THE ELEPHANT IN THE ROOM

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GOWLING WLG

CONTENTS

"The Elephant in the Room"

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1 INTRODUCTION

Last year, my paper was entitled "And then there were three" to identify the arrival in the Patents Court of Mr Justice Henry Carr. It is just as well that he arrived, as 2016 turned out to be a year of many substantial and complex cases - a good few deputy judges making themselves visible as well, such was the volume of court time on patent related matters.

For all the activity, it is hard to identify a legal trend, but there are some slightly worrying statistics on patent success rates.

And of course, there is "the Elephant in the room…". It is hard not to look at everything without half a mind on the Unified Patents Court, and our position within it, or otherwise …

There were quite a few "cliff-hangers" from last year which were awaiting Court of Appeal consideration. It is time to see what happened and how much more we have learned from the court's deliberations on patent matters over the last 12 months.

I will be adopting my usual format, dealing first with construction and infringement issues, then damages, remedies and costs, before moving on to the various grounds for invalidation and some general cases on technical matters and procedure.

2 INFRINGEMENT

(a) Construction

"Obtainable by"

Each year there are significant cases regarding the way we read patents. 2016 was no different and I will start with a judgment of Henry Carr J in ***Regeneron v Kymab***[1].

This case dealt with the particularly tricky issue of the words of the expression "obtainable by", in a product by process claim.

Regeneron claimed for infringement of its European patent and, as usual, Kymab counter-claimed for revocation on the basis of insufficiency, lack of novelty, lack of inventive step and added matter - the full house.

The technical background was complex, and the parties were given credit for preparing a technical primer which was relatively short and which the judge found useful. This has become something of a trend in recent years.

Quoting from a 2014 judgment of Birss J (*Hospira v Genentech*[2]), Henry Carr J noted ([178)]:

[1] *Regeneron v Kymab* [2016] EWHC 87 (Pat) (1 February 2016) Henry Carr J

"*(i) their purpose is to claim a product irrespective of how it was made but with a shared characteristic which results from using a given process;*

(ii) the claim has to specify the characteristic being referred to;

(iii) "obtainable by" claims present clarity problems and should only be permitted if there is no alternative way of defining the product in question; and

(iv) for a product to be "obtainable by" a process it must have every characteristic which is the inevitable consequence of that process"

Henry Carr J agreed with Regeneron that certain claims covered products resulting from the use of claim 1 and extended to products (cells and mice) which contained human heavy chain variable region genes. The consequence of this construction was that claims 5 and 6 were, in the end, wider in scope than claim 1, though claim 1 itself was also very broad. This meant that Kymab's product infringed.

Although there is a risk with "obtainable by" claim wording, it clearly can work in the right circumstances.

Numerical terms

I am always interested in cases where the claims are defined numerically, or at least in mathematical language.

In ***Unwired Planet v Huawei (22 March 2016)***[3], Birss J found himself considering the effect of the use of mathematical notation. This was a case involving a Standard Essential Patent, where there appeared to be a minor discrepancy between the wording of the Standard and the wording of the patent. The Standard required that the value in question be "≥" whereas the patent claim used only ">". The defendants submitted that the claim could not properly be construed to cover the Standard. Unwired Planet submitted that in the context of a set of discrete values, to say that a discrete value is greater than or equal to a threshold is to say the same thing as saying that the discrete value is greater than a threshold one unit lower.

Applying the usual mathematical rules regarding rounding, Birss J concluded ([78]):

> "*The words in the claim are indeed clear as the defendants point out, nevertheless I find that the skilled reader would understand the proper construction of the claim to include a test such as the one applied by the Standard. Article 2 of the Protocol on the Interpretation of Article 69 of the EPC provides additional support for that conclusion.*"

This concurs comfortably with previous cases on mathematical limits and the criteria for rounding.

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[2] *Hospira v Genentech* [2014] EWHC 3587

[3] *Unwired Planet v Huawei* 2016] EWHC 576 (Pat) (22 March 2016) Birss J

A comprehensive case, with many issues at large, was ***Napp v Dr Reddy's & Sandoz***[4]. This was a case notable for its speed if nothing else. From commencement to appeal decision took the grand period of six months. The Court of Appeal confirmed the conclusions of the first instance judge.

Napp commenced proceedings for patent infringement in February 2016 and applied for an interim injunction. After Dr Reddy's and Sandoz sought trial of preliminary issues relating to infringement in mid-March, Arnold J ordered an expedited trial of the case for early June 2016. The case was duly heard from 7 - 9 June.

Napp's patent (which had an earliest claimed priority in 1997) was to a transdermal patch for use in the treatment of pain with a dosing interval of at least seven days. Napp has been selling a product of that nature since 2005. By the time of the trial, Sandoz had obtained marketing authorisation and Dr Reddy's was seeking marketing authorisation, both on the basis of bioequivalence to the Napp product. Napp's claim against Sandoz was primarily of a *quia timet* nature, whilst its claim against Doctor Reddy's was wholly *quia timet*.

The principle issues in relation to construction concerned the interpretation of the numerical limits of the ranges claimed (percentage weights of various components).

First, the judge concluded that the claim was to output ratios (i.e. the ratios present in the product) not the input ratios (i.e. the ratios used in the manufacturing process by which the product was generated). The claim was not written by reference to its ingredients and method of manufacture. The examples were directed to the manufacturing process and described weights of ingredients; the percentage of weight language of the claim was consistent with the output being claimed.

Turning to the specific ranges claimed, one item was identified as representing 10% of the weight. The construction sought by Dr Reddy's and Sandoz was from 9.5% - 10.5%. There was nothing in the patent to shed any light on the precision of this numerical limit and on its face it appeared to be expressed to the nearest whole number. Napp sought a more substantial and generous construction, contending that 10% should be construed as anywhere between 7.5% and 12.5%. However the judge did not consider that such a construction would provide a reasonable degree of certainty for third parties.

Similarly, where the patent claimed 10% - 15% weight, the claim by Napp that the construction should extend from 7.5% to 17.5% was dismissed.

The last item in question was slightly more interesting in that it included the word "about". The claim was for a component representing "about 10%" by weight. Napp contended for a wider interpretation and the judge agreed but only slightly. He felt that rather than normal rounding to the nearest .5, in this case the 10% figure should be construed as meaning between 9% and 11% by weight. He said that the word "about" should not be disregarded by the skilled person as being meaningless, but that it was "very difficult indeed" to ascertain what was intended to be signified by its inclusion. The judge decided that rather than stating that the claim lacked clarity, the

[4] *Napp v Dr Reddy's & Sandoz* [2016] EWHC 1517 (Pat) (28 June 2016) Arnold J; [2016] EWCA Civ 1053 (1 November 2016)

better course was to take "about" as connoting a "small degree of permitted imprecision over and above that implied by the usual rounding convention".

Therapeutic claim language

The case of ***GlaxoSmithKline v Wyeth***[5] is one which will recur regularly through this consideration of last year's cases. It is one of those compendious patent cases where virtually every issue appears to have been considered.

Meningitis B remains a substantial health problem in most countries. The quest for vaccines that provide effective immunisation against a broad spread of the bacterial strains responsible is long-standing.

GSK's meningitis B vaccine was given regulatory approval at the European level in 2013. Wyeth's equivalent vaccine awaited approval in Europe.

GSK sought to "clear the way" for its own vaccine by challenging the validity of Wyeth's European patent on multiple grounds. Wyeth duly counter-claimed for infringement of their patent by the GSK vaccine.

Henry Carr J set out on the construction of the patent by reminding himself of the guidelines described by the Court of Appeal in *Virgin Atlantic Airways v Premium Aircraft Interiors*[6]. He went on to make a number of rulings on the construction of the claim language in issue ([69]):

> "*The essential question for the court is to determine what the person skilled in the art would have understood the patentee to have been using the language of the claim to mean.*"

Claim 1 of the patent was to a composition containing a protein. Considering the meaning of later composition claim language, "to use as a vaccine" and, to "use in a method of inducing an immune response in a mammal", Henry Carr J held that the words did not require more than a discernible effect in the treatment of meningitis B. He noted that the technical contribution of the patent was "a composition and vaccine which provides protection for a population of patients against a broad range of diverse strains". He said that it was not correct to characterise the technical effect of the patent in terms of individual patients, nor did the vaccine have to be effective against every strain of meningitis B. However, he was keen to ensure that the construction applied would give reasonable certainty to the public, and he rejected a broad construction of certain claims propounded by the patentee.

Another comprehensive judgment which will feature regularly in this paper is the case of ***Hospira v Cubist***[7].

This case involved three patents belonging to Cubist Pharmaceuticals. They all concerned the antibiotic daptomycin, and in the end they were all found to be invalid.

[5] *GlaxoSmithKline v Wyeth* [2016] EWHC 1045 (Ch) (12 May 2016) Henry Carr J

[6] *Virgin Atlantic Airways v Premium Aircraft Interiors* [2009] EWCA Civ 1062; [2010] RPC 8

[7] *Hospira v Cubist* [2016] EWHC 1285 (Pat) (10 June 2016) Henry Carr J

Two patents concerned manufacturing/purification processes. The other patent claimed in Swiss form a dosing regimen (3-10 mg/kg administered once every 24 hours) for treating a bacterial infection. The interesting construction issue arising in this case was that none of the Swiss form claims were limited to any type of bacterial infection: they included use of daptomycin for the treatment of skin and soft tissue infections, bacteraemia, and all strains of endocarditis. The judge settled on what he described as a "practical construction" of the claims in the following terms ([113]):

> "*…daptomycin at the dose range and dose interval claimed cannot have such severe side effects as to preclude its use in the treatment of a human patient. However, the claims do not require any particular reduction in toxicity, nor that CPK levels in patients will remain below a specified amount, nor that SMT must be reduced or eliminated. This is evident from the absence of such limitations in any of the claims.*"

It is always useful when judges take the trouble to complete the job of construction with a passage of that nature.

The case of ***Actavis v Eli Lilly (tadalafil)***[8] turned out to be less entertaining than perhaps it might have been given its subject matter.

The dispute concerned two patents for the dosage regime and formulation of the drug CIALIS for the treatment of erectile dysfunction.

I will be returning to this case later in relation to a number of other issues, in particular priority, but a single, semantic argument arose in relation to construction. Claim 1 of the patent protecting the dosage regimen was stated in the following terms ([5]):

> "*A pharmaceutical unit dosage composition comprising 1 to 5mg of a compound having [a particular structural formula] said unit dosage form suitable for oral administration up to a maximum total dose of 5mg per day*."

The judge noted that the claim was to a product such as a tablet, liquid or capsule. He also noted that there was a notable absence of any reference to the clinical indication, the words "suitable for" having their conventional meaning: a tablet containing 1 to 5mg of tadalafil was inherently "suitable for" administration of up to a total dose of 5mg per day. Whether a doctor prescribed its use in that way was not relevant. Such a tablet could be administered in that way. The words "up to a maximum total dose of 5mg per day" would therefore have no effect on the scope of the claim. The alternative, said the judge, would be to say that such a tablet can never be suitable for that sort of administration unless one knows how it has been prescribed. But that would be "unreal" and since the patent included subsequent claims which included information on indication, the skilled reader would see no reason to interpret claim 1 in that restrictive way.

It is perhaps surprising that the meaning of the expression "up to a maximum total dose of 5mg per day" appeared to cause what the judge described as "real confusion". Birss J explained ([135]):

[8] *Actavis v Eli Lilly (tadalafil)* [2016] EWHC 1955 (Pat) (10 August 2016)

> "*Subject to the word "maximum", a skilled reader would understand that what the inventor was using the words of those claims to mean is that the invention is concerned with treating sexual dysfunction by administering a dose of no more than 5mg of tadalafil per day to a patient. Doing this provides the efficacy with minimal side effects provided for in the patent. Again subject to the word "maximum", the skilled reader would not think the inventors intended to exclude the idea that higher doses could be administered to patients if the doctor (and clinical regulators) regarded the balance of efficacy and side effects to be acceptable.*"

The key point at issue here was whether, in the event that the regulators authorised differing dosages, outside the scope of that claimed in the patent, the use would not fall within those claims. The judge said ([135]):

> "*So marketing authorisation documents from the regulators which approved doses of 2.5mg per day or 5mg per day as well as 10mg per day would not mean that a use in accordance with the invention had not been approved by the regulator. On the contrary. It would have been.*"

The judge said that if the regulators only approved use at the rate of, say, 20mg per day, then the claim would never be infringed. However, if the regulator approved both 20mg per day and 5mg, then the latter use would infringe and the existence of the additional higher approved dose would make no difference.

Trivial variants

We saw Daniel Alexander QC sitting as a deputy judge in the case of ***Meter-Tech v British Gas***[9]. I think that this is Daniel Alexander's first substantive patent judgment in his role as a deputy judge, and consequently he has set out to "put the world to rights" on each aspect of the law relating to patents as he encountered it.…

In relation to the question of construction, he adopted the traditional approach of setting out the guidelines in the *Virgin Atlantic* case, and reminded himself of the "Protocol questions". It had been noted by other judges, in particular Arnold J, that the so called Protocol questions had fallen out of fashion in judgments of the English courts. Daniel Alexander QC thought that was unfortunate, given the structured approach they provide, particularly to the question of equivalence. He said ([131]):

> "*I agree with Meter-Tech's submission, that they are of particular utility where a feature of a claim strictly construed would exclude a variant but there is no technical reason to do so and they are applied with greatest utility in this context. They remain useful so long as it is borne in mind that the key issue is whether a technically trivial or minor difference between an element of a claim and a corresponding element of the alleged infringement nonetheless falls within the meaning of the claimed element, when read purposively.*"

One issue relating to construction which has been common in recent years is the question of whether claim language should be construed so as specifically to avoid

[9] *Meter-Tech v British Gas* [2016] EWHC 2278 (Pat) (16 September 2016) Mr Daniel Alexander QC

invalidity in the light of the common general knowledge. The deputy judge quoted the passage from the case of *ASSIA v BT*[10], where Floyd LJ said ([45]):

> "*However it is not appropriate to read limitations into the claim solely on the ground that examples in the body of the specification have this or that feature. The reason is that the patentee may have deliberately chosen to claim more broadly than the specific examples, as he is fully entitled to do.*"

However, should claim language be construed so as to avoid added matter? This is what the deputy judge said ([137]):

> "*However, the approach may, in an appropriate case, be somewhat different if it is said that a given construction would add matter (such as by reading implicit requirements into a claim which were not disclosed in the specification or application) or if a given construction would result in insufficiency. In those circumstances, the reason that it is appropriate to take that into account in construing the claim is that the points on construction are internal to the document itself: there is no particular reason to construe a claim in such a way as would result in the specification, taken as a whole, disclosing additional matter. That is not because of a desire to construe the claim to avoid invalidity of the patent on the ground of added matter but rather because it is inappropriate, in any event, to construe a claim by reading into it matter which was not disclosed in the specification or the patent itself.*"

Applying all of this to the question of added matter in relation to the case in hand, the deputy judge said ([441]):

> "*In my judgment, stepping back from the detail, what is really going on here, is that a specification which does not contain or disclose an allegedly critical feature at all and which is silent on an issue is now said at trial (by construing it in a given way many years after it was filed) to speak volumes on it. Patentees in such a position may actually be reluctant to make such allegedly crucial matter explicit by making a specific claim to such a feature, because the absence of the feature in the application would thereby be highlighted by that contrast. So, instead, the patentee attempts to say that, in the patent, the concept is present, not by words, but by implication.*"

The deputy judge concluded ([442]):

> "*The court must be astute to guard against such attempts in construing claims, since they suffer from similar vices that added matter objections are designed to prevent. However, the way that the court addresses this kind of artifice is not by way of an added matter objection but by ensuring that the claims are properly and fairly construed in the first place, having regard to the description. I have done that above.*"

[10] *Adaptive Spectrum and Signal Alignment v British Telecommunications* [2014] EWCA Civ 1426

Mental element of a Swiss form claim

All of this brings us to last year's great cliff-hanger - the case of ***Warner-Lambert v Generics (UK)***. This case has now worked its way through the courts twice, first reaching the Court of Appeal in relation to an interim injunction application, and subsequently in relation to the substantive trial judgment.

By way of recap, Warner-Lambert is the proprietor of a European patent. The patent protects, in Swiss form claims, pregabalin for treating pain.

Warner-Lambert applied for an interim injunction against Actavis, to restrain the sales of Actavis' generic pregabalin product. The injunction application was rejected by Arnold J on the grounds that there was no arguable case of infringement, and that in any event the balance of justice favoured refusal.[11] Actavis then made an application to strike out Warner-Lambert's claim for infringement. That application also came before Arnold J, who did indeed strike out the claim for infringement insofar as it was made under section 60(2) of the Patents Act[12], but allowed the claim under section 60(1) to proceed to trial, notwithstanding his earlier conclusion that there was no arguable case of infringement[13]. Later in 2015, the Court of Appeal dismissed Warner-Lambert's appeal against the refusal of the interim injunction but allowed an appeal against the striking out of the claim for s.60(2) infringement.[14]

As well as Actavis, Generics (trading as Mylan) sought revocation of Warner-Lambert's patent and the cases were heard together. In his substantive judgment[15], Arnold J made a series of key rulings on construction. I described them in detail last year but will repeat them again by way of revision:

- The word "treating" in the claim language was a functional technical feature of the claim i.e. the actual attaining of the therapeutic benefit was a technical feature of the claimed invention. Arnold J ruled that the criteria for establishing such efficacy was a positive result in one of three animal models used in the patent.

- Claim 1 required the use of pregabalin for treating "pain", which Arnold J ruled embraced all types of pain. The judge disagreed with Warner-Lambert's contention that the skilled team would interpret it as restricted to "types of pain characterised by hyperalgesia and/or allodynia and having a central sensitisation component", saying there was, for example, no mention of "central sensitisation" anywhere in the patent.

- Claim 3 was its use for treating "neuropathic pain", which Arnold J ruled encompassed both central and peripheral types of neuropathic pain and was

[11] *Warner-Lambert v Actavis* [2015] EWHC 72 (Pat) (21 January 2015) Arnold J

[12] *Warner-Lambert v Actavis* [2015] EWHC 249 (Pat) (6 February 2015) Arnold J

[13] *Warner-Lambert v Actavis* [2015] EWHC 223 (Pat) (6 February 2015) Arnold J

[14] *Warner-Lambert v Actavis* [2015] EWCA Civ 556 (28 May 2016)

[15] *Generics v Warner-Lambert* [2015] EWHC 2548 (Pat) (10 September 2016) Arnold J

> not (as Warner-Lambert contended) as the skilled person would understand it, limited to peripheral neuropathic pain. Arnold J reasoned that the term appeared to be used in the patent quite generally, and with no reference to "peripheral neuropathic pain", nor any indication that central neuropathic pain was not intended to be included.

In 2016, in short, Arnold J's conclusions on construction were upheld by the Court of Appeal.[16] The court's pithy conclusion was that, in relation to claim 1, if the patentee had intended to limit the claims to pain characterised by hyperalgesia or allodynia, he could easily have done so.

With regard to claim 3 and the issue of the construction of "neuropathic pain", the comments of Lord Justice Floyd, albeit *obiter*, are worth noting. He said ([117]):

> "*I would add that I arrive at the same conclusion even taking into account the judge's conclusions (to which I will have to come) that the claims to peripheral and central neuropathic pain were plausible and implausible respectively. I would think that, in a clear case, where there are two possible meanings of a term, it might be legitimate to adopt the narrower meaning if there were common general knowledge reasons for saying that the wider meaning led to the claim extending to implausible embodiments. In the present case it is not realistic to suppose that the skilled reader would conclude from a comparative evaluation of plausibility that neuropathic pain was confined to the peripheral kind.*"

Of course the other big issue of construction which arose in this case related to the use of the word "for" in a Swiss form claim. The issue was considered by the Court of Appeal in the interim injunction application, and then came before Arnold J at the trial, who appeared to disagree with Lord Justice Floyd's judgment in the Court of Appeal's interim decision. Floyd LJ had said ([124]):

> "*If [Counsel for Actavis] were correct that a subjective mental element on the part of the manufacturer were necessary in order to provide the claim with novelty, there would be powerful reasons for adopting it. However, I do not see how that can in fact be so. If a product is "for" a particular therapeutic indication if it is reasonably foreseeable that it will be used intentionally for the treatment of pain, then it will not be rendered lacking in novelty by showing that products in the prior art have been manufactured in circumstances when it was not possible to foresee such a result.*"

Arnold J considered Floyd LJ's judgment to be *obiter*. He explained his doubts as to the correctness of Floyd LJ's interpretation but said that as he was not entirely convinced that it was wrong, he was prepared to follow it. Arnold J proceeded to conclude that in the circumstances of the case the mental element of the claim was not met.

So it was expected that the issue of the so called "mental element" in relation to foreseeability would be a major issue in the Court of Appeal's judgment in the substantive case, particularly given the apparent disagreement between Lord Justice

[16] *Warner-Lambert v Generics* [2016] EWCA Civ 1006 (13 October 2016)

Floyd and Arnold J. Disappointingly, it did not turn out to be quite as controversial as all that, though there are certainly some interesting comments from Lord Justice Floyd in the Court of Appeal's decision.[17]

Summarising his comments, to avoid lengthy quotes, I would distil the reasoning as follows:

- The law is struggling on the one hand to give the patentee a proper reward for his contribution to the art by elucidating the new use for a drug, whilst at the same time not excluding the competing manufacturer from making and marketing the drug for its own purpose.

- The parties agreed that the word "for" in a Swiss form claim imported a mental element. Lord Justice Floyd said that packaging may be a means of demonstrating the necessary mental element, whatever that may be, but it cannot possibly be the only means of doing so.

- Floyd LJ discussed decisions on construction and infringement of Swiss form claims from Germany, France, Denmark, the Netherlands, Sweden and the EPO. He said ([201]):

  > "*These cases continue to show a spectrum of different approaches. Some countries have gone for the "only packaging will do" approach. Some countries look more generally for some element of encouragement of the use of the drug for the new use by the manufacturer before being prepared to find infringement. Others look to see what steps are being put in place in the marketplace to prevent use for the prohibited indication. I do not think a universal principle has yet emerged.*"

- In the present case, Floyd LJ considered that the debate about the mental element of the claim had been distorted by reference to subjective intention. He said that he had "no doubt" that an objective approach was necessary; and from an objective standpoint one would normally regard a person to intend what he knows or can reasonably foresee as the consequence of his actions. That, said Floyd LJ, was the test formulated in the Court of Appeal's previous decision.

- The absence of the patented indication from the label "cannot conceivably be sufficient to negative" any intention. Rather, he said ([208]):

  > "*The intention will be negatived where the manufacturer has taken all reasonable steps within his power to prevent the consequences occurring. In such circumstances his true objective is a lawful one, and one would be entitled to say that the foreseen consequences were not intended, but were an unintended incident of his otherwise lawful activity. I think this approach is in line with that adopted in the decision of the Tribunal de Grande Instance, in that it recognises an obligation on the manufacturer to take steps if he is to enter the*

[17] *Warner-Lambert v Generics* [2016] EWCA Civ 1006 (13 October 2016)

market where he stands to benefit from the patentee's contribution to the art."

- The policy considerations which are in play in the present case are different from those which apply in the case of joint torts and crime. There is no general principle that the law does not impose liability as an accessory on the basis of a mental element which is less demanding than that of the person primarily responsible. In addition, statute has intervened in the area of patent infringement, as section 60(2) demonstrates.

- In considering whether there was intentional use of Actavis / Mylan's products for pain, the judge considered the state of mind of the doctor, the pharmacist and the patient. In Floyd LJ's view, the judge (Arnold J) had fallen into error in seeking to dissect the requirement for intentional treatment of pain in the way that he had. Floyd LJ explained ([216]):

  "*Because claims in this form rely for their novelty on the purpose of the use of the drug, it is only essential that the manufacturer is able to foresee that there will be intentional use for the new medical indication. Intentional use is to be distinguished from use where the drug is prescribed for a different indication and, without it in any sense being the intention of the treatment, a pain condition is fact treated.*"

- Floyd LJ said that the issue which the judge was called upon to decide was whether Actavis knew or could foresee that at least some of the prescriptions written generically for pregabalin to treat pain would in fact be fulfilled by the competing drug. Had Warner-Lambert succeeded in upholding valid claims on which they relied for infringement, it would then have been necessary to decide whether, at any of the various dates analysed by the judge, that test of knowledge or foresight was satisfied. If so, the judge should have gone on to consider whether Actavis had taken all reasonable steps in its power to prevent the competing drug from being used to treat pain.

- On the interpretation of section 60(2) (the supply of essential means), Floyd LJ saw "danger" in translating a requirement for a downstream act of manufacture. He said that "the process of the invention would be put into effect by the subsequent ascription of purpose by the pharmacist to generic pregabalin supplied by the manufacturer". Although one way in which this might be done was by an express statement on a label applied by a pharmacist, this was not the only way. Floyd LJ concluded ([223]):

  "*What is required is that means are provided which are for putting the invention into effect.*"

- The invention in the present case is the use of pregabalin in the manufacture of a pharmaceutical composition for treating pain. As the example of labelling by a pharmacist shows, that process is not completed when the pregabalin has been formulated into a pharmaceutical composition by a manufacturer. The process of preparing the composition can continue through any packaging step performed by the manufacturer and includes the labelling step

performed by the pharmacist. Floyd LJ agreed with the Danish court's conclusion to that effect.

- Lord Justice Floyd said ([225]):

> "*I have already concluded when considering direct infringement that the significance of a packaging step is only that it demonstrates the necessary intention. I am therefore unable to understand why other acts of the pharmacist in preparing the composition for delivery to the patient cannot also be regarded as relevant acts of preparation, if done with the necessary intention. I cannot agree with the judge that there is no relevant act of preparation by pharmacists, nor any prospect of such act.*"

In relation to the interpretation of the word "for" in a Swiss form claim, the take home point from the Court of Appeal's judgment must be that such a use requires an objective approach, and from an objective standpoint one would normally regard a person to intend what he knows or can reasonably foresee as the consequence of his actions. Because claims in this form rely for their novelty on the purpose of the use of the drug, it is only essential that the manufacturer is able to foresee that there will be intentional use for the new medical indication. Intentional use is to be distinguished from use where the drug is prescribed for a different indication and, without it in any sense being the intention of the treatment, the claimed condition is in fact treated.

In the context of contributory (section 60(2)) infringement of a claim in Swiss form, the process of preparing the composition can continue through any packaging step performed by the manufacturer and includes, but is not limited to, the labelling step performed by the pharmacist.

(b) **Infringement**

There is always a considerable overlap between matters of construction and matters of infringement. The lengthy consideration of the Warner-Lambert case could have fallen into either category.

Foreseeability

In relation to infringement issues more specifically, the case of ***Actavis v Eli Lilly (pemetrexed)***[18], before Mr Justice Arnold, contains some interesting issues.

In June 2015, the Court of Appeal had overturned Arnold J's decision to award declarations of non-infringement (DNIs) to Actavis in respect of its generic pemetrexed medicine. Actavis' DNI request had concerned its medicine which would be marketed with instructions for reconstitution in saline solution. The Court of Appeal concluded that Actavis would indirectly infringe Lilly's patent, which concerned the same compound formulated in saline solution.

[18] *Actavis v Eli Lilly (pemetrexed)* [2016] EWHC 234 (Pat) (12 February 2016) Arnold J

After the Court of Appeal's draft judgment had been circulated to the parties, Actavis requested a further DNI for its pemetrexed medicine when marketed with instructions for reconstitution in dextrose solution. Arnold J ordered an expedited trial.

The judge agreed with Eli Lilly that the burden of establishing entitlement to the DNIs lay on Actavis; it was not for Lilly to establish that dealings in the Actavis product would amount to infringement.

Arnold J considered the previous authorities of *Grimme v Scott*[19] and *KCI v Smith & Nephew*[20], and concluded ([32]):

> "*It is clear from these decisions that it is sufficient that a proportion of users would intend to use the means so as to infringe. Even if the majority of users will not intend to use the means to infringe, that is only relevant to remedies, and in particular to financial remedies … On the other hand, one should disregard "speculative, maverick or unlikely use" of the means.*"

Lilly submitted that a negative declaration can only properly be made where the underlying issue has been "sufficiently clearly defined to render it properly justiciable". Arnold J accepted this, but did not accept that it would be wrong in principle to grant a declaration based on assumed hypothetical or contingent facts. However he did accept that "if the facts on which an application for a declaration is based are assumed, hypothetical or contingent, then that may well be relevant to the exercise of the court's discretion."

Lilly's case was that it was foreseeable (and hence obvious) that the Actavis product would be diluted in saline by some customers. Lilly did not allege that Actavis was taking any steps to encourage such use. Nevertheless, Lilly contended that Actavis was infringing the patent because it was foreseeable that some of the product sold by Actavis at launch would still be held in stock somewhere in the supply chain after stability data had become available for the Actavis product in saline, and such stock would then be diluted in saline. Further, where Actavis won a tender to supply pemetrexed, their bid would constitute an offer to supply the Actavis product for the whole of the tender period; this would include an offer to supply the Actavis product at a time after which it was foreseeable that stability data would have been published and pharmacists would have switched to diluting the Actavis product with saline.

The steps taken by Actavis to prevent the product being diluted in saline are set out in the judgment. They included, for example, not including instruction for dilution of the product in saline, writing to the relevant competent authorities, implementing a policy of explaining to hospitals the requirement that dilution be in dextrose, and setting up a system enabling supply to be turned off at will where there was concern about the proposed use of saline to dilute the Actavis product in any particular hospital.

Arnold J noted that there was no evidence that Lilly had taken, or was planning to take, any steps to prevent the Actavis product being diluted in saline. He said ([82]):

[19] *Grimme v Scott* [2010] EWCA Civ 1110

[20] *KCI v Smith & Nephew* [2010] EWCA Civ 1260

> "*There is a striking contrast in this regard between Lilly's inaction and the extensive steps taken by Pfizer in the recent case concerning pregabalin. Counsel for Actavis submitted that it was to be inferred that Lilly did not want to prevent the infringement of the patent. I am not sure that that inference is justified, but I do consider that it is legitimate to infer that Lilly is content for Actavis to have to assume the entire burden of policing Lilly's patent.*"

Arnold J did not mention that he had found Warner-Lambert/Pfizer liable[21] for making unjustified threats!

It was agreed by the parties that, to begin with at least, pharmacists would follow the instructions on the Actavis product and would dilute it with dextrose solution. The issue concerned the likelihood of pharmacists departing from that in the future, and this was an assessment made by the judge based upon the evidence in the case.

In short, the judge concluded that the only remotely plausible motivation identified by Lilly for the use of saline was a possible concern on the part of oncologists and/or pharmacists about the effect of administering dextrose to diabetic patients. In this respect, Lilly relied upon the evidence of its expert oncologist, Professor Thatcher. His evidence was that he would be concerned about giving unnecessary dextrose to a diabetic patient. However, in cross examination, he accepted that if an oncologist or pharmacist were to have any such concern they would simply consult an endocrinologist.

Actavis duly produced an expert endocrinologist, Dr Powrie, and he said that he would reassure anyone consulting him that there was no need for concern. The judge noted that "Lilly chose not to call an endocrinology expert, despite the fact that its case hinges on concerns about giving the Actavis product to patients with diabetes". The judge continued ([17]):

> "*Counsel for Actavis submitted that it was to be inferred that Lilly had failed to find an endocrinologist who would support its position. I accept that submission.*"

The judge went on to conclude that, on the evidence before him, even if stability data for the Actavis product in saline were to become available, there would be no motivation to use saline rather than dextrose solution to dilute the Actavis product. He said ([136]):

> "*Nevertheless I accept that I do not have a crystal ball, and I cannot exclude the possibility, remote as it presently seems, that in a few years some pharmacists will decide to switch diluents, perhaps for a reason which has not been canvassed in evidence.*"

The judge concluded that Lilly's arguments on infringement were speculative and farfetched. He did not consider that it was foreseeable that the Actavis product would be diluted in saline. Rather, for the foreseeable future, the supply would not amount to an indirect infringement of the patent.

[21] *Generics v Warner-Lambert* [2015] EWHC 2548 (Pat)

The judge was satisfied that Actavis had a real commercial interest in obtaining DNIs and that granting such declarations would serve a useful purpose, since this would make it clear that the supply of the Actavis product was lawful in circumstances where Lilly had "resisted that conclusion tooth and nail".

In the circumstances, the judge concluded that he would grant the DNIs against each of the four designations in issue, and that the parties would have liberty to apply in the event of a material change in circumstances - in other words if his crystal ball had failed him.

De minimis principle

In the case of ***Napp v Dr Reddy's & Sandoz***[22], a very interesting issue of infringement arose which has been a concern in a number of cases I have been involved in over the years - we can call it the "de minimis" principle.

In short, the gist of the argument is, what is the position if, as a result, for example, of minor manufacturing tolerances, a tiny proportion of products actually made infringe a patent?

Arnold J considered the legal history. Focussing on patent cases, he considered:

- *Hoechst Celanese v BP*[23] where the *de minimis* principle was not considered by Mr Justice Jacob as he then was, in a claim for damages.

- *Monsanto Technology v Cargill*[24] - where Pumfrey J said "there is, generally, no authority in favour of trace quantities of infringing material not being held to infringe, and some authority against it".

- *Napp v Ratiopharm*[25] - where Jacob LJ said "if a single tablet is tested and is shown to be within the claim, it follows that the defendant has infringed" and did not consider the *de minimis* principle.

- *Lundbeck v Norpharma*[26] - where Floyd J said "obviously if the time is so short that no product is made during that time, then this does not infringe. I did not hear argument on whether there should be a *de minimis* limit, and if so what it might be".

[22] *Napp v Dr Reddy's & Sandoz* [2016] EWHC 1517 (Pat) (28 June 2016) Arnold J; [2016] EWCA Civ 1053 (1 November 2016)

[23] *Hoechst Celanese v BP* [1998] FSR 586

[24] *Monsanto Technology v Cargill* [2007] EWHC 2257

[25] *Napp v Ratiopharm* [2009] EWCA Civ 252

[26] *Lundbeck v Norpharma* [2011] EWHC 907

- *Generics v Warner-Lambert*[27] - where, at first instance, Arnold J said "save in a small number of exceptional cases which I consider that it is proper to regard as *de minimis*".

Arnold J distinguished the *Hoechst* case on the basis that the "after the event damages" claim in that case was the exact opposite of a *quia timet* case. He distinguished *Monsanto* on the basis that it was not clear what authority Pumfrey J had had in mind when suggesting there was "some authority" against a *de minimis* principle, and because the 5% in issue in that case equated to 250 tonnes of potentially infringing product. He distinguished *Napp v Ratiopharm* on the basis that the dispute was not about infringement by one tablet but by 7% of tablets, and also was not a claim based on a prediction, statistically speaking, that one in a million tablets will infringe.

The judge considered that in the present case the court was forced, as a matter of practical reality, to draw a line somewhere. He said that it was common ground that Napp bore the burden of proving that Sandoz had infringed and would infringe. The judge concluded that Napp therefore also had the burden of establishing that the acts which Sandoz proposed to do in the period before expiry of the patent would result in infringement on a scale which was "more than *de minimis*".

Considering the question of remedies, the judge also noted that where infringement cannot be discounted as *de minimis*, but is nevertheless on a "very small scale" (e.g. 0.1% randomly distributed, this not being *de minimis*), an injunction would be both disproportionate and a barrier to legitimate trade contrary to Article 3(2) of the IP Enforcement Directive. He commented on the law as follows ([168]-[170]):

> "*What remedy or remedies should the court grant if it finds that the defendant is threatening to do acts which will fall within the claim sufficiently often that they cannot be discounted as* de minimis*, but which nevertheless amount to infringement on a very small scale? Suppose, for example, it is concluded on the balance of probabilities that the defendant will sell 2,000 infringing patches randomly distributed among 1,998,000 non-infringing patches, and it is also concluded that that quantity cannot be discounted as* de minimis*?*
>
> *As counsel for Napp accepted, remedies for patent infringement, and in particular the remedy of an injunction, must be effective, proportionate and dissuasive and must be applied in such a manner as to avoid the creation of barriers to legitimate trade …*
>
> *It seems to me that these principles provide the answer to the question posed. Even if the level of infringement cannot be discounted as de minimis in such a case, I consider that an injunction would be both disproportionate and a barrier to legitimate trade. It would be disproportionate because the harm to the patentee for an infringement on such a small scale would be indistinguishable from the harm caused by wholly non-infringing acts. It would be a barrier to legitimate trade because the practical effect of such an injunction would be to require the defendant to operate even further outside the boundaries of the claim, and would thus effectively extend the scope of*

[27] *Generics v Warner-Lambert* [2015] EWHC 2458 (Pat)

> *the patentee's monopoly. In such a case, the appropriate remedy would be a financial one*."

Although the judge has clearly gone out of his way to avoid any attempt to define where the "line should be drawn", it must be that the effect of the judgment is to introduce the concept of *de minimis* infringement into UK patent law. Considering the issues posed by the case, Arnold J thought that the questions for him in relation to the alleged threatened infringement by Sandoz were as follows:

- What proportion of patches has Napp proved, on the balance of probabilities, will fall within the claim?

- Is this proportion more than *de minimis*?

Bearing in mind the lack of statistical analysis, and indeed the small sample provided by Napp, the judge concluded ([167]):

> "*In my judgment Napp is not entitled to take advantage of the uncertainties which flow from its own choices when it comes to the selection of the appropriate statistical test. On the contrary, those uncertainties are matters that Sandoz is entitled to rely upon. To the extent that those uncertainties make it more difficult for Napp to establish on the balance of probabilities what proportion of patches will fall within the claim, Napp has only itself to blame.*"

In the judgment there is a detailed discussion of the statistical evidence and the issues between the parties as to the appropriate model. The judge favoured the Sandoz approach, which predicted that one patch would infringe in every 69 million patches made. He said that this was "plainly de minimis". He went further and said that even on Napp's approach, resulting in 1 in 256,000 patches infringing, in his view that would still be *de minimis*.

Accordingly, Arnold J ruled that there was no threat by Sandoz to infringe the patent.

<u>*Quia timet action derived from marketing authorisation process*</u>

In ***Actavis v Lilly (tadalafil)***[28], Birss J was required to consider the question of the appropriateness of a declaration of non-infringement on a purely *quia timet* basis. By way of recap, he had concluded in the context of construction that ([137]):

> *"Administration of tadalafil up to a maximum total dose of 5mg per day is one of the approved dosing regimes provided for by the regulators. It is not the only one and dosing up to higher maximum total doses which are outside the claims are also approved. However given the approval of 5mg daily dosing, I find that the use of tadalafil 2.5mg and 5mg tablets … would infringe claims 7 and 10. If the relevant claimants were to launch their 2.5mg and 5mg tadalafil tablets on the UK market based on these marketing authorisations, the claims will be infringed."*

[28] *Actavis v Lilly (tadalafil)* [2015] EWHC 1955 (Pat) (10 August 2016) Birss J

The question which arose was whether a generic pharmaceutical company can seek to clear the way with a revocation action, with a purely contingent launch to a product if the action succeeds, without being held to be threatening to infringe the patent and thereby be subject to an infringement counterclaim.

Birss J considered his own previous judgment in *MSD v Teva*[29] in which he had reviewed the authorities and concluded that to justify coming to court requires there to be a concrete, strong and tangible risk that an injunction is required in order to do justice in all the circumstances; this not being a question confined to the alleged infringer's subjective intentions. In keeping with that approach, he said he would consider the objective position, the subjective position, and then the position overall.

He said that objectively, the UK market for the product was large and invaluable. Actavis and Mylan were in the process of obtaining marketing authorisation, which was an expensive and time consuming process. Objectively, it only made sense if they were actually planning to sell the product at some time. Subjectively, there was nothing inherently improbable in a contingent intention to sell. However, intentions can change. Circumstances might arise that would make an at risk launch attractive. No undertaking was on offer when the counterclaim was brought to abandon the marketing authorisation applications if they lost the revocation action and a surreptitious launch of a generic product can be very attractive and profitable, even if it is subsequently stopped by an emergency injunction. Overall, said the judge, there was a sufficiently strong probability that an injunction would be required to prevent Actavis and Mylan infringing, to justify bringing the infringement counterclaim. He concluded ([356]):

> *"The inference on which this* quia timet *infringement action is based does not derive solely or even predominantly from the fact that they have sought to clear the way by applying to revoke patents. It derives from the marketing authorisation process. Furthermore, while there is a cost and trouble associated with product and process descriptions, that only arises because there is an issue on infringement. The companies are entitled not to admit infringement, but in that case infringement is in issue and should be sorted out in advance just as much as validity. The logic of clearing the way covers both infringement and validity."*

(c) **Defences, Stays, and Evidence**

Since the Court of Appeal's decision in *IPCom v HTC*[30], there has been relatively little activity in the courts in relation to stays, the position having been made somewhat clearer.

Stays

This year, in ***Eli Lilly v Janssen***[31], Mrs Justice Rose was called upon to consider issues arising out of a stay application.

[29] *MSD v Teva* [2013] EWHC 1958 (Pat)

[30] *IPCom v HTC* [2013] EWCA Civ 1496

[31] *Eli Lilly v Janssen* [2016] EWHC 313 (Pat) (18 February 2016) Rose J

In June 2013, Arnold J had found that Janssen's parent patent ('937) was invalid for insufficiency.[32] Had the patent been valid, Lilly's product would have infringed. Janssen lodged an appeal but withdrew the appeal before it was heard.

The Opposition Division held that the '937 patent was invalid for insufficiency and declined to consider Lilly's challenges of anticipation and obviousness. However, a subsequent divisional patent ('282) was duly granted. In December 2015, Lilly sought revocation of Janssen's '282 patent and a declaration of non-infringement. Janssen sought to stay the proceedings pending the decision of the EPO in the opposition to the '282 patent.

Rose J considered the 12 points of guidance provided by Lord Justice Floyd in the *IPCom* case, and also the application of that guidance by Arnold J *Actavis v Pharmacia*[33] where undertakings offered by Pharmacia tipped to the balance in favour of a stay. Those undertakings included that during the life of the patent it would not seek any form of injunction, and it would only seek damages of 1% of net sales in the UK.

For the purposes of the current case, Rose J noted that the key issues were ([12]):

> *"(i) What are the relative likely timings of the English and EPO proceedings?*
>
> *(ii) Is Eli Lilly prejudiced by significant commercial uncertainty if the English proceedings are stayed and it has to wait for the EPO proceedings to be finalised?*
>
> *(iii) Are the undertakings offered by Janssen sufficient to reduce the commercial uncertainty faced by Eli Lilly to an acceptable level if a stay is granted?*
>
> *(iv) Do the other factors in* IPCom *as applied to the facts here point in favour or against the grant of a stay?"*

Looking at those issues the judge noted that the Opposition Division's hearing was scheduled to be heard in June 2016 with a likelihood that any appeal could be accelerated. Accordingly the EPO's decision on validity would be available potentially before the result of the English proceedings. This was a very different position to the *Actavis* case.

With regard to the issue of commercial certainty the judge said this was critical to the decision of the court. Both validity and infringement were in issue in the English proceedings. Janssen undertook only to seek damages on a reasonable royalty basis for the life of the patent and any SPC, in the event that the patent was upheld. The patent was due to expire in November 2018 but if Lilly's product was authorised before then Janssen would be likely to apply for a supplementary protection certificate. Consequently there was uncertainty as to both the duration and the

[32] *Eli Lilly v Janssen* [2013] EWHC 1737 (Pat)

[33] *Actavis v Pharmacia* [2014] EWHC 2265 (Pat)

amount of any royalty payment and so there was "considerable value" for Lilly in knowing as soon as possible both whether its product would infringe Janssen's patent if valid, and whether Janssen would be able to rely on Lilly's marketing authorisation in order to obtain an SPC.

As regards costs, the sums of money in issue were not significant in light of the sums of money at stake commercially for the parties. Lilly and Janssen had both spent over $500 million and $700 million respectively on product development.

The judge said that in the context of a therapy which had the potential to be a "blockbuster product" for the treatment of Alzheimer's, there was some public interest in dispelling the uncertainty, pointing against the grant of a stay, but she said this was not a weighty factor.

Finally, Rose J said that the prospect of a fully reasoned judgment of the English court on validity and infringement providing an important tool for settlement of the parties' Europe wide disputes was "neutral". This was because the EPO proceedings might conclude that neither patent was valid and this would be a binding ruling which resolves the disputes anyway.

The judge concluded that she should refuse to grant the stay, explaining ([38]):

> *"It may be that the EPO proceedings do produce a clear determination in Eli Lilly's favour rendering the English proceedings redundant. There is a risk therefore that some costs in pursuing the English proceedings will be wasted between now and then. However there is a chance that even though the EPO proceedings are resolved before the English proceedings, they will not be determinative of all the issues between the parties. The infringement issues are important in this case and it is better that the English proceedings which are before the only forum in which the infringement issue can be decided continues. Neither party was attracted by the idea of the English proceedings splitting out infringement from validity in some way. I therefore dismiss Janssen's application for a stay."*

Looking at the judge's reasoning overall, it seems that the level of commercial certainty was crucial, and in particular the effect of that certainty on the proposed undertakings by the patentee. In the *Actavis* case, Pharmacia's proposed undertaking defined both the duration and level of royalty. In the current case, uncertainty both as to term and royalty level left the need for commercial certainty to be resolved, and that appears to have been the crucial factor in the court's decision.

Experimental use

The relatively rarely litigated issue of the experimental use defence arose in the case of ***Meter-Tech v British Gas***[34]. This case concerned Meter-Tech's patent to a "smart meter". Many aspects of the case are discussed elsewhere in the paper, but the particular issue regarding experimental use arose because a small scale trial, where 1,000 meters had been ordered and 120 installed in consumer properties, was alleged by British Gas to constitute "experimental use" and so exempt from

[34] *Meter-Tech v British Gas* [2016] EWHC 2278 (Pat) (16 September 2016) Daniel Alexander QC

infringement. The court was satisfied that the deployment of 120 meters was for experimental purposes. However, the court was not satisfied that this experimental use related to the subject matter of the invention, as the systems installed had been made by a third party and were essentially being used as off-the-shelf products. Furthermore, the use by British Gas was not directed at improving the underlying system, but was concerned primarily with customer satisfaction surrounding installation time and usability.

The court also found that an ongoing implementation on a far larger scale was experimental but again, it did not relate to the subject matter of the invention. Accordingly, had the patent been valid (which it was not) the experimental use defence would not have been of assistance to British Gas in these particular circumstances.

The court is drawing a clear distinction between experimental use designed to bring about adaptation and improvement to the technology, and experimental use designed to test customer satisfaction and commercial viability.

(d) **Remedies and Costs**

Damages

In the case of ***AP Racing v Alcon***[35], the principles of a damages enquiry were considered by His Honour Judge Hacon. AP Racing was successful in the case and was awarded damages for Alcon's patent infringement. Alcon manufactured 1,179 infringing products. Of these, 242 were supplied before the patent application was published. 70 remained unsold, and Alcon had undertaken to destroy them. 132 were supplied as free of charge replacements for defective products sold earlier. This left actual sales of 735 products.

Alcon argued that the structure of the industry and the contractual contexts were such that, in the factual scenario, if Alcon's infringing products had not been available non-infringing products sold by third parties would have been supplied instead. Alcon said that consequently the number of calipers considered for the assessment of damages should be reduced. On the evidence before the court, this did not succeed. The 735 calipers remained relevant to AP Racing's claim for damages.

HHJ Hacon noted that when considering the proportion of sales that would have been made by the patentee, this is generally done by reference to the market share enjoyed by the claimant. Alcon asserted that at the relevant time the top teams used different calipers which enjoyed 30% of the market, and consequently AP Racing would have picked up 70% of the sales made possible by the absence of Alcon's infringing products. However, the judge did not agree with that reasoning. He held that every infringing sale laid by Alcon constituted a lost sale by AP Racing. He said:

> *"AP Racing lost 735 sales of calipers because of Alcon's infringement of the patent."*

[35] *AP Racing v Alcon* [2016] EWHC 116 (IPEC) (28 January 2016)

A simple calculation was conducted, multiplying the number of sales by the average sales price, then establishing the profit margin, yielding a loss of £217,928.

AP Racing also sought to recover loss of profits from reduced convoyed sales. The judge found that it was necessary for the claimant to prove that, assessed objectively, there was a causative link in the mind of the purchaser between his or her purchase of the infringing product and their purchase of one or more specific other products. Only in those circumstances will the sale of the infringing product have caused the loss of sale of the other products (within the legal sense of causation). If causation is proved, then subject to unusual facts being raised by the defendant, losses relating to the later sales would be expected to satisfy the requirements of the law on remoteness generally.

Applying this to the facts of the case, the judge accepted that for every caliper sold by AP Racing, it also sold £410 worth of goods exclusively associated with that sale. Further, for every caliper sold, AP Racing also sold a further £1,565 worth of associated goods. The judge accepted Alcon's evidence that such associated sales happened on average 70% of the time. This computed to £201,298 (£1565 x 0.7 x 0.25).

Finally, the question of prejudgment interest rates arose. Historically there was a presumption that the appropriate rate was 1% over base rate. However, the judge held there was no longer any such presumption and where appropriate the court may reach a view as to the appropriate rate of interest, even in the absence of evidence. Generally speaking public companies of some size and prestige will be required to pay less to borrow money than smaller less prestigious concerns. Bearing in mind those principles, interest before judgment was awarded at the rate of 2%.

Last year we considered some of the legal issues arising out of the case of ***Stretchline v H&M***. This year that case reached the stage of remedies.

In November 2015, Henry Carr J found that H&M had breached the terms of a settlement agreement by infringing Stretchline's patents[36]. Stretchline sought an injunction to restrain further breach, and an account of profits.

In his decision on the remedies[37], Henry Carr J noted that injunctions are available as a remedy for breaches of contract where the contract prohibits acts akin to infringement of an intellectual property right. He said ([7]):

> *"A [party] should have no more difficulty obtaining an injunction where [the other] party has broken its word than in a case where no settlement has been reached and the court has found infringement of a patent."*

The judge therefore intended to imply the same principles for the grant of injunctive relief as would be applied had Stretchline been successful in a claim for patent infringement. This meant that consideration of the potential injunction would be done

[36] *Stretchline v H&M* [2015] EWHC 3298 (Pat)

[37] *Stretchline v H&M* [2016] EWHC 162 (Pat) (21 January 2016) Henry Carr J

on the well established principle that injunctive relief is a discretionary remedy and the court must be satisfied that it is appropriate in all circumstances.

Henry Carr J noted that as long as the patent was in force and the settlement agreement was in place any dealings by H&M that fell within the scope of the patent amounted to actionable breaches of contract. This entitled Stretchline to normal contractual remedies.

The 2001 settlement agreement prohibited H&M from infringing Stretchline's patent and imposed policing duties on it. However, in the circumstances there could be no presumption that infringement would reoccur. H&M's infringements were historic and unlikely to reoccur again. Stretchline, which was likely continuing to test garments on an ongoing basis, had failed to present any new infringing products to the court. By implication, the court was of the view that there were no infringing garments. In addition, H&M had shown that their suppliers were instructed not to use the infringing products and none had been found in their stores.

Accordingly, Henry Carr J stated that it would be disproportionate to impose a blanket injunction in circumstances where the policing of infringement was difficult, it was a mutual obligation of both parties under the settlement agreement to police, and H&M could be held in contempt of court in respect of accidental breaches.

He made it clear that Stretchline remained at liberty to return to court to seek injunctive relief in the event of future infringements. He emphasised that the fact that he was declining to award an injunction did not mean that breaches of contract were not serious; they were.

This case does raise questions in relation to the drafting of settlement agreements. Patentees should be aware that although the English courts have jurisdiction to grant relief for breach of contract in forms usually obtained following a finding of infringement of a patent, they may well be less inclined to do so. Broad mutual policing obligations in a settlement agreement may count against the patentee should it later seek injunctive relief or an account of profits pursuant to a breach of contract.

Turning to issues of costs in the same case, it is perhaps amusing to note that the original estimation of quantum by H&M was £2,500. In the end, when it came to the assessment of costs, it became clear that Stretchline had incurred well over £1.5 million, and H&M around £1.2 million in costs.

Henry Carr J refused to deduct from the costs awarded to Stretchline amounts in relation to H&M's validity challenge, the costs of late experiments (even though earlier experiments had not been permitted), and costs in relation to a possible claim for repudiated breach of contract.

A 2% deduction was made in relation to H&M's contention that Stretchline had misused confidential disclosure documents by providing them to its US lawyers.

H&M submitted that, in the UK, only about 51,000 infringing products were sold and that given the going rate for purchasing the relevant material would be about 5p, the damages should be £2,500. Set against this, H&M submitted that the costs incurred were disproportionate and that the assessment of costs should be adjourned until

after determination of the issue of quantum of damages so that proportionality could be assessed.

Henry Carr J disagreed[38]. He reasoned that:

- H&M chose to spend sums broadly in proportion to the sums spent by Stretchline.

- A defendant who believes the damages are likely to be small can protect itself by making a payment into court or possibly a Calderbank offer. H&M did not do so.

- Since this was a case based on repeated breaches of a settlement agreement, it was a serious case and one that Stretchline was entitled to bring to the High Court.

- So while H&M could argue proportionality, this was not a reason to postpone an interim payment.

The judge took his starting figure for costs at £1.35 million and ordered an interim payment of 65% of that amount.

There are some clear warnings there as regards parties engaged in litigation with a potentially low damages value. Settlement offers, either in Part 36 or Calderbank form, may be advisable.

Account of profits

In the case of ***Design & Display v OOO Abbott***[39], an account of profits for patent infringement was assessed by His Honour Judge Hacon, but subsequently overturned by the Court of Appeal, which made some notable rulings regarding causation and the deduction of overheads.

The patent concerned display panels incorporating inserts to protect and strengthen the panels. Needless to say, the key question arose as to whether the recoverable profits should relate to the panels as a whole, or merely the strengthening inserts.

Lord Justice Lewison pointed out that ([7]):

> *"Section 61(1)(d) of the 1977 Patents Act entitles a patentee to claim against an infringer for an account of profits "derived by him from the infringement". An account of profits is confined to profits actually made, its purpose being not to punish the defendant but to prevent his unjust enrichment."*

The judge went on to say that the broad principle is that the patentee is entitled to profits that have been earned by the use of his invention. If the patentee does not recover those profits, the infringer will have been unjustly enriched. So the purpose of

[38] *Stretchline v H&M* [2016] EWHC 163 (Pat) (22 January 2016) Henry Carr J

[39] *Design & Display v OOO Abbott* [2016] EWCA Civ 95 (24 February 2016)

the account is to quantify the extent to which the infringer would be unjustly enriched if he were to retain profits derived from the infringing act. That requires the fact finder first, to identify the invention and second, to decide what (if any) profits the infringer derived from the use of that invention. It is the second of these questions which gives rise to difficulty where the infringer sells products associated with the subject matter of the patent, or products into which the subject matter of the patent is incorporated. The court must determine what profit has been earned, in a legal sense, by the infringer's wrongful acts.

It is clear, then, that an account of profits looks at the facts through the lens of what the infringer has done; and what the patentee might have suffered by way of loss in the real world is irrelevant.

At first instance[40], Judge Hacon had reasoned that Design & Display was either going to make a sale of inserts and panels both, or no sale at all. He found that the sales went "hand in hand". He concluded ([32]-[33]):

> *"As I have said, part of the inventive concept was embodied in the shape of a section of the panel. The fact that it was a modest section makes no difference. The sale of that section of the panel both caused the sale of the panel as a whole and the latter sale was a foreseeable consequence of the former.*
>
> *Design & Display did infringe and in my view the scope of the profit derived from such infringement extends to the profit made from sales of panels in which the infringing inserts were incorporated".*

In the Court of Appeal, there was a discussion about the appropriateness of the use of "common sense answers" to questions of causation, which may differ according to the purpose for which the question is asked, and will always differ in relation to the factual circumstances of each case. Having taken all these items into account, Lewison LJ delivered a substantial comment which is worth repeating in full:

> *"Let me revert to the example given by the Full Court in Dart Industries Inc v Decor Corp Pty Ltd. A manufacturer sells a car which includes a patented brake. If the car did not have brakes, the manufacturer could not have sold it, but it did not have to have that particular brake. In those circumstances, the Full Court clearly thought that it would be unjust to charge the manufacturer with the whole profit made on the car; and I agree with them. In my judgment the legal error that the judge made was to ask whether the sale of the panel plus insert would have happened separately rather than to ask himself how much of the profit on the sale was derived from the infringement. In a case in which the infringement does not "drive" the sale it seems to me that it is wrong in principle to attribute the whole of the profit to the infringement. In particular it does not follow from the fact that the customer wanted a slat wall that incorporated* an *insert, that the customer wanted a slat wall that incorporated the* infringing *insert. [Council for OOO Abbott] argued that the infringing inserts and the slot were the "very essence" of the incorporated and unincorporated panels. But the judge made no such finding, and his*

[40] *OOO Abbott v Design & Display* [2014] EWHC 2924 (IPEC)

observations suggest the contrary. In addition I do not consider that the judge was correct in saying that "because sales went together, the sale of the inserts … caused the sale of the panels". The mere fact that the two went together is not, in my judgment, sufficient to establish that the whole of the profit earned on the composite item was derived from the invention. One might just as well say that the sale of the panel caused the sale of the insert. As the judge himself recognised the customer specifies panels, and on the hypothesis that he was considering…the customer is indifferent about the inserts (provided that some form of insert is included). On the judge's approach, because the sale of the patented brake went with the sale of the car, the whole of the profit on the car would be included in the account. If the judge had found on the facts that the infringing insert was "the essential ingredient in the creation of the defendant's whole product" then he would have been justified, on the facts, in declining to apportion the profit. But I cannot see that he made that finding.

In my judgment therefore in cases simply falling within the factual hypothesis discussed, the judge should have apportioned the overall profit. The question of apportionment will therefore have to be returned to IPEC, although the judge would not be precluded from finding as a fact that the infringing insert was the "essential ingredient" of the incorporated panel."

It seems that the issue in the case is more one of a shortcoming in the judge's stated findings of fact, than the merits overall. It will be interesting to see, if we can find out, what the outcome ultimately was. It may well be that it was indeed the strengthening sections which were the driving force in the sale of the panels overall, in which case, had he made that simple finding of fact, the judge's initial reasoning would have been justified.

Arrow *declarations*

This brings us to the year's stand out case – ***FKB v AbbVie Biotechnology***.

This is a case involving the very interesting issue of what had become known as "Arrow declarations". This follows the case of *Arrow v Merck*[41], where Arrow sought a declaration as to its right to make and sell its own product. Underlying the whole issue is the question, arising out of section 74 of the Patents Act 1977, as to the proceedings in which the validity of a patent may be put in issue. The issue can perhaps best be summed up by the following passage from the judgment of Kitchin J (as he then was) in the *Arrow v Merck* case ([55]):

"Arrow seeks a declaration as to its right to make and sell its own product. In my judgment clear words are required to exclude that right and section 74 should be interpreted no more widely than necessary to give effect to its purpose. What then is that purpose? I consider it must be to ensure that patents which are invalid are not merely declared to be invalid but are in fact revoked. But revocation proceedings cannot be commenced until a patent has been granted. Had it been intended that section 74 should exclude the right of a person to seek a declaration in relation to his own product,

[41] Arrow v Merck [2007] EWHC 1900 (Pat)

> *particularly in circumstances where the need to do so arises from the existence of a published application, then it could have said so in express terms. But it does not and in my judgment it should not be so construed."*

Kitchin J found that Arrow's claim had a reasonable prospect of success and must be allowed to proceed to trial. The case did not reach a full first instance decision. However in parallel proceedings in the Netherlands, the Dutch court did indeed make the declaration sought.

In the FKB case, FKB initially sought the revocation of two AbbVie patents relating to the antibody adalimumab (sold under the brand name Humira). FKB also sought a declaration that it was obvious at the relevant priority date to treat the various indications by a 40mg dosage regime. This would create a squeeze between infringement and validity, such that an action for infringement could not succeed in the United Kingdom, whether it was based on an existing patent or a later granted divisional.

AbbVie applied to strike out the claim for declaratory relief on the basis that the court did not have jurisdiction to make the order sought. It contended that Kitchen J's decision in *Arrow v Merck* was wrong.

FKB sought to narrow its declaration somewhat and to plead facts which had occurred subsequent to the commencement of proceedings: six days after the claim form was issued, AbbVie wrote to the EPO stating that it no longer approved the text of one of the granted patents which was in a late stage of opposition proceedings. FKB contended that the purpose of AbbVie abandoning the patent was to avoid adjudication on its patentability by the UK court and the Opposition Division whilst seeking to ensure that the subject matter of the alleged invention was maintained by a still pending divisional application, such that it would be many years before the EPO would be in a position finally to adjudicate on the patentability of the subject matter of any granted patent resulting. FKB relied upon these allegations to demonstrate why the granting of the declaration which it now sought would serve a useful purpose, by achieving commercial certainty in respect of its FKB327 product by the date of its intended launch in the summer of 2018.

AbbVie were effectively inviting Henry Carr J to overrule the equivalent judgment of Kitchin J at first instance. Henry Carr J commented[42] ([31]):

> *"AbbVie invites me to find that the Arrow judgment was wrongly decided. It is correct that a judge at first instance can decline to follow a judgment of a court of coordinate jurisdiction, but only where he or she is convinced that the judgment is wrong."*

Henry Carr J concluded that *Arrow v Merck* was not wrongly decided. He found that *Arrow* did not have the effect of usurping the function of the EPO in its examination of European patent applications. A declaration directed at clearing the way for the launch of the FKB product, by creating a squeeze between infringement and validity, cannot be done before the EPO, which has no jurisdiction over issues of infringement. This is a matter of substance, not merely form.

[42] *Fujifilm Kyowa Biologics v AbbVie Biotechnology* [2016] EWHC 425 (Pat) (1 March 2016) Henry Carr J

Nor did the judge agree with AbbVie that the declaration sought would mean that AbbVie would be prevented by *res judicata* or issue estoppel from asserting any such granted patent against other companies, who were neither party nor privy to the present proceedings. AbbVie also argued that exceptional circumstances were needed for the court to exercise its discretion to grant a declaration in the nature of that sought by FKB, but the judge disagreed. He concluded ([56]):

> *"In spite of Mr Alexander's most attractive submissions, I am not convinced that the* Arrow *judgment was wrongly decided. On the contrary, I am convinced that it was correctly decided. If there was no jurisdiction to grant* Arrow *declarations, then it would be impossible for parties who wished to clear the way for the launch of a product to do so, without facing years of commercial uncertainty posed by cascading divisionals pending before the EPO. This would be so even where a patent had already been revoked or abandoned in the jurisdiction of intended launch, as the patentee could seek to re-monopolise essentially the same subject matter by filing further divisionals. Whilst the jurisdiction needs to be exercised with caution, both the UK and the Dutch courts have found that it exists. I agree with their conclusions and will proceed to consider whether there is a realistic prospect that the trial judge will exercise the discretion to grant the declaration in the present case."*

Looking at the factors at play relevant to the exercising of the court's discretion, he found that the declaration would serve a useful purpose as it would dispel real commercial uncertainty and remove the risk of a large damages claim in the United Kingdom. He found that the underlying issue was sufficiently clearly defined to make it properly justiciable, and that there were no special circumstances why the court should not grant the declaration. There was a realistic prospect that the trial judge would exercise his or her discretion to grant the relief sought.

Balancing the justice to the parties, he found that AbbVie's claim that it should not have to face the costs or burden of a UK trial in respect of the issues raised by the declaration did not outweigh the potential injustice to FKB if it could not clear the way prior to the launch of its own product.

Consequently AbbVie's strike out application failed and FKB was permitted to amend its pleadings.

The dispute rumbled on through the year. First, Henry Carr J refused leave to appeal, and subsequently, in a further application by AbbVie, he dismissed a subsequent additional attempt to strike out on the grounds that circumstances had changed in the meantime.[43] AbbVie's subsequent application was made on the basis that since the first application, the circumstances had changed and there was now no real prospect of the court finding that the declarations sought served a useful purpose, and that the continuation of them would be an abuse of process and a disproportionate waste of court resources.

Basically, AbbVie abandoned its UK patents. It de-designated the UK from one patent and informed the EPO that it no longer approved the text of another. AbbVie

[43] *Fujifilm Kyowa Biologics v AbbVie Biotechnology* [2016] EWHC 3383 (Ch) (29 December 2016) Henry Carr J

relied on a particular passage from the judgment of Kitchin J in the *Arrow* case where he said ([60]):

> *"The existence of the divisional applications gives rise to the need and justification for seeking declaratory relief. Merck could withdraw the "GB" designations of the divisional applications or acknowledge that it can have no claim under them in this country in respect of a product having the specified characteristics of Arrow's product. If it did so then the commercial purpose of the declarations sought would likely fall away. But it has chosen not to take that course."*

AbbVie said that it had done precisely that, and consequently Kitchin J's ruling in *Arrow* was no longer applicable. FKB argued that the undertakings offered by AbbVie fell short of the declarations sought and the award of declaratory relief would still serve a useful purpose.

There was a considerable degree of factual evidence, some relating to AbbVie's portfolio of patents, which included several divisionals which would potentially continue patent protection, and others relating to the words of AbbVie's CEO who had threatened on a number of occasions, including in conference calls to investors, to seek injunctive relief to prevent any "at risk" launches.

Henry Carr J concluded that there was at least a good arguable case that AbbVie was operating a well established strategy of dragging out proceedings in the EPO for as long as possible, causing maximum expense and inconvenience to its opponents, and then throwing in the towel just before its patents were scrutinised by the court, whilst covering the same subject matter with further divisionals, and thereby perpetuating commercial uncertainty with a view to impeding launch of the claimant's competing biosimilars.

The judge said that if the declarations sought would serve no useful purpose, and the steps taken by AbbVie had the same effect as clearing the way, it was "very difficult to see" why AbbVie refused to submit to judgment, or alternatively give an acknowledgment in the same form as the declarations. In the absence of any explanation in the evidence, there was a strong inference that AbbVie recognised that the declarations were more damaging to its strategy in relation to its Humira patent portfolio than the "rather complex set of undertakings and abandonment of UK patent protection that it proposes".

The judge thought that an *Arrow* declaration would provide, in effect, a *Gillette* defence to allegations of infringement in the United Kingdom, and any such declaration must be limited to the United Kingdom. However, depending on the facts of the case, the grant of such a declaration may serve a number of useful purposes, in circumstances where the defendant resisted such relief, and the claimant regarded any offers of settlement as unsatisfactory.

He went on to say that the spinoff value of a judgment in a contracting state could be very valuable, and it was legitimate for parties to rely upon such judgments in other contracting states. This was not the only relevant factor relied upon, but one which would be weighed in the balance. He said that there was force in the claimant's submission that the declarations sought would serve a useful purpose in protecting their supply chain to the UK as well as other parts of Europe. It was important to

remember that AbbVie's CEO's threats of worldwide litigation were intended to have, and were likely to have had, a chilling effect on competition from biosimilars including on third party suppliers.

The judge concluded that there was a real prospect that the judge at trial would exercise his or her discretion to grant the declarations sought, notwithstanding the changed circumstances, and the attempts by AbbVie to move the goal posts. He concluded ([55]):

> *"This is a case where a great deal is at stake. The size of the UK market is huge. There is a real prospect that the court will consider that the grant of the declarations will serve a useful purpose, and that this is the reason why AbbVie continues to resist them. This is not a case where it can be said that the game is not worth the candle. On the contrary, it is worth a great many candles."*

Earlier in the year FKB had commenced a second application for declaratory and related injunctive relief against AbbVie. This declaration was sought in respect of the application of the medicine in relation to Crohn's disease. In addition to a further *Arrow* declaration, FKB also sought an injunction to restrain the defendants from threatening or commencing proceedings for patent infringement in respect of acts covered by the declaration.

Once again AbbVie sought to strike out the application, and the issue this time was heard by Arnold J.[44]

Much of the same ground was covered, in particular the question of whether an *Arrow* declaration serves a useful purpose because it is, in effect, a declaration that the claimant will have a Gillette defence to a subsequent claim for patent infringement in relation to its product. Similarly, the question of whether an *Arrow* declaration contravenes section 74 was dismissed because it does not involve the validity of a patent being put in issue. Rather, it enables the court pre-emptively to determine a patent infringement case before the patent has even been granted without having to decide whether the patent would be invalid, or not infringed because the claimant's product will not fall within the claims, when granted.

A side issue arose concerning the ownership of the AbbVie patents. The patents are predominantly owned by AbbVie Bermuda, and consequently the second defendant, AbbVie UK, contended that it had no interest in the subject matter of the relevant filings and no involvement, and that therefore a declaration against it would serve no useful purpose. Arnold J disagreed ([35]-[36]):

> *"FKB contends that granting a declaration against AbbVie UK would serve a useful purpose for two reasons. The first is that it is probable that AbbVie Bermuda will grant AbbVie UK an exclusive license in respect of the subject matter of [a relevant] patent at some point in the future. In this regard, Counsel for FKB submitted that the evidence of AbbVie Bermuda quoted [in the preceding paragraph] can only be a statement of its present intention, given that AbbVie Bermuda has not offered any undertaking not to do so.*

[44] *Fujifilm Kyowa Biologics v AbbVie Biotechnology* [2016] EWHC 2204 (8 September 2016) Arnold J

Absent an exclusive license to AbbVie UK, the only financial remedy which the AbbVie group would be able to claim for infringement of patents would be a reasonable royalty payable to AbbVie Bermuda. To disable itself from claiming the lost profits suffered by AbbVie UK would not be acceptable to the AbbVie group shareholders. Accordingly, at some point, AbbVie Bermuda would change its intention.

The second reason is that even if AbbVie Bermuda does not grant to AbbVie UK an exclusive license, it remains the case that it is AbbVie UK which exploits the inventions in the UK and which therefore has a substantial financial interest in maintaining a monopoly which will be conferred by valid patents in that family. FKB contends that in those circumstances it has a legitimate interest in obtaining a declaration which is binding on AbbVie UK, particularly so as to forestall the possibility of AbbVie making threats to its customers or making statements that its product infringed."

The judge concluded that it was arguable that, in a claim for negative declaratory relief, it is not necessary for the claimant to show that the defendant would be a necessary party to any claim against the claimant, and it is sufficient for the claimant to show that it has a legitimate interest in ensuring that the defendant is bound by the declaration.

AbbVie sought to deploy the Re-cast Brussels Regulation, in particular arguing that under Article 24, a claim for an Arrow declaration did not fall within the jurisdiction of the UK court because it was not "concerned with the validity of any European Patent (UK)". Arnold J disagreed saying [78]:

"In my judgment FKB's claim for an Arrow *declaration is "concerned with" the validity of such respective European patents (UK) because it will require the Court to determine the single question of whether FKB has infringed a valid claim of such patents. The fact that it will enable the court to do so pre-emptively before the patents have even been granted is neither here nor there. Nor does it matter that the court will not have to decide whether any or all of the claims of the patents will be invalid or whether FKB's product will not infringe any or all of the claims of the patents because it will fall outside them. If the court grants the declaration it will mean that the claims will either be invalid or not infringed, and it does not matter which. But FKB's claim cannot be characterised as purely concerned with infringement of the patents."*

The Court of Appeal did grant leave to AbbVie to appeal both the decisions of Henry Carr J and Arnold J. In the Court of Appeal's first civil judgment of the year[45], handed down on 12 January, the Court of Appeal conducted a substantial review of the jurisdiction, the habits of some pharmaceutical companies in relation to divisional patents, and a close legal analysis of the *Arrow* jurisdiction. It noted that so called "submarine divisionals" are divisional patent applications which have not yet been published or which have not yet even been filed.

Obviously we have now risen from High Court level to the Court of Appeal, and consequently the very basis of *Arrow* declarations was capable of being reviewed.

[45] *Fujifilm Kyowa Biologics v AbbVie Biotechnology* [2017] EWCA Civ 1 (12 January 2017)

The Court of Appeal felt that its first role was to construe section 74 of the Patents Act. It concluded that the practical effect of section 74 is that proceedings in which the validity of a patent is put in issue will always be before a court or a tribunal which has jurisdiction under the Act to revoke the patent if the grounds of invalidity are made out. In that way the public interest in securing the revocation of invalidly granted patents is protected.

The Court of Appeal also noted that section 74 is concerned with putting in issue the validity of patents, that is to say granted patents. There is no known domestic law concept of the validity of an application. It is impossible to see how, in a case where there are no relevant granted patents, it can be said that validity of a patent is put in issue. Lord Justice Floyd concluded ([75]]):

> *"However if your action is not one in which the validity of a granted patent is put in issue, you do not need the authorisation of the section."*

Lord Justice Floyd identified what he described as "AbbVie's real complaint" in the following terms ([84]):

> *"By asserting that the dosing regimen is old or obvious, the declarations are making it clear that a future patent claim to the regimen would be invalid. Accordingly, if AbbVie were to obtain the grant of claims in that form, the resulting patent would have been pre-emptively adjudged invalid. There is therefore, implicit in the* Arrow *declaration, an* inter partes *declaration of invalidity of a putative patent, not yet granted, having those claims."*

Lord Justice Floyd, reflecting on that, said that if that was indeed the case, then FKB must wait and see whether such a patent is indeed granted and avail themselves of the remedies by way of opposition in the EPO or revocation before the National Court. That may never happen. In the meantime there would be continuing commercial uncertainty over whether their product would be held to infringe.

The final word from the Court of Appeal on *Arrow* declarations was as follows ([86]):

> "*In our judgment there is nothing in the scheme of the EPC and the Act to prevent such declarations in cases where there is a real justification for their grant. It is necessary to examine quite carefully the ways in which it is suggested that the grant of such a declaration would conflict with that scheme.*"

The court went on to consider that, so far as the EPO is concerned, an *Arrow* declaration has no impact on what the EPO can or cannot do in relation to any given application. It will apply its own internal legal order and procedures irrespective of any decision of the national court. The court is not being asked to review or adjudicate on any past action within the EPO. Accordingly, the declaration is not a collateral attack on EPO proceedings. On the contrary, it is an inevitable feature of the scheme set up under the EPC that national courts will have to decide whether combinations of features are old or obvious, and that they will have to do so while possible divisional applications are still pending in the EPO (or indeed in the national patent office).

It was argued on behalf of AbbVie that *Arrow* declarations are incompatible with the Patents Act. The Court of Appeal summarised the argument as follows ([90]):

> "*At its most straightforward, the argument is that it is the Act which grants the patent rights enjoyed by the patentee, and which provides for the manner in which their validity is to be examined. It is not for the courts in those circumstances to find other ways of making findings of invalidity which are not contemplated in the statute. The statute provides the exclusive remedy*."

Acknowledging that this was indeed a clever answer, the Court of Appeal did not agree. It said that the Arrow declarations sought "do not declare any patent invalid". Further, the remedy which the statute provides exists only in relation to granted patents. Lord Justice Floyd said ([92]):

> "*It is one thing to say that the statute should be understood to be providing an exclusive statutory remedy in relation to granted patents (which it does). It is going much further to say that it is providing an exclusive remedy in relation to patents which have not and may never be granted. We do not think it can have been the intention of Parliament to preclude the grant of declarations, however strongly justified, in circumstances where the statutory remedy is simply not available.*"

The Court of Appeal concluded that this is all a matter of the exercise of the court's discretion. It said ([93]):

> "*A claimant cannot seek an Arrow declaration simply because it would like to know whether a patent application in the course of prosecution will result in a valid patent. The course envisaged by the statute is that he should wait and see what, if any, patent is granted. The statutory remedy does not constitute a bar in principle to the granting of preparatory relief in appropriate cases, however. Where, for example, it appears that the statutory remedy is being frustrated by shielding subject matter from scrutiny in the national court, it should be open to the court to intervene.*"

The Court of Appeal was not persuaded that declarations in the *Arrow* form would somehow open floodgates. Noting that the *Arrow* decision itself is of some age, it has not resulted in many such applications being brought. Similarly, the Court did not think that the availability of such declarations would undermine the system of allocation of jurisdiction under the Re-cast Brussels Regulation. Summing up the Court of Appeal said ([98]):

> "*We have said enough to explain why we do not consider that here is any issue of principle which prevents the granting of* Arrow *declarations in appropriate cases. Drawing the threads together:*
>
> *(i) A declaration that a product, process or use was old or obvious at a particular date does not necessarily offend against section 74 of the Act.*
>
> *(ii) Such a declaration may offend against the Act where it is a disguised attack on the validity of the granted patent.*

(iii) *Such declarations do not offend against the scheme of the EPC or the Act simply because the declaration is sought against the background of pending divisional applications by the counter-party.*

(iv) *On the other hand the existence of pending applications cannot itself be a sufficient justification for granting a declaration.*

(v) *Whether such a declaration is justified depends on whether a sufficient case can be made for the exercise of the court's discretion in accordance with established principles.*"

To cut a long story short, the Court of Appeal considered that there was a realistic prospect that a trial judge may grant the declarations sought in relation to all the applications, and consequently AbbVie's appeal was dismissed.

This is a case of very significant potential importance, particularly as regards the issue of "clearing the way" and the practices of companies in some sectors, particularly the pharmaceutical sector, of relying on multi-layered divisional patent applications to perpetuate protection, and to avoid proper scrutiny for many years. Some of the criticism levelled at AbbVie, albeit on the basis of assumed facts, is quite pertinent, and will cause ripples across the industry.

Costs

I do not propose to go into any considerable detail about the case of ***Varian Medical Systems v Elekta***[46], beyond noting that Birss J took the opportunity to bash the parties' heads together and remind future litigants of their duty to cooperate. The issue that arose concerned the award of costs of an application for directions regarding the provision of further information. The judge rapidly lost patience with the prevarication and obfuscation of the parties, eventually ordering them each to bear their own costs of the application.

After what had seemed to be a lengthy and tense battle concerning the provision of information, shortly before the hearing the parties agreed, subject to costs, that the defendants would provide information requested by the claimant, and two weeks later the claimant would provide information requested by the defendants. The parties contacted the judge one hour before the scheduled hearing (and after the judge had read into the case) and asked whether the matter could be dealt with on paper.

The judge decided to go ahead with the hearing as he felt not only was that most efficient, but it gave him an opportunity to tell the parties roughly what he thought of them. In an age of increased case management, this is a salutary warning not to get on the wrong side of the judge.

A more sophisticated consideration of costs was given in the case of ***Actavis v Lilly (tadalafil)***[47], once again with Birss J at the helm.

[46] *Varian Medical Systems v Elekta* [2016] EWHC 2679 (Pat) (12 October 2016) Birss J

[47] *Actavis v Lilly (tadalafil)* [2016] EWHC 2690 (Pat) (11 October 2016)

This was the costs decision following the court's ruling that one of Lilly's patents regarding the dosage of CIALIS medicine was valid and potentially infringed but the other was invalid.

The judge noted that the starting point normally was first to identify the overall successful party, and secondly to consider whether there were any suitably circumscribed issues in respect of which the overall winner should be deprived of its costs, and if so whether the overall loser should be awarded its costs.

In this case, the parties disagreed in relation to the most basic question - who had won? Actavis and the other claimants contended that their win in respect of one of the patents ('092) meant that when Lilly's supplementary protection certificate expired they would have access to 70% of the market. The judge disagreed. He said that Lilly's victory in relation to the other patent ('181 - for the low dose market) was not just a victory on some particular issues in an action on which they had lost overall. The claimants fought hard on this part of the dispute and incurred, probably, the majority of the costs in the proceedings - approximately 55 - 60%.

So the judge considered the position in respect of each patent on its own. Taking a very broad brush approach to the consideration of the issues alleged to be suitably circumscribable, he decided that Lilly would, on this approach, pay to the claimants 93% of the claimants' costs relating to the '092 patent. Taking a similarly broad brush approach the claimants would on the patent by patent approach, pay to Lilly 86% of Lilly's costs relating to the '181 dispute. Bearing in mind the numbers, this would entail a balancing payment of approximately £500,000 to Lilly - approximately 13% of Lilly's overall costs in the proceedings.

However, he felt that this did not give significant weight to the overlap in the evidence between the issues relating to the two cases. One side's costs attributable to the overlapping issues represented well over 13% of that side's costs and this applied to either side so a result whereby one side paid the other a sum in the order of 13% of their costs, which without taking the overlap into account, would be unfair.

Summing up, the judge felt that, investigating the matter to reach precision would more likely than not end up with a modest payment to Lilly. However, reaching such precision would take disproportionate time and cost. Standing back, no order as to costs as between Actavis, Teva and Mylan on the one hand and Lilly on the other was a fair reflection of the overall outcome in the proceedings.

Costs was also the key issue in a decision by Roger Wyand QC, sitting as a deputy judge, in the case of ***Sony v SSH***[48]. This was the first case of its kind which looked at the relationship between budgets set earlier in the case, and recoverable costs under the current regime. It is now the practice in some cases that a cost budget has to be submitted by the parties, and agreed by the judge. Any costs in excess of that budget may well not be awarded, even to the winning party, at the end of the case.

Considering a case where budgets had indeed been set, Roger Wyand QC said that the budget is not a cap but a guideline which the court has power to depart from. It will only do so where it is satisfied that there is a good reason to do so taking into

[48] *Sony v SSH* [2016] EWHC 2985 (Pat) (24 November 2016) Roger Wyand QC

account all the circumstances of the case. Particular considerations include the function of the budget and ensuring that the costs incurred are proportionate and reasonable, and the value to the opposing party of understanding what is being done and what it is going to cost. Each phase of the budget is to be considered separately and it is not legitimate to combine two phases where one is overspent and the other is underspent.

Dealing with a couple of other matters of contention, Roger Wyand QC ruled:

- The court's budget approval relates only to the budget figures for each phase, not to any suggested apportionment by issue. Where it is apparent that the allocated apportionment is wrong, it would be invidious if the court could not, with the assistance of the parties, make its own assessment.

- The Practice Direction did not intend that any distinction should be drawn between budgets which have been agreed and those which have been approved.

- Following the outcome of the underlying case, it is difficult to get a dispassionate view as to what are reasonable and proportionate costs; in the event of dispute the other side's budget may be an indication of what is reasonable and proportionate.

Interim injunctive relief

Finally in this section, returning to the Warner-Lambert litigation, there was an interesting order by Arnold J in the case of ***Warner-Lambert v Sandoz***[49].

The judge refused to lift the interim injunctive relief restraining launch of Sandoz' full label generic pregabalin medicine. Warner-Lambert's position regarding the enforcement of the key patent claim 3 (to neuropathic pain) had altered since the Court of Appeal's decision made earlier in the year; it no longer sought injunctive relief with respect to that claim. This being a material change in circumstances the judge reconsidered the merits of the interim relief against Sandoz. He decided that Warner-Lambert had not merely an arguable, but a strong case that dealings by Sandoz in its full label generic pregabalin would infringe claims 10, 11 and 12, and the balance favoured interim relief. He decided not to lift the relief although some tweaks would be likely to be made to the form of order.

A key point to note from the *Warner-Lambert v Sandoz* decision is the judge's acceptance, in a patent case, that CJEU case law on the interpretation of the IP Enforcement Directive applies in respect of relief granted pursuant to national law. This includes in respect of final and interim injunctions, the key word being "proportionality". I raise this case merely as an illustration of one of the issues which may come into play at some point in the future as regards the jurisdiction of the CJEU.

[49] *Warner-Lambert v Sandoz* [2016] EWHC 3317 (Pat) (21 December 2016) Arnold J

(e) **FRAND / Competition Law**

The opening case I propose to discuss in this context is the case of ***Samsung v Ericsson***[50].

This decision is a part of the *Unwired Planet* litigation. Unwired Planet owns a portfolio of telecommunications patents, many of which have been declared essential to various telecommunications Standards, including 2G, 3G and 4G Standards. Unwired Planet acquired its interest in the patents from Ericsson pursuant to various agreements and assignments. It asserts that the patents have been infringed by Samsung and Huawei.

Samsung pleaded a number of defences to Unwired Planet's claim including defences based on alleged breaches by Ericsson of EU Competition Law. In short these were that:

1 The sale agreements (between Ericsson and Unwired Planet) failed fully to transfer the FRAND undertakings given by Ericsson to the European Telecommunications Standards Institute (ETSI) so as to bind Unwired Planet.

2 By dividing its portfolio in the way that it did, Ericsson caused unfair higher royalties to be earned, thus restricting or distorting competition.

3 Certain terms of the agreements were stand alone "price fixing" infringements of Article 1 of the Treaty on the Functioning of the European Union.

Ericsson applied to strike out each of Samsung's allegations, arguing that they had no reasonable prospect of succeeding at trial. At first instance[51], Birss J struck out Samsung's first alleged breach but refused to strike out the second and third breaches. Samsung appealed in relation to the first breach, namely that it had failed fully to transfer the FRAND undertakings which Ericsson had given to ETSI.

The particular arguments raised on appeal are specific to the case and of no general interest. Samsung's arguments in the Court of Appeal focussed upon the "non-discrimination" aspect of FRAND: that if an owner of standard essential patents sells them on, then it should do so on terms which avoid discrimination occurring between, on the one hand, commercial undertakings which have taken licences from the seller, and on the other hand, commercial undertakings which in future take licences from the purchaser. Samsung contended that such discrimination could damage the process of competition downstream and so harm consumer interests.

Kitchen LJ noted the force of the points made by the judge in rejecting Samsung's contentions on these points, but nevertheless he considered that Samsung had a realistic prospect of persuading a judge at a full trial that "in the circumstances of this case Article 101 TFEU required the effective transfer to Unwired Planet of Ericsson's FRAND obligation so that Unwired Planet could not obtain more favourable terms from its licencees than Ericsson could itself have obtained".

[50] *Samsung v Ericsson* [2016] EWCA Civ 489 (27 May 2016)

[51] *Unwired Planet v Huawei* [2015] EWHC 2097 (Pat)

Following this decision an 8-week FRAND trial was heard in late 2016. Judgment is expected in early 2017.

3 VALIDITY

(a) Common General Knowledge and the Skilled Person

I started last year having a short section on the common general knowledge (CGK) and the skilled person, before moving on to the separate aspects of validity, as a means of "scene setting". This is because the evidence relating to CGK and the skilled person is so often highly significant in the cases to be considered.

Last year I reported on a decision of HHJ Hacon[52] that the nature of the skilled person might be different depending on whether they are being deployed to consider insufficiency or inventive step. This drew upon the Court of Appeal's ruling in *Schulmberger v Electromagnetic Geoservices*[53]. If you set a hare like that running just watch it go!

This year, in ***Accord v medac***[54], Birss J had cause to consider the issue again. Medac argued that the skilled team for the purpose of obviousness would be different to that for the purpose of sufficiency. Medac's patent had claims in Swiss and EPC form to methotrexate for subcutaneous administration for the treatment of inflammatory autoimmune diseases, wherein the concentration of methotrexate is about 50mg/ml. Medac's case was that it was not obvious to the clinician to think that there was any need to produce a new formulation of subcutaneous methotrexate, and so the clinician would not approach the formulator for input.

Birss J was not impressed. He discussed the legal principles which govern the question of whether the skilled person or team were the same for both purposes and went on to say ([18]):

> "*First, if an invention brought together two disparate fields and was therefore "art changing", then the identities of the person/team from the two different perspectives may be different. Second, the court explained that a key question is generally - what problem was the patentee trying to solve? That leads one to consider the art in which the problem lay. It is the notional team in that art which is relevant. Third, you cannot assume that a person in one field would know what was known by a person in another field, proof is required. Fourth, and importantly in my judgment, the skills (and mind sets) of real persons or teams in the art are what matter when one is constructing the notional skilled person/team to whom the invention must be obvious if the patent is to be found invalid.*"

Birss J's view was that the present case was not one in which the invention was "art changing". It was not an exercise in hindsight to consider the issues of inventive step from the point of view of the skilled team which comprised a formulator.

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[52] *VPG v Air-Weigh* [2015] EWHC 1862 (IPEC)

[53] *Schulmberger v Electromagnetic Geoservices* [2010] EWCA Civ 819

[54] *Accord v medac* [2016] EWHC 24 (Pat) (13 January 2016)

In ***GSK v Wyeth***[55] the subject matter in question was, as we have seen, a vaccine against meningitis B. In considering the nature of the skilled addressee, Henry Carr J summarised the position as follows ([25]):

> "*(i) A patent specification is addressed to those likely to have a real and practical interest in the subject matter of the invention (which includes making it as well as putting it into practice).*
>
> *(ii) The skilled addressee has practical knowledge and experience of the field in which the invention is intended to be applied. He/she (hereafter "he") reads the specification with the common general knowledge of persons skilled in the relevant art, and reads it knowing that its purpose is to disclose and claim an invention.*
>
> *(iii) A patent may be addressed to a team of people with different skills. Each such addressee is unimaginative and has no inventive capacity.*
>
> *(iv) Although the skilled person/team is a hypothetical construct, its competition and mind set is founded in reality. As Jacob LJ said in* Schlumberger v Electromagnetic Geoservices*:*
>
> > *"The combined skills (and mind sets) of real research teams in the art is what matters when one is constructing the notional research team to whom the invention must be obvious if the patent is to be found invalid on this ground.""*

Turning to the question of common general knowledge, Henry Carr J cited the normal authorities, and noted in particular that he agreed with the following analysis of Sales J in *Teva v Astrazeneca*[56] when he said ([29]):

> "*The authorities indicate that CGK includes not just information directly in the mind of the notional skilled person, but such information as he would be able to locate by reference to well-known textbooks. This guidance needs to be adapted and kept appropriately up to date with the procedures for dissemination of scientific knowledge in the age of the internet and digital databases of journal articles. Searches of such databases are part and parcel of the routine sharing of information in the scientific community and are an ordinary research technique. In my view, if there is a sufficient basis (as here) in the background CGK relating to a particular issue to make it obvious to the unimaginative and uninventive skilled person that there is likely to be - not merely a speculative possibility that there may be - relevant published material bearing directly on that issue which would be identified by such a search, the relevant CGK will include material that would readily be identified by such a search.*"

[55] *GlaxoSmithKline v Wyeth* [2016] EWHC 1045 (Ch) (12 May 2016) Henry Carr J

[56] *Teva v Astrazeneca* [2014] EWHC 2873 (Pat)

Possibly concerned by the potential scope of such a search, Henry Carr J noted that the passage did not mean that all material available online constitutes common general knowledge. Rather it "indicates that material which the skilled addressee knows to be available on line and which is generally accepted as a good basis for further action may constitute common general knowledge".

In ***Merck Sharp & Dohme v Shionogi***[57], Arnold J was called upon to describe the relevant skilled team. He did so in a helpful and somewhat generic fashion as follows [(79)]:

> "*A patent specification is addressed to those likely to have a practical interest in the subject matter of the invention, and such persons are those with practical knowledge and experience of the kind of work in which the invention is intended to be used. The addressee comes to a reading of the specification with the common general knowledge of persons skilled in the relevant art, and he or she reads it knowing that its purpose is to describe and demarcate an invention. Purely for convenience, I will hereinafter refer to the skilled person as "he". He is unimaginative and has no inventive capacity. In some cases the patent may be addressed to a team of persons having different skills.*

Arnold J continued ([84]):

> *"The correct approach to identifying the skilled person to whom a patent is addressed was considered in detail by Jacob LJ, with whom Sullivan and Waller LJJ agreed, in* Schlumberger Holdings v Electromagnetic Geoservices. *The issue under discussion was whether the addressee is the same, and has the same common general knowledge, when considering both obviousness and insufficiency. In the course of that discussion, however, Jacob LJ drew the following conclusion from the decision of the Court of Appeal in* Dyson Appliances Limited v Hoover:
>
> > *"I think one can draw from this case that the court, in considering the skills of the notional "person skilled in the art" for the purposes of obviousness will have regard to the reality of the position at the time. What [are] the combined skills (and mindsets) of real research teams in the art is what matters when one is constructing the notional research team to whom the invention must be obvious if the Patent is to be found invalid on this ground.""*

That is probably the most helpful and constructive contribution towards this issue we have seen during the last 12 months. The trend seems to be moving towards identifying the skilled person with practical experience and knowledge of the work in question. It has never been a good idea to try to match expert witnesses to the skilled person - that is something which simply cannot be done and is not worth trying. However, the move towards a more practical approach, as opposed to top level academics, may be reflected in the appointment of experts in due course.

[57] *Merck Sharp & Dohme v Shionogi* [2016] EWHC 2989 (Pat) (25 November 2016)

Finally under this heading, it is worth considering the case of ***Idenix v Gilead***[58]. The question of the scope of common general knowledge was, as is often the case, in dispute. Kitchen LJ referred (in [70]) back to the venerable authority of *British Acoustic Films*[59] and the judgment of Luxmoore J when he said:

> "*In my judgment it is not sufficient to prove common general knowledge that a particular disclosure is made in an article, or series of articles, in a scientific journal, no matter how wide the circulation of that journal may be, in the absence of any evidence that the disclosure is accepted generally by those who are engaged in the art to which the disclosure relates. A piece of particular knowledge as disclosed in a scientific paper does not become common general knowledge merely because it is widely read, and still less because it is widely circulated. Such a piece of knowledge only becomes general knowledge when it is generally known and accepted without question by the bulk of those who are engaged in a particular art; in other words, when it becomes part of their common stock of knowledge relating to the art. ….It is certainly difficult to appreciate how the use of something which has in fact never been used in a particular art can ever be held to be common general knowledge in that art.*"

In *Idenix v Gilead*, at first instance, Arnold J had found that various publications and certain presentations given at a conference in Savanna were not part of the common general knowledge. Kitchen J did not consider that the judge had erred in any way. He was entitled to hold that Idenix had not established that it was part of the skilled team's general knowledge, merely because items had been discussed at a particular conference.

I think the dawn of realisation by judges that we live in an internet age has brought about an attempt to control the proliferation of CGK. It could, of course, virtually kill all patents if a piece of knowledge parked in a tiny corner of the internet was necessarily found to be CGK purely because it had been published.

(b) **Anticipation / Priority**

In recent years there have been fewer material cases regarding anticipation, though rather more involving connected issues regarding priority, particularly since the somewhat unhelpful intervention of the European Patent Office in relation to the question of poisonous priority.

In the case of ***GSK v Wyeth***[60], Henry Carr J, who seems to be getting into this habit, has given some helpful guidance on core principles relating to anticipation and priority.

Substantive priority

On priority he made the following comments ([128]):

[58] *Idenix v Gilead* [2016] EWCA Civ 1089 (8 November 2016)

[59] *British Acoustic Films* [RPC 53RPC 221

[60] *GlaxoSmithKline v Wyeth* [2016] EWHC 1045 (Ch) (12 May 2016) Henry Carr J

"*(i)* *A claim to priority of the "same invention" is referred to in Article 87(1) of the European Patent Convention. Section 5 of the Patents Act 1977, which provides for entitlement to priority, is to be interpreted as having the same effect as Article 87, pursuant to section 130(7) of the Act;*

(ii) *The requirement for the same "invention" means that priority is to be acknowledged only if the skilled person can derive the subject matter of the claim directly and unambiguously, using common general knowledge, from the priority document as a whole;*

(iii) *The approach is not formulaic: priority concerns technical disclosure, explicit or implicit. The question is whether there is enough in the priority document to give the skilled person essentially the same information as forms the subject of the claim and enables him to work the invention in accordance with that claim;*

(iv) *The important thing is not the consistory clause or the claims of the priority document, but whether the disclosure as a whole is enabling and directly and unambiguously gives the skilled person what is in the claim whose priority is in question. It must "give" this disclosure directly and unambiguously. It is not sufficient that it may be an obvious development from what is disclosed;*

(v) *Plausibility, as part of the requirement of an enabling disclosure, applies to issues of priority as well as sufficiency.*"

The last paragraph points to the ever increasing encroachment of the concept of "plausibility" into patent litigation. In the same way as, for many years, we became highly fixed on the expression "inventive step" which appears nowhere in the Patents Act, so the term "plausibility" has become central to many of the key concepts in patent litigation.

Novelty - general

Moving on to the question of novelty as a whole, Henry Carr J found that he could do no better than to quote the words of Lord Hoffmann in *Synthon v SKB*[61] when he said:

"*(i)* *The prior art must disclose subject matter which, if performed, would necessarily result in infringement of the patent;*

(ii) *The skilled addressee must be able to perform the claimed invention by using the matter disclosed in the prior art, read and understood together with his common general knowledge. The test for enablement is the same as in the context of sufficiency.*"

In this case, Wyeth submitted that anticipation required a sufficiently individualised disclosure, which would be a matter of degree. The judge agreed with that. He

[61] *Synthon v SKB* [2006] RPC 10

referred to the judgment of Jacob LJ in *Dr Reddy's v Eli Lilly*[62] when he had rejected the argument that disclosure of a large class of compounds constitutes a disclosure of each member of the class, and therefore deprives each member of the class of novelty. The Court of Appeal held that this was wrong, as a matter of basic reasoning, and because it was inconsistent with settled EPO case law.

Anticipation by prior use

Turning to anticipation by prior use, Henry Carr J summed up his interpretation of the law by quoting (in [93]) from Lord Hoffmann in the House of Lords' decision in *Merrell Dow v Norton*[63]:

> "*(i) Article 54 of the EPC makes it clear that, to be part of the state of the art, the invention must have been made available to the public. An invention is a piece of information.*
>
> *(ii) Making matter available to the public within the meaning of section 2(2) therefore requires the communication of information. The use of a product makes that information part of the state of the art only so far as that use makes available the necessary information.*
>
> *(iii) The 1977 Act therefore introduced a substantial qualification into the old principle that a patent cannot be used to stop someone doing what he has done before. If the previous use was secret or uninformative, then subject to section 64, it can.*
>
> *(iv) Likewise, a gap has opened between the tests for infringement and anticipation. Acts done secretly or without knowledge of the relevant facts, which would amount to infringements after the grant of the patent, will not count as anticipations before.*"

The judge also called in aid (in [97]) the decision of the House of Lords in *Synthon* when it said:

> "*An essential purpose of any technical teaching is to enable the person skilled in the art to manufacture or use a given product by applying such teaching. Where such teaching results from a product put on the market, the person skilled in the art will have to rely on his general technical knowledge to gather all information enabling him to prepare the said product. Where it is possible for the skilled person to discover the composition or the internal structure of the product and to reproduce it without undue burden, then both the product and its composition or internal structure becomes state of the art.*"

In the context of the case in hand, Henry Carr J explained that in order for the use of a particular vaccine to be an anticipation, it had to be established not just that the vaccine contained the protein in question, but also that it was possible at the priority

[62] *Doctor Reddy's v Eli Lilly* [2009] EWCA Civ 1362

[63] *Merrell Dow v Norton* [1996] RPC 76

date for the skilled person to identify the presence of that protein and to reproduce it without undue burden.

Nothing by way of rocket science in there, but useful guidelines to keep in mind when assessing each of these core issues in relation to the law of anticipation and priority.

Prior art anticipation

Henry Carr J gave more guidance on the question of anticipation and novelty in the case of ***Hospira v Cubist***[64]. Having referred once again to the judgment of Lord Hoffmann in *Synthon*, the judge noted that the requirements that must be met for prior art to deprive a patent of novelty include the following ([146]):

> "*If a claim comprises a particular technical effect, then that therapeutic effect is a functional technical feature of the claim and must be taken into account when assessing its novelty.*

Henrr Carr J continued, noting (in [147]) that when considering the novelty of functional technical features in the context of a Swiss form claim, Arnold J had said in *Hospira v Genentech*[65]*:*

> *"…such claims are generally regarded as novel over a mere proposal to administer the drug to patients in the manner claimed. This is because the mere proposal does not disclose that the treatment is indeed efficacious. If it was obvious that the treatment would be efficacious, or at least it was obvious to conduct a trial of the treatment which would involve treating patients, then the claim is likely to lack inventive step, but that is another matter.*"

I must say that I have a little problem with this assertion, though it tends not to be important in practice, as, of course, disclosure lacking assertion of efficacy can render a patent invalid for lack of inventive step.

By way of revision, it is worth remembering that section 2(3) of the Patents Act states:

> "*The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied, that is to say - (a) that matter was contained in the application for that other patent both as filed and as published; and (b) the priority date of that matter is earlier than that of the invention.*"

With that in mind, we turn to ***Actavis v Lilly (tadalafil)***[66], and the judgment of Birss J. One of the items of prior art, Stoner, was prior art under section 2(3) - novelty only prior art, but only if it was entitled to its claimed priority. The issue was of legal priority

[64] *Hospira v Cubist* [2016] EWHC 1285 (Pat) (10 June 2016) Henry Carr J

[65] *Hospira v Genentech* [2015] EWHC 1796

[66] *Actavis v Lilly (tadalafil)* [2016] EWHC 1955 (Pat) (10 August 2016) Birss J

only. Lilly contended that the burden of proof to establish legal priority was on the claimants as applicants for revocation. The claimants had served on Lilly a Notice to Admit. Lilly had made no admission. Neither side had sought to call evidence of the result of any investigations into legal priority. All the court had to go on was the published application and the copy of the priority document which had been obtained from the relevant public file.

There have long been questions in this area of law, and there remain questions where it is the legal priority of the patent in suit that is challenged, but the conclusions of Birss J in this case are worth noting. He said ([245]-[246]):

> "*In principle this point will arise every time section 2(3)/54(3) prior art is relied on as long as the prior application's relevance depends on its own claim to priority and in particular when the applicant in whose name the prior application was filed is not a party to the proceedings. That will not be an uncommon occurrence, particularly in the EPO. Nevertheless neither side cited any case in which this question had been considered. I infer that the EPO's approach is just to assume that legal priority exists in such a case.*
>
> *The correct general approach must be as follows. Legal priority does need to be established. It is a mandatory requirement for priority. Without it the relevant application is not prior art under section 2(3). The legal burden of proof lies on the party attacking validity, in this case the claimants. However, if sufficient evidence is available to support any inference that legal priority exists, an evidential burden will have shifted to the patentee to call evidence to rebut that inference.*"

Looking at the facts of the case in question, the judge decided that the Notice to Admit, and Lilly's answers to it, did not alter the overall analysis. Lilly had submitted that, given the Notice from the claimants, it was reasonable to expect that the claimants would take on the burden of proving legal priority. The judge accepted that but only in the sense that the legal burden of proof always did rest on the claimants. Nothing in the Notice itself could be taken by Lilly to indicate that the claimants were representing that they would call evidence from Merck or the inventors of Stoner or that they would accept an onus to do so. If the material before the court shifted an evidential burden onto Lilly, the Notice and Lilly's response to it did not change anything. Had it wished to do so, Lilly could always have sought evidence from Merck or the inventors itself.

"Made available to the public"

A familiar tale of woe arose in the case of ***Thoratec v AIS***[67]. This was a medical device patent case, and that does appear to give rise to a regular occurrence causing complication in the field of anticipation and priority.

A number of catheter units, which were conceded to fall within the scope of some claims of the patents in issue, were supplied to a Dr Dekker and his colleagues for the purpose of carrying out a study. But did the supply render the catheter units a part of

[67] *Thoratec v AIS* [2016] EWHC 2637 (Pat) (28 October 2016) Arnold J

the state of the art? This depended upon whether the supply had made them available to the public. Section 2(2) of the Patents Act states:

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

It was not contended that there was any express obligation of confidence on Dr Dekker. Nor was there any documentary evidence as to the terms on which Dr Dekker and his colleagues carried out the study which was ultimately reported in the document which went on to form other prior art in the case. Dr Dekker gave witness evidence that he did not sign a confidentiality agreement, was not told that the work was confidential and did not consider that it was confidential. Dr Dekker considered his own data to be confidential but it did not follow, said the judge, that there was confidentiality in the arrangement of the magnetic couplings in the device supplied to him.

The key question was whether Dr Dekker and his colleagues were free to disclose to others the arrangement of the magnetic coupling. The judge was satisfied that, as a whole, the evidence firmly rebutted any presumption that the supply to Dr Dekker and his colleagues was subject to any implied obligation of confidentiality. In the absence of confidentiality it was common ground that the prior use anticipated some of the claims of the patent in suit.

Interestingly, the paper which Dr Dekker prepared did not anticipate it because it did not clearly and unmistakably disclose a magnetic clutch. All it said about the connection between the drive shaft and the drive unit was ([191]):

> "*The other end of the driveshaft is a permanent, disc-shaped magnet, which is placed in the driving unit. The driving unit consists of a rotating magnet …*"

On the evidence the judge concluded that although the skilled reader would consider it more likely than not that the arrangement being described was a magnetic clutch rather than a friction coupling, he would not be sure. The judge dismissed counsel for Thoratec's "ingenious" argument that if the disclosure was ambiguous then it disclosed both possibilities. He felt that was not the case.

(c) **Obviousness**

As always, there is a lot of material on the subject of obviousness. To misquote something recently said of the Prime Minister, the judges appear to be using a lot of words to say very little. I have given up looking for any form of "bright line" that will assist us in guiding clients "case by case" - I have been doing that for years and it has proved to be a triumph of hope over experience. For the time being I have just settled for looking for small shafts of light shed on dark corners on the law of obviousness which may help our consideration to some degree.

Keeping the prior art in its place

In ***Accord v medac***[68], Birss J made the usual formulaic opening, approving the test set out in *Pozzoli*[69]. The judge also noted the need to remember that it would be hindsight for the skilled person to read the prior art with an assumption that it contains pointers towards the invention. He said ([64]):

> "*Medac referred to the point addressed by Floyd J (as he then was) in* Dr Reddy's Laboratories v Ely Lilly… *There the judge observed that there can be risk in focussing too much on the disclosure of any particular document and losing sight of the whole common general knowledge. Medac submitted that while the law requires that the pleaded prior art be notionally read with interest by the skilled person, that person does not approach it on the assumption that that particular document (out of all the others directed to the same problem) in fact contains pointers towards the solution, and an unnatural focus on it may lead to an unbalanced analysis and hindsight. I agree with that submission. The key issue is that the skilled person does not approach a document on the assumption described. To do so would indeed involve hindsight.*"

Obviousness over CGK

Accord v medac was also one of a number of cases this year where an argument of obviousness over common general knowledge alone was run. First, this places a heavy burden on the party seeking to make the argument to have a comprehensive and agreed definition of common general knowledge. Floyd J warned some years ago that such attacks need to be scrutinised with care since they can be favoured by parties because the starting point is not obviously encumbered by inconvenient details of the kind found in documentary disclosures. To this thought, Birss J added his own comments including the following ([123]):

> "*The problem with arguments over common general knowledge alone is that the combination of features relied on is always and necessarily one created with hindsight knowledge of the invention, and worse, is one which the person attacking validity has not been able to find as a pre-existing combination in the concrete prior art. If they had they would have relied on that concrete prior art. Either the combination has not been made in the concrete prior art at all or it only appears with additional inconvenient details. If an invention is not obvious over the concrete prior art which is relied on, the court is entitled to be sceptical that an argument that it is nevertheless obvious over common general knowledge alone is correct.*"

These comments mark a trend visible across a number of cases, and it is fair to say that challengers must be increasingly courageous to run this argument.

[68] *Accord v medac,* [2016] EWHC 24 (Pat) (13 January 2016)

[69] *Pozzoli v BDMO* [2007] EWCA Civ 588

In ***Unwired Planet v Huawei (29 January 2016)***[70], Birss J considered the question of inventive step. After the *Pozzoli* formulation, the other most quoted passage in relation to the assessment of inventive step is that of Kitchen J (as he then was) in *Generics v Lundbeck*[71] when he said ([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 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.*"

The *Unwired Planet v Huawei (29 January 2016)* case was one in which the existence of multiple different avenues did not show that the avenue actually pursued and claimed in the patent was inventive. Birss J summarised the law in this context as follows ([141]):

> "*As a matter of law the availability of different avenues may or may not show that a step is inventive. Multiple avenues can be indicative that one avenue, which leads to the invention, is not obvious but on the other hand the existence of a number of obvious ways forward does not mean one of them is not obvious. It depends on the facts.*"

In this case, as well, an argument of obviousness over common general knowledge was somewhat dismissively rejected. There were a number of patent cases between Unwired Planet and Huawei, all part of a wide dispute, and the attempt to argue obviousness over CGK alone was run in both of the patent cases decided in 2016. It received similar treatment in each case. One particular passage from Birss J in his ***Unwired Planet v Huawei (22 March 2016)***[72] decision is worth considering ([233]):

> "*I have addressed the obviousness arguments on their merits. However in my judgment the argument based on common general knowledge alone contained a good number of the familiar flaws in arguments of this kind which were discussed by Floyd J in* Ratiopharm v Napp*…and by me in* Accord v medac*… The argument in the case has not been properly pleaded…..the case then shifted very close to trial, which demonstrated why it should have been pleaded properly in the first place. Furthermore the argument presented a combination of common general knowledge features which had been created with hindsight knowledge of the patent. It was presented in a way which lacked inconvenient details which were found when the same ideas appeared in the committee documents and it presented points of common general knowledge at a level of generality which itself was crafted with hindsight.*"

I think we are beginning to get the message!

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[70] *Unwired Planet v Huawei* [2016] EWHC 94 (29 January 2016)

[71] *Generics v Lundbeck* [2007] RPC 32

[72] *Unwired Planet v Huawei* [2016] EWHC 576 (Pat) (22 March 2016) Birss J

In ***American Science & Engineering v Rapiscan***[73], the invention claimed in the patent concerned technology used in security scanners and wider security systems in airports, ports, etc. Infringement was conceded (provided the patent was valid). Validity was challenged on the basis of obviousness.

By the end of the trial, one piece of prior art, "Swift", was relied upon. It was conceded that the other cited prior art did not add to the challenge. The question was whether the claimed features identified as integers (f) and (g) were obvious over Swift. The features were:

> [f] "the detector module is contained entirely within the body of the enclosed conveyance while the conveyance is in motion during the course of inspection"; and
>
> [g] "characterised in that the system further comprises a relative motion sensor for generating a relative motion signal based on a relative motion of the enclosed conveyance and the inspected object"

The judge found that even if either feature (f) or feature (g) was obvious individually, they had not been shown to be obvious in combination. There were plenty of obvious avenues for the development of Swift, some of which were flagged in the paper itself, but changing the whole method of operation of the system in order to reach the claimed invention was far removed from these, and it was only with hindsight that the necessary changes could be seen as relatively simple.

Interestingly, Arnold J found "modest support" in the secondary evidence for his conclusion that claim 1 was not obvious, namely that nobody came up with the invention in the six years following the publication of Swift, and the evidence of Rapiscan's response to the commercial success of the commercial vehicles which implement the invention.

It is probably worth noting one particular comment made by Arnold J in relation to the international focus of the skilled person and common general knowledge when he said ([79]):

> "*Because of the relative size of the US Government and military, the USA was the leading national market and was the market driver in terms of development. Moreover, most of the key players were based in the USA or had a US presence. Thus any skilled person working anywhere in the western world would be interested in developments in the US market, even if they did not intend to enter that market themselves.*"

We are being posed interesting questions regarding the need to look at the international nature of markets when assessing items such as the identity of the skilled person, and indeed the scope of common general knowledge.

[73] *American Science & Engineering v Rapiscan* [2016] EWHC756 (Pat) (11 April 2016) Arnold J

Obvious resources

Although a relatively minor case in terms of content, for reasons which will be apparent, the case of ***Richter Gedeon v Generics***[74] has proved to be one of my favourites of the year. This case comprised a Court of Appeal bench of Lord Justice Floyd, Arnold J and Sir Robin Jacob. That is either a dream team or Counsel's worst nightmare, depending on your views!

This was an appeal from Mr Justice Sales. The subject matter of the case was an oral contraceptive, and the prior art which supposedly gave rise to a claim for obviousness was a World Health Organisation report. In the report, the dosage regime was stated to be 1.5g. This would have constituted a very substantial dose indeed. Sales J had concluded that it was obvious that this massive dose was wrong and so the document could be read as disclosing a sensible dose of 1.5mg. He said that required no invention, and there was every incentive to make that jump. Simple enquiries were all that was needed.

Possibly from sentimentality, the judgment was delivered by Sir Robin Jacob. He opened as follows:

> "*For the last time, with some sadness, I have pressed the "start new civil appeals judgment" button of the judgment template.*"

I will have more to say on that subject later.

He quoted (in [21]), with approval, the words of Arnold J in *KCI v Smith & Nephew*[75] where Arnold J said:

> "*…even if information is neither disclosed by a scientific item of prior art nor common general knowledge, it may nevertheless be taken into account as part of a case of obviousness if it is proved that the skilled person faced with the problem to which the patent is addressed would acquire that information as a matter of routine. For example, if the problem is how to formulate a particular pharmaceutical substance for administration to patients, then it may be shown that the skilled formulator would as a matter of routine start by ascertaining certain physical and chemical properties of that substance (e.g. its aqueous solubility) from the literature or by routine testing. If so, it is legitimate to take that information into account when assessing the obviousness of a particular formulation. But that is because it is obvious for the skilled person to obtain that information, not because it is common general knowledge.*"

Sir Robin Jacob said that it was not logical to distinguish between a case where it is obvious to look something up and one where it is obvious to ask and clear that the answer would be given and clear. The notional asking is equivalent to the notional looking up.

[74] *Richter Gedeon v Generics* [2016] EWCA Civ 410 (26 April 2016)

[75] *KCI v Smith & Nephew* [2010] EWHC 1487 (Pat)

Sir Robin Jacob further held that the judge had not been wrong to attribute the likely action of a real person with that of a notional person. He said ([24]):

> "*On the contrary, the notional person, hampered by lack of any spark of inventive capacity, will act in the same way as real people provided that action involves no imagination. Ringing up a man who you know knows is clearly not inventive.*"

So in his final judgment, Sir Robin did get one last chance to make his point that it is not appropriate to detach the person skilled in the art from the real world.

This case is notable not only for Sir Robin Jacob's last judgment, but for Arnold J's shortest ever judgment. He said merely "I agree".

Obvious to try

In ***Hospira v Genentech (27 July 2016)***[76], the Court of Appeal was reviewing a decision of Birss J in which two Genentech patents, to lyophilized formulation of trastuzumab, were found to be obvious. Trastuzumab is a monoclonal antibody which is the active ingredient in Genentech's Herceptin medicine for HER2 receptor positive breast cancer.

Floyd LJ took the opportunity to provide an excellent summary of the law of inventive step. I will attempt to summarise as follows.

Beginning with Kitchin J's well known quote on the question of obviousness in *Generics v Lundbeck*, Floyd LJ continued to say:

> "*It follows that the court is required to embark on a multi-factorial assessment. The approach of the appellate court to such questions is well-known: the decision is not open to independent evaluation in this court unless the judge has made an error of principle.*"

He said that there was only one statutory question, namely, whether the invention was obvious at the priority date. He sternly pointed out that "obvious to try" is not a substitute test for obviousness. Whether the invention was obvious to try is merely one of many considerations which it may be appropriate for the court to take into account in addressing the statutory question. It must in any case be coupled with a reasonable or fair prospect of success.

A judge's assessment of whether an approach has a reasonable or fair prospect of success is itself another multi-factorial assessment. There is no single standard that amounts to a fair expectation of success. Floyd LJ quoted Jacob LJ's statement in *St Gobain v Fusion-Provida*[77], when he said that it must be "more-or-less self-evident that what is being tested ought to work". Floyd LJ said that this was "far from being a test of universal application". Floyd LJ warned against imposing a straight-jacket on the law by adopting any form of words as a standard, and rejected a submission that

[76] *Hospira v Genentech* [2016] EWCA Civ 780 (27 July 2016)

[77] *Saint Gobain v Fusion-Provida* [2007] EWCA Civ 117

the court can only make a finding of obviousness where it is manifest that the test ought to work. Rather, how much of an expectation is needed depends upon the facts of the case.

Floyd LJ said that a finding of obviousness does not require that the skilled person "would" have arrived at the claimed invention without inventive effort. A "would" test would be misleading as it is liable to bring in irrelevant considerations; a "would" test would also place another straight jacket on the law of obviousness. The skilled person may be faced with a range of obvious possibilities, making it statistically unlikely that he will settle on any one of them, but they will all be obvious.

Floyd LJ referred to the 1991 decision of *Hallen v Brabantia*[78] where the Court of Appeal rejected a suggestion that a "would" test was always to be preferred, but accepted that the "could" test was a minimum condition. He also noted that the *Pozzoli* formulation continues to provide a useful structured approach for judges and tribunals assessing obviousness.

Turning to the decision of Birss J in this particular case, the judge had concluded that the differences between the claimed invention and the prior art were "the result of nothing more than the application of routine screening techniques to common general knowledge" by the motivated skilled team.

Floyd LJ said ([51]):

> "*In an empirical field it will be seldom possible to predict in advance that any individual experiment will work. In many cases the fact that a routine screening exercise could be carried out would be inadequate to establish obviousness. Nevertheless on the facts of an individual case such as the present, the team may have a reasonable degree of confidence that a series of experiments will produce some which will work. To impose a requirement that the skilled team must be able to predict in advance which would be the successful combinations is wholly unrealistic. It could lead to the grant of patents for a whole variety of combinations which in fact involve no inventive effort.*"

Floyd LJ went out of his way to distinguish the case from the recent decision by Sir Robin Jacob in *Teva v Leo*[79], where Sir Robin had noted that "it was not even proved that there was a good expectation that if you did try 20 non-aqueous solvents, one of them would work". Floyd LJ was at pains to emphasise that the facts of different cases could result in different approaches being taken.

He concluded with a very specific warning regarding the question of appeals on the subject of obviousness. He said ([53]):

> "*It is always necessary to remind oneself that it is not the function of this court to second-guess the judge's finding of obviousness. The judge was evaluating a large number of inter-dependent factors. Despite counsel's very*

[78] *Hallen v Brabantia* [1991] RPC 195

[79] *Teva v Leo* [2015] EWCA Civ 779

> *clear and well sustained arguments, I do not think that the judge fell into any error of principle which would justify this court in undertaking its own evaluation.*"

We have seen other evidence this year that the courts are adopting a different approach to appeals and I will return to this later.

This decision by Floyd LJ could be seen as putting Sir Robin Jacob's commentary in *St Gobain* slightly to one side. Floyd LJ and Kitchen LJ are perhaps looking to take a firmer line on inventive step than Sir Robin indicated he was willing to consider. This case does provide a concise and current statement of the law regarding obviousness and "obvious to try", and the role of the Appeal Court in reviewing an obviousness decision.

Later in the year, in ***Hospira v Genentech (30 November 2016)***[80] (a case concerning a different patent relating to trastuzumab), the Court of Appeal continued its statement of this area of the law of obviousness with further guidance on the requirement for a fair expectation of success.

The earlier *Hospira v Genentech* decision (27 July 2016) had concerned a patent with claims to lyophilised formulation of trastuzumab. The 30 November 2016 decision concerned Swiss form claims to trastuzumab administered in combination with a taxoid.

Floyd LJ posed himself the question of what is meant by "fair expectation of success" in a case in which the actual attaining of clinical benefit is a requirement of the claimed invention. In such a case, did it need to be obvious that the claimed combination necessarily would work?

The answer was no. Authorities, including Lord Hoffmann's judgment in *Conor v Angiotech*[81], expressly recognised that the concept of 'obvious to try' was useful where there was a fair expectation of success.

Did it need to be a very high expectation of success, such that it was more or less self-evident that it ought to work? Once again the answer was no. This would amount to the creation of a special law for claims which include as part of their technical subject matter a therapeutic effect or benefit. There was no basis for imposing such a rigid rule. Floyd LJ summarised saying ([46]):

> "*It is very common for claims, whether expressly or by necessary implication, to include a feature which secures a defined technical effect. Such claims may nevertheless be obvious if it is obvious to try to achieve that technical effect by making something within the claims, provided that there is the necessary fair prospect of success.*"

[80] *Hospira v Genentech* [2016] EWCA Civ 1185 (30 November 2016)

[81] *Conor v Angiotech* [2008] UKHL 49

Surprising results

In ***Actavis v Lilly (tadalafil)***[82], Birss J made one notable comment regarding empirical research in the pharmaceutical sector.

He said that pharmaceutical development work involves a number of rounds of routine testing which are costly and have an uncertain outcome. The fact that a skilled team would carry out routine testing without any expectation as to what any particular result would be does not turn the results of truly routine testing into an invention. The fact that the results are not predictable from the outset does not make the decisions taken in the course of the project indicative of invention. However, at each stage, a fair prospect of success is needed for that step to be obvious and in the end the programme has to be considered as a whole.

Turning to the facts, claim 7 of Lilly's '181 patent was in Swiss form and concerned the pharmaceutical unit dosage composition comprising 1 to 5 mg of [tadalafil] suitable for oral administration up to a maximum total dose of 5 mg per day. The judge considered that in light of the prior art (Dougan), the skilled team would undertake a series of trials, but at the third stage it would not have a fair expectation of success with respect to the 5mg dosage. The claim was therefore not obvious**.**

AgrEvo *obviousness*

One form of obviousness which has become used fairly regularly in recent years is what is known as *AgrEvo* obviousness, namely that a claimed invention was not inventive because it made no technical contribution to the art. It reflects the fundamental principle of patent law, which underpins many of the grounds of objection to validity, that the extent of the monopoly conferred by a patent must be justified by the technical contribution to the art.

This is an area of the law in which the concept of plausibility has taken a prominent place, and it has been ripe for review by the Court of Appeal. ***Idenix v Gilead***[83] presented an opportunity. Arnold J's first instance decision[84] in this case was a whopping 621 paragraphs, so the Court of Appeal had ample space to undercut this; it managed with 273 paragraphs – the longest patent decision from the Court of Appeal this year.

Idenix' patent claimed a broad class of compounds (over 50 billion) by reference to a Markush formula, for treating HCV and other *Flaviviridae* infections. It was common ground that inventive step should be assessed on the basis that the claims were to compounds with anti-*Flaviviridae* activity. (Arnold J observed that were it otherwise they would lack an inventive step on the basis that the only technical problem they solved was the provision of additional nucleoside analogues).

[82] *Actavis v Lilly (tadalafil)* [2016] EWHC 1955 (Pat) (10 August 2016) Birss J

[83] *Idenix v Gilead* [2016] EWCA Civ 1089 (8 November 2016)

[84] *Idenix v Gilead* [2014] EWHC 3916 (Pat)

Gilead's contention was that the patent was invalid for AgrEvo obviousness because it was not plausible that substantially all of the compounds falling within the scope of the claims would be effective against *Flaviviridae*.

Kitchin LJ referred (in [106]) to *Generics v Yeda*[85], in which Floyd LJ considered the authorities from the EPO and derived the following principles:

> *"39. As with any consideration of obviousness, the technical results or effects must be shared by everything falling within the claim under attack. This follows from the fundamental principle of patent law, which underpins many of the grounds of objection to validity, that the extent of the monopoly conferred by a patent must be justified by the technical contribution to the art. If some of the products covered by a claim demonstrate a particular property, but others do not, then the technical problem cannot be formulated by reference to that property. Either the products which do not exhibit the property must be excised from the claim by amendment, or the problem must be formulated by reference to some other, perhaps more mundane, technical contribution common to the whole claim".*

Kitchin LJ said ([107]):

> *"It follows that the scope of the monopoly claimed must correspond to and be justified by the technical contribution or, put another way, everything falling in the scope of the claim must be inventive. In the case of a claim to a new class of chemical compounds, the selection of those compounds must not be arbitrary but justified by a technical effect which distinguishes the claimed compounds from many other compounds. Moreover, this technical effect must be shared by substantially all of the claimed compounds."*

As to the question of the extent to which the technical effect needs to be supported by the evidence disclosed in the specification or can be established by later evidence, Kitchin LJ referred to *Johns Hopkins*[86], and said:

> *"The claimed technical effect must therefore be plausible in light of the teaching of the specification and the common general knowledge. The claimed technical effect cannot be established solely by post-published evidence."*

Kitchin LJ then reverted to *Generics v Yeda*, and Floyd LJ's discussion in that case of *Conor v Angiotech* [2008] UKHL 49, and *Dr Reddy's v Eli Lilly* [2009] EWCA Civ 1362. Kitchin LJ quoted (in [110]) Floyd LJ's well-known summary of the principles:

> *"(i) Article 56 of the EPC is in part based on the underlying principle that the scope of the patent monopoly must be justified by the patentee's contribution to the art;*

[85] *Generics v Yeda* [2013] EWCA Civ 925

[86] *Johns Hopkins* [2006] EPOR 8

(ii) If the alleged contribution is a technical effect which is not common to substantially everything covered by a claim, it cannot be used to formulate the question for the purposes of judging obviousness;

(iii) In such circumstances the claim must either be restricted to the subject matter which makes good the technical contribution, or a different technical solution common to the whole claim must be found;

(iv) A selection from the prior art which is purely arbitrary and cannot be justified by some useful technical property is likely to be held to be obvious because it does not make a real technical advance;

(v) A technical effect which is not rendered plausible by the patent specification may not be taken into account in assessing inventive step;

(vi) Later evidence may be adduced to support a technical effect made plausible by the specification;

(vii) Provided the technical effect is made plausible, no further proof of the existence of the effect is to be demanded of the specification before judging obviousness by reference to the technical effect propounded."

So what was meant by plausible in this context? Kitchin LJ then turned to the Supreme Court's decision in *HGS v Eil Lilly*[87].

In short, the patent must disclose a practical application for the claimed product and a plausible or reasonably credible claimed use. An educated guess as to such use could be sufficient, but a merely speculative use would not suffice. "Plausible" conveys the sense that there must be some real reason for supposing that the statement is true, but the standard is not any higher than that. Further experiments are not needed if sufficient information is provided in the description, when CGK is taken into account, to show that a positive answer can be given to the question whether a profitable use can readily be identified.

Finally, Kitchin LJ turned to the CA's recent decision in *Warner-Lambert v Generics*[88], quoting (in [113]) the following reasoning of Floyd LJ in that case:

"46. The EPO and domestic cases do, however, indicate that the requirement of plausibility is a low, threshold test. It is designed to prohibit speculative claiming, which would otherwise allow the armchair inventor a monopoly over a field of endeavour to which he has made no contribution. It is not designed to prohibit patents for good faith predictions which have some, albeit manifestly incomplete, basis. Such claims may turn out to be insufficient nonetheless if the prediction turns out to be untrue. A patent which accurately predicts that an invention will work is, however, not lightly to be revoked on the ground that the prediction was based on the slimmest of evidence. Thus, the claims will easily be seen not to be speculative where the inventor provides a reasonably credible theory as to why the invention will or

[87] *HGS v Eil Lilly* [2011] UKSC 51

[88] *Warner-Lambert v Generics* [2016] EWCA Civ 1006

might work. The same is true where the data in the specification is such that the reader is encouraged to try the invention.

47. We heard argument as to whether the invention is only to be treated as plausible if the reader of the specification would be encouraged to try the invention with a reasonable prospect of success, thereby bringing the test for plausibility into line with that sometimes used in the context of obviousness. I do not accept that there is any reason to align the tests in this way. A test designed to prevent speculative claiming need go no further than requiring the patentee to show that the claim is not speculative: the specification does not need to provide the reader with any greater degree of confidence in the patentee's prediction than that."

Kitchin LJ then said ([114]):

"In my judgment the same approach should be adopted in considering obviousness and whether a technical effect is plausible in the light of the teaching in the specification and the common general knowledge. There must be a real reason for supposing that the claimed invention will indeed have the promised technical effect."

Kitchin LJ proceeded to consider the judge's conclusions in respect of the patent in issue. In light of the evidence of Idenix' own expert that the skilled person would not expect all the compounds covered by the claim to have the relevant activity, Idenix sought to defend the validity of claim 1 in proposed amended form only. However, the judge had ruled, and the Court of Appeal agreed, that the proposed amended form would still be AgrEvo obvious. In particular, there was nothing in the specification by way of experimental data to suggest that substantially all of these compounds were effective against *Flaviviridae*. Nor was there anything in the specification by way of theory or rationale as to why the claimed compounds may be effective. (Even the wording used "may inhibit…" and "can be screened…" appeared no more than speculation). Nor did the common general knowledge assist: so little was known of the ternary structure of the relevant protein and its substrates that it was not possible to predict from the structure of a nucleoside analogue whether it would be effective.

AgrEvo obviousness was ruled upon in the Patents Court later in the same month, in ***Merck Sharp & Dohme v Shionogi***[89]. Shionogi's patent claimed, in Swiss and EPC form, compounds covered by a Markush formula (or a pharmaceutically acceptable salt or solvate), as an integrase inhibitor for preventing or treating a viral disease. It counterclaimed that MSD's HIV medicine, Isentress, infringed.

Arnold J drew upon the key passages of the Court of Appeal's decisions in *Generics v Yeda*, *Idenix v Gilead* and *Warner-Lambert v Generics* discussed above. Turning to the patent in issue, he said that the presence of a functional limitation in the claim language did not defeat an objection of *AgrEvo* obviousness. *Idenix v Gilead* (a product claim to a class – which Idenix and Gilead agreed should be interpreted as being to compounds with anti-*Flaviviridae* activity) was not to be distinguished. The identification of a very large class of compounds, only some of which had such activity, would not make a technical contribution to art. It made no difference that the claim was limited to the compounds which did have activity.

[89] *Merck Sharp and Dohme v Shionogi* [2016] EWHC 2989 (Pat) (25 November) Arnold J

Arnold J referred back to the words of Kitchen LJ in *Novartis v Johnson & Johnson* where he said:

> "*A claim to a class of products said to possess a useful activity must be based upon the identification of a common principle which permits a reasonable prediction to be made that substantially all the claimed products do indeed share that activity. Further, it is not permissible to bypass that requirement simply by adding a functional limitation which restricts the scope of the claim to all the products which do have the relevant activity, that is to say all those which "work".*"

Before leaving the question of obviousness, let me make one final point regarding the case of ***Novartis v Focus***[90]. This is a practical point arising out of the question of how evidence is presented. It is always tempting, when seeking to defeat an allegation of obviousness, to call the inventor as a witness to say how jolly hard it was to reach the invention, and how it could not possibly be obvious given the blood, sweat and tears shed in the process. That is a temptation which it is generally best to resist. Kitchen LJ commented ([59]):

> "*A court must of course be wary before attaching weight to an inventorship story in assessing obviousness for inventions may result from inspiration or serendipity. However, I believe that the judge was here doing no more than pointing to the inventor's account of their own reasoning, the fact that this was essentially the same as that said by the defendants to be obvious and the fact that the inventors observed that trans-dermal administration was "expected to reduce side effects". As the judge put it, there was nothing to suggest that the inventors took a risk that the ordinary skilled team would not have countenanced. As such it provided some confirmation that the defendant's approach was valid.*"

That is just one of the potential hazards which open up if an inventor is called as a witness.

(d) **Insufficiency**

Following on from the cliff-hanger at the end of 2015, it has been a busy year for the law of insufficiency, and in this area the issue of plausibility has of course raised its head. The key decisions to note came at the end of the year, but first let me note a few points on sufficiency in judgments that came before *Warner-Lambert v Generics*[91].

[90] *Novartis v Focus* [2016] EWCA Civ 1295 (21 December 2016)

[91] *Warner-Lambert v Generics* [2016] EWCA Civ 1006 (13 October 2016)

Obviousness/insufficiency squeeze

First, a brief statement from Birss J in ***Accord v medac***[92]. Referring with approval to the judgment of Henry Carr J in *Actavis v Lilly (tadalafil)*[93], Birss J went on to say ([128]):

> *"Medac referred to* Actavis *as authority for the proposition that the law does not require a patent to contain experimental data in order for the plausibility test to be satisfied. The judge so held and I respectfully agree. However* Actavis *can be distinguished in this case because in* Actavis *although there was no experimental data the patent did contain information and reasoning on the issues. It was that reasoning which the judge held made it plausible that the drug would have utility as a treatment for the disease…The judge was not talking about a patent which contained no reference to the issue at all. In the present case there is no experimental data nor is there any reasoning or information at all addressed to side effects. There is nothing on which a skilled reader could base a view about the credibility of the dosage and whether it does or does not have a side effect problem."*

The case in hand effectively illustrated why there can be a squeeze between plausibility for insufficiency and obviousness ([131]):

> *"If it was not obvious to administer a 25mg dose using 50mg/ml concentration in a 0.5ml volume subcutaneously because of a concern about the risk of side effects, then the patent does not give the skilled person any comfort at all about that risk."*

Ambiguity

Second, it is perhaps worth considering the judgment of Birss J in ***Unwired Planet v Huawei (22 March 2016)***[94]. He summarised the law regarding insufficiency, including ambiguity, and commented a little further, as follows ([149]):

> *"A patent specification must disclose the invention clearly and completely enough for it to be performed by a person skilled in the art. Different kinds of insufficiency have been identified. One is sometimes…called classical insufficiency. There the problem is that the skilled person just cannot make the invention work either at all or without undue effort. Another type is sometimes called* Biogen *insufficiency. There the problem is that the claim is too wide and is not commensurate with the inventor's technical contribution. This case is concerned with a third type, ambiguity. Some forms of ambiguity pose no legal difficulty. An ambiguity in a descriptive passage in the specification which causes the skilled person to be unable to make anything at all is a kind of classical insufficiency which falls squarely within the section. However other cases are about ambiguity in the way the invention is defined in the claim. There is no doubt that ambiguities of this latter kind can be a*

[92] *Accord v medac* [2016] EWHC 24 (Pat) Birss J

[93] *Actavis v Lilly (tadalafil)* [2015] EWHC 3294 (Pat)

[94] *Unwired Planet v Huawei* [2016] EWHC 576 (Pat) (22 March 2016) Birss J

basis for a finding of insufficiency but to put the cases into context it is worth briefly considering the legal background.

Before the EPC and the 1977 Act being passed to give effect to it, UK law included quite an extensive suite of separate grounds for revocation of patents. In the 1949 Patents Act, as well as lack of novelty and obviousness, the grounds for revocation included "insufficiency", failure to disclose the best method, lack of fair basis, claim ambiguity, inutility, and false suggestion. The word "insufficiency" is in inverted commas because its definition in the 1949 Act is not coextensive with the definition of insufficiency in the modern law. I have used the expression "claim ambiguity" to make clear that the ground under the 1949 Act was about the claims. That term was not used at the time. Some of the leading cases were of some antiquity and need to be read bearing in mind that the common law of validity was only completely replaced by legislation in the 1949 Act.

Today what I have called classical insufficiency corresponds broadly to 1949 Act "insufficiency" together with inutility, Biogen *insufficiency corresponds to lack of fair basis, while failure to disclose best method and false suggestion have been abolished completely. The question is then, what happened to claim ambiguity."*

The judge considered that it was necessary to distinguish between claims that are difficult to construe or that have a "fuzzy boundary" on the one hand from claims that are truly ambiguous on the other. If it is truly ambiguous, so that it is unclear what the correct test is to determine whether or not a product or process infringes, then the claim is insufficient.

The factual circumstances in which such a truly ambiguous claim has been identified so far in the modern law are ones which depend on carrying out a technical test to find out if a product or process is within the claim or not: if the skilled person cannot know whether they are carrying out the right test, then the claim is truly ambiguous and therefore insufficient. While the principle cannot be limited just to technical tests, it does not apply simply because one can imagine difficult cases to judge at the edge of the claims. In the present case, the ambiguity challenge failed. The judge noted ([163]):

"When a defendant has been found to infringe, demonstrating that the claim's scope is at least clear enough to work that out, an argument that the claim should be regarded as truly ambiguous is likely to be met with scepticism."

Plausibility

In ***GlaxoSmtihKline v Wyeth***[95], Henry Carr J took the opportunity, given the current popularity of plausibility as a concept, to set out a decent test of how it should be considered. Observing that plausibility underpins many pleaded arguments of insufficiency and obviousness, he summarised the legal principles as follows ([94]):

[95] *GlaxoSmtihKline v Wyeth* [2016] EWHC 1045 (Ch) (12 May 2016) Henry Carr J

"(i) In relation to sufficiency, the assertion that the invention will work across the scope of the claim must be plausible and in the case of claims involving a medical use, the patent must show that the claimed medical effect is plausible.

(ii) "Plausible" means that there must be some real reason for supposing that the statement is true; this excludes speculative patents based on mere assertion.

(iii) Plausibility is a "threshold test" which is satisfied by a disclosure which is "credible", as opposed to speculative.

(iv) "Plausibility" is also relevant to AgrEvo-type obviousness as it is the same threshold test.

(v) A mere arbitrary selection from a class makes no technical contribution and lacks any inventive step."

The parties dealt with the issues of AgrEvo obviousness and insufficiency together, and the judge's reasoning did too.

Last year I set the audience a short test and asked which they thought presented the higher barrier – credibility or plausibility? The majority thought that plausible was the easier test to satisfy, whereas in fact dictionary definitions suggest the opposite. In late 2015, three cases[96] indicated that Arnold J might be adopting a slightly stricter standard for plausibility than Birss J, and Henry Carr J slightly less strict then him.

This year, the Court of Appeal considered the appeal of the first, and most high profile, of those decisions, when it ruled in ***Warner-Lambert v Generics***[97].

This is the case regarding Warner-Lambert's patent with claims in Swiss form to pegabalin for various types of pain. In his first instance judgment, Arnold J concluded that key claim 3, to neuropathic pain, encompassed both central and peripheral types of neuropathic pain; it would not be understood by the skilled person as limited to peripheral neuropathic pain. The judge also concluded that the skilled person would not consider that it was plausible that pregabalin would be effective to treat central neuropathic pain. Consequently he concluded that claim 3 was insufficient. There was no dispute that claim 3 could, in fact, be performed across its "neuropathic pain" scope.

In the Court of Appeal, Warner-Lambert submitted that the judge had been wrong to "salami slice" claim 3 into different types of neuropathic pain. It complained that it was an illegitimate process that was unfair to patentees. It also felt it was unfair in the context of the particular claim, because *inter alia* it ignored the facts that there were

[96] *Generics UK Ltd (t/a Mylan) v Warner-Lambert* [2015] EWHC 2548 (Pat) (10 September 2015) Arnold J; *Merck Sharp & Dohme v Ono* [2015] EWHC 2973 (Pat) (22 October 2015) Birss J; *Actavis v Eli Lilly* [2015] EWHC 3294 (Pat) (16 November 2015) Henry Carr J

[97] *Warner-Lambert v Generics* [2016] EWCA Civ 1006 (13 October 2016)

no concrete definitions of the categories of pain at the time and central neuropathic pain was not a significant part of the genus covered.

Floyd LJ began by summarising the law regarding insufficiency, quoting from section 72 of the 1977 Act saying that the court may revoke a patent for insufficiency if ([28]):

> *"the specification of the patent does not disclose the invention clearly enough or completely enough for it to be performed by a person skilled in the art."*

Insufficiency, explained Floyd LJ, may be deployed as an attack on validity not only where the directions in the specification are inadequate to enable the skilled person to perform the invention at all, but also where a claim is excessively broad having regard to the patentee's contribution to the art. Lord Justice Floyd referred (in [29]) with approval to the judgment of Kitchin LJ in *Regeneron v Genentech*[98] when he had said:

> *"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."*

Floyd LJ noted that the requirement for plausibility or credibility (the court seems to adopt them as alternative terms now) originated in the EPO, and that similar requirements arise in the jurisprudence in several different contexts. He considered a number of EPO cases, in particular *Salk*[99] and *Johns Hopkins*[100], drawing the following conclusions ([39]):

> *"(i)* *A mere assertion that compound X is suitable for treating disease Y is not sufficient without any more to render the invention plausible;*
>
> *(ii)* *The disclosure of the patent specification does not have to be definitely predictive of the efficacy of the invention:* in vitro *tests which may well not be reproducible in humans or animals may suffice;*
>
> *(iii)* *An example of adequate support to amount to a plausible disclosure would be experimental tests, showing that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease;*
>
> *(iv)* *Later published data are not admissible if they alone render the invention plausible;*

[98] *Regeneron v Genentech* [2013] EWCA Civ 93

[99] T 0609/02 *Salk Institute for Biological Studies*

[100] T 1329/04 *Johns Hopkins University School of Medicine*

(v) *Ultimately the purpose of the requirement of sufficiency is to place the reader in possession of the invention without imposing undue burden on him by way of further investigation or research."*

Concluding his comments on the law of insufficiency, Lord Justice Floyd said ([46]-[47]):

> *"The EPO and domestic cases do, however, indicate that the requirement of plausibility is a low, threshold test. It is designed to prohibit speculative claiming, which would otherwise allow the armchair inventor a monopoly over a field of endeavour to which he has made no contribution. It is not designed to prohibit patents for good faith predictions which have some, albeit manifestly incomplete, basis. Such claims may turn out to be insufficient nonetheless if the prediction turns out to be untrue. A patent which accurately predicts that an invention will work is, however, not likely to be revoked on the ground that the prediction was based on the slimmest of evidence. Thus, the claims will easily be seen not to be speculative where the inventor provides a reasonably credible theory as to why the invention will or might work. The same is true where the data in the specification is such that the reader is encouraged to try the invention.*
>
> *We heard argument as to whether the invention is only to be treated as plausible if the reader of the specification would be encouraged to try the invention with a reasonable prospect of success, thereby bringing the test for plausibility into line with that sometimes used in the context of obviousness. I do not accept that there is any reason to align the tests in this way. A test designed to prevent speculative claiming need go no further than requiring the patentee to show that the claim is not speculative: the specification does not need to provide the reader with any greater degree of confidence in the patentee's prediction than that."*

In short, Floyd LJ said that the test "represents a very low threshold" – plausibility is barely a barrier at all in relation to defeating an allegation of insufficiency. However in the present case, the skilled person would know from the common general knowledge definition of neuropathic pain that it divided naturally into the central and neuropathic parts. There was no data in the patent from which one could make predictions about central neuropathic pain and there was no other basis to render plausible the claim that pregabalin was effective for central neuropathic pain.

There is some uncertainty as to whether the *Warner-Lambert* case is on its way to the Supreme Court. The Court of Appeal has stamped its mark on the test of 'plausibility' but the word does not appear in either the EPC or the 1977 Act, so the fact that it has become integral to many aspects of patent law may invite consideration by the Supreme Court. In the *Warner-Lambert* case there is also the question of whether a claim which can properly be performed across its scope should be considered insufficient because at the time of filing, a portion of it did not meet the "plausibility" test.

The Court of Appeal's decision in *Idenix v Gilead*[101] was handed down two weeks later. Idenix's patent claimed a broad class of compounds by reference to a Markush

[101] *Idenix v Gilead* [2016] EWCA Civ 1089 (8 November 2016)

formula, the invention being concerned with treating HCV and other *Flaviviridae* infections. The AgrEvo obviousness challenge in the case is discussed above – Lord Justice quoting paragraphs [46]-[47] of the Court of Appeal's judgment in *Waner-Lambert v Generics* in respect of plausibility. Kitchin LJ then considered the challenges of insufficiency.

There were three limbs to Gilead's insufficiency attack:

Limb 1: The disclosure of the patent, read in the light of the common general knowledge, did not make it plausible that the invention would work across the scope of the claims, whether as granted or as proposed to be amended.

Limb 2: The patent did not enable the skilled team to perform the invention (i.e. synthesize the 2'-methyl-up-2'-fluoro-down compounds claimed) without undue burden.

Limb 3: The invention could not be performed across the breadth of the claims without undue burden because making and testing the analogues to find those which were active would amount to a research project.

Considering the case, Kitchin J approved a couple of his own judgments in *Eli Lilly v HGS*[102] and *Regeneron v Genentech*[103], and went on to say ([136]):

> *"The sensitivity of the requirement of enablement to the nature of the invention and the claim in issue is well illustrated by the case of a claim to the use of a product to make a medicine for a particular therapeutic purpose."*

He continued ([137]):

> *"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."*

Kitchin LJ said that the meaning of the term plausible had been explained by Floyd LJ in *Warner-Lambert*, in other words he was adopting the low, threshold approach.

Turning to the analysis, the Court of Appeal confirmed the judge's conclusions with respect to each of the first two limbs. It declined to rule in respect of the third, but Kitchin LJ noted that he was inclined to conclude, as the judge had, that Idenix's patent was insufficient in this respect also.

It is perhaps worth noting one final comment from Kitchin LJ. He said that a finding of insufficiency, like a finding of obviousness, involved the weighing of a number of

[102] *Eli Lilly v Human Genome Sciences* [2008] EWHC 1903 (Pat)

[103] *Regeneron v Genentech* [2013] EWCA Civ 93

factors. Absent an error of principle, an appellate court would be very cautious in differing from the judge's evaluation.

In ***Merck Sharp & Dohme v Shionogi***[104], the patent claimed, in Swiss and EPC form, compounds covered by a Markush formula, for preventing or treating a viral disease. The focus of the insufficiency attack was Merck's contention that the specification did not enable the claimed inventions to be performed over the whole scope of the claim without undue burden. As a part of this objection, Merck contended that the disclosure of the patent did not make it plausible that the invention would work across the scope of the claims.

On the law, the judge, Arnold J, summarised as follows ([233]-[234]):

> *"Accordingly 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. In some cases, it is convenient to divide the second stage into two parts, first considering whether the invention can be performed without undue burden at all, and then whether the claim is of excessive breadth. At this stage, evidence which post-dates the patent is inadmissible.*
>
> *As noted above, the Court of Appeal in* Idenix v Gilead *held that the criterion of plausibility was the same in this context as in the context of inventive step. There must be a real reason for supposing that the claimed invention will indeed have the promised technical effect."*

It is perhaps interesting that the judge formulated the test for insufficiency, encompassing both excessive claim breadth and 'cannot be performed/without undue burden' aspects, by placing plausibility as the first hurdle.

It is also interesting that the judge adopted a slightly selective approach to the authorities he drew upon – focussing upon *Idenix v Gilead* in favour of *Warner-Lambert v Generics* and not mentioning "low, threshold test".

Arnold J concluded in the context of this case that the patent presented the skilled team with a vast research project with a high likelihood of failure, but claimed the results if they happened to succeed – even in such cases where the success had nothing to do with the teaching of the patent. Accordingly it was not possible to perform the claimed inventions across the scope of the claim. The patent was invalid for insufficiency (as well as AgrEvo obvious).

[104] *Merck Sharp & Dohme v Shionogi* [2016] EWHC 2989 (Pat) (25 November 2016)

(e) **Added Matter**

The case of ***Nicocigs v Fontem***[105] was decided by John Baldwin QC sitting as a deputy judge. This is a case with which we are familiar – our own client struck a deal and got out early.

The judge summed up the court's task in assessing the question of added matter as being ([19]):

> *"…to identify and compare the disclosures of the patent application and the granted patent to determine whether the skilled addressee would learn any information about the invention from the patent which he could not learn from the patent application. The three part test formulated in* Houdaille *provides a convenient structured approach but it is not the only approach."*

The three part test he had in mind was the following:

> *"It is the view of the Board that the replacement or removal of a feature from a claim may not violate Article 123(2) EPC provided the skilled person would directly and unambiguously recognise that (1) the feature was not explained as essential in the disclosure, (2) it is not, as such, indispensable for the function of the invention in the light of the technical problem it serves to solve, and (3) the replacement or removal requires no real modification of other features to compensate for the change."*[106]

The product which was described in the invention as disclosed by the patent application comprised three elements ([26]):

> *"…a battery assembly, an atomiser assembly and a cigarette bottle assembly and the disclosure provides for the arrangement of these items. The battery assembly and atomiser assembly are connected together and are both located in a one piece shell, and the cigarette bottle assembly is mounted in one end of that shell so as to fit with the atomiser assembly."*

The patent included reference to a liquid storage component. This would fit with the porous component of the atomiser assembly and was located in one end of the shell which was detachable.

Nicocigs contended that the change in wording was dramatic and rendered the patent invalid for added matter for a number of reasons. These included the fact that: an important teaching of the application was the use of an integrally formed shell to house the battery assembly and the atomiser assembly and that the atomiser in that shell fitted with the cigarette bottle assembly so as to provide a two piece device which solved one of the problems in the art which it had identified; whereas the patent used the word "shell" to describe the outer casing of the whole device (battery assembly, atomiser assembly and liquid storage component). Nicocigs contended that by relegating the essential teaching of an integrally formed shell, the patentee

[105] *Nicocigs v Fontem* [2016] EWHC 2161 (Pat) (2 September 2016) Mr John Baldwin QC

[106] T 0331/87 *Houdaille* at [6]

had added information to the effect that the invention would work without the need for an integrally formed shell.

John Baldwin QC agreed. He said ([43]):

> *The disclosures of the patent application and the patent are not the same. The disclosure of the patent application is explicit. It is of an integrally formed shell housing the battery assembly and atomiser assembly, being a shell to which is attached the cigarette bottle assembly. The disclosure of the patent is also explicit. … It also discloses a different device. It is the one … where the word "shell" is used to describe a hollow body with an end which is detachable."*

This case represents an abject lesson in how not to manage patent filings. The patent was effectively killed by poisonous priority, and the added matter issue was merely the icing on the cake.

In ***Merck Sharp & Dohme v Shionogi***[107], Arnold J considered the issues arising in respect of selections from the disclosure of the application, specifically selections from lists of possible compounds or substitutes.

The judge cited, with approval, the usual authorities of *Vector v Glatt*[108] and *Nokia v IPCom*[109]. He said that where a selection is made of a specific item from a single list, the established case law of the boards of appeal of the EPO is that the selection does not individualise a new disclosure. In other words, a skilled person, presented with a single list, would consider it reasonable to make selections from the list when compiling claims for a patent.

The position may however be different where the selection is made from multiple lists. Where a specification contains a series of lists of variables, but does not point to a particular combination of choices from the respective lists, an amendment which narrows to that particular combination will ordinarily add matter. A selection from two lists can be novel for the purposes of patentability, and by the same logic it will also constitute added matter if it was not disclosed in the application as filed.

The degree of narrowing is an important factor in the analysis. There is much case law in the boards of appeal of the European Patent Office on this.

Noting the need to be aware of his fellow judges, Arnold J quoted (in [293]) from the judgment of Henry Carr J in *GSK v Wyeth*[110] when he said that the rule against selections from multiple lists was not a "rigid" one. Henry Carr J said that:

> *"the whole contents of the application as filed must be considered, including its general disclosure"*

[107] *Merck Sharp & Dohme v Shionogi* [2016] EWHC 2989 (Pat) (25 November 2016) Arnold J

[108] *Vector v Glatt* [2007] EWCA Civ 805

[109] *Nokia v IPCom* [2012] EWCA Civ 567

[110] GlaxoSmithKline v Wyeth [2016] EWHC 1045 (12 May 2016) Henry Carr J

Henry Carr J felt that a mechanistic approach to the question was to be avoided. Arnold J agreed, but said that nevertheless the case law of the boards of appeal did provide useful guidance to the correct approach.

In Arnold J's judgment, some of Merck's challenges to the patent as granted, which incorporated various conditional and unconditional amendments, failed because they were relying on a misreading or over literal reading of the application. All that was happening was a mere shrinking of the claim without the skilled person being taught anything different about the invention.

However, the challenge to a second conditional amendment succeeded. The judge said that it did not merely amount to a shrinkage of the covering of the claim, but singled out a specific combination of restrictions which was not hinted at in the application. It therefore taught the skilled team something new about the invention. Nor was it accidental: the purpose was to exclude compounds which "don't work".

(f) **Amendment**

It is rare that there is anything to say on the subject of amendment, and this year is not really any different. However, there is a cautionary word arising from the case of ***Warner-Lambert v Generics***[111]. Warner-Lambert sought to make amendments to claim 3 after the first instance decision, to reflect the findings of the judge in relation to its sufficiency. Arnold J found that the post-judgment application was an abuse of process and the Court of Appeal agreed with him. Floyd LJ said ([177]):

> *"It is not fair to Mylan and Actavis to treat a trial in which only the construction issue is in play as equivalent to one in which an amendment is in play as well. Mylan and Actavis may have taken the view that their position on the construction argument was very strong, and there was no need to focus their firepower on the narrow construction. That view may (I do not say would) have changed if they had known that Warner-Lambert conditionally intended to seek amendment in the event that they failed on construction. That modified view could have caused them to refocus their attack, with a consequence for the evidence which they would have sought to adduce."*

The usual authorities regarding fairness of process were cited, including *Henderson v Henderson*[112] and *Johnson v Gore Wood*[113]. Floyd said that re-writing amendments are particularly unlikely to be allowed after a trial because they create new issues which are, in the normal run of a case, unlikely to have been decided at the trial. The evidence on the issue of validity would not have been directed to the feature or features sought to be introduced for the first time by amendment because it was never made clear, either by the existing claims or any application to amend, that the patentee would be seeking to assert or defend a monopoly of that scope.

[111] *Warner-Lambert v Generics* [2016] EWCA Civ 1006 (13 October 2016)

[112] *Henderson v Henderson* 3 Hare 100

[113] *Johnson v Gore Wood* [2002] 2 AC 1

4 TECHNICAL MATTERS AND PROCEDURE

Expert advisers

In ***Electromagnetic Geoservices v Petroleum Geoservices (13 January 2016)***[114], Birss J gave noteworthy guidance on a number of procedural issues.

He gave permission for the defendants to rely on experiments which were the subject of certain notices, to prove the facts which were set out in those notices. He also directed the claimant to respond to the notices and gave directions for witnessed repeat if necessary. He said that notices of experiments operate as notices to admit facts. If the facts are admitted but a party is still seeking to rely on its experiments, it must be asked why the experiment is still necessary. If the experiment is supposed to be proving something else which is not in the notice, that tends to indicate that the notice is deficient.

In the present case the parties, steeped as they were in parallel Norwegian litigation, thought the issue about experiments could be resolved without the court needing to understand in any depth what role the modelling work was to play in the case. The judge said that that was not correct ([18]):

> *"When the court is being asked to make the "further directions in respect of such experiments" which are contemplated by the standard directions, it is necessary for the party seeking to rely on the experiments to explain to the court what role they are to play in the case. Great detail may not be required but the experiments do need to be put into context. Simply referring to a full expert's report does not help."*

Referring to earlier authority[115], Birss J said that computer modelling and simulations should generally be subject to the experimental notice regime; they create the same difficulties as any other experiments. The output from the modelling depends on the input and running the same tests with different input data will or may produce a different result. So the choice of appropriate inputs to rely on is an exercise in judgment.

Birss J noted that it may be that the counterparty does not need to see a repeat in a given case or that a repeat would be disproportionate, but it is the availability of a witnessed repeat which is important. With computer modelling it may be that the need to have a witnessed repeat is removed by providing the totality of the input data and the computer software to the other party so that they can run the model themselves and see that the result is genuine. However that does depend on all the data and code being made available. In the present case, Birss J noted that if the defendants had been required to carry out a witnessed repeat of the model then that would have involved giving the claimant access to the data points in any event.

The other procedural point of note in this case concerned the appointment of a scientific adviser. Birss J declined to appoint a scientific adviser to sit with the court during the trial. Instead he concluded that the parties should arrange for the judge hearing the trial to have a non-controversial introductory course, probably over no more than a day, before reading into

[114] *Electromagnetic Geoservices v Petroleum Geoservices* [2016] EWHC 188 (Pat) (22 January 2016) Henry Carr J

[115] *Consafe v Emtunga* [1999] RPC 154

the case in any depth. The best person to act in this regard was a marine "controlled source electromagnetic" expert.

He said that any written materials produced by a scientific adviser for the judge should be given to the parties after the introductory course had taken place – the purpose being to allow the parties to see what had been provided, not to vet the materials.

The reasons he gave for reaching this decision were predominantly related to the availability of category 4/5 judges. A technical adviser had been appointed in the *Schlumberger* trial regarding the same patent because the judge scheduled to hear the case (initially Floyd J as he then was) changed to a new judge (Mann J) who was not a category 4/5 judge.

In this case the judge agreed with the claimant EMGS that the court did not need the assistance, suggested by the defendants, as the case was manageable with the existence of primers, which were already agreed, and explanations from counsel and the experts. EMGS was concerned that a scientific adviser might unwittingly impart views to the judge which the parties would be unaware of and unable to address.

As things turned out, the trial of the dispute took place but before the court had returned its judgment, EMGS and Petroleum Geo-Services settled their differences. Birss J issued a further judgment: ***Electromagnetic Geoservices v Petroleum Geoservices (19 April 2016)***[116]***.*** He said that normally, following settlement, there would be no reason to give any sort of judgment but the present case was unusual and warranted a short one. He used it to follow up on his earlier decision by explaining the course the parties and the court took in relation to the teach-in, and also to thank the expert who did the teach-in.

Draft judgments

A trend which we have seen more in recent years is the tendency for people to make comments going beyond mere typographical corrections in relation to draft judgments submitted by the sitting judge for comment before being handed down.

In ***Regeneron v Kymab***[117], this point arose. The judge, Henry Carr J noted that after the draft judgment had been sent to the parties' legal representatives for correction of obvious errors, he received a further written submission on behalf of Regeneron alleging material omissions from the draft judgment. The judge explained that these were attempts to re-argue issues regarding sufficiency which had already been argued at trial.

Henry Carr J said that these sorts of points, if they are to be made, should be made by way of appeal, and he made some general observations about submissions on draft judgments. He said ([287]-[288]):

> *"It is very important that counsel should draw to the attention of the court any material omissions in the judgment, rather [than] attempting to save up such points for the Court of Appeal….I should make it clear that I make no criticism of counsel for Regeneron for complying with what they consider to be their obligations to the court in drawing attention to what they perceive to be omissions in judgment in a very*

[116] *Electromagnetic Geoservices v Petroleum Geoservices* [2016] EWHC 881 (Pat) (19 April 2016)

[117] *Regeneron v Kymab* [2016] EWHC 87 (Pat) (1 February 2016) Henry Carr J

complex case. However, as a general observation for assistance in future cases, it should be possible to do this very simply, as the omission will be obvious. I would hope that this will rarely be necessary, particularly where the parties have provided a list of issues on which judgment is required. Although in complex, high value cases, there is always a temptation to make just one more point after the trial has concluded, this should be resisted. The primary purpose of circulating a draft judgment is to allow typographical or other obvious errors to be corrected, and it is not an opportunity to re-argue the case."

If, as we are seeing, the question of leave to appeal to the Court of Appeal becomes a stricter test, then we may see more of this sort of activity, born of desperation.

Expert witnesses

One issue which has arisen in recent years is the question of how expert witnesses should be instructed. There is considerable guidance on this point from Arnold J in the case of ***American Science & Engineering v Rapiscan***[118].

Arnold J was critical of the instructions given to both experts. Both had been instructed to consider the person skilled in the art and the common general knowledge, then to consider the prior art relied upon by Rapiscan, and only then to consider the patent. But there were, nevertheless, differences in the way the parties' respective approaches had been structured.

AS&E's expert was asked to consider obvious developments of the prior art before being shown the patent. This resulted in criticism that he had failed to address whether the differences between the prior art and the patent constituted steps which would have been obvious to the person skilled in the art.

In contrast, Rapiscan's expert was only asked to consider obviousness after being shown the patent. While this avoided the difficulty of ASE's approach, Rapiscan's approach resulted in its expert appearing not to have understood the importance of trying to avoid hindsight. Previously, in *Medimmune v Novartis*[119], Arnold J himself noted that the correct approach for the lawyers instructing the experts to take was to ask the expert to consider first the prior art, then the priority documents and then the patent. This enabled 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 patent.

The approach taken by the parties' representatives when instructing their respective expert witnesses would appear to have been consistent with the judge's earlier guidance. Nevertheless, both approaches were criticised without a solution being spelt out by the judge. Rapiscan's approach, of asking its expert only to consider the question of obviousness after being shown the patent, appeared to receive the greater criticism.

So how should expert witnesses be asked to proceed when retained in the context of an obviousness challenge?

[118] *American Science & Engineering v Rapiscan* [2016] EWHC 756 (Pat) (11 April 2016)

[119] *Medimmune v Novartis* [2011] EWHC 1669 (Pat)

The correct question for the expert to be asked to consider in the context of an obvious dispute is whether, viewed without any knowledge of the claimed invention, the differences constituted steps which would be obvious. The expert must understand the importance of trying to avoid hindsight.

ASE's approach, of asking its expert to consider obvious developments before showing him the patent, had the "advantage" of enabling the expert to consider obvious developments of the prior art free from knowledge of the patent, and so would seem the better course, but this alone is not enough. It would seem advisable for the expert to then to be asked to consider whether the differences between the prior art and the claimed invention constituted steps which would have been obvious to the person skilled in the art, and whether or not they occurred, in fact, to him.

In more complex disputes, where issues of priority, added matter, sufficiency and/or multiple challenges to validity arise, very careful consideration must be given to the order in which documents are first put to an expert witness.

The question of expert witnesses can become vexed in patent litigation, and that was certainly the case in Arnold J's judgment in ***Thoratec v AIS***[120]. The subject matter of the invention was medical devices for implant in, and assistance in the operation of, the human heart.

At the time of the case management conference, the parties were permitted to call two technical expert witnesses because, said the judge, it appeared possible that they would need to adduce evidence from a biomedical engineer and from a clinician (although the order did not specify that the experts were to be in those fields). The judge said "as should have been clear, I did not intend to give either party permission to call two experts in the same discipline". In the event, neither party had used evidence from a clinician. AIS sought to supplement its lead expert's evidence with expert evidence from another expert in the same discipline. That witness was described by the court as "not independent" as he was both a senior manager of AIS and a person with a financial interest in the outcome of the litigation. The judge said that his evidence was "not properly integrated into the AIS case", contradictory and not reliable.

There appear to be two lessons to be learned here. One is that it does not pay to irritate a judge by playing fast and loose with CMC directions. Even though the order may not have stipulated the specialist fields from which the experts should be drawn, the judge had clearly made the position plain and he was not impressed to find two experts from the same field. Secondly, the question of using "in-house" experts has been a vexed one over the years. On occasions, a well briefed, objective and sensible in-house expert can provide the best possible support for the judge. However, in a case of this nature, with technology well considered by the academic world, it is generally best to avoid using an expert who is connected to one of the parties.

A further issue arose concerning the use of legal expert witnesses. The parties were not given permission to adduce legal expert evidence, but did so anyway. This was because the prior use occurred in the Netherlands so any confidentiality was a matter of Dutch law. By the end of the trial AIS, which had instigated the introduction of Dutch law into the case, submitted

[120] *Thoratec v AIS* [2016] EWHC 2637 (Pat) (28 October 2016) Arnold J

that there was no relevant difference between English and Dutch law. Accordingly the money spent on the evidence turned out to be entirely wasted.

Disclosure

In ***Positec Power Tools v Husqvarna***[121], standard disclosure was refused. It was made quite clear by the judge, Birss J, that there is no longer any default position that disclosure should take place. Standard disclosure is not the default option anymore. There is no prima facie rule for standard disclosure and careful consideration should be given to the alternatives.

The judge said that factors which could make disclosure more pertinent include cases where:

- the patentee relies on commercial success;
- the patentee relies on the reactions of others to its invention;
- the patentee is calling the inventor as a witness;
- the patentee plans to rely on its own internal documents in support of inventive step;
- there is some sort of smoking gun.

It is hard to understand how the presence of a smoking gun could be known before disclosure is given?!

The reasoning in *Positec* was promptly applied in the case of *Illumnia v Premiatha Health*[122]. In this case, Henry Carr J refused standard disclosure on the grounds of proportionality given the very substantial costs which would be involved in a review of over 10,000 documents. The cost of reviewing 14 years' worth of documents to see whether any document improved or detracted from either side's case would involve several times the figure of £200,000 already spent on disclosure, and would not be worth the effort. Whilst historically it had not been uncommon for parties in major patent actions to review 10,000 or more documents, given the changes to CPR r.31.5(7) requiring the court to limit disclosure to that which was necessary to deal with the case justly, and the menu-based choice of options, that practice needed to be reassessed against a proper cost-benefit analysis.

Disclosure was also the topic in the case of ***Varian Medical Systems v Elekta***[123]. Birss J was the judge here and said ([11]):

> *"The point that I have to resolve is about disclosure. The claimants contend that offering for disposal is in issue but no disclosure has been given in relation to it. That is true. The only disclosure that could be said to relate to it is that in the Product Description the defendants contend that they do not offer for disposal a machine with the relevant characteristic. What they also say is that once the patent has expired*

[121] *Positec Power Tools v Husqvarna* [2016] EWHC 1061 (Pat) (10 May 2016) Birss J

[122] *Illumnia v Premiatha Health* [2016] EWHC 1516 (Pat) (27 May 2016) Henry Carr J

[123] *Varian Medical Systems v Elekta* [2016] EWHC 2678 (Pat) (12 October 2016) Birss J

they may well, or I think they plan to, produce a machine which would fall within the claims of the patent, but they say they are not doing that now. However these assertions may or may not be right, that is where this issue arises."

Considering the importance and effect of product descriptions, the judge went on to say ([147]):

"The practice direction provides that when a party serves a Product Description they are relieved of the obligation of standard disclosure relating to "the infringement of a patent by a product or process". In my judgment what that is concerned with is the nature and characteristics of the product or process in issue and the question of whether the product or process falls within the claims. What it is not concerned with is a factual issue of whether certain acts have or have not been carried out. Of course, in many cases, as a practical matter, there is either no debate about the acts, or the Product and Process Description contains admissions such that no disclosure relating to acts is necessary. But sometimes one sees a distinction."

He went on to say that the fact that a Product and Process Description has been served does nothing to alleviate the defendants from whatever obligation they would otherwise have to give in relation to disclosure relating to acts of infringement.

This is an interesting finding – I think that most litigators had thought that filing a product/process description obviated any possible need for disclosure. That is clearly not the case.

Jurisdiction

An interesting point on jurisdiction arose in the case of ***Anan Kasei v Molycorp***[124].

In an interim decision, Arnold J ruled that pursuant to the Re-cast Brussels Regulation, the English court did not have jurisdiction to hear a claim for infringement of the German designation of Molycorp's European patent, even where the claim was conditional upon the German designation not being invalid.

The judge considered the scope of Articles 24 and 27 of the re-cast Brussels Regulation and the UK and CJEU case law in respect of these provisions. The judgment provides a good current summary of the law in this area. Basically, a claim for infringement is considered interrelated with the validity of the designation in question, and therefore within the exclusive competence of the courts of that state.

In case he was wrong on jurisdiction, the judge noted that it would have been expedient for the English court to make the order because Molycorp was domiciled within the court's jurisdiction, it was likely that the products of which samples would be required would be much the same for the purposes of the claimant's infringement claims in the UK and in Germany, and it would allow for a single sampling process. However, the jurisdictional issues "got in the way".

[124] *Anan Kasei v Molycorp* [2016] EWHC 1722 (Pat) (14 July 2016) Arnold J

Proceedings in the UKIPO

In the case of ***NGPOD Global v Aspirate N Go***[125], an issue very close to my heart from previous cases came to be considered.

The issue concerned a reference under section 37 of the Patents Act to determine entitlement to a granted patent. Section 37(8) says:

> *"If it appears to the comptroller on a reference under this section that the question referred to him would more properly be determined by the court, he may decline to deal with it and, without prejudice to the court's jurisdiction to determine any such question and make a declaration,…the court shall have jurisdiction to do so."*

UK IPO hearing officer Mr Stephen Probert refused to decline to deal with NGPOD's claim to entitlement. Aspirate appealed. The case came before Mr Justice Mann, whose reasoning provides guidance on the approach that should be taken when considering such an application.

Mann J noted the guidance given by Warren J in *Luxim v Ceravision*[126]. The question was not whether the comptroller was unable to determine or incapable of determining the case; it was whether the court can more properly do so. To adopt the language of the standard of proof, it certainly requires something like "beyond all reasonable doubt", whereas appearance requires only something more akin to "balance of probabilities".

After the hearing officer refused to decline to deal with NGPOD's claim, further pleadings were exchanged by the parties. As a result, Mann J said that he had the benefit of a clearer articulation of the areas of dispute than the hearing officer had had. There were likely to be significant legal disputes (including a significant question on the construction of a contract) and equally significant questions of fact (including a conflict of evidence). They were significantly beyond the likely experience of a hearing officer, while being rather more standard fare for a judge. The case was plainly one more properly tried in the court.

Mann J noted that the hearing officer seemed to have suggested that the case as advanced could be cut down by the hearing officer so as to make its scope more manageable, thereby making the IPO a more appropriate venue. Mann J said that that was not the correct approach. The question was whether the case, as currently constituted, would be more properly tried in the High Court, not whether it could be cut down to a size which would make it appropriate for trial in the IPO. That did not mean to say that an assessment of the venue should not take a realistic view of the size of the case, shorn of the extra trimmings which do not contribute much to complexity or which are added to give a false impression of complexity but that was a different point,

In the now historical case of *Cinpres v Melea*[127], a hearing officer who insisted on hearing a case involving a complex conflict of evidence triggered litigation which lasted ten years and ended in a second hearing before the Court of Appeal.

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[125] *NGPOD Global v Aspirate N Go* [2016] EWHC 3124 (Pat) (2 December 2016) Mann J

[126] *Luxim v Ceravision* [2007] RPC 33

[127] *Cinpres v Melea* [2008] EWCA Civ 9

In summing up in *NGPOD v Aspirate*, Mann J said:

> *"Whether or not the patents, and the success in the case, are very significant to NGPOD, they are undoubtedly patents of real financial and commercial significance to Aspirate, and that is a strong pointer to the High Court. When one couples that with the nature of the dispute as it now emerges in relation to non-patent matters, and the techniques for trying this case (including the need for properly policed disclosure), and the lack of familiarity of non-legally trained hearing officers to deal with both the complexity of the litigation and the points of law that are likely to arise, those factors would, in my view, make any other conclusion an unreal one."*

I wish that we had heard something along those lines at the outset of the *Cinpres* litigation in the 1990s.

Permission to appeal in patent cases

Given that this is a topic which I will return to in my conclusion, it seems appropriate to comment on the guidance regarding appeals in the case of ***Teva v Boehringer Ingelheim***[128]. The gist of the case is that the Court of Appeal has ruled that "the time has come" to depart from the *Pozzoli*[129] ruling on permission to appeal in patent cases. Both Kitchin and Floyd LLJ said that there is no justification, in granting or refusing permission to appeal, for treating patent cases any differently to other cases. There is nothing to justify a different, more lenient approach.

Boehringer Ingelheim was refused permission to appeal a 2015 decision of Morgan J. He had refused permission to amend the claims of its patent as the proposed amended claims lacked inventive step.

Floyd LJ noted (in [2]) that the guidance given in the *Pozzoli* case on appeals was as follows:

> *"I would add this about a permission to appeal in patent cases generally. Unless the case is very clear and can be understood sufficiently readily in an hour or so, the better course is normally for permission to be granted by the trial judge. For, unlike the trial judge, the Court of Appeal judge(s) who have to decide whether permission should be granted (where the trial judge has refused it) will not be immersed in the technology and evidence in the same way as the trial judge. Faced with but an incomplete understanding and a plausible skeleton argument seeking permission, the Court of Appeal will generally be likely to grant permission, even if it later discerns that the case is indeed clear."*

Floyd and Kitchin LLJ considered that neither the public interest (in securing that valid monopolies are respected and in sweeping away invalid monopolies), nor the technically complex background to many patent cases, justified a departure from the normal tests for permission to appeal. Their judgment, delivered by Floyd LJ, goes on to say ([10]-[12]):

> *"In my judgment, whilst the public interest aspect of patents justifies painstaking analysis of the issues which arise, including the grant or refusal of permission to*

[128] *Teva v Boehringer Ingelheim* [2016] EWCA Civ 1296 (16 December 2016)

[129] *Pozzoli v BDMO* [2007] EWCA Civ 588

appeal, it does not justify a different, more lenient approach to the granting of permission to appeal…

I think the time has come to say that the technical complexity of the background is not a factor which trial judges should take into account in favour of granting permission to appeal. For that reason, there is no justification, in granting or refusing permission to appeal, for treating patent cases any differently to any other cases. In my judgment the approach in Pozzoli *should no longer be followed."*

Generally there are far more appeals than there used to be. Much of this is down to appeals by litigants in person, but in the world of patents, it is certainly true to say that there is a normal expectation that leave to appeal will be granted, either by the trial judge, or the Court of Appeal itself.

Whether or not this proposed new approach is driven in any way by the tremendous pressure on Court of Appeal judges, and the backlog which emerged when there was illness among them, remains to be seen.

5 SUMMARY AND CONCLUSION

This has been what my mother would call a "bitty piecy" year. Beyond perhaps plausibility and its impact in relation to obviousness and insufficiency, there have been no big themes, no overriding cases, and nothing from the Supreme Court - although we hope that will be remedied next year. We have not quite had the controversies we had in 2015, and the cliff-hangers turned out not to be quite as controversial as we had thought (hoped) they might be, although that still remains to be put to rest.

Some external factors are clearly at play in the courts. Costs and availability of judges is an issue, with rumours of a massive wipe-out of appeals when the backlog got to a certain level. We have now seen legal justification being given for raising the bar for appeals, though whether this is in truth driven by commercial factors behind the scenes is something we may never know.

The three main High Court patents judges are working well. Some of the judgments are still way too long, and maybe we are seeing the "anti-patent" trend re-emerging? The last time this happened was when there were three highly established and experienced High Court judges working together. They were Jacob J, Laddie J, and Pumfrey J, as they were then known. It has been suggested that they became a bit "too clever" and suddenly everything was obvious. The title of my annual paper in 2007 was "when is a patent not a patent?". The answer was when it had been litigated in the UK High Court. The UK had become the place where patents went to die. It took the House of Lords decision in *Conor v Angiotech*[130] the following year to reverse the trend, and I gratefully titled my talk that year "the waters had subsided from the earth".

This time last year, I made the following comment in my conclusion:

"This time next year, barring an unfortunate turn of events in the summer referendum, or further unforeseen delay, we will be considering the preparation for our first cases in the Unified Patents Court."

[130] *Conor v Angiotech* [2008] UKHL 49

So there it is … the elephant in the room, trumpeting for all it is worth.

I went on to say:

> *"Those who choose to opt out of the Unitary System, or indeed choose to opt out of Europe-wide patenting altogether and opt for a few national patents, will need the UK courts to be functioning at their best. We have the personnel, the experience and the brain power to deliver great justice – now we just need the teamwork."*

Now, more than ever, those comments are important and pertinent. Far from cooperating and participating in the UPC, we may be competing with it. We certainly cannot afford to do so under the context of a reputation as a patent graveyard.

So who is going to be this year's judge of the year? As with last year, I did not have to think too hard. Reading the judgments is a very interesting pastime. Many prejudices and little points emerge, but it is clear when some judges are trying to be particularly helpful, and to derive guidance and tests which will help practitioners in their daily professional lives. We really do appreciate that, and on that basis Mr Justice Henry Carr, in only his second year of eligibility, is this year's judge of the year. His judgments are sensible, sometimes brief, understated and wise. I suspect he may take some shifting from this position in years to come.

However, it would be completely inappropriate for me not to adopt a BAFTA standard of delivering a "lifetime achievement award". That must go to Sir Robin Jacob. He has been sitting for a number of years now as, effectively, a deputy judge in the Court of Appeal, although his official retirement took place in 2011. At the ceremony he made a short but amusing and moving speech. He said:

> *"Seventeen and a half years ago, in thanking everyone for their speeches of welcome to me as a new judge, I ended by promising to do my best.*
>
> *Well I tried.*
>
> *But sometimes higher courts, and the European Courts of Justice said that "my best wasn't good enough". For the purposes of today at least, I forgive them. They knew not what they were doing."*

I always struggled to forgive him for *BA v Ryanair* – the low point of my career. I saw toppling his *Unilin* edifice in the *Virgin v Zodiac* case as "payback". But I have never had anything but the utmost respect for him as a jurist and as a person. He is a judge with a moral compass.

After all that 2016 delivered, we need as many people with a functioning moral compass around us as we can find.

Gordon D Harris
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