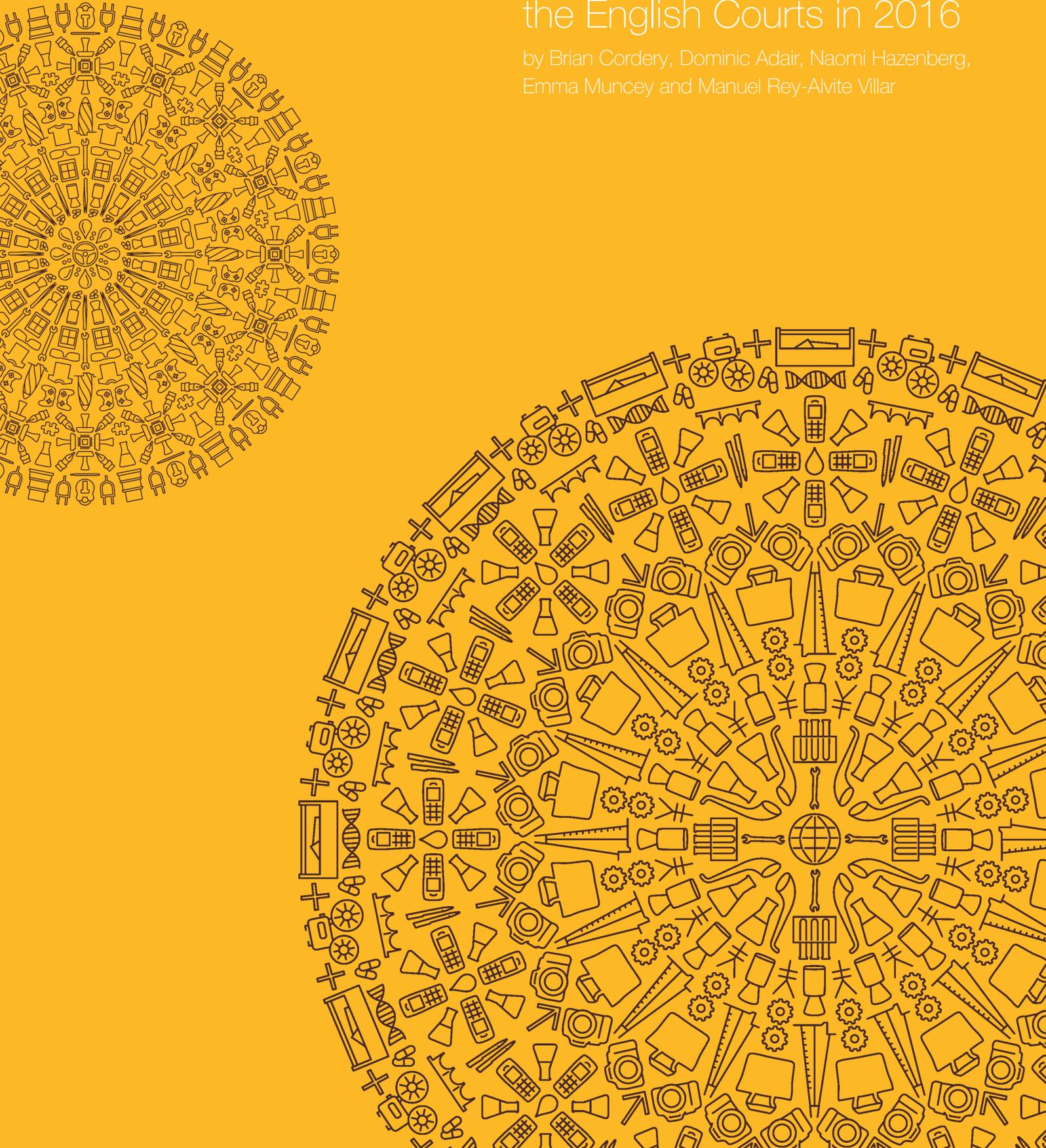


BRISTOWS

Review of Patent Cases in the English Courts in 2016

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Quotation of the Year

“For the last time, with some sadness, I have pressed the “Start New Civil Appeals Judgment” button of the judgment template.”

Per **Sir Robin Jacob** in *Gedeon Richter v Generics (UK)* [2016] EWCA Civ 410

The information contained in this document is intended for general guidance only. If you would like further information on any subject covered by this Bulletin, please e-mail Brian Cordery (brian.cordery@bristows.com), Dominic Adair (dominic.adair@bristows.com) or the Bristows lawyer with whom you normally deal. Alternatively, telephone on + 44 (0) 20 7400 8000.

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Introduction

2016. What a year it was. By the end of it, we had learnt to expect the unexpected, but until that time each unexpected event seemed more remarkable than the last. Putting aside Leicester City's Football Premiership title win, Brexit was the first, and most immediate, shock which left many patent practitioners in a state of confusion, if not depression. Was this the end of the UPC project? What would happen to our beloved SPCs? How long would it take to sort out the mess?

Then Donald Trump was elected US President, and the world reeled again. But that wasn't the end of it. Just a few weeks later, another shock, at least in the patent community: although the UK is leaving Europe, the UK announced it would still ratify the UPC Agreement. All bets are back on – at least for now. What a year. Our usual UPC author Alan Johnson provides his personal perspective at the end of this review.

In amongst these gargantuan events, the law relating to patent litigation in the UK continued to evolve and there were a number of developments to keep patent practitioners on their toes. The following are particularly noteworthy:

- A change in the approach to permission to appeal in patent cases, set out by **Floyd LJ** in *Teva v Boehringer Ingelheim*¹. From now on, patent cases will be treated no differently from other cases, losing their easier passage to permission on account of their technical complexity.
- A new approach to disclosure in patent cases, set forth by **Birss J** in *Positec v Husqvarna*² and confirmed by **Henry Carr J** in *Illumina v Premaitha*³. Standard disclosure is no longer the default option.
- *Arrow*⁴ declarations are back on the menu after a 10-year absence. The idea of getting a declaration to say that a product is immune from infringement because it represents nothing more than the state of the art (or obvious modifications thereof) was reawakened by Fujifilm Kyowa Kirin Biologics in a case against AbbVie relating to the world's top-selling drug, Humira⁵.
- Plausibility remains a popular theme. The *Gilead*⁶ and *Shionogi*⁷ cases illustrate that claims containing Markush formulae covering billions or trillions of compounds (or more) risk being found invalid on the basis that it is not plausible that they make a technical contribution across the scope of the claim.

- The law on indirect infringement in second medical use claims was examined by the courts in the pemetrexed⁸ and pregabalin⁹ litigations, with some clarity emerging on the steps necessary to avoid liability.

- The year was not a good one for appellants. In addition to the change in approach to granting permission to appeal, the statistics on appeal showed that all first instance decisions on the merits were upheld, the Court of Appeal reminding the parties on more than one occasion that issues such as obviousness and insufficiency are multifactorial assessments with which, absent a clearly identified error of principle, the Court is unlikely to interfere¹⁰.

- The English courts continue to position themselves as being competitive in Europe. A clear example of just how quickly a case can progress from inception of claim to conclusion of appeal emerged with the *Napp v Dr Reddy's*¹¹ case. The answer is less than 6 months.

- As reflected in our quotation of the year, 2016 also saw the last decision in **Sir Robin Jacob's** long and fruitful judicial career. **Floyd LJ** spoke for the profession when he said *"all those who have practised in this field of law are very greatly indebted to him for sharing with us, in the vast number of so clearly expressed judgments which he has drafted on [the Civil Appeals Judgment] template, his great depth of learning in this subject"*¹².

The courts were as busy as ever. In fact, it is remarkable how consistent the number of patent decisions is in any given year. In 2016 the total number of substantive decisions from the High Court and the Court of Appeal was 82 decisions, compared to 78 in 2015 and 79 in 2014.

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

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

Claim Construction and Infringement

Numerical Ranges

The single question from *Kirin Amgen*¹³ remains the bedrock of claim construction in the English courts, namely what the

1 [2016] EWCA Civ 1296

2 [2016] EWHC 1061 (Pat)

3 [2016] EWHC 1516 (Pat)

4 From *Arrow Generics v Merck* [2007] EWHC 1900 (Pat)

5 *Fujifilm v AbbVie* [2016] EWHC 425 (Pat)

6 *Idenix v Gilead* [2016] EWCA Civ 1089

7 *Merck v Shionogi* [2016] EWHC 2989 (Pat)

8 *Actavis v Eli Lilly* [2016] EWHC 234 (Pat)

9 *Warner-Lambert v Actavis* [2016] EWCA Civ 1006

10 E.g. *Idenix v Gilead* [2016] EWCA Civ 1089 at para 167

11 [2016] EWHC 1517 (Pat) and [2016] EWCA Civ 1053

12 *Gedeon Richter v Generics (UK)* [2016] EWCA Civ 410 at paragraph 30

13 *Kirin Amgen v Hoechst Marion Roussel* [2004] UKHL 46

person skilled in the art would have understood the patentee to be using the language of the claims to mean. As ever, context is king. Readers will recall the decision of the Court of Appeal in *Smith & Nephew v ConvaTec*¹⁴, which related to a patent concerned with silverised wound dressings. It was held that the skilled person would interpret the numerical limits in the claims using a whole numbers approach (i.e. a claim to a range between 1% and 25% was held to extend from 0.5% to <25.5%). The same approach was applied by **Arnold J** in *Napp v Dr Reddy's*¹⁵ in relation to Napp's patent for the composition of a buprenorphine transdermal patch for use in the treatment of pain. He held that ranges expressed as "10% to 15%" should be construed as "≥9.5% to <15.5%". Additionally, on the construction of the phrase "about 10%", the Judge held that "about" should be taken to allow a small degree of permitted imprecision over and above the usual rounding, which in this case amounted to a permitted range not broader than ≥9.0 to <11.0%. Finally, distinguishing the case from *Cephalon v Orchid Europe*¹⁶, he held that the figures referred to the composition of the finished product rather than the ingredients in the recipe. The Court of Appeal (**Floyd LJ** giving the leading judgment) upheld **Arnold J's** decision on all three points¹⁷.

De Minimis Infringement

In *Napp v Dr Reddy's*¹⁸ **Arnold J** also considered the issue of *de minimis* patent infringement on a quia timet basis, with reference to the possibility that a small number of products to be manufactured in the future by Dr Reddy's and Sandoz could fall within the scope of the patent's claims. Having reviewed the case law on this topic, on the facts before him the Judge set the threshold below which infringement could be discounted as *de minimis* as 1 in 10,000 products. In fact, based on the evidence presented, only between 1 in 153 million and 1 in 69 million products would potentially fall within the claims. Therefore, **Arnold J** held there could be no threatened infringement by Dr Reddy's and Sandoz.

Second Action for Infringement

In the ongoing dispute between AP Racing and Alcon¹⁹, on appeal from an Order of **HHJ Hacon** in the IPEC, **Henry Carr J** had to consider whether it was an abuse for AP Racing to include in a new infringement action seven brake callipers that were made and distributed by the defendant at the time of the initial infringement action. In considering Alcon's strike out application, the Judge reaffirmed the principle that there was no duty on a patentee to investigate all possible infringements at the outset of a claim and that not doing so did not preclude the availability of relief in respect of them. Indeed, he noted that having to examine all possible infringements in the initial liability trial would be "wasteful, time consuming and a recipe for delay". It was found that there was no abuse of process by AP Racing and **HHJ Hacon's** order to reject the strike out application was upheld.

Indirect Infringement

The issue of indirect infringement is a hot topic in pharma patent cases. There are two long-running disputes in which the issue has arisen: the pregabalin and pemetrexed cases.

As readers will recall, indirect infringement carries a knowledge requirement such that for liability to attach, the supplier of the goods in question (i.e. the means relating to an essential element of the invention) must know or it must be obvious to a reasonable person in the circumstances that some end users will intend to use the goods to infringe. In the pregabalin litigation, the question of intention was whether the goods would be prescribed for the patented indication of pain. In the pemetrexed litigation, the question was whether preparations of pemetrexed salts would be reconstituted with saline, thus creating the solution of patented pemetrexed disodium. In both cases, the alleged infringer took extensive steps to demonstrate that it did not have the requisite knowledge, such as writing letters and issuing notices to end users stating that the patented use should be avoided. Practitioners advising clients on the steps necessary to avoid indirect infringement will be grateful for the main judgments in these cases.

The pemetrexed case²⁰, more accurately referred to as "the dextrose remission judgment", follows the Court of Appeal's decision²¹ that Lilly's patent for pemetrexed disodium was not infringed directly by Actavis' pemetrexed products consisting of other salts, but that indirect infringement would occur when preparations containing those salts were diluted with saline (containing sodium ions). Actavis requested that the Court remit to first instance the issue of whether indirect infringement would occur if the pemetrexed products were diluted with dextrose solution instead (lacking sodium ions). The bulk of the judgment on the dextrose remission issue deals with the likelihood that, notwithstanding the instructions to reconstitute with dextrose, healthcare practitioners would nonetheless reconstitute with saline, and whether Actavis would know that. The issue was made more difficult to determine by the long period of time left remaining before Lilly's patent expired, during which time the circumstances could change (e.g. a motivation to prefer saline could arise). In a typically thorough judgment, **Arnold J** found that Actavis did not possess the requisite knowledge that an end user might dilute its products with saline. The Summary of Product Characteristics, indicating dilution with dextrose, would be adhered to unless good reasons to depart existed. There were no such reasons and, in particular, no reason to prefer saline on the basis that a saline solution would be more stable nor that any data showing a greater stability in saline would be published in the foreseeable future. Accordingly, the Judge granted Actavis the declaration of non-infringement sought.

14 [2015] EWCA Civ 607

15 [2016] EWHC 1517 (Pat)

16 [2011] EWHC 1591 (Pat)

17 *Napp v Dr Reddy's* [2016] EWCA Civ 1053

18 See footnote 15, *ante*

19 *AP Racing v Alcon* [2016] EWHC 815 (Ch)

20 See footnote 8, *ante*

21 *Actavis v Eli Lilly* [2015] EWCA Civ 555

In the pregabalin appeal²², the comments on infringement of Swiss-form second medical use claims were *obiter*. **Floyd LJ** examined **Arnold J**'s comments that he did not understand the previous *obiter* comments from the Court of Appeal on indirect infringement²³. He reviewed the pregabalin decisions from across Europe, noting that sometimes the outcome of the infringement question can turn on a technical distinction as to the nature of the acts performed downstream of manufacture. For example, the Danish decision²⁴ highlights that a pharmacist who merely intends to dispense the drug for the patented indication does not bring the upstream manufacturer into liability because there is no "downstream act of manufacture". However, if the same pharmacist applies a label, this can result in direct infringement by the pharmacist – having undertaken an act of manufacture – as well as indirect infringement by the manufacturer. **Floyd LJ** noted that he agreed with the Danish analysis (i.e. that 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) and noted that he disagreed with **Arnold J**'s view that there is no prospect of any downstream infringing act. In the context of direct infringement, **Floyd LJ** also considered what would be sufficient to negate the existence of the relevant intention by the manufacturer, and concluded that it must be more than merely skinny labelling; the manufacturer must take "all reasonable steps within his power to prevent the consequences occurring". No further guidance on what is enough to satisfy this requirement was provided.

FRAND and Competition Defences

The Court of Appeal confirmed that an ETSI FRAND declaration given by a company that is not a member of the European Telecommunications Standards Institute (ETSI) provides the same rights to third parties as one made by an ETSI member²⁵. This arose as part of an appeal from **Birss J**'s decision to strike out elements of Samsung's competition law defences to Unwired Planet's standard-essential patent infringement action, which argued that the French law that governs ETSI declarations of members and non-members confers different rights on third parties²⁶. **Kitchin LJ** decided that **Birss J**'s decision on this point was unimpeachable and upheld the strike out. However, the Court of Appeal did restore a second aspect of the defence relating to the incomplete transfer of the non-discrimination obligation from Ericsson to Unwired Planet. Samsung was held to have a realistic prospect of persuading a judge at a full trial that, in the circumstances of the 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 licensees than Ericsson could itself have obtained. Samsung had argued that as part of Unwired Planet's much smaller portfolio, the patents would achieve

a higher royalty rate than they would as part of the large Ericsson portfolio, and that this was contrary to the FRAND obligations which should follow the patents transferred to Unwired Planet. Overturning the Judge's decision to strike out this element, the Court of Appeal stated that it was arguable that this potential for a higher royalty rate would distort or restrict competition.

The *llumina* litigation, concerned with gene sequencing technology, has proved that competition law defences are not the sole preserve of mobile phone or computer chipset cases²⁷. The defendants made allegations of abuse of dominant position and anti-competitive agreements in response to Illumina's claim for patent infringement. However, these defences were raised late in the day and it fell to **Roth J** to decide how to manage them. He adjourned the application to plead the competition law defences until after the "technical trial", i.e. the infringement/validity trial. He noted that only then would the competition law aspects take shape – e.g. there may be no abuse at all if there is no infringement.

In contrast, **John Baldwin QC** (sitting as a Deputy Judge) granted HTC's application that its licence defence be dealt with as a preliminary issue in its case against Philips relating to High-Speed Packet Access (HSPA) standard essential patents²⁸. HTC argued that, as a consequence of a non-assert provision in a licence agreement between Philips and Qualcomm, it had a defence to the majority of the claims in the action. HTC argued that dealing with this issue first could dispose of a large portion of the action without the need for a full technical liability trial and that, whilst it was relying on the provision, it was not able to challenge the validity of the patents in suit. Philips argued that on the correct construction of the agreement there was no licence, and that, in any event, the agreement was void because it was contrary to the competition law provisions of the **TFEU**. Using the criteria set out by **Birss J** in *Wagner v Earlex*²⁹, the Deputy Judge allowed the preliminary issue to proceed, stating that there was likely to be substantial savings in costs and resources.

Validity

Novelty

*Merrell Dow v Norton*³⁰ is a difficult case. If it were otherwise, the judgment from **Lord Hoffmann** would not need a separate section headed "The Intuitive Response", explaining why the intuitive response is wrong. Reliance was placed on this case in *GSK v Wyeth*³¹, GSK stating that it supported their argument that prior use of a vaccine in Cuba anticipated Wyeth's patent for a meningitis B vaccine. Anticipation was one of many grounds of invalidity pleaded against the patent and dealt with by **Henry Carr J** in a wide-ranging judgment.

²² See footnote 9, *ante*

²³ *Warner-Lambert v Actavis* [2015] EWCA Civ 556

²⁴ *Warner-Lambert v Krka*, decision of the Maritime and Commercial High Court dated 25 June 2015

²⁵ *Samsung v Ericsson* [2016] EWCA Civ 489

²⁶ *Unwired Planet v Huawei* [2015] EWHC 2097 (Pat)

²⁷ *Illumina v Premaitha* [2016] EWHC 1726 (Pat)

²⁸ *Koninklijke Philips v Asustek* [2016] EWHC 867 (Pat)

²⁹ [2011] EWHC 3897 (Pat)

³⁰ [1995] UKHL 14

³¹ [2016] EWHC 1045 (Ch)

It was argued that *Merrell Dow* made it unnecessary for the skilled person to analyse and identify the relevant protein administered in the vaccine at the priority date; it was sufficient that the vaccine was given and worked. **Henry Carr J** disagreed. Mere prior use by patients of the vaccine without knowledge of its constituents was not enough for anticipation. To anticipate, the skilled person must have been able to identify the relevant protein in the vaccine and reproduce it without undue burden. On the evidence before the Court, **Henry Carr J** held that the analyses necessary to identify the protein would not have been within the capability of the skilled person at the priority date. In contrast, regarding the allegation that the patent lacked entitlement to the second of two priority dates, **Henry Carr J** held that the priority document did contain an enabling disclosure despite the fact that it did not include the gene sequence listings which were set out in the patent. The Judge held that there were sufficient directions to conduct experiments which would yield the relevant sequences and that it did not matter that there were mismatches between the experimental output and the claimed sequence.

In a claim for revocation of a medical device patent in *Thoratec v AIS*³², Thoratec was successful in arguing public prior use based upon the provision of another ventricular assist device for a study in the Netherlands which had been reported in a medical publication. AIS had claimed that, under Dutch law, the provision of the device for the study was under an implied duty of confidence. **Arnold J** noted the position under English law that Thoratec had the burden of proof in showing that the prior use made the product available to the public, but if this was satisfied the burden of proof would shift to AIS to show confidentiality. Based on evidence from Dutch legal experts from both parties, the Judge held that under Dutch law there was a rebuttable presumption that research carried out for a third party by a university or other academic institution is confidential. However, the Judge was convinced, on the evidence, that the presumption had been rebutted.

Entitlement to Priority

The test for entitlement to priority is different from that for novelty. To lack novelty, the prior document need only disclose one thing which falls within the claims. However, to be entitled to the priority of the prior document, the claims must be supported by that document across their whole breadth. Sometimes it will be possible to generalise a specific disclosure without losing entitlement to priority (for example, in *Samsung v Apple*³³, **Floyd J** (as he then was) opined that the disclosure of a “nail” in a priority document

could be generalised into a claim for “fixing means” without losing priority because the skilled person could derive the generalisation directly and unambiguously from the disclosure). In *Nicocigs v Fontem*³⁴, this was not possible. The claims of Fontem’s patent, concerned with an aerosol-forming electronic cigarette, covered any spatial arrangement of an atomiser component and a liquid reservoir component whereas the disclosure of the priority document concerned only one configuration. Entitlement to priority having been lost, the claims were anticipated by the disclosure of the priority document which had been reproduced in a co-pending patent application.

The person claiming the right to priority must be the applicant or his successor in title³⁵. Although obiter, in *Idenix v Gilead*³⁶ **Kitchin LJ** agreed with **Arnold J** at first instance³⁷ and said that what constitutes an effective transfer is a matter for national law and as far as English law is concerned, a transfer of the substantive right – equitable title – is probably enough where the formalities effecting transfer of legal title have not been perfected.

In *Actavis v ICOS*³⁸ **Birss J** held that the burden of proof for the priority of a co-pending patent application (relevant under **section 2(3)** of the **Act**) lies with the party attacking the novelty of the patent, but shifts to the patentee if “sufficient evidence is available to support an inference that legal priority exists”. The relevant patent application, “Stoner”, was made in the name of Merck & Co. and Ms Waldstreicher for jurisdictions outside the USA and Ms Stoner for the USA (this difference arises from US practice whereby patent applications have to be made in the name of the inventor even if subsequently assigned to the employer). The priority document named the inventors as Ms Stoner and Ms Waldstreicher. There was no evidence as to the correct transfer of rights. However, the Judge found that the Court could draw the necessary inference where the third party applicant is a major international pharmaceutical company, such as Merck & Co., with a professional patent department whose function is partly to ensure formalities are correctly complied with. ICOS were unable to rebut this inference (by, for example, adducing evidence from Merck or the inventors of Stoner) and therefore **Birss J** found that Stoner was entitled to its priority. However, **Birss J** did note that the position might have been different had Stoner been an application belonging to one of the parties to the dispute. Although Stoner was entitled to its priority, the Judge found that the disclosure in the co-pending application was not enabling and, therefore, did not anticipate ICOS’ tadalafil dosage regimen patent. The patent was held valid and infringed.

³² [2016] EWHC 2637 (Pat)

³³ [2013] EWHC 467 (Pat)

³⁴ [2016] EWHC 2161 (Pat)

³⁵ Article 4A of the Paris Convention for the Protection of Intellectual Property (as amended, 1979)

³⁶ See footnote 6, *ante*

³⁷ [2014] EWHC 3916 (Pat)

³⁸ [2016] EWHC 1955 (Pat)

Obviousness

To bring a drug to market, clinical trials are necessary. Recent case law has shown that publications surrounding those clinical trials can put the validity of an associated patent in peril. For example, readers may recall the case of *Hospira v Genentech*³⁹ in last year's review, in which one of Genentech's trastuzumab patents was held to lack inventive step over a prior art citation which disclosed a Phase III trial of trastuzumab in combination with paclitaxel and other agents, but did not disclose any results from that trial. The patent was held to be novel over the disclosure because the claim required an effective therapy and the prior art, lacking results, was silent about efficacy. However, the disclosure was fatal to inventive step. In 2016, this decision was upheld by the Court of Appeal⁴⁰. On the obviousness question, **Floyd LJ** rejected Genentech's submission that for claims requiring a therapeutic effect to be obvious the expectation of success must be so high that it is more or less self-evident that the purported invention ought to work. The Court refused to create a *lex specialis* for such claims. **Floyd LJ** also dismissed Genentech's argument that **Arnold J** had failed to put himself in the position of the skilled person when assessing the work that would be required to carry out a Phase III clinical trial, confirming that although the necessary clinical trials would consume significant time and expense, the work was not technically challenging and was within the skilled person's capacity.

A not dissimilar situation arose in the case of *Hospira v Cubist*⁴¹. Cubist, the patentee, had published a press release stating that it would be conducting certain clinical trials, including a Phase III trial of a dosage regimen which fell within the scope of the claims. The press release was published after the first priority date but became an issue because **Henry Carr J** found that the relevant patent was not entitled to that priority date. The disclosure of the clinical trials was cited for both anticipation and obviousness. In keeping with the trastuzumab case, the novelty attack failed because the publication said nothing about efficacy and Cubist's claimed dosage regimen had to be interpreted as a therapy that was efficacious. Nevertheless, **Henry Carr J** found the claimed dosage regimen obvious in light of the press release because the skilled team would consider that the proposed clinical trials would have a fair expectation of success in demonstrating efficacy. Arguments from Cubist that there was a cloud over the drug because its development had been previously abandoned by Eli Lilly did not gain traction. The Judge held that positive results about the drug were part of the CGK. Furthermore, the pursuit of Phase III trials clearly indicated that the Phase II results must have been encouraging. It seems pharma companies should proceed cautiously with pre-priority (or pre-filing) publications around clinical trials in the future.

It is often said that hard cases make bad law; that out of extreme fact patterns emerge judgments that can be difficult to reconcile. Conversely, but usually unsaid, is the idea that clarity in the law emerges from fact patterns that are similar, but different. A good example of this is the other Court of Appeal judgment in *Hospira v Genentech*⁴², and the question of whether it is obvious to pursue a particular formulation in a screening programme. Here the Court of Appeal was asked to overturn an obviousness finding by **Birss J** in respect of two trastuzumab formulation patents: the Judge found it obvious to include in a screening programme a number of excipients from the CGK and that the resulting formulations would include those claimed. It was argued that this fell foul of the EPO's "could/would" test, which finds obvious anything that a skilled person would do (not just could do). **Floyd LJ** explained that the English courts are not tied to the "could/would" test and that the skilled person can sometimes be faced with a range of obvious possibilities; the fact that the statistical likelihood of settling on any one of them is low (i.e. there is no "would") does not make that option inventive. Equally, the fact that one cannot point in advance to those options which might work does not prevent a finding of obviousness. A comparison was made with the previous year's case of *Teva v Leo*⁴³, another decision of **Birss J** on a formulation patent that was appealed. In that case **Birss J** was overturned, the Court of Appeal finding that it would not have been obvious to include a particular non-aqueous solvent in a screening programme because the circumstances were such that there was no expectation that a non-aqueous solvent would work.

Obviousness for lack of technical contribution, or "AgrEvo obviousness"⁴⁴, was at the forefront of the appeal decision in *Idenix v Gilead*⁴⁵. Idenix's patent claimed a family of nucleoside analogues for treating HCV and other infections caused by viruses in the Flaviviridae family. The patent, claim 1 of which specified compounds under a Markush formula effective against Flaviviridae, was in trouble from the moment that Idenix's own expert conceded during trial that the claim, which was conservatively estimated to cover about 50 billion compounds, covered classes of compounds which it was not plausible would be effective. In light of this concession, Idenix had made a conditional application to amend the claims to focus on the sub-class of compounds which was said to be efficacious. Nevertheless, the claims in amended form were held by **Arnold J** to lack inventive step for making no technical contribution to the art, a finding upheld on appeal. For example, there were no experimental data for the compounds in question and no credible theory or rationale why the compounds in this class might all be effective.

An even broader claim was the subject of an AgrEvo obviousness attack in *Merck v Shionogi*⁴⁶. Drafted in the

39 [2015] EWHC 1796 (Pat)

40 *Hospira v Genentech* [2016] EWCA Civ 1185

41 [2016] EWHC 1285 (Pat)

42 [2016] EWCA Civ 780

43 [2015] EWCA Civ 779

44 From *AgrEvo* T 0932/92

45 See footnote 6, *ante*

46 See footnote 7, *ante*

Swiss form and relating to use of a class of compounds as integrase inhibitors for the treatment of viral diseases, the Markush formula in the main claim had so many variable substituents that the number of chemical compounds covered was said to be in the order of 10^{39} . To put the size of this number in context, Merck's counsel estimated that if 200 compounds a week were tested for efficacy, even to test 0.01% of the claimed compounds would take a period of time 2×10^{21} times the age of the Earth. Arnold J dismissed Shionogi's argument that no lack of technical contribution attack could be made because the claims contained a functional limitation, i.e. the technical contribution was written into the claims. Referring to *Idenix v Gilead*⁴⁷ and *Novartis v Johnson & Johnson*⁴⁸ he noted that in order for such claims to make a technical contribution, the patentee must identify a principle which permits a reasonable prediction to be made that substantially all the products falling within the scope of the claim share the functional characteristic claimed. In this case, what was lacking in terms of principle was a defined "pharmacophore" – i.e. the relative positioning of the functional groups identified by structure-activity relationship studies – which would enable a prediction of integrase inhibition to be made. Furthermore, the specification did not include any data demonstrating the compound's antiviral efficacy, merely some biochemical assay results which were held to fall short of the mark. Amendments proposed by Shionogi were held not to affect the conclusions reached.

In *American Science and Engineering v Rapisan Systems*⁴⁹, the patentee raised a familiar question when arguing that there were secondary indicia of non-obviousness, namely: if it was obvious, why wasn't it done before? The case concerned x-ray backscattering for security imaging and, although the period between the priority date and the publication of the prior art was only six years, the field was very active. The defendant argued that nobody else could develop the claimed invention because of the patentee's existing patent protection and, as a result, the burden moved to the patentee to show that this was not the case. Arnold J dismissed this "extraordinary submission". He confirmed that, if a party attacks a patent on the grounds that it is obvious and wishes to rely upon a fact to explain why it was not done earlier, the burden of proving the existence and relevance of this fact lies with that party. This was equally true whether that fact was the availability of raw materials, a regulatory restriction, a commercial factor or the existence of earlier patent protection.

The Court of Appeal dismissed Gedeon Richter's appeal on the obviousness of its emergency contraception dosage regimen patent over prior art which repeatedly stated the incorrect dosage⁵⁰. Giving his last judgment, and following Sales J's finding at first instance that the skilled person

would contact the author of the prior art who would then revert with the correct dosage, Sir Robin Jacob stated that he couldn't see any logical distinction between a case where it is obvious to look something up and a case where it is obvious to ask the author and clear that the answer would be given because in both cases "the prior art spurs the action of [the skilled person] finding out [the answer] in a non-inventive way". It is possible that the case may come to be seen as being confined to its facts.

Several cases this year reiterated the caution advised by Floyd J (as he then was) in *ratiopharm v Napp*⁵¹ in pleading a case of obviousness over the CGK alone and highlight the difficulties with this approach. In *Accord v Medac*⁵² Birss J found Medac's patent for the use of methotrexate for the treatment of inflammatory autoimmune diseases inventive over the CGK alone but obvious over a piece of prior art combined with the CGK. In so doing, the Judge elaborated on Floyd J's position with regard to the necessary scrutiny that such attacks should be given, stating that:

*"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. 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"*⁵³.

The importance of properly pleading a case on obviousness over the CGK alone was underlined both by Birss J in the third *Unwired Planet* technical trial⁵⁴ and by Daniel Alexander QC, sitting as a Deputy Judge in *Meter-Tech*⁵⁵. In the *Unwired Planet* case, the need for a proper pleading was mentioned by the Judge despite an agreement between the parties that the defendants' expert report would serve as the statement of case; the case had shifted slightly before trial. The defendants' case was said to have created a hindsight-driven combination of features that sidestepped the inconvenient details contained in contemporaneous documents and at a level of generality which itself was crafted with hindsight. Later in the year, Daniel Alexander QC explained that a party's statement of case should set out not only what the CGK was at the relevant time, but also how that differs from the invention and why it renders the claim obvious. In addition to setting out the starting point, this was said to require pleading the allegedly obvious route to the invention so that the notional thinking of the skilled person can be evaluated. Having made these observations, the Judge declined to make a finding on the argument – not because the claims in question were not obvious in light

47 See footnote 6, *ante*

48 [2009] EWHC 1671 (Pat)

49 [2016] EWHC 756 (Pat)

50 *Gedeon Richter v Generics (UK)* [2016] EWCA Civ 410

51 [2008] EWHC 3070 (Pat)

52 [2016] EWHC 24 (Pat)

53 *Ibid*, at para 123

54 *Unwired Planet v Huawei* [2016] EWHC 576 (Pat)

55 *Meter-Tech v British Gas* [2016] EWHC 2278 (Pat)

of the CGK alone but because it would not be fair to make such a finding given the manner in which the pleadings developed in the case. Whilst this seems to impose a heavy burden on parties wanting to take this route to attack a patent, **Daniel Alexander QC** noted that the Court should not place “undue forensic weight” on the precise manner of the pleading and that the fact that the argument develops in light of the patentee’s points should carry only limited weight. This caution was echoed again by **Roger Wyand QC**, sitting as a Deputy Judge in *Sony v SSH*⁶⁶. When Sony failed to establish that its four key propositions were CGK, it was found that no identifiable starting point had been established for an assessment of obviousness and, as a result, it was not possible to apply the *Pozzoli* questions, leading to a fatal flaw in the attack.

Skilled Addressee

In *Saertex v Hexcel*⁶⁷ **HHJ Hacon** revisited the oft-cited statement of **Lord Diplock** in *Catnic*⁶⁸ where it was said that the patentee addresses the patent to “those with a practical interest in the subject matter of his invention”⁶⁹. **HHJ Hacon** held that this “practical interest” referred to “an interest which is held by the putative skilled person in directly performing the invention as claimed – either by himself or, where the facts require, in co-operation with one or more other skilled persons, each with different expertise”. With this emphasis on direct performance of the invention as claimed, it would seem that account should be taken of the category of claim, such that, to take an example used by the Judge, a skilled user of a product made according to a patented method will not necessarily be part of the skilled team.

Insufficiency

Although the concept of plausibility was born at the EPO in the context of inventive step, it is in the context of insufficiency that it is becoming most well developed in English jurisprudence. In 2016 there were several notable cases in this area.

The Court of Appeal decision in the pregabalin case confirms that the test for plausibility is a “very low threshold”⁶⁰. The patent in suit claimed that pregabalin was an effective treatment for pain (claim 1) and, more specifically, neuropathic pain (claim 3). **Floyd LJ** rejected the appeal by Warner-Lambert against **Arnold J**’s decision that neither claim was plausible across its scope, essentially because neuropathic pain had two components – central and peripheral – and only efficacy in the treatment of peripheral neuropathic pain was plausible. The fact that plausibility is a low threshold test meant that it is not necessary for there to be enough in the patent specification for the skilled person to make a firm prediction, or to be motivated to carry out tests with a reasonable expectation of success; it is enough that a patent specification contains a reasonably credible theory or some data encouraging the reader to

try the invention. In this case, animal model data (rat paw formalin test) in the specification suggested that the drug might be effective for treatment of peripheral neuropathic pain – so that was plausible. This conclusion was fortified by it being established by the evidence at trial that the skilled team would be encouraged by the data in the patent to carry out simple tests to confirm the suitability of pregabalin for peripheral neuropathic pain. But it was not possible to extend this to other types of pain based on a theory that there was a unifying principle at work. EPO jurisprudence, and particularly *Salk*⁶¹, suggests that a disease as a whole can be made plausible by narrow data if that data shows that the drug has a direct effect on a molecular mechanism specifically involved in the disease. But there was nothing in the patent or CGK to support the patentee’s argument that there was a unifying characteristic or principle in the present case.

Unsurprisingly, having held that the patent in suit in *Idenix v Gilead*⁶² did not make a plausible technical contribution to the art, the Court of Appeal also dismissed the appeal from **Arnold J**’s decision that the claims were insufficient because it was not plausible that any technical contribution extended across the full breadth of the claims. The appeal decision also upheld **Arnold J**’s findings on other aspects of insufficiency, including the fact that the skilled person would not be able to make the compounds claimed or perform the invention without undue burden. It was contended that **Arnold J** had made an error of principle by focussing on whether the compounds could be made via “routine methods” instead of asking whether the effort involved would amount to an “undue burden”. **Kitchin LJ** dismissed this argument, noting that the Judge’s approach had been “entirely appropriate”. The appeal decision serves as a reminder that the Court of Appeal will be reluctant to interfere with a first instance decision relating to insufficiency unless there is a clear error of principle, something that **Kitchin LJ** himself underlined with reference to the House of Lords decision in *SmithKline Beecham’s Patent*⁶³.

A similar conclusion was reached by **Arnold J** in *Merck v Shionogi*⁶⁴, the Judge finding that the patent presented the skilled team with a vast research project with a high likelihood of failure. Both parties submitted evidence of experimental work done on compounds falling within the claimed Markush formula within the four-year disclosure window. **Arnold J** concluded that the evidence demonstrated that a significant proportion of the compounds either did not possess antiviral activity or did possess antiviral activity but were unduly toxic.

Regeneron’s patent for transgenic mice that could be used as platforms for therapeutic antibody discovery was found insufficient by **Henry Carr J**⁶⁵ on the basis that claim 1 of the patent covered large insertions and deletions of mouse

56 [2016] EWHC 2584 (Pat)

57 *Saertex France v Hexcel Reinforcements* [2016] EWHC 966 (IPEC)

58 *Catnic Components v Hill & Smith* [1982] RPC 183

59 *Ibid*, at para 242

60 *Warner-Lambert v Actavis* [2016] EWCA Civ 1006, at para 130

61 *Salk Institute for Biological Studies* T 0609/02

62 See footnote 6, *ante*

63 [2006] RPC 323

64 See footnote 7, *ante*

65 *Regeneron v Kymab* [2016] EWHC 87 (Pat)

genome which could not be performed by the skilled person without undue burden.

In the third technical trial of the *Unwired Planet* case⁶⁶, **Birss J** agreed with **Arnold J**'s finding in *Generics v Yeda*⁶⁷ that the fact that a claim has a “fuzzy boundary” does not render it insufficient for ambiguity. He noted that the only instances of truly ambiguous claims in modern law were in the cases of *Kirin-Amgen*⁶⁸ and *Sandvik*⁶⁹ and that these claims were invalid because the skilled person could not know if they were carrying out the correct technical test to establish if a product/process fell within the claim. However, the Judge commented that the principle was not limited to claims including technical tests, as shown in *SmithKline Beecham*⁷⁰. If a defendant is found to infringe, that in itself demonstrates that the claim is at least clear in some respects, which will mean that an insufficiency by ambiguity argument is likely to be met with scepticism. In considering the claim in question, it was noted that it did not matter that it was wide in scope. The important thing was that the skilled person would be able to implement a scheme in accordance with the claim without undue effort. In coming to this conclusion, the Judge distinguished the claim, which required a conversion to be carried out to allow a comparison of value from two different systems, from that considered in *Kirin-Amgen*, because the claim scope was not dependent on the outcome of the comparison.

Arrow Declarations

One of the most notable developments of 2016 was the reawakening of the so-called “Arrow declaration” as a form of relief, used against patentees when clearing the way. Named after the interim decision of **Kitchin J** (as he then was) in *Arrow v Merck*⁷¹, the form of the order is to declare that certain products or acts were known or obvious at the priority date of a patent, thereby giving immunity from future claims for infringement by deploying a *Gillette* defence⁷².

There were three judgments of substance during the year. All related to the same patentee and product: AbbVie and its antibody product Humira (adalimumab), the world's biggest selling drug. Seeking the Arrow declarations were biosimilar product manufacturers Fujifilm Kyowa Kirin Biologics (FKB) and Samsung Bioepis. The cases related to the question of whether such declarations can be granted as a matter of principle, which remained unanswered because the original Arrow case had settled before trial. AbbVie contended that the declarations were not available, and sought to strike out the biosimilars' claims.

It is important to note that the background facts were unusual. The claims for declarations were originally made alongside applications for revocation of granted European patents. During the course of the proceedings, certain

divisional patent applications that were also the subject of the declarations whilst pending, granted. But in each case, during the pendency of the proceedings, AbbVie took steps unilaterally which led to the revocation of the patents at the EPO or their de-designation from the UK. It was alleged that AbbVie was deliberately avoiding adjudication on the merits of the patents' validity and that the declarations were therefore necessary to achieve commercial certainty in respect of the pending applications in the same family which was not available via any other route.

In the first case⁷³ **Henry Carr J** refused AbbVie's application to strike out FKB's claim for a declaration, explaining that: “[i]f 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 divisional applications pending before the EPO”. In the second case, relating to a different set of AbbVie's Humira patents, **Arnold J** agreed⁷⁴. FKB had a real prospect of establishing that AbbVie's actions at the EPO were “to shield some or all of the subject matter of [its patent] from timely scrutiny by the Court, or at least to prolong the uncertainty as to whether such subject matter founds a valid patent”. The Judge also held that the Court has jurisdiction to grant an anti-suit injunction to restrain the bringing of any infringement suits in relation to acts covered by the declarations. The decisions in these first and second cases were appealed⁷⁵.

In the third case⁷⁶, **Henry Carr J** dismissed a further application by AbbVie for summary judgment or strike out. By this time, in addition to taking steps which led to the loss of its granted patent rights in the UK, AbbVie had also offered undertakings that it would not obtain any patent protection in the UK that would be infringed by use of the dosage regimen for FKB's products for which the declarations were sought. AbbVie then argued that the declarations sought would not serve any useful purpose because, as a result of AbbVie's acts, FKB had already cleared the way. However, **Henry Carr J** held that there was a real prospect that the judge at trial would grant the declarations sought because: (i) it could be implied from AbbVie's refusal to submit to judgment, or to provide an acknowledgement to the declarations sought, that the declarations serve a useful purpose to FKB; (ii) the spin-off value of a judgment in a contracting state could be very valuable; (iii) the declarations sought would protect FKB's supply chain to the UK and other parts of Europe in the sense that it would comfort third parties; (iv) the declarations sought would provide more clarity than AbbVie's undertakings; and (v) the declarations sought would promote settlement in that they change the parties' negotiating positions.

⁶⁶ See footnote 54, *ante*

⁶⁷ [2012] EWHC 1848 (Pat)

⁶⁸ See footnote 13, *ante*

⁶⁹ *Sandvik v Kennametal* [2011] EWHC 3311 (Pat)

⁷⁰ [2004] EWCA Civ 1568

⁷¹ [2007] EWHC 1900 (Pat)

⁷² From *Gillette Safety Razor Company v Anglo-American Trading* (1913) 30 RPC 465, in particular Lord Moulton's speech at pp. 480-481

⁷³ See footnote 5, *ante*

⁷⁴ *Fujifilm v AbbVie* [2016] EWHC 2204 (Pat)

⁷⁵ In its first decision of 2017, the Court of Appeal has upheld the first instance decisions and held that as a matter of principle the declarations can be made: *Fujifilm v AbbVie* [2017] EWCA Civ 1

⁷⁶ *Fujifilm v AbbVie* [2016] EWHC 3383 (Ch)

The upshot of the three decisions is that the case against AbbVie proceeded to trial and was heard in January 2017.

Supplementary Protection Certificates (SPCs)

What was once a torrent of references to the Court of Justice of the European Union (CJEU) on SPCs has now become a trickle⁷⁷. But the trickle continues. There was one reference in 2016: *MSD v Comptroller of Patents*⁷⁸, in which **Arnold J** referred questions concerning the application of **Articles 3(b)** and **10(3)** of the **SPC Regulation**⁷⁹, i.e. whether a valid MA had been granted at the time of the SPC application and, if not, whether an irregularity could be subsequently rectified by the applicant⁸⁰. At the time of MSD's SPC application in relation to its ezetimibe/atorvastatin product, whilst the decentralised procedure had concluded and an 'End of Procedure' notice had been sent, the Medicines and Healthcare products Regulatory Agency had not yet adopted the decision to grant a UK MA. MSD no doubt chose to file its SPC application before MA grant because the patent on which it relied was due to expire the day after the application was filed, hence it was left with little room for manoeuvre. **Arnold J** asked the CJEU whether an End of Procedure notice can be considered equivalent to a granted MA for the purposes of **Article 3(b)** and, if not, whether MSD could cure the irregularity under **Article 10(3)** upon grant of the UK MA. **Arnold J** agreed with the IPO's reasons in rejecting the application, namely that an End of Procedure notice is not only not mentioned in the SPC Regulation, but does not have any legal effect and certainly does not allow a third party to market its product in the UK. Also, the Judge noted that **Article 10(3)** allows an applicant to remedy a failure to file a copy of its MA with the application but, in his opinion, cannot be used to overcome the requirement in **Article 3(b)** to hold a granted MA at the time of the application.

The sole decision from the CJEU in 2016 concerning the interpretation of the **SPC Regulation** followed a reference from the Estonian Supreme Court⁸¹. The case concerned the chemotherapeutic agent capecitabine, which is marketed by Roche under the brand name Xeloda. Roche had obtained an MA in Switzerland in 1998 and in Estonia in 2001. Calculating the duration of the SPC on the basis of the former would have resulted in SPC expiry in 2013 and on the latter in 2016. Roche contended that as the SPC was issued prior to Estonia joining the EU, Estonian law applied – according to which the duration of the SPC should be calculated by reference to the Estonian MA. The CJEU disagreed; the Swiss MA was to be considered the relevant MA.

The UKIPO issued an interesting decision concerning Abraxis' application for an SPC for paclitaxel formulated as albumin nanoparticles ("nab-paclitaxel"), the formulation of its anti-cancer drug Abraxane⁸². Abraxis contended that nab-paclitaxel was a new single active ingredient and therefore a new "product" for the purposes of **Article 1(b)** of the **SPC Regulation** that was distinct from paclitaxel, which had previously been the subject of an MA. The Hearing Officer disagreed and concluded that nab-paclitaxel was in fact a combination of active ingredients. Despite demonstrating that nab-paclitaxel had a distinct pharmacological activity when compared with paclitaxel, Abraxis was not able to demonstrate that the albumin component had a therapeutic effect of its own. As a result, in accordance with CJEU jurisprudence stating that all active ingredients in a combination must have their own therapeutic effect⁸³, Abraxis was not entitled to an SPC. In the alternative, Abraxis argued that the CJEU decision in *Neurim* (C-130/11) should be construed broadly to allow for SPCs not only for new indications but also for new formulations. The Hearing Officer also rejected this submission. However, the decision has been appealed and **Arnold J** has subsequently decided to refer the latter issue, concerning **Article 3(d)**, to the CJEU⁸⁴.

Damages

Section 69 Deductions

HHJ Hacon dealt with an interesting point on damages following the Court of Appeal's finding on infringement in AP Racing's favour⁸⁵. Despite accepting that the infringing brake calipers fell within the claims of the application, Alcon argued that AP Racing was not entitled to all damages back to the date of publication of the application under **section 69** of the **Act**. It asked for a deduction to be made under **section 69(3)** because, as there was prior art cited against the majority of the claims in both the EPO and UK IPO search reports, the skilled person would not reasonably expect those claims to be granted and, therefore, did not reasonably expect the patent to grant with the same scope of protection. The Judge noted that, even if it was right to say that the skilled person would look at the search reports, it did not follow that the prior art in the search reports gave rise to a reasonable expectation that those claims would not be granted. In any event, **HHJ Hacon** recorded Alcon's evidential difficulty in sustaining its argument, the Judge having taken the deliberate decision in an earlier case management conference to refuse further evidence on the skilled person's reasonable expectations in all the relevant circumstances on the basis that the issue did not satisfy the cost/benefit test applied to all issues in the IPEC.

77 Albeit that, with two references already made in 2017 at the time of writing, the flow may return

78 [2016] EWHC 1896

79 Regulation (EC) No. 469/2009

80 CJEU reference C-567/16

81 *F. Hoffmann-La Roche v Accord Healthcare* (C-572/15)

82 *Abraxis BioScience BL* O/410/16

83 *MIT* (C-431/04), *GSK* (C-210/13)

84 *Abraxis BioScience v Comptroller-General of Patents* [2017] EWHC 14 (Pat)

85 *AP Racing v Alcon Components* [2016] EWHC 116 (IPEC)

Costs

Overall Winner

Generally, when assessing costs, the English courts continue to follow the issue-based approach exemplified by **Jacob LJ** in *SmithKline Beecham v Apotex*⁸⁶ and repeated in *MMI v Cellxion*⁸⁷:

"An issue-by-issue approach is therefore one that should be applied so far as it reasonably can. On the other hand such an approach is not the be-all and end-all. Whether or not "it was reasonable for a party to raise, pursue or contest a particular allegation" remains a relevant factor to be taken into account as part of the conduct of the parties."

Henry Carr J's costs decision in *Hospira v Cubist*⁸⁸ concerned the circumstances in which costs payment may be shifted, such that the overall winner pays the loser's costs of a particular issue. Referring to *MMI v Cellxion* and the commentary in the "White Book", it was established that an issue-based costs order should only be made in a "suitably exceptional case", requiring something more than success on the issue in question. **Henry Carr J** also made clear that "exceptional" is not intended to imply that the award of costs will be extremely rare. In the case before him, he decided to shift the order for payment on two issues: (i) Hospira's case that the patent in suit was insufficient, "obviously a bad point" on which it failed at trial; and (ii) Hospira's challenge to the first priority date, a point on which Cubist succeeded at trial. The latter fell into the "suitably exceptional" category because upon receiving a first tranche of disclosure from the patentee, Hospira refused to admit certain facts and insisted on pursuing further disclosure to see if anything inconsistent turned up.

Following his finding that Unwired Planet's patent was invalid⁸⁹, **Birss J** looked carefully at the law relating to when not to simply make deductions for distinct issues on which the overall winner did not prevail, but also award costs to the losing party. The Judge took the view that the law had moved on from the "suitably exceptional" test described in *Monsanto*⁹⁰ to a more measured test: whether it is appropriate, in the circumstances of the case, to make the Order the Court is considering. The Judge also commented on the percentage approach to costs that has become the "norm" in patent cases. Although the approximate nature of this exercise cannot be overstated, it was considered that the alternative of having a detailed assessment does not obviously produce a better approximation of justice, especially in view of the significant extra cost. However, one must be aware of the difficulties associated with the rough and ready assessment of these percentages using the proxy methods available, especially as a small percentage

difference can equate to a large sum of money. Applying this logic, the Judge made several deductions to the successful defendants' costs, but did not award the patentee any costs. Part of his consideration was that the patentee had initially contended that 69 claims were independently valid but, by trial, this number had reduced to three.

Indemnity Basis

Rapiscan were ordered to pay the costs of AS&E's infringement case on an indemnity basis after it failed to admit that offers to dispose of the infringing products had been made in its marketing materials⁹¹. Despite it being abundantly clear from the outset that the marketing materials were in issue, Rapiscan only admitted infringement after the first day of trial following concessions during cross examination of its managing director. **Arnold J** noted that it must have known all along that it had been making these offers and that its failure to make the necessary admissions cause the expenditure of a great deal of money.

Summary Assessment

For the first time, the costs of a patent action have been summarily assessed following cost budgets being drawn up and accepted as reasonable and proportionate⁹². Having found that SSH's patent was infringed but invalid, **Roger Wyand QC**, sitting as Deputy Judge, had to grapple with the provisions allowing a party to depart from an approved budget. Following the approach set out by the Court of Appeal in *Henry v News Group*⁹³, it was noted that whilst it was possible to depart from the budget, it should only be done when the Court is satisfied that there are good reasons to do so having considered all the circumstances. Sony was allowed to increase the budget for both the expert report and trial phases as the case was said to have developed in a way that neither party had anticipated. Sony was also permitted to amend the apportionment figures that it had voluntarily added to the cost budget to estimate the split of costs between the issues of validity and infringement and it was noted that where that was wrong it would be invidious of the Court not to make its own assessment. This seems to be a lenient approach, given the rigours of the cost budgeting regime.

Procedural Issues

Experts

Readers may recall the guidance given by **Arnold J** in *MedImmune v Novartis* on the preparation of expert reports in patent cases⁹⁴. **Arnold J** highlighted, in particular, two "common traps for the unwary", the first of which was to take care to present a balanced view of the prior art and not just cherry-pick the bits that best support the expert's view.

86 [2004] EWCA Civ 1703

87 [2012] EWCA Civ 139

88 [2016] EWHC 2661 (Pat)

89 *Unwired Planet v Huawei* [2016] EWHC 410 (Pat)

90 *Monsanto v Cargill* [2008] FSR 417

91 *American Science & Engineering v Rapiscan* [2016] EWHC 1384 (Pat)

92 *Sony v SSH* [2016] EWHC 2985 (Pat)

93 [2013] EWCA Civ 10

94 [2011] EWHC 1169, at paras 99-114

Interestingly, in *Hospira v Cubist*⁹⁵, **Henry Carr J** seemed to be quite relaxed about this point. Upon reviewing criticism of Cubist's expert for selectively quoting from a textbook, he noted that *"it is important to keep criticisms of this nature in perspective (...) Experts have to choose which sections to quote from texts, and it is often suggested that they have not included material passages. I do not consider that [Cubist's expert] was trying to mislead the court"*⁹⁶.

Arnold J has now issued further guidance relating to experts, this time on the cross-examination of expert witnesses in patent cases. Set out over two pages in his judgment in *Merck v Shionogi*⁹⁷, he urges caution if criticising an expert for omissions from evidence unless it is clear that the fault lies with the expert rather than the instructing legal team: *"cross-examiners must refrain from using the fact that the expert has not mentioned something in their report as a stick to beat the witness with unless the cross-examiner has real grounds for suggesting that this reflects on the witness' impartiality, competence or approach to the issues rather than upon the instructions they have been given"*⁹⁸. More generally, he takes the view that too much time is spent by cross-examiners in patent cases on personal attacks that are unfair to the witness, unhelpful to the Court and wasteful of expensive time.

Continuing to have a strict view on the approach to expert evidence, **Arnold J** considered two different approaches to an expert's consideration of obviousness in *American Science and Engineering v Rapiscan Systems*⁹⁹. Both parties followed the structured approach of asking their expert to consider the skilled person and the CGK, then the prior art and finally the patent. The difference arose at the point that each expert was asked to consider obvious steps. AS&E's expert considered this question before seeing the patent. As a result, his considerations were necessarily conducted in the absence of knowledge of the patent but his evidence did not address whether the differences between the prior art and the claimed invention were obvious. However, the Judge viewed this favourably compared to Rapiscan's approach. Its expert was not asked to consider the question of obviousness until after he had read the patent. Further, when asked in cross examination, its expert confirmed that his understanding of the question of obviousness was by reference to the claims. As a result, the Judge noted that he did not appear to have understood the importance of trying to avoid hindsight. It would appear that to avoid criticism the expert must state that he is aware of the dangers of hindsight and has avoided it.

Scientific Advisers

The body of case law on scientific advisers was reviewed by **Birss J** in a case management hearing between EMGS and PGS¹⁰⁰. PGS proposed that the Court be assisted by an adviser versed in the relevant technology. EMGS

resisted, arguing that the case was no more complex than usual and that, crucially, it was concerned that there would be a lack of transparency about what information the Court was receiving. Furthermore, as there was a dispute about the fundamental science involved, EMGS argued that a scientific adviser might unwittingly impart views on this topic without the parties being aware. This problem had been acknowledged by the Court of Appeal in *Halliburton*¹⁰¹, but the Judge reiterated that a fair minded and reasonable observer would understand the respective roles of the Court and the scientific adviser and that it was the task of the Court, not the scientific adviser, to decide the case. Adopting a similar approach to *Nokia v Interdigital*¹⁰², the Judge received a non-controversial private day-long teach-in from a neutral scientific adviser, following which the adviser played no further role in the case. Despite the parties settling after trial, **Birss J** gave judgment on the utility of the teach-in¹⁰³. He noted that, without the parties present, he was able to ask candid questions and learned a lot. This allowed the trial to proceed more briskly, saving time and cost. Having the adviser's instructions settled by the Court in advance and then making the written material available to parties after the teach-in ensured an appropriate degree of transparency.

Jurisdiction

Readers will be familiar with the early decisions in the *Actavis v Eli Lilly* litigation concerning pemetrexed, where the English courts held that they did have jurisdiction to grant declarations of non-infringement in relation to foreign designations of a European patent in circumstances where validity was not in issue¹⁰⁴. An interesting contrast came before **Arnold J** last year in *Anan Kasei v Molycorp*¹⁰⁵. The patentee had brought proceedings before the Patents Court for infringement of the UK and German designations of its European patent. The defendant wished to challenge the validity of the patents and having commenced nullity proceedings in Germany, consequently challenged the jurisdiction of the English court to hear the infringement case on the basis that the German courts have exclusive jurisdiction to consider the validity of the German patent under **Article 24(4)** of the **Recast Brussels I Regulation**¹⁰⁶ and the two were intertwined. **Arnold J** applied the reasoning in *GAT v LuK* (C-4/03) and *Solvay v Honeywell* (C-616/10), holding that the infringement claim was *"concerned with"* or, at least, *"principally concerned with"* the validity of the German patent (therefore within the exclusive jurisdiction of the German courts under either **Articles 24** or **27** of the **Regulation**), as it was implicit in a finding of infringement that the patent was valid, as there cannot be infringement of an invalid patent. This was despite the claimant's *"transparent attempt"* to circumvent the scope of the **Regulation** by drafting the claim in such a way that it was acknowledged that any finding of infringement would be conditional on a ruling of validity in the German proceedings.

⁹⁵ See footnote 41, *ante*

⁹⁶ *Ibid.*, at para 21

⁹⁷ [2016] EWHC 2989 (Pat), at paras 87-93

⁹⁸ *Ibid.*, at para 89

⁹⁹ See footnote 49, *ante*

¹⁰⁰ *Electromagnetic Geoservices v Petroleum Geo-Services* [2016] EWHC 27 (Pat)

¹⁰¹ *Halliburton v Smith International* [2006] EWCA Civ 1599

¹⁰² [2007] EWHC 3007 (Pat)

¹⁰³ *Electromagnetic Geoservices v Petroleum Geo-Services* [2016] EWHC 881 (Pat)

¹⁰⁴ [2012] EWHC 3316 (Pat) and [2013] EWCA Civ 517

¹⁰⁵ [2016] EWHC 1722 (Pat)

¹⁰⁶ Regulation (EU) No. 1215/2012

Meanwhile, the concurrent jurisdiction of the Patents Court and the Competition Appeal Tribunal (“CAT”) was considered by **Birss J** when considering the correct forum for the non-technical aspects of a case involving standard essential patents¹⁰⁷. It has only been possible to transfer a stand-alone case to the CAT since 1 October 2015, so this is a relatively new issue with which to grapple. The large scale litigation between Unwired Planet and Samsung and Huawei involved disputes about FRAND licences as well as counterclaims for breaches of competition law based on Unwired Planet’s acquisition of the patents from Ericsson. Samsung applied to transfer the competition aspect under **section 16(1)(a)** of the **Enterprise Act 2002**, which provides that the court can transfer to the CAT “so much of any proceedings before the court as relates to an infringement issue”. In this context, an “infringement issue” is one relating to a possible breach of **Art 101** or **102** of the **Treaty on the Functioning of the European Union**. The Judge considered relevant provisions of **CPR Practice Direction 30** as well as the decision of **Barling J** to transfer the case to the CAT in *Sainsbury’s v Mastercard*¹⁰⁸. Considering these together with the overriding objective, the Judge set out some key factors to consider, including creating delay or additional cost, the assistance of the two economic and competition specialist panel members in the CAT as well as the issues created by dividing the case between the two tribunals. However, when considering the breadth of the possible transfer, it was noted that the power conferred by the section was not wide enough to allow the transfer of the distinct issues that did not themselves concern a competition law infringement issue, even if they arise in the same context and raise closely related factual, legal and policy questions. In particular, the contractual FRAND issues, which did not relate to a breach of competition law, could not be transferred. As a result, and “not without some regret”, **Birss J** concluded that it was not practical to divide the case, especially considering the centrality of the FRAND issues in suit. To do so would have been a recipe for confusion.

Trial Dates

“An important change to the management of patent cases” is how **Henry Carr J** described the Practice Statement of 7 December 2015¹⁰⁹, the purpose of which is to bring patent cases on for trial where possible within 12 months of the claim being issued, something which the parties are expected to cooperate to achieve. Explaining that the policy of the new practice is to make the English courts more competitive with courts in Europe generally, and Germany in particular, in *Celltrion v Biogen*¹¹⁰ **Henry Carr J** used the practice direction to order a split trial of a multi-patent revocation action within the 12-month guideline.

The same Practice Statement was used by **HHJ Hacon** in *Fujifilm v AbbVie*¹¹¹ to decide that it was not appropriate to adjourn the listing of a trial pending the determination of the jurisdictional challenge and strike out application. While it was true that the 12-month goal was not a straitjacket, the Judge ruled that it should not be set aside just because of the existence of the jurisdictional challenge and the strike out application.

The *Napp v Dr Reddy’s* proceedings are a remarkable example of the degree of expedition which can be achieved with adequate case management and the cooperation of the parties. Despite the complexity of the issues in suit, the case proceeded from issue of the claim to a final decision on appeal within less than six months¹¹². Both **Arnold J** at first instance and **Floyd LJ** on appeal saw fit to record this feat, appreciating the effort of the parties’ legal teams.

Amendment

An interesting question relating to amendment arose on the appeal of the *Warner-Lambert v Actavis* case¹¹³, namely whether it was an abuse of process for Warner-Lambert to seek post-trial amendment of one of the claims, being a limiting amendment which made express the meaning of the claim Warner-Lambert put forward at trial (which had been rejected). The Court of Appeal upheld **Arnold J**’s decision that to do so would amount to an abuse of process. Although **Floyd LJ** confessed to being attracted at one point by Warner-Lambert’s argument that it would not be abusive because in principle there would not be any new subject matter before the court, the case at trial may have run a different course had Warner-Lambert indicated at the start of trial that the amendment would be sought on a conditional basis – in particular, the focus of Actavis’ evidence may have changed. In the Court’s view there was no getting away from the fact that Warner-Lambert should have raised the amendment issue earlier. Pursuing the amendment post-trial would have effectively constituted Warner-Lambert having a second bite of the cherry.

Disclosure

2016 marked a turning of the tide in relation to disclosure in patent cases. In truth, the tide had turned some years earlier with the amendment of **CPR 31.5** in 2013, following the Jackson reforms. **CPR 31.5** sets out a menu of options for disclosure, ranging from an order dispensing with it to an order to give standard disclosure. As a result there is no longer a *prima facie* rule in favour of standard disclosure. This applies even in patent cases, where the parties’ disclosure obligations are already limited by **CPR Practice Direction 63 para 6.1**. This was made clear by **Birss J** in *Positec v Husqvarna*¹¹⁴ in a case about robotic lawnmowers. Having quoted **CPR 31.5(7)**, the Judge said:

¹⁰⁷ [2016] EWHC 958 (Pat)

¹⁰⁸ [2015] EWHC 3472 (Ch)

¹⁰⁹ Practice Statement: Listing of Cases for Trial in the Patents Court

¹¹⁰ [2016] EWHC 188 (Pat)

¹¹¹ Unreported. LTL 28/6/2016 EXTEMPORE

¹¹² The Court of Appeal informed the parties that the appeal would be dismissed extempore at the hearing on 2 August 2016, the claim having been filed on 19 February 2016. The full reasoned judgment was published on 1 November 2016.

¹¹³ See footnote 9, ante

¹¹⁴ See footnote 2, ante

*“Two things emerge from this. First is the reference to the overriding objective and the need to limit disclosure to that which is necessary to deal with the case justly. This helps to focus the court’s mind on the task to be undertaken. Second, and critically, is that the effect of this provision is that standard disclosure is one of six options. Counsel for Husqvarna submitted that this meant that standard disclosure was not the default option any more. I agree. The Chancery Guide (paragraph 17.35) makes the same point. As the Guide states, careful consideration should be given to the alternatives to standard disclosure.”*¹¹⁵

Although it was contended by Positec, the defendant seeking 4-year window disclosure from Husqvarna, that *Nichia v Argos*¹¹⁶ prevented the Court adopting a *prima facie* rule dispensing with standard disclosure, **Birss J** held that *Nichia* was no longer binding authority in light of the amendment to **CPR 31**. In *Positec*, the value of the dispute was characterised as somewhere in the middle of the range usually before the Patents Court. The Judge held that the cost of the disclosure exercise (£90,000, against total budgeted costs of about £1 million on each side) was not justified by its probative value, bearing in mind that it went only to the pleaded issue of obviousness and no reliance had been placed by the patentee on the invention story, aspects of which could have been illuminated by the exercise.

Some months later, the change to **CPR 31.5** and the *Positec* case was used by **Henry Carr J** to refuse a disclosure request in the *Illumina v Premaitha* proceedings¹¹⁷, on any view a large, high value and important case pending before the Patents Court. The Judge encapsulated the change in climate as follows:

*“[The defendant’s solicitors], both very experienced solicitors, have made the point that in major patent actions in the United Kingdom, such as the present, it is not uncommon for the parties to review 10,000 or more documents. No doubt this has historically been the case. The judgment of Birss J in the Positec case and the present judgment, I hope, indicate that, given the changes in the rules and the menu-based option, this practice needs to be re-assessed against a proper cost benefit analysis. For these reasons, I decline to grant [the defendant’s] request.”*¹¹⁸

The request refused in the *Illumina* case was for documents traversing a 14-year period, estimated to require review of tens of thousands of documents, but which documents had already been disclosed in related proceedings in the US. The documents were said to support the argument that the invention, relating to a gene sequencing tool used

for non-invasive antenatal screening, overcame significant difficulties in the prior art. Disclosure of a similar scope had already been ordered in connected proceedings in relation to one of the other patents in suit, just a few months earlier, but before *Positec* had been decided. **Henry Carr J** noted that the same order would no longer be made. However, he did agree that the documents which had already been disclosed in the connected proceedings could be shared with the defendants in the present proceedings given that the cases were to be heard together.

Meanwhile, **Birss J** confirmed that the service of a Product and/or Process Description (PPD) dealing with the nature and characteristics of the product or process in issue and the question of whether that falls within the claims, does not relieve a party of the obligation to provide disclosure in relation to other factual issues in the case. This dispute arose in *Varian v Elekta*¹¹⁹, in which the defendants had not provided disclosure in relation to the factual question of whether certain acts had been carried out. It was noted that, although in many cases there is no debate on these issues or the PPD includes admission such that no disclosure is needed, **CPR 63 r63.9** and **Practice Direction 63 para 6.1** do not negate the obligation to provide disclosure on these issues. Although some disclosure was later provided, it was found not to comply with Elekta’s obligation and the Judge put in place an “unless order”, of which Elekta was subsequently found to be in breach¹²⁰.

In *Anan Kasei v Molycorp*¹²¹, **Arnold J** rejected an application for the provision of samples to support infringement proceedings in Germany. The Judge held that the question of whether the Court has the power to grant such an order was a matter of English law independent of the application of the **Recast Brussels I Regulation**. Having reviewed the available routes whereby the Court has the power to order the provision of samples, **Arnold J** concluded that the Court would only have such power pursuant to a request from the German court (the patentee had not even commenced German proceedings yet). The Judge however noted that, were the Court to have power, it would be expedient in the circumstances to grant the order sought.

Experiments

Birss J confirmed in *Electromagnetic Geoservices*¹²² that computer modelling should be subject to the regime for Notices of Experiments and endorsed the reasoning of **Pumfrey J** in *Consafe v Emtunga*¹²³. He stressed that the same difficulties arise as with any other experiments, namely that the output of modelling depends on the input and that running the same test with different data could produce a different result. The key factor to ensure that the experimental result relied upon is genuine is the availability of witnessed repeats. Whilst it may be that the other party can

¹¹⁵ [2016] EWHC 1061 (Pat), at para 21

¹¹⁶ [2007] EWCA Civ 741

¹¹⁷ See footnote 3, *ante*

¹¹⁸ *Ibid*, at para 29

¹¹⁹ [2016] EWHC 2679 (Pat)

¹²⁰ *Varian v Elekta* [2017] EWHC 55 (Pat)

¹²¹ See footnote 105, *ante*

¹²² See footnote 100, *ante*

¹²³ [1999] RPC 154

run the model themselves, this critically depends on all the data and code being made available to it. He also stressed the importance of explaining to the Court the role the experiments would play in the case so as to allow the Court to make further appropriate directions.

Interim Injunctions

One of the consequences of the Court of Appeal decision in *Warner-Lambert v Actavis*¹²⁴ is that, although Warner-Lambert is continuing to pursue an appeal to the Supreme Court, it has stated that it will not prevent generics from marketing pregabalin for indications which are protected only by claims held invalid by the Court of Appeal. In particular, it said it would not seek an injunction based on claim 3, directed specifically at neuropathic pain and held to be invalid on the basis that it was not plausible that pregabalin was an effective treatment for both central and peripheral neuropathic pain. This was seized upon by Sandoz, which had been the subject of an interim injunction in respect of its full-label product at the end of 2015, having launched shortly after the patent had been held invalid at first instance. Although **Arnold J** rejected Sandoz' submission that the Court of Appeal's decision to uphold the first instance decision on validity amounted to a material change in circumstances that might justify reconsideration of the interim injunction decision, **Arnold J** accepted that Warner-Lambert's concession regarding the enforcement of the claims held invalid was material.

Notwithstanding Sandoz' argument that it would be disproportionate for the injunction to remain in place given that the asserted claims covered a small proportion of the market, **Arnold J**, admitting that he had "*not found this an easy question to decide*", upheld the injunction against Sandoz. Having conducted an assessment of the *American Cyanamid* questions¹²⁵, he was persuaded that the harm to Warner-Lambert in allowing Sandoz' product on to the market was greater than the loss of first mover advantage to Sandoz under the injunction. In particular, Sandoz was using a full label and full-label products are very much preferred by certain pharmacy chains because they only have to keep in stock and dispense one product. The Judge held that entry of a Sandoz full-label product would mean other full-label generics would quickly follow, and soon there would be a "*free-for-all in the full label market*" (in which, presently, the only full-label product is Warner-Lambert's). The Judge also took note of the fact that the size of the market at risk included indications which were outside the full label, but covered by the claims of the patent, and that these off-label uses, amounted to almost 14% of the market. He was unpersuaded by Sandoz offering to take steps to prevent prescribing of its full-label product.

Until 2016, *Novartis v Hospira*¹²⁶ stood alone as an example of a case in which an unsuccessful patentee still managed to secure an interim injunction pending appeal. Readers will recall that in that case, Novartis' patent relating to zoledronic acid was revoked at first instance but Novartis nevertheless secured an injunction, which was lifted when the Court of Appeal upheld the revocation decision. 2016 brought a further example of this type of "Hail Mary" injunction. In *Napp v Dr Reddy's*¹²⁷, Napp lost on the merits of the infringement case relating to its patent for buprenorphine transdermal patches, **Arnold J** dismissing Napp's *quia timet* action against Dr Reddy's and Sandoz. However, **Arnold J** granted Napp permission to appeal the non-infringement decision on claim construction, including the point relating to numerical ranges mentioned earlier in this review. Napp applied for an interim injunction. **Arnold J** granted the application¹²⁸ on the basis that the fixed period of the injunction he granted was short (based on the information before him and the limited nature of the appeal, he estimated that the Court of Appeal could determine the case within a couple of months) and that the balance of injustice favoured Napp. A number of generics were waiting in the wings and it seemed inevitable that, if Dr Reddy's or Sandoz launched, there would be a price war and significant price depression. Although the decision risked causing irreparable harm to Dr Reddy's and Sandoz, promotion by Napp of an authorised generic product in the intervening period meant that the generics' first mover advantage was already compromised. Interestingly, the Judge expressed concern that the Court of Appeal decision granting the injunction in *Novartis v Hospira* had not considered the Privy Council case of *National Commercial Bank of Jamaica v Olint*¹²⁹, in which **Lord Hoffmann** made clear that the strength of the arguments on the merits of the proposed appeal was a factor the courts may take into account. Here, his view was that Napp's case was weak, but he felt obliged to follow the Court of Appeal in *Novartis v Hospira*. This emphasises that the Court will not normally form a view on the strength of the merits provided the threshold has been cleared of showing that there is a real, as opposed to a fanciful, prospect of success on appeal.

Final Injunctions

Are the remedies for a contractual breach of a settlement agreement not to infringe any different than for infringement *per se*? This issue was explored by **Henry Carr J** in *Stretchline v H&M*¹³⁰. Readers may recall from the Court of Appeal case¹³¹, reported last year, that the parties had entered a settlement agreement to compromise claims of patent infringement in relation to the use of fusible yarn in brassieres to prevent penetration of the underwires. The Court of Appeal refused to allow the validity of the patent to be challenged owing to the existence of the settlement agreement. The question now arising was whether the Court would grant an injunction to restrain further breach

¹²⁴ See footnote 9, *ante*

¹²⁵ *American Cyanamid v Ethicon* [1975] UKHL 1

¹²⁶ [2013] EWCA Civ 583

¹²⁷ See footnote 15, *ante*

¹²⁸ *Napp v Dr Reddy's* [2016] EWHC 1581 (Pat)

¹²⁹ [2006] UKPC 16

¹³⁰ [2016] EWHC 162 (Pat)

¹³¹ *Stretchline v H&M* [2015] EWCA Civ 516

following the identification of certain acts alleged to infringe in breach of the agreement. **Henry Carr J** noted that, in principle, an injunction could be granted for breach of contract in these circumstances. However, on the evidence, it was not appropriate. Injunctions are discretionary remedies and there was no evidence of a continuing threat to infringe. Also, the terms of the settlement agreement required the parties to pursue a cooperation mechanism before bringing court proceedings. The Judge also refused Stretchline's request for *Island Records*¹³² disclosure to enable it to elect between damages and an account of profits. An account of profits is a statutory remedy for patent infringement and, whilst it was possible in principle for the Court to make the same order for breach of contract¹³³, this was appropriate only in exceptional circumstances, which did not exist here.

In *Actavis v ICOS*¹³⁴ **Birss J** shed further light on his approach to *quia timet* injunctions in *Merck v Teva*¹³⁵. In that case, he considered that all of the relevant circumstances should be viewed objectively and subjectively to decide whether there is a sufficiently strong probability that an injunction would be required to prevent the harm to the claimant such that it is justified in bringing proceedings for infringement. Significantly, in this case the Judge added that, although bringing revocation proceedings is not proof of an intention to sell, it does help support that inference based on the existence of an MA application. In other words, the act of clearing the way can add to the injunction risk. **Birss J** found that ICOS' infringement counterclaim with regard to its tadalafil dosage regimen patent was justified because: (i) the UK market for tadalafil is large and valuable; (ii) it was obvious that a generic would want to sell tadalafil once the SPC had expired; (iii) Actavis had applied for an MA which is an expensive and time consuming process; (iv) Actavis had brought proceedings to clear the way; (v) launching at risk could be attractive and profitable even if stopped by an emergency injunction; and (vi) Actavis had not given any undertaking that it would abandon its MA if the revocation action was lost. Therefore, it appears that, in some circumstances, to avoid being subject to a *quia timet* injunction, a generic seeking to clear the way should also provide an undertaking to the relevant patentee that it will not launch its generic product unless the patent is revoked or until the patent expires.

Permission to Appeal

Until recently, applications for permission to appeal in patent litigation were treated by the courts as a special case, such that permission to appeal should be granted more easily than in other cases because of the complex technical subject matter¹³⁶. However, the Court of Appeal has held that this approach is no longer correct and that when considering permission to appeal, patent cases should no longer be treated differently to any other case¹³⁷. In *Teva v Boehringer*

Ingelheim, **Floyd LJ** stated: "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*¹³⁸ should no longer be followed"¹³⁹.

Unjustified Threats

We reported in last year's review on **HHJ Hacon's** refusal to grant summary judgment in *Global Flood Defence v Van Den Noort*¹⁴⁰, an action for groundless threats of patent infringement proceedings in relation to a patent application that had yet to grant, the Judge relying on the Court of Appeal's ruling in *Brain*¹⁴¹ to hold that a patent owner can seek to rely on the defence of justification upon patent grant under certain circumstances. The case took another turn when **HHJ Hacon** ordered the adjournment of the trial in circumstances where the EPO had at that time issued a notice of intention to grant the patent, but where formal grant would not take place until a week after the trial date¹⁴². Appeals against both decisions of the IPEC were decided in the Patents Court by **Arnold J**¹⁴³, who held that *Brain* (which concerned a threat to bring proceedings made on a contingent basis, i.e. if and when the patent application was granted) was not a direct authority on whether a threat of proceedings for infringement of a granted patent made when only the patent application existed was capable of being justified. Nevertheless, the Judge decided that **HHJ Hacon** had been correct to hold that such threats were capable of justification. He relied on the fact that **section 70 of the Act** provides for strict liability, meaning that there need be no proof of damage in order for a threat to be actionable. Were the Court to conclude that such threats could not be justified, it may inhibit commercial freedom of speech and prove an obstacle to settlement negotiations. In addition, in considering justification, the Court must consider whether the threat related to acts which would constitute infringement (which may take place pre-grant) and not whether the terms of the threat were justified. **Arnold J** also concluded that **HHJ Hacon** had not erred in principle in exercising his discretion to adjourn the trial pending the grant of the patent, as grant was imminent. However, it remains to be seen whether the trial date would be postponed in circumstances where the grant date was unclear or distant.

Stays Pending EPO Proceedings

In contrast to the old *Glaxo*¹⁴⁴ guidelines, the new *IPCom*¹⁴⁵ guidelines favour the stay of English proceedings, pending the outcome of parallel EPO proceedings, if all other things are equal. The relative timing of the two concurrent proceedings is often heavily influential as a factor in deciding whether or not to stay. This makes the decision of **Rose J**

¹³² *Island Records v Tring International* [1995] FSR 560

¹³³ *Attorney General v Blake* [2001] 1 AC 268

¹³⁴ See footnote 38, *ante*

¹³⁵ [2013] EWHC 1958 (Pat)

¹³⁶ *Pozzoli v BDM* [2007] EWCA Civ 588

¹³⁷ See footnote 1, *ante*

¹³⁸ See footnote 136, *ante*

¹³⁹ See footnote 1, *ante*, at 12

¹⁴⁰ [2015] EWHC 2087 (IPEC)

¹⁴¹ *Brain v Ingledew Brown Bannison & Garrett* [1996] FSR 341

¹⁴² *Global Flood Defence v Van Den Noort* [2016] EWHC 99 (IPEC)

¹⁴³ *Global Flood Defence v Van Den Noort* [2016] EWHC 1851 (Pat)

¹⁴⁴ *Glaxo Group v Genentech* [2008] EWCA Civ 23

¹⁴⁵ *IPCom v HTC Europe* [2013] EWCA Civ 1496

in *Eli Lilly v Janssen*¹⁴⁶ particularly interesting. Here, the EPO proceedings against Janssen's patent were well advanced and the English proceedings only just starting. However, a stay was refused on the basis that Lilly needed commercial certainty which the English proceedings were better placed to deliver. That is because the question of infringement was central to the English proceedings – Lilly was seeking a DNI. Furthermore, and most interestingly, Lilly needed to know in the near future whether to apply for an MA for its product, the risk being that, if granted, this could be used by Janssen as the basis for an SPC, thus subjecting Lilly to up to five more years of liability. Janssen offered various undertakings to provide Lilly with commercial certainty, but its failure to specify a royalty rate for damages or an account of profits in the event of a successful infringement claim meant that such undertakings were not enough.

Issues from the IPEC

The overall cap on costs in IPEC proceedings was subject to a new challenge in *Global Flood Defence v Van Den Noort*¹⁴⁷. The proceedings involved three issues: (i) a claim for unjustified threats of infringement proceedings that was adjourned; (ii) a claim for misrepresentation that failed; and (iii) a counterclaim for outstanding royalties that succeeded. A decision on whether to adjourn the assessment of costs turned on the meaning of the word "claim" in **CPR 45.31**, the relevant provision on the costs cap. If it meant the proceedings as a whole, costs could not be assessed until all issues were decided, whereas, if it meant all of the claims which had been the subject of a final determination, costs could be determined in relation to the second and third issues (applying the statutory cap) and the assessment of costs in the remaining issue could be done at a later stage (a separate cap applying to that part of the proceedings).

HHJ Hacon held that "claim" referred to a single set of proceedings and could therefore not be assessed until all issues were resolved, noting that any other interpretation would create uncertainty as to the potential liability for costs of litigants at the start of proceedings and could even incentivise parties to argue preliminary points or summary judgment applications in relation to individual issues in order to increase the maximum recoverable costs.

Unitary Patent / Unified Patent Court¹⁴⁸

Every year your author of this section re-reads his effort for the previous year to see how clear (or foggy) was his crystal ball. This year he has looked back not just to last year, but the year before when he said:

"Hence 2017 is more realistic, and your author's current best guess is second half 2017. To be predicting anything earlier would be a triumph of hope over experience...."

Last year he said:

"...don't bank on a Brexit de-railing the UPC, and certainly not in terms of your UPC planning."

Of course to pick and choose quotes in this way is a little mischievous. So to give balance, last year's piece also said:

"... one must ... have firmly in mind that it is not possible to be a part of the UPC if not also a part of the EU. That was decided by the CJEU in March 2011 in Opinion 1/09."

This last comment now seems a less wise insight. It is a view with which everyone who had ever expressed an opinion would have agreed a year ago, but is now very much a minority view. And it is this topic which will be of most interest to readers: can, and if so will, the UK continue its membership of the UPC now that the UK has decided, despite the 23 June 2016 referendum result, to proceed with ratification of the UPC? But first, a quick review of 2016.

2016 in a Nutshell

The Bristows UPC website reported over 40 latest news items in the pre-23 June period of 2016. These were mostly incremental progressions toward UPC start-up, notably including progress in both the UK and Germany toward their ratifications in the early part of the year. In May, Italy too started its process. Also in May, the application process for UPC judges was opened. Then came 23 June. Surprisingly (to some) business carried on as usual. Within a week of the UK vote, the Netherlands had ratified the UPC Agreement (UPCA) and a crucial Protocol on the Privileges and Immunities of the Court had been signed by 13 states including France and Germany. On 5 July at its first post-23 June meeting, with the endorsement of the UPC Preparatory Committee, the Chair (Alexander Ramsay) stated that work related to the technical implementation of the UPC should continue as normal. This would include the completion of the judicial recruitment process, and in line with that position, the Preparatory Committee:

- Agreed the Code of Conduct for representatives who appear before the UPC;
- Agreed consequential amendments to the Rules of Procedure to reflect the agreement on court fees;
- Endorsed a number of papers setting out the rules on financial management during the provisional application period, corporate function structure and regulations relating to judges and staff; and
- Endorsed the draft UPC budget and recognition that the budget will be a "living document" subject to amendment before its adoption by the Administrative Committee.

¹⁴⁶ [2016] EWHC 313 (Pat)

¹⁴⁷ [2016] EWHC 189 (IPEC)

¹⁴⁸ The Authors are grateful to Alan Johnson of Bristows for drafting this section of the review

On 2 August, the UK IPO published a guide: 'IP and BREXIT: The facts', in which it stated: *"The UK remains a Contracting Member State of the Unified Patent Court at present. We will continue to attend and participate in UPC meetings in that capacity. There will be no immediate changes."*

Nonetheless, it seemed to many that the combination of politics and the common understanding of the effect of CJEU Opinion 1/09 already referred to would make it very unlikely that the UK would ratify, because all that would happen would be that it would join the system, then leave it again within two years. This view was reinforced by the Prime Minister's "Brexit means Brexit" mantra and her references to freeing the UK of its deference to the CJEU – an integral part of the UPC system.

Pressure then built up on the UK to come to a decision. It was widely rumoured that if the UK would not ratify, or would not make a decision, the other states would go ahead without the UK. There was even a Protocol drafted (apparently removing the UK as a mandatory ratification country by reducing the number of mandatory countries from three to two) which was circulating round the capitals of Europe and was planned to be signed in February 2017 if necessary. Baroness Neville-Rolfe promised a decision at the Competitiveness Council meeting on 28 November, and it was a clear, no-strings-attached "yes". In its press release that day, the IPO quoted the Baroness as saying:

"The UK will continue with preparations for ratification over the coming months. It will be working with the Preparatory Committee to bring the UPC into operation as soon as possible."

And as a first step back on the track toward ratification, the UK signed the Protocol on Privileges and Immunities on 14 December. The Protocol was then laid before Parliament on 20 January to sit for 21 days as the next part of the process.

The most significant announcement since the UK decision to proceed was, of course, that by the Preparatory Committee on 16 January that the new system would start in December 2017 – given the terms of Article 89 UPCA (the commencement provision), on 1 December 2017.

The timetable going forward

The IPO's plan is to have the remaining steps toward UK ratification completed if possible before notice is given under Article 50, so by the end of March 2017. That may be slightly ambitious and certainly even if the remaining Parliamentary steps are completed in that timescale (approval in Committee of the Statutory Instrument ratifying the Privileges and Immunities Protocol), the preparation and signature of the formal instrument of ratification will come a little later. It will also be about May (officially 'spring') before Germany completes its own, delayed, ratification process. Nonetheless, all of this is consistent with the Preparatory Committee's 16 January 2017 announcement which said

that the Provisional Application Phase should start in about May. Since one important process to complete in this Phase is judicial appointments, anyone who has applied to be a UPC judge (legal or technical) can expect to hear about the fate of their application and potentially receive a call to interview, any time after then – although there are so many interviews to conduct that the waiting time may be several months.

Another significant date for the diary – especially for in-house patent attorneys – is "early September" which is the predicted start date for the "sunrise period" for opting out existing European patents.

And finally, before moving on and for the avoidance of doubt, the decision of the Supreme Court that Parliament must save a say in the giving of Article 50 notice can have no impact on the UPC timetable, whether or not the Bill has a smooth passage through Parliament.

The UK in it for the long haul?

Will the UK stay in the UPC post-Brexit or not? That is a very big question requiring a state of the art crystal ball. As already mentioned, the question has both a political and a legal element. The political element is one where no-one can have much more than an educated guess. It is clear, however, that the UK is genuinely committed to the UPC in the short term, and is entering into the system with at the very least an understanding that it will not necessarily be leaving on Brexit. The new IP Minister Jo Johnson (brother of Boris) seems unlikely, based on his initial statements, to change the Government's direction – and in any event it seems probable that the decision to proceed with the UPC was taken at a far higher level than the IP Minister – indeed probably at the highest level. Further, whilst Italy may not be ecstatic that Milan will lose the opportunity to host the London part of the UPC Central Division, there is for the most part great support in continental Europe for the UK to continue in the system. That being so, and if the domestic politics permits the UK to remain in the UPC, that leaves the legal element. The view that Opinion 1/09 means it is unlawful to be in the UPC whilst outside the EU is a very real issue and deserves at least a brief analysis, as do some related issues.

To re-cap, Opinion 1/09 was requested so as to approve (or not as it transpired) a previous iteration of what is now the UPCA. The Court held the then-existing draft Agreement incompatible with EU law. In so doing, it criticised various short-comings of the arrangements. These short-comings were remedied by including specific provisions in Chapter IV of the UPCA such as explicitly recognising the primacy of "Union law in its entirety". At no point in its Opinion did the CJEU state that the UPC was limited to EU member states, but the UPCA was drafted as an EU-only "club". With those amendments, it was thought unnecessary to re-seek CJEU approval, and in any event for technical reasons it would have been difficult to do so. Hence, it was merely

an assumption that the EU-only part of the arrangements was necessary. As the implications of the Brexit vote were thought through, so too was this assumption. Most pertinently, CIPA, IP Federation, and a few IPLA members including Bristows, sought an opinion of Counsel (Gordon/Pascoe) that concluded that the assumption was wrong. Continued membership of the UPC is possible from both a UK constitutional perspective and an EU constitutional perspective, in the latter case if the Chapter IV protections for EU law are retained and certain other steps are taken.

Unfortunately that is not the end of the story. At present no-one seems able to agree exactly what are the aforementioned “other steps” which need to be taken. They would obviously include technical (and rather minor) amendments to the UPCA to change references to such things as EU Member States. There would also be needed some way to extend the Unitary Patent and Language Regulations (1257/2012 and 1260/2012) to the UK if the UK wished to remain in the unitary patent part of the system as well as the UPC (though a hybrid arrangement where the UK was in the UPC, but not the UP, is eminently possible). But what else? The Gordon/Pascoe view is that the CJEU would need a new legal basis for accepting references from the UPC rather than reliance on the present version of Article 267 TFEU which entitles only national courts of EU member states to refer matters to the CJEU. The UPC is a curious beast, but can be regarded as a national court common to member EU states for so long as all relevant states remain in the EU, but not, according to Gordon/Pascoe, once the UK has left. That would therefore suggest that what is needed is an EU Treaty change, possibly as part of the Article 50 exit agreement, to enable the post-Brexit UPC to remain able to refer matters to the CJEU, and hence be fully compliant with EU law.

In the end, the old adage “where there’s a will, there’s a way” springs to mind when it comes to the legal element. One cannot predict the reaction of the CJEU to whatever is agreed, but the fact that the UPC has already survived two legal challenges in the CJEU by Spain/Italy then Spain alone, must give one hope, perhaps even confidence, that it would survive a third challenge in the future. In case it is not politically possible, however, for the UK to remain in the system post-Brexit, steps would have to be taken to ensure that a smooth UK departure from the UPC is possible. The UPCA has no exit provisions. This omission was pointed out in a paper written in June 2011 by, among others, your author, entitled “Concerns of Principle”. Regrettably this paper was largely ignored, including on this issue, but it should fortunately be relatively easy to draft and agree a transitional protocol to deal with a UK exit from the UPC. But let us hope that, not only will 2017 be the year when the UPC actually comes into force with the UK as a fully paid-up member, but that it will stay that way in the long term.

Looking Ahead to 2017

2017 is already shaping up to be an important year. Unless the cases settle, we can expect the Patents Court to decide whether to grant the first UK *Arrow* declaration in the FKB and Samsung Bioepis litigation against AbbVie; the Supreme Court to issue a decision in the *Actavis v Eli Lilly* case; and the first decision from the English courts on what constitutes a licence on FRAND terms in the *Unwired Planet* case. SPC enthusiasts can dwell on the further references that have already been made in 2017 on **Articles 3(a) and 3(d) of the SPC Regulation**. Procedurally, we can expect the courts to continue their drive to running cases in a more streamlined fashion, with proper consideration given to the cost-benefit analysis, and the timetable being such that most cases at first instance will be heard within a year. Of course, the most significant event of all will be the opening of the UPC in December. We look forward to reporting on all these events, and more, in next year’s edition.

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