK is to continue to be an attractive patent jurisdiction in the post-Brexit world. The shortage of judges was also compromising the timely delivery of justice. Strangely perhaps, in the light of the other events, I find myself in much better spirits now.

We now have a real expert IP judge in the Supreme Court. Lord Kitchin has, as Kitchin LJ and merely Kitchin J, consistently produced top quality judgments – clear, concise (relatively) and logical. I hope that he will have plenty of opportunities to bring those qualities to bear on some of the tricky issues which continue to vex patent practitioners at all levels.

Arnold LJ now graces the Court of Appeal where, it occurs to me, his awesome intellect and insightful reasoning will be to the fore, without the need for his meticulous attention to detail giving rise to quite such lengthy judgments! Birss LJ is joining him, in readiness for the retirement of Floyd LJ later in the year.

At first instance Meade J has joined a strong group of general Chancery judges and Deputies, backed by HHJ Hacon and HHJ Clark in IPEC. . The brand new appointment of another specialist IP judge, capable of hearing the most complex cases, James Mellor QC, is the cherry on the icing on the cake.

I recently had the great pleasure of interviewing Professor Sir Robin Jacob for a video podcast. I asked him to compare the current crop of judges to the days when he, Hugh Laddie and Nicholas

Pumfrey sat behind Aldous LJ and Lord Hoffman. Perhaps modestly, he felt that we were as well served, if not better, by the new team. I certainly can see cause for optimism going forward.

The cost of UK patent litigation remains an issue of concern. Last year I mentioned the possibility of pursuing a cost cap for Shorter Trial Scheme cases. That is still "out there" somewhere, but it has stalled in the face of the Covid crisis. I hope that it will re-emerge in 2021.

I think that great credit must go to the judges, but also the incredibly patient court staff in respect of the ongoing delivery of justice through the Covid crisis. Ingenuity, inventiveness, determination and hard work have combined to ensure that not only have the courts continued to function with barely any delay, but new systems are in place which will outlive the pandemic, and will improve service overall.

Birss J has already indicated that a great many more basic interim hearings will be done remotely, avoiding the need for the parties and their representatives to travel from wherever they may be for short, and sometimes adjourned, hearings in London. Many trees will now survive the hungry needs of court bundles which are often redundant as soon as the hearing is over.

I must also pay tribute to the IP world as a whole. I have seen so many examples of pragmatic rights sharing, free licences, and general cooperation to help the overall cause of supporting those affected by the pandemic. From ventilators to vaccines, the IP professionals have come together for the common good.

Without further ado, I move to the "Judge of the Year". There is, once again, an element of lifetime achievement award about this year's choice. There have been some outstanding efforts by all the judges and Meade J looks likely to be a future winner of this award for sure. However, by the time we re-gather next year, hopefully in person, Lord Justice Floyd will have retired.

His contribution to the IP world over the years, as counsel and subsequently as a judge, has been incomparable and his calm, courteous and tolerant manner in court have made appearances before him a pleasure. I have certainly not always agreed with him, but I think that I can safely say that he has never made a clearly "bad" decision. This year he particularly endeared himself to me in the Hozelock case. He stuck to his guns, and although he went down fighting in a split judgment, I personally think he was right and that his stand for the "surprising discovery" invention was the way we should be going.

So this year's award goes to Lord Justice Floyd, with gratitude for his many years of service to the IP professions.

That is a wrap. Thank you and huge respect to any reader who got this far. Whether it is because I was doing this in the comfort of my own, warm home, or because of the sheer quality and interest of the judgments, I have really enjoyed my part in the preparation of this year's paper. Ailsa tells me I can say the same for her. As ever, we are happy to invite comments, criticism, and downright disagreement from anyone who wishes to engage.

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