BRISTOWS

Review of Patent Cases in the English Courts in 2015

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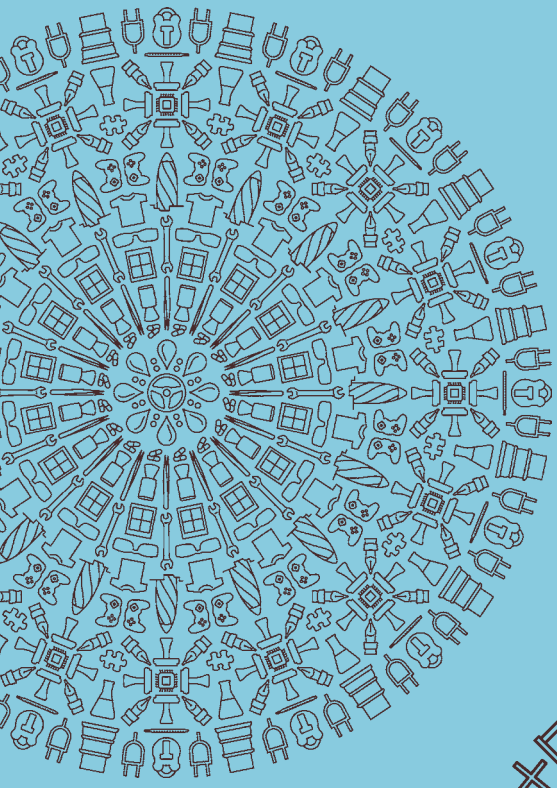

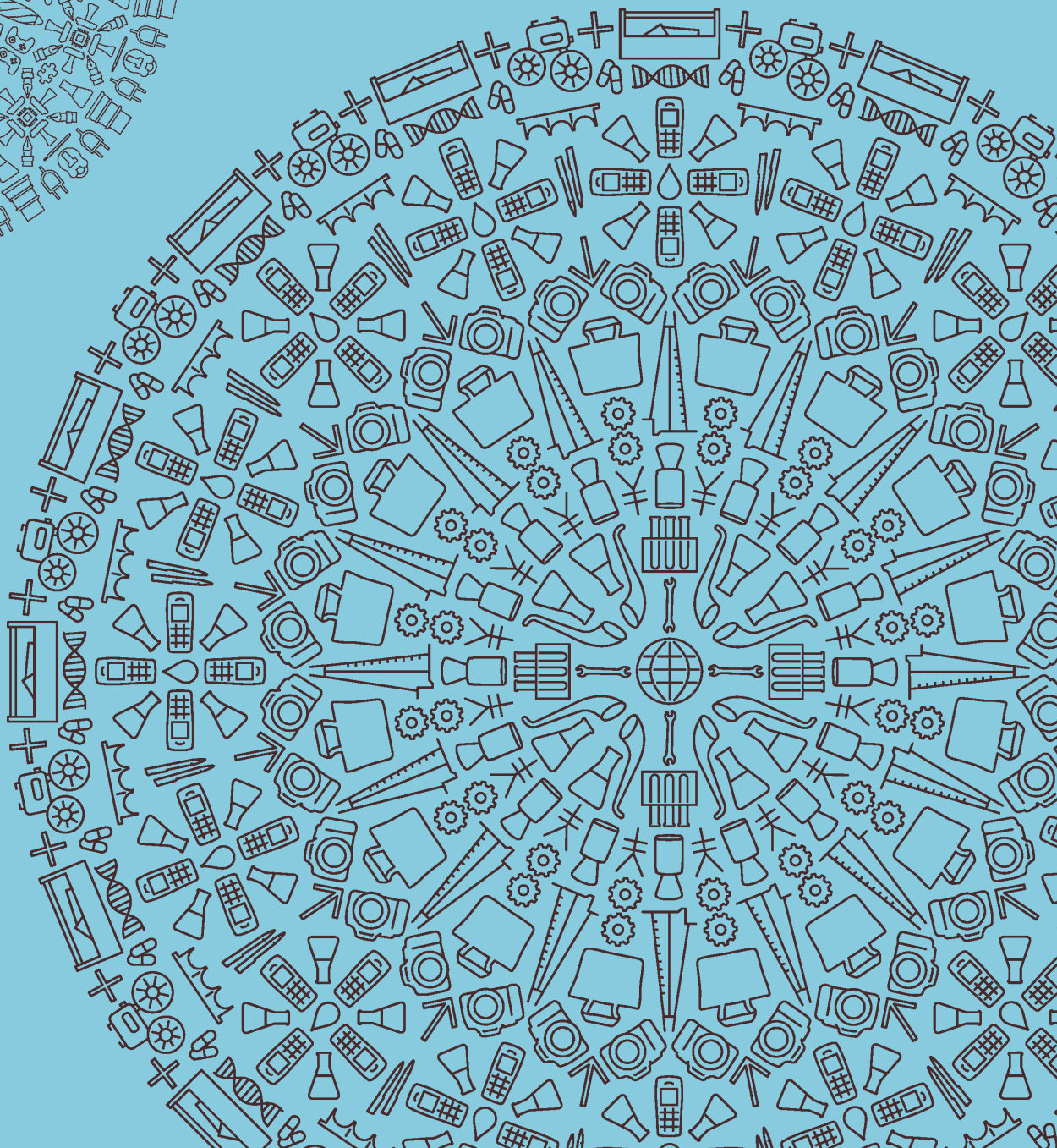

Quotation of the year

"The law does not require perfection."

Per **Birss J** in *Merck v Ono* [2015] EWHC 2973 (Pat)

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Introduction

In terms of the number of substantive decisions from the High Court and the Court of Appeal, 2015 was another busy year with 78 decisions compared to 79 in 2014 and 81 in 2013.

There can be little doubt that the most significant patent dispute of 2015 was between Warner-Lambert and several generics companies concerning a patent with Swiss-type claims for the use of the drug pregabalin in the treatment of pain. There were no fewer than 14 substantive judgments, including some important rulings on the construction and infringement of second medical use claims which are considered further below. However, although the pregabalin litigation grabbed most of the headlines, there were several other important cases. The following developments are particularly noteworthy:

- In October, Henry Carr QC was appointed as a High Court Judge empowered to hear patents cases and expected to be one of the judges handling the more technical category 4 and 5 cases. **Carr J**'s first substantive patents judgment as a full time Judge, which concerned a second medical use patent for the drug tomoxetine[1], reflects the intelligent and sensible approach that he used to take as an advocate. English patent practitioners are now blessed with their very own "ABC club"[2] as well as very experienced patent lawyers in the Court of Appeal[3].

- The UPC edges closer to becoming a reality with most commentators forecasting that the Courts will open for business in early 2017 and that the sunrise period for patentees to opt out their patents from the jurisdiction of the Unified Patent Court will commence towards the middle of 2016. As has been the convention for many years, the final section of this review consists of a short summary of the latest developments in this area written by Bristows' partner, Alan Johnson.

- The English Courts are continuing to develop the way in which plausibility influences inventive step and insufficiency. Two important cases this year on plausibility were *Merck v Ono*[4] and *Actavis v Eli Lilly*[5].

- The pemetrexed case[6] contained several important findings including that file wrapper estoppel plays a very limited role in English patent law and that it is not inappropriate to use the *Improver*[7] questions when considering infringement on a purposive construction.

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

The English Courts continue to construe claims in accordance with the guidance given by **Lord Hoffmann** in *Kirin-Amgen*[8] and **Jacob LJ** in *Virgin Atlantic v Premium Aircraft*[9].

Construction of Swiss-type claims

As noted above, the *Warner-Lambert v Actavis (and others)* (pregabalin) cases were before the English Courts on numerous occasions in 2015. The litigation began in June 2014 when Mylan issued revocation proceedings against Warner-Lambert's patent with Swiss-type claims to the use of pregabalin in the treatment of pain. The litigation gathered momentum in September 2014 when Actavis also commenced revocation proceedings and informed Warner-Lambert that they had sought a marketing authorisation to sell a pregabalin medicine with pain carved out of the label (a so-called "skinny label"). The parties corresponded during the rest of 2014 but, when they were unable to reach agreement on the steps that Actavis should take to minimise cross-label use[10] of its pregabalin medicine, Warner-Lambert issued an application for an interim injunction which was heard

[1] *Actavis v Eli Lilly* [2015] EWHC 3294 (Pat)
[2] Arnold, Birss and Carr JJ
[3] Kitchin and Floyd LJJ (and Lewison LJ who also has considerable experience of the discipline)
[4] [2015] EWHC 2973 (Pat)
[5] See footnote 1, *ante*
[6] *Actavis v Eli Lilly* [2015] EWCA Civ 555
[7] *Improver Corporation v Remington Consumer Products Limited* [1990] FSR 181
[8] *Kirin-Amgen v Transkaryotic Therapies* [2004] UKHL 46
[9] [2009] EWCA Civ 1062
[10] "Cross-label" use is when a generic medicine is used for an indication which, although not on the generic's label, is listed on the originator's label. Cross-label use is distinguished from the term "off-label" use where a medicine (originator or generic) is used for a condition for which it is not authorised.

by **Arnold J** in January 2015. As will be discussed further below, Warner-Lambert's application was dismissed. However, of more interest was **Arnold J**'s approach to the construction of Swiss-type claims. Following *Hospira v Genentech*[11], **Arnold J** found that the word *"for"* in a Swiss-type claim meant *"suitable and intended for"* and that it *"imports a requirement of subjective intention on the part of the manufacturer that the medicament or pharmaceutical composition will be used for the specified condition".* In May, the Court of Appeal (**Floyd LJ** giving the leading judgment) upheld **Arnold J**'s interim decision but found that Swiss-type claims were directed to what the manufacturer knew or could reasonably foresee about the ultimate intentional use of the product, not the specific intention that the manufacturer itself had. The trial of the main action took place in July, again before **Arnold J**, following which he expressed *"considerable doubts as to the correctness of **Floyd LJ**'s interpretation"* of Swiss-type claims[12]. Despite this criticism, **Arnold J** applied the test outlined by the Court of Appeal and held that it was not reasonably foreseeable that Actavis' generic pregabalin would have been *"intentionally administered for the treatment of pain"* and, therefore, that Actavis did not infringe.

Swiss-type claims were also considered in *Actavis v Eli Lilly*[13] where, somewhat to our surprise, use of the *Improver*[14] questions was not criticised by **Floyd LJ** as long as it was kept in mind that they were not legal rules but guidelines used to assist with the basic principles of claim construction. The Judge was also clear that use of the file wrapper as a guide to claim construction was not inadmissible but should be strongly discouraged.

Numerical ranges

For the 18 months that elapsed between the first instance and appeal decisions in *Smith & Nephew v Convatec*[15], the world of patent professionals had lived with the understanding that under English law numerical ranges were generally to be interpreted according to a significant figures approach, meaning that a claimed range of 1-25% meant ≥0.95 to <25.5%. As such, Smith & Nephew's use of 0.77% of a particular binding agent to produce silverised wound dressings did not infringe. However, with **Kitchin LJ** giving the leading judgment, the Court of Appeal held that the whole numbers approach was the correct approach to be used for Convatec's patent, meaning that a claimed range of 1-25% is to be understood as ≥0.5 to <25.5% and hence Smith & Nephew did infringe. It seems that the Judge's main reason for favouring the whole numbers approach was that the significant figures approach gives rise to a significant asymmetry when applied to the number 1 (i.e., ≥0.95 to <1.5) and therefore delivers different results when applied to the different ranges. Even though the relative error margin is greater at the lower end of the range when using the whole numbers approach, the skilled person would accept this as an inevitable consequence of the adoption by the patentee of such a wide range of permissible concentrations. Despite this guidance, the overall message remains that the crucial question is what would the skilled person have understood the patentee to have used the language of the claim to mean, and that guidance in the specification on the interpretation of numerical ranges will generally be key in this analysis, i.e., every case will turn on its own facts.

Breach of settlement agreement

In an unusual case[16], **Kitchin LJ** rejected arguments by H&M and Stretchline that the issues of infringement and validity could be re-opened following settlement based upon a new construction of the claims of a patent relating to a fusible woven barrier which prevented the ends of bra underwires from penetrating the fabric which housed them. The Court of Appeal held that the new method of testing proposed by Stretchline, which formed the basis of the alleged new construction, had been in the mind of H&M at the time of settlement and was no different in scope to the construction taken in the original settled proceedings. Therefore, the issues of infringement and validity remained closed by the settlement agreement. However, this did not preclude Stretchline from asserting breach of the settlement agreement in relation to subsequent sales of allegedly infringing products by H&M. This infringement case was heard separately by **Carr J**[17]. Applying the conventional approach to claim construction, he found the subsequently marketed bras to have infringed the patent. Interestingly, in assessing the functional

[11] [2014] EWHC 1094 (Pat)
[12] [2015] EWHC 2548 (Pat)
[13] See footnote 4, *ante*
[14] See footnote 7, *ante*
[15] [2015] EWCA Civ 607
[16] *Stretchline v H&M* [2015] EWCA Civ 516
[17] [2015] EWHC 3298 (Pat)

integer of claim 1 that the bra should possess a barrier to the penetration of underwires, the Judge allowed use of a test that post-dated the patent specification. The patent referred to use of the "L+M sewability test", whereas Stretchline had used the "M&S pin penetration test". This was permitted on the basis that it was the industry standard and that any conventional industry test could be used.

Pleadings

Parties would be very well advised to include all arguments in their pleadings, including those on construction, to avoid any risk of having part of their case disregarded, opined **HHJ Hacon** in *Glass v Freyssinet*[18]. However, the Judge noted that arguments on construction fall under a special category as these are liable to remain open up to and throughout trial and therefore, relying on *Consafe*[19] and *Scanvaegt*[20], he held that unpleaded arguments on construction would be unlikely to be resisted by the Court provided there is no deliberate concealment and the opposing party is unable to prove significant prejudice caused by a failure to plead.

Burden of proof

The reversal of the burden of proof for infringement of a claim to a process for obtaining a new product, provided in **section 100** of the **Act**, has famously been difficult to interpret and there has been no UK case law to date on its actual meaning. In an application for service of proceedings out of the jurisdiction in *Magnesium Elektron v Molycorp*[21], when determining whether there was a serious issue to be tried, **Birss J** was faced with the question of "what is a process for obtaining a new product?" If the word "new" was taken to mean the same as the novelty requirement, then **section 100** would be pointless as the patentee could claim the new product in addition to the process to obtain it. Therefore, the Judge held that a product obtained by the patented process would be "new" if it has not previously been made available to the public. In the present case, the product manufactured by the patented process presented a particular fingerprint which was unique to that process, making it a "new" product under **section 100**.

Second action for infringement

Turning to a decision on the rule in *Henderson v Henderson*[22] and following **Floyd LJ**'s judgment last year[23] which found that AP Racing's patent was valid and infringed by Alcon, AP Racing sought disclosure prior to choosing between an account of profits and damages. Alcon asserted that the disclosure request included products not included in the original claim, leading AP Racing to restrict the disclosure request and file a second claim for infringement. Alcon applied for a strike-out of the second claim following the rule in *Henderson v Henderson*. **HHJ Hacon** applied *Johnson v Gore Wood*[24] highlighting that the modern law on the rule in *Henderson v Henderson* is underpinned by an emphasis on efficiency and economy in the conduct of litigation. He dismissed Alcon's application finding that it was just to hear AP Racing's further claim for infringement because it was short and required no further evidence.

Indirect infringement

Returning to *Warner-Lambert v Actavis* and the pregabalin saga, there was a strong difference of opinion between **Arnold J** and **Floyd LJ** on the question of whether Swiss-type claims can be indirectly infringed when a skinny-label[25] medicine is sold cross-label for the patented indication. Perhaps because **Arnold J** seems to regard the manufacturing element of the claim as its corner stone, in the interim injunction application he held that there could be no arguable case that acts downstream of manufacture could be regarded as supplying the means relating to an essential element of the invention for the purposes of **section 60(2)** of the **Act**. However **Floyd LJ** seems to believe that a more purposive approach to such claims is appropriate and that *"the skilled person would understand that any manufacturing step is adequate"*[26] to ensure that the claim did not fall foul of the "method of treatment" exclusion contained in **Article 53(c)** of the **EPC** (formerly **Article 52(4)** of the **EPC 1973)**.

Although **Floyd LJ** reinstated the indirect infringement allegations on the appeal of the interim injunction, in the judgment on the main action **Arnold J** was strongly critical of **Floyd LJ**, saying that he was *"baffled"* by this part of the ruling of the Court of Appeal. A lot remains to be played out on this aspect of the case

[18] [2015] EWHC 2972 (IPEC)
[19] *Consafe Engineering v Emtunga* [1999] RPC 154
[20] *Scanvaegt International v Pelcombe* [1998] FSR 786
[21] [2015] EWHC 3596 (Pat)

[22] (1843) 3 Hare 100 – the doctrine provides that, where reasonably possible, parties should litigate all issues relating to a particular subject matter in the same litigation
[23] *AP Racing v Alcon Components* [2014] EWCA Civ 40
[24] [2000] UKHL 65
[25] i.e., a medicine from which the patented indication has been carved-out pursuant to Regulation (EC) No. 726/2004
[26] [2015] EWCA Civ 556

– the question seemingly revolving around whether the skilled person would understand the language of the claim to describe a multi-step process including manufacture as well as other downstream steps or whether he would (like **Arnold J**) view the claim as principally directed to the manufacturing element.

Indirect infringement was also considered by the Court of Appeal in the pemetrexed litigation[27]. The claim in question was a Swiss-type claim to the use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumour growth when co-administered with vitamin B12. **Floyd LJ** held that there was indirect infringement of this claim by the supply of alternative pemetrexed salts such as dipotassium in lyophilised form to be made up in saline solution by the healthcare professional prior to administration. In the authors' view, it is strange that infringement of a Swiss-type claim depends on whether the drug is supplied as a tablet or capsule on the one hand or as a lyophilisate on the other, although it would appear to be consistent with the Judge's approach in the *Warner-Lambert v Actavis* case, discussed above.

Validity

Novelty

The metaphor employed by **Sachs LJ** in *General Tire*[28] is well known. To destroy novelty, "*the prior inventor must be shown to have planted his flag at the precise destination before the patentee*"[29]. As **Birss J** made clear in *Synthon v Teva*[30], this is intended to indicate necessity and inevitability in outcome, i.e., if the skilled person has a choice as to how to proceed, there is no anticipation. However, fanciful choices do not count and patentees will sometimes argue that a choice exists when in fact there is no genuine choice and the patented way forward really is inevitable. Synthon argued that Teva's patent for an improved process of glatiramer acetate manufacture lacked novelty over Teva's prior commercial operations and over a prior art citation called Lemmon. Both were rejected. The improvements promised by the patent in suit related to a reduced level of free bromine and the avoidance of metal ions through the use of glass-lined reaction vessels and other precautions. Although Teva had made admissions about the use of glass-lined vessels before the priority date, the Court accepted Teva's arguments about the possibility of contamination from other metal surfaces. As a result, Teva's admissions did not go far enough to destroy novelty. The argument based on Lemmon failed because even though it was likely that the skilled person faced with Lemmon would avoid free bromine, it was not inevitable that they would do so. This was a case where the Court considered that real choices existed.

Planting the flag at the precise destination of the patentee requires two discrete elements to be satisfied: disclosure and enablement. It was the disclosure element of the test that arose for consideration in *Hospira v Genentech*[31] in the context of second medical use claims, and two questions in particular: (i) what is required to anticipate a claim which includes a specified therapeutic effect?; and (ii) what is required to anticipate a purpose-limited claim? The prior art upon which Hospira relied disclosed the details of clinical trials but not the results, which were comprised in the patent specification and which illustrated the enhanced therapeutic effect of the invention. In relation to the first question, **Arnold J** noted that it is well settled by the case law of the Boards of Appeal of the EPO that the prior disclosure of the existence of a clinical trial does not destroy the novelty of a claim to a specified therapeutic effect unless the effect can be derived directly and unambiguously from the prior disclosure[32]. A mere proposal for treatment does not disclose that the treatment is efficacious. As to the second question, **Arnold J** relied upon the Court of Appeal's decision in *Warner-Lambert*[33] as authority that it is the mental element of intention that is at the heart of a purpose-limited claim. Accordingly, one cannot intend to achieve enhanced therapeutic efficacy unless one knows in advance that the clinical benefit will be achieved. On the facts at hand, there was insufficient information in the cited prior art from which the clinical benefit could be clearly and unambiguously derived and hence there could be no such intention. The patent was novel, regardless of whether or not the clinical benefit was the inevitable result of carrying out the directions in the prior art. However, the patent was held to lack inventive step on the basis that the disclosed clinical trial would be obvious to try because

[27] See footnote 6, *ante*

[28] *General Tire & Rubber v Firestone Tyre & Rubber* [1972] RPC 457

[29] *Ibid*, at 486

[30] [2015] EWHC 1395 (Pat)

[31] [2015] EWHC 1796 (Pat)

[32] *Pfizer* T 158/96, *Pfizer* T 715/03, *Pharma Mar* T 385/07 and *Genentech* T 1859/08

[33] See footnote 26, *ante*

the skilled person would be motivated to do so with a fair expectation of success.

Enablement, rather than disclosure, came up for consideration in *Merck v Ono*[34]. **Birss J** held that plausibility can be an aspect of enablement in a second medical use claim because, in order to amount to an enabling disclosure and thereby deprive the claim of novelty, the prior art has to make the therapeutic effect plausible. In relation to the prior art alleged to anticipate Ono's patent, the Judge held that the citation satisfied the disclosure limb of the test for anticipation insofar as there was an individualised disclosure of the use of anti-PD-1 antibodies for the treatment of cancer. However, the citation was very long and, as the Judge put it, it hedged its bets. Given the uncertainty concerning the mode of action of PD-1 receptors in the common general knowledge, the skilled person faced with the publication would not be presented with a clear and unambiguous teaching of how to achieve the desired effect.

An interesting point on the publication of a piece of novelty-destroying prior art arose in *Unwired Planet v Huawei and others*[35]. The priority document of Unwired Planet's patent was filed at the USPTO at approximately 5pm local time on 8 January 2008. However, some 14 hours earlier, the patentee uploaded a potentially novelty destroying technical submission to the server of the European Telecommunications Standards Institute (ETSI) making it globally available for download. The timing of the upload was such that in certain jurisdictions, including the west coast of the US, it was accessible on 7 January 2008. Therefore, the question before the Court was how the date of publication should be established: by reference to the local time where the document is available, or by reference to the time at the location in which the priority document was filed. **Birss J** determined that publication of the prior art throughout the world must always be determined by reference to the controlling time-zone at the patent office at which the priority document was filed. As a result, the ETSI submission was not available as prior art.

Obviousness

Although it has never been compulsory, by and large, the English Courts continue to use the four-stage *Pozzoli*[36] test to address the question of obviousness. A key concept within the *Pozzoli* test is the common general knowledge. Common general knowledge has been variously defined in English jurisprudence. As **Birss J** explained in *Merck v Ono*[37], the Court of Appeal in *General Tire*[38] preferred the definition *"generally regarded as a good basis for further action"* to *"accepted without question"* (per **Luxmoore J** in *British Acoustic Films)*[39] on the basis that the latter may have set the bar too high. **Birss J**'s judgment explains that the common general knowledge in principle can include matters on which there exists doubt and uncertainty and must be capable of including contradictory ideas on a topic, provided always that the information reaches the required standard for common general knowledge. In this case, **Birss J** decided that the common general knowledge contained defined areas of uncertainty in the mode of action of anti-PD-1 antibodies, there being conflicting reports in the literature as to whether the receptor signalling was always negative or co-stimulatory. This proved to have a decisive effect on the Judge's finding that Ono's patent was inventive, there being less than a fair expectation of success that PD-1 inhibition would be fully effective.

Amongst the plethora of issues in the pregabalin litigation (*Warner-Lambert v Actavis*, see above) lurks an interesting point on the common general knowledge which is likely to become increasingly important in the digital age. The point is whether it is necessary to show that the matter alleged to form part of the common general knowledge was generally known and accepted by the relevant scientific community in the UK or whether if, for example, it was so known in the US, that would be good enough. Following the guidance of **Floyd LJ** in *Teva v Merck*[40], **Arnold J** held that it must at least be shown that the matter qualified as common general knowledge in the UK[41].

An issue with regard to common general knowledge also arose in *Saab v Atlas*[42] in relation to a product known as SeaSting which was developed in the early 1990s for disposing of underwater mines. The priority date of the patent was August 2010. The SeaSting project received some publicity in the 1990s in the form

[34] See footnote 4, *ante*

[35] [2015] EWHC 3366 (Pat)

[36] *Pozzoli v BDMO SA* [2007] EWCA Civ 588

[37] See footnote 4, *ante*

[38] See footnote 28, *ante*

[39] *British Acoustic Films v Nettlefold Productions* [1935] 53 RPC 221

[40] [2009] EWHC 1952 (Pat)

[41] *Warner-Lambert v Actavis* [2015] EWHC 2548 (Pat), at §§123-124

[42] *Saab Seaeye v Atlas Electronic* [2015] EWHC 3163 (Pat)

of brochures and coverage in an annual publication in the field. It was also presented to a number of naval forces and at several conferences. However, SeaSting was never sold and the project was abandoned in 2000. **Mann J** held that SeaSting was not part of the common general knowledge considering that: (i) the skilled team would not look back to past publications when working at the priority date; and (ii) the project was not sufficiently memorable to have been common general knowledge even if the skilled person had attended one or more of the original conferences at which it was presented.

It is an undeniable fact that English Patent Court judgments have been getting longer as the years have rolled by. Bucking this trend, the judgment of the Court of Appeal in *Teva v Leo*[43] was a mere nine pages (including the cover page) and overturned the first instance finding that a patent to calcipotriol, betamethasone and the solvent, Aramol E, was obvious. Giving the leading judgment, **Sir Robin Jacob** held that **Birss J** had been incorrect to find that the notional skilled person would have included Aramol E, which was not a solvent commonly used in the relevant field, in his or her list of solvents for testing when the evidence was that a real formulator would not have done so. Referring to the *Saint-Gobain*[44] decision, it was also held that the trial judge had set too low a standard for "obvious to try" and that merely including something in a research programme on the basis that something might turn up was not sufficient to render an invention obvious.

The significant limitations of the obvious to try test were also noted by Carr J when he upheld Eli Lilly's patent for the use of tomexetine in the treatment of attention-deficit/hyperactivity disorder (ADHD)[45]. In particular, the Judge quoted with approval the observations of **Kitchin LJ** in *Medimmune v Novartis*[46] that: *"there are areas of technology such as pharmaceuticals and biotechnology which are heavily dependent on research, and where workers are faced with many possible avenues to explore but have little idea if any one of them will prove fruitful. Nevertheless they do pursue them in the hope that they will find new and useful products. They plainly would not carry out this work if the prospects of success were so low as to not make them worthwhile. But to deny patent protection in all such cases would act as a significant deterrent to research"*[47].

Readers will remember that in the first instance decision in *Teva v Leo*[48] **Birss J** confirmed that regulatory considerations could be taken into account for the purposes of inventive step but that their significance would vary case to case. In *Teva v Boehringer*[49], **Morgan J** considered that **Birss J**'s comments were not relevant to the present case and that he was bound by the Court of Appeal in *Richardson-Vicks Inc's Patent*[50] with the question being whether the alleged delay or difficulty in obtaining regulatory approval was an obstacle to the manufacture of the product resulting from the claimed invention. He held that there was no such obstacle to the manufacture of the hydroxypropylmethylcellulose (HPMC) capsules covered by Boehringer's patent and that, therefore, it was obvious from the prior art to use HPMC as the capsule material instead of gelatine.

The Herceptin litigation between Hospira and Genentech made it up to the Court of Appeal in 2015. Readers will recall that Hospira had previously succeeded in revoking several of Genentech's secondary patents relating to trastuzumab so as to clear the way for Hospira's biosimilar product. **Floyd LJ** gave judgment[51] in relation to the appeal against **Birss J**'s finding[52] that a particular dosage regimen patent was obvious over the dosage regimen indicated by the FDA label for Herceptin because, faced with the information on the label and a number of other considerations (including the fact that the frequency of the claimed regimen matched that of the co-administered drug paclitaxel) the skilled team would be motivated to perform a small clinical trial to test the safety and efficacy of the claimed regimen which would result in success. Genentech's case focussed on the fact that the Judge below had erred in holding the patent obvious at the same time as rejecting a second piece of evidence. **Floyd LJ** disagreed stating that there were ample reasons why the patent was obvious based on the first piece of evidence alone.

Insufficiency

In contrast to the EPO where the topic is usually

[43] [2015] EWCA Civ 779
[44] *Saint-Gobain v Fusion Provida* [2005] EWCA Civ 177
[45] See footnote 1, *ante*
[46] [2012] EWCA Civ 1234
[47] *Ibid*, at §90
[48] [2014] EWHC 3096 (Pat)
[49] [2015] EWHC 2963 (Pat)
[50] [1995] RPC 568
[51] *Hospira v Genentech* [2015] EWCA Civ 57
[52] See footnote 11, *ante*

confined to inventive step[53], the concept of plausibility has recently become rather pervasive in English patent law. It has become fashionable to plead lack of plausibility in most cases challenging the validity of a patent on the grounds of obviousness and, particularly, insufficiency. A notable example was the challenge by Mylan and Actavis to the pregabalin pain patent where it was held that using the disclosure in the patent, it was not plausible that pregabalin would be effective for all types of pain (claim 1), central neuropathic pain (claim 3) or certain other specific types of pain (several other claims)[54]. However, in what may come to be seen as a turning of tide on this issue, two judgments handed down later in the year have explained that the requirement of plausibility is perhaps a lower threshold than was previously thought.

The first of these cases concerned tomoxetine[55]. The relevant facts were that Eli Lilly's patent disclosed for the first time that tomoxetine was effective in the treatment of ADHD. It disclosed the mechanism of action of tomoxetine as a norepinephrine reuptake inhibitor and cited a relevant paper in support. However, there were no data in the patent to support the assertions of safety or efficacy. Actavis contended that there was a squeeze between lack of inventive step and lack of plausibility. It alleged that the patent contained no more than a bald assertion that tomoxetine was effective and safe for the treatment of ADHD. Actavis further claimed that, insofar as the patent disclosed a theory to support that assertion, it was known from the prior art. Such a line of attack has become increasingly common in the English Patents Court and, on some occasions, the challenges have been successful. However, **Carr J** took the opportunity to emphasise that plausibility challenges must be kept under control. He noted that:

> "*[t]here is no requirement in the **EPC** that a patent should contain data or experimental proof to support its claims.... In respect of claims to therapeutic applications which are of wide scope, such experimental tests may well be required. In the case of narrow claims, they may not be. In my judgment, the policy considerations underlying plausibility for sufficiency are different from those underlying fair expectation of success for obviousness, which indicates that the standard for assessment of plausibility is not the same as assessment of obviousness. For obviousness, a fair expectation of success is required because, in an empirical art, many routes may be obvious to try, without any real idea of whether they will work. The denial of patent protection based upon the "obvious to try" criterion alone would provide insufficient incentive for research and development in, for example, pharmaceuticals and biotechnology, and would lead to the conclusion that a research program of uncertain outcome would deprive a patent of inventive step. The reason why the court requires that the invention of a patent should be plausible is different. It is to exclude speculative patents, based on mere assertion, where there is no real reason to suppose that the assertion is true. The cases on which Lilly relies (to which I have referred above) establish that the test of plausibility is a threshold test which is satisfied by a disclosure which is "credible", as opposed to speculative. That disclosure may be confirmed or refuted by further evidence obtained subsequent to the priority date. If it is subsequently shown that the invention does not work with substantially all of the products or methods falling within the scope of the claim then the scope of the monopoly will exceed the technical contribution and the patent will be invalid. This indicates why plausibility is only a threshold test. A plausible invention may nonetheless be shown to be insufficient. In my judgment the standard for assessment of plausibility is not the same the standard for assessment of expectation of success in the context of obviousness"*[56].

The second case related to anti-PD-1 antibodies. Plausibility's role in sufficiency is fairly well settled following the Court of Appeal's decision in *Regeneron*[57], i.e., for a claim to be sufficient it must be plausible that it works across the entire scope of the claim. However, for broadly drafted claims, this begs the question of how much flexibility is permitted in assessing whether the invention is demonstrated to "work". Readers may recall that, in *Regeneron*, it was argued that the patent was insufficient because some evidence suggested that anti-VEGF therapy would be ineffective against certain diseases which

[53] E.g., *AgrEvo* T 939/92

[54] See footnote 12, *ante*

[55] *Actavis v Eli Lilly* [2015] EWHC 3294 (Pat)

[56] *Ibid*, at §§175-177

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

fell within the claim. This argument was dismissed on the basis that it had not been conclusively proven that the diseases fell within the claim insofar as they were mediated by angiogenesis, the disease mechanism upon which anti-VEGF therapy was said to act. Against this background, **Birss J**'s decision in *Merck v Ono*[58] makes for interesting reading. The main claim in Ono's patent related to the use of an anti-PD-1 antibody in treating cancer, i.e., any and all cancers in general. As the Judge noted, *"[it] is as wide as possible."* The challenge for Ono was that Merck contended that there were three cancers on which an anti-PD-1 antibody was said to have no significant therapeutic effect. Indeed, the Judge found on the evidence available today that anti-PD-1 treatment was not effective for these cancers. Nevertheless, he still found the teaching of the claim to be sufficient across its breadth. He did so on the basis that the claim was *"a fair generalisation"* at the time and that the generality of principle was not undermined by the lack of success in certain instances. The key point appears to be that when considering the plausibility of a medical use claim, success need not be 100%. Indeed, **Birss J** states that *"[s]uccess in this context does not mean success in every patient in all circumstances, no treatment will achieve that".* This appears to mark a softer approach to that taken in Regeneron, perhaps motivated by the desire to uphold Ono's patent to what the Judge described as *"a major advance".*

Added matter

In English jurisprudence, the test for added subject matter has been put in a number of different ways. For many practitioners, **Aldous J'**s three-step test in *Bonzel v Intervention*[59] does not provide much in the way of practical assistance, merely requiring, at step 3, a comparison of disclosures and a decision on whether any subject matter has been added. Those needing further guidance often turn to **Jacob J**'s single sentence test in *Richardson-Vicks Inc's Patent*[60] which asks *"whether a skilled [person] would, upon looking at the amended specification, learn anything about the invention which he could not learn from the unamended specification"*[61].

In *Novartis v Focus*[62], Novartis' patent for a rivastigmine transdermal patch was held to be invalid for added matter because it told the skilled team for the first time that the invention concerned a particular starting dose of rivastigmine to be delivered by the patch. According to **Arnold J**, previously the skilled team would have understood from the patent application that the structure and composition of the patch was the core of the invention. The Judge decided that the main claim of the patent was an impermissible intermediate generalisation insofar as it took the feature of the starting dose delivered by a $5cm^2$ reference patch out of the context of an example in the specification and made it generally applicable.

A further interesting judgment on intermediate generalisation was handed down in *IPCom v HTC*[63]. The case concerned IPCom's amended patent relating to regulating access for devices to a UMTS mobile radio network, with prioritisation based on the user class encoded on the devices' SIM cards. HTC succeeded in persuading **Birss J** that on IPCom's preferred construction, the amended claim was an intermediate generalisation. As construed, it would cover multiple bit patterns and also multiple access class bits. This was wider than the patent's narrow second embodiment (which disclosed only one physical access class bit and one bit pattern) and narrower than the wide general disclosure in the specification (which was not limited to bit patterns and allowed for any access class information in general). The Judge agreed with HTC that, in terms of its coverage, the claim did indeed cover something more general than the patent's second embodiment. In that sense, as a matter of coverage, the claim was held to be an intermediate generalisation. However, **Birss J** upheld the patent, noting that coverage was not the same thing as disclosure. He explained: *"English patent law draws a distinction between coverage and disclosure. To amount to added matter the intermediate generalisation must be a generalisation in terms of disclosure, not coverage. ... Read in the context of the specification as a whole, nothing further is disclosed beyond what is described in the second embodiment. The skilled addressee reading the claim is not given new information as compared to the second embodiment. The language may cover more schemes than the second embodiment but that is not the issue"*[64].

[58] See footnote 4, *ante*
[59] [1991] RPC 553
[60] See footnote 50, *ante*
[61] *Ibid*, at §576
[62] [2015] EWHC 1068 (Pat)
[63] [2015] EWHC 1034 (Pat)
[64] *Ibid*, at §§125-126

Supplementary protection certificates (SPCs)

Unusually, the English Patents Court (**John Baldwin QC** sitting as a Deputy Judge) declined to make a reference to the Court of Justice of the European Union (CJEU) in a dispute between ViiV Healthcare and Teva regarding an SPC[65]. The SPC was for the combination of abacavir (A) and lamivudine (B), the active ingredients in ViiV's Kivexa medicine, which is used in the treatment of HIV. The patent upon which the SPC was based included a claim to a combination comprising A+B. The MA for A+B upon which the SPC was based dated from December 2004. Importantly, ViiV also marketed another medicine for the treatment of HIV called Trizivir, a triple combination which in addition to A+B also contained azidothymidine (C). The MA for Trizivir was granted in January 2001. The A+B+C combination was also protected by a different claim of the same patent but no SPC was available because the MA for Trizivir was granted within five years of the filing of the application for the patent.

ViiV asked the Court to make a reference to determine a question concerning **Article 3(d)** of **Regulation (EC) No. 469/2009** (the **SPC Regulation**) which, as readers will recall, requires that the marketing authorisation relied upon for the purposes of an SPC application should be the first authorisation to place the product on the market as a medicinal product. Teva contended that it was *acte clair* that **Article 3(d)** was not satisfied since the Trizivir (A+B+C) marketing authorisation was the first marketing authorisation for A+B. ViiV argued that this issue had not been determined previously and that it was highly arguable that a marketing authorisation for A+B+C should not be treated as the first marketing authorisation for A+B, particularly when, as ViiV contended, A+B was innovative over A+B+C. ViiV had also made a conditional application to amend the patent to include a claim consisting of A+B (many readers will be familiar with the EPO drafting convention that "consisting of A+B..." means that the claim is limited to those two active ingredients, but "comprising of A+B..." leaves open the possibility of other active ingredients being included).

The Judge considered that it was *"far too early"* to make a reference to the CJEU because: (i) the patent could be revoked at trial in which case the corresponding SPC would fall; (ii) ViiV's conditional application to amend might be refused, in which case all the issues relating to the amended claims would no longer be relevant; and (iii) if A+B was not innovative over A+B+C, an important plank in ViiV's argument would fall away. He expressly did not decide whether the issue on **Article 3(d)** was *acte clair*.

Damages

Compensation pursuant to cross-undertakings
We reported in last year's review that the generics company Krka had been awarded substantial damages (circa £27M) to compensate it for the profits lost during the period of an interim injunction that was subsequently lifted, as well as for future loss attributable to the loss of its *"first mover advantage"*[66]. That decision included a discount of 20% to account for *"vicissitudes and uncertainty"*. AstraZeneca's (AZ) appeal was dismissed on the basis that the first instance trial Judge had not made any error of principle[67]. The case concerned Krka's generic esomeprazole capsule products, which as many readers will know, were due to be launched in competition with AZ's esomeprazole tablets that were sold under the brand name Nexium and enjoyed annual sales of around £65M in the UK. Given the different dosage forms (capsules versus tablets), the situation was more complicated than the simple generic substitution that typically occurs at a pharmacy level, and the case proceeded on the basis that take up of Krka's product required a change (or "switch") in prescribing practices by doctors, which in turn required the switch to be promoted by medicine managers working in the Primary Care Trusts (PCTs) within the UK. Krka's case at first instance was therefore supported by evidence from a number of medicine managers who provided after the event evidence as to the degree of switch from esomeprazole tablets to capsules they would have expected to secure in their PCT but for the injunction.

On appeal, AZ argued that it was not possible to extrapolate from the evidence provided by the limited number of medicine managers who appeared at trial,

[65] [2015] EWHC 1074 (Ch)

[66] *AstraZeneca v Krka* [2014] EWHC 84 (Pat)

[67] *AstraZeneca v Krka* [2015] EWCA Civ 484

particularly in light of the alleged lack of correlation between the amount of savings a PCT could make and their propensity to switch products. AZ also argued that the damages award should have been based on a different model, namely the market share Krka actually obtained following its launch after the interim injunction had been lifted, that was said to be supported by the sales estimates made by Krka prior to the interim injunction and sales data from a selection of *"comparable"* cases.

Whilst the Court of Appeal (**Kitchin LJ** giving the leading judgment) acknowledged the potential value of comparables in cases such as this, it noted the fact sensitive nature of the first instance decision and that each of the comparables in the case had been dismissed by the Judge on the facts before him. The Court also noted the Judge's finding, again on the facts before him, that there had been striking consistency between the evidence of the medicine managers. Finally, whilst acknowledging that the Judge's reasoning underlying the amount of the uncertainty discount was very concise, the Court of Appeal was satisfied that it was adequate based on the facts before him and the inherently imprecise exercise he was required to carry out. AZ's appeal was therefore dismissed.

Costs

Indemnity basis

As a starting point in *Rovi v Virgin*[68], it was admitted by Rovi that they should pay Virgin's costs. Rovi had discontinued its infringement claim against Virgin and consented to the revocation of the patent in suit during the course of dealing with Virgin's responsive counterclaim. **Arnold J**'s decision on costs dealt with the issue of whether Rovi should pay Virgin's costs on the indemnity basis. The Judge held that the indemnity basis was appropriate for the costs associated with Rovi's infringement claim, described as always having been speculative. On the facts before him, the Judge noted *"It is very difficult for me to see how Rovi could ever have had a real belief that this patent was actually being infringed as opposed to a surmise that it might be being infringed"*[69]. The Judge also criticised Rovi for not seeking information about Virgin's alleged infringement from relevant third parties; had it done so, Rovi would have discovered at a much earlier stage that its claim was unfounded.

In contrast to the infringement case, the revocation case had no special features which took it outside the normal costs regime. Accordingly, Rovi was ordered to pay Virgin's costs on the standard basis. A 3% deduction in the costs of the validity case was made to cover the wasted costs spent by Rovi dealing with a prior art citation that was abandoned by Virgin.

The Judge also decided that the general costs of the case (attributable neither to infringement or validity) should be paid on the indemnity basis, and ordered that Rovi should make an interim payment of 60% of Virgin's costs, less the 3% deduction. This equated to a sum of £575,000 indicating that Virgin's total costs bill was just under £1 million.

Overall winner

An interesting argument on the question relevant to costs of "who is the overall winner?" was ventilated in the Unwired Planet litigation at the end of 2015 before **Birss J**, who was deciding the costs of what is known as "Trial A"[70]. Trial A is the first of five so-called "technical trials" between the litigants dealing with patent matters, and will be followed by one "non-technical trial" dealing with competition law and FRAND issues. The patentee, Unwired Planet, won Trial A, **Birss J** concluding that the Trial A patent in suit was valid and infringed by the relevant sample products, and was essential to the relevant standard. However, it was argued that there remains the possibility that when the non-technical trial is determined, Samsung may be found to have a licence, making them, in a sense, the overall winner of the litigation as a whole. Accordingly, Samsung sought an order in terms equivalent to the costs of Trial A being reserved.

The Judge dealt with the matter by looking at the relief ordered in Trial A. He noted that the real issues determined at Trial A were that the patent is valid and essential. The declarations on these points would not be undermined by the outcome of the non-technical trial. Whilst the Judge accepted that the declaration

[68] [2015] EWHC 646 (Pat)

[69] *Ibid*, at §21

[70] *Unwired Planet v Huawei and others* [2015] EWHC 3837 (Ch)

that Samsung infringed does need to be qualified because it may turn out that Samsung has a licence, the outcome of the non-technical trial would not make any difference to the determination of the Trial A costs. Had there been no splitting up of the litigation, the Court would have followed an issue-based approach in which the validity and essentiality of the Trial A patent in suit would have been sufficiently distinct for Unwired Planet to deserve its costs. Accordingly, the Judge declined to include in his order for costs a proviso that some of the Trial A costs could be recovered depending on the outcome of the non-technical trial.

Procedural issues

Bifurcation

The normal practice in English patent proceedings is for the issues of validity and infringement to be tried together. However, the Court does have the power to order the issues to be tried separately and there is precedent both for validity being tried before infringement and vice versa. Sitting in the IPEC in *British Gas Services v VanClare*[71], **Arnold J** held that, to depart from normal practice, good reason must be shown why bifurcation is the better way to proceed. The Judge held that British Gas' submission that the validity case was simple to try but the infringement case was complex and not yet ready for trial was not a good enough reason.

Expedition

As noted above, the Court of Appeal found that Eli Lilly's patent with Swiss-type claims to the use of pemetrexed disodium plus vitamin B12 in the use of cancer was indirectly infringed by Actavis when the lyophilised product was made up in saline solution prior to injection[72]. The Court of Appeal decided to remit the issue of whether the alternative salts, such as pemetrexed dipotassium, would infringe when directed to be reconstituted with dextrose as opposed to saline solution. Actavis applied for the trial of the remitted issues to be expedited. Applying the guidance of **Lord Neuberger** in *W.L. Gore v Geox*[73], **Arnold J** found that some degree of expedition was warranted notwithstanding the fact that the Judge had some sympathy with Eli Lilly that: (i) Actavis were at fault for not having the dextrose issue determined at the same time as the other issues; and (ii) the final determination of the issues was unlikely to happen before expiry of the SPC.

Summary judgment

Norris J[74] confirmed that, although patent infringement claims can be suitable for summary judgment even if construction of the patent is in issue (as per *Nampak v Alpla*[75]), if such issues of construction require expert evidence then the claim must go to trial. The Judge also refused to grant a stay of the English proceedings pending the outcome of an opposition at the EPO because: (i) such a stay was likely to be lengthy; (ii) the electronic cigarette market is dynamic and, therefore, it is desirable to achieve commercial certainty as soon as possible; (iii) the existence of active proceedings is conducive to settlement; and (iv) the continuation of the English proceedings was unlikely to generate significant costs.

Following **Arnold J**'s finding that Warner-Lambert had not established that there was a serious issue to be tried in relation to the infringement of its patent to the use of pregabalin in the treatment of pain[76], Actavis moved to strike-out the claim, it being an established principle in English law that the threshold for serious issue to be tried on the one hand and summary judgment/strike out on the other are similar. However, **Arnold J** refused to strike out the issues of direct infringement, acknowledging that the Court of Appeal might disagree with his assessment of the mental element aspect of Swiss-type claims and that this was an important and developing area of the law that seems to be destined for the Supreme Court[77]. The claims of indirect infringement were struck out, **Arnold J** holding that *"it would be wrong to allow a claim which I cannot see ever succeeding to proceed to trial"*[78].

Amendment

In contrast to several other jurisdictions around the world, the English Patents Courts are reasonably flexible when it comes to the issue of pre-trial applications to amend patents. Whilst an EPO-style cascade of auxiliary requests is not permitted, a patentee in the English Court can present an application to amend on a conditional or unconditional

[71] [2015] EWHC 153 (IPEC)
[72] See footnote 6, *ante*
[73] [2008] EWCA Civ 622
[74] *Fontem v Ten Motives* [2015] EWHC 2752 (Pat)
[75] [2014] EWCA Civ 1293
[76] *Warner-Lambert v Actavis* [2015] EWHC 72 (Pat)
[77] *Warner-Lambert v Actavis* [2015] EWHC 223 (Pat), at §60
[78] [2015] EWHC 249 (Pat)

basis and also a reasonable number of fall-back positions which the Court will consider. However, in contrast to the pre-trial position, if claims are held invalid following the trial, it is much harder for a patentee to apply to amend to seek to cure the invalidity after the fact – it being a general principle of English litigation that a party should not be twice vexed in the same matter[79]. Following these rules, Warner-Lambert was not permitted to amend claim 3 of its pregabalin pain patent to restrict it from "neuropathic pain" to "peripheral neuropathic pain", **Arnold J** held that *"Warner-Lambert not only had ample opportunity to make a conditional application to amend prior to the trial, but also ought to have appreciated that it needed to do so if it wished to contend a claim limited in that manner would be independently valid"*[80].

Disclosure

The story is a familiar one. A patentee writes to a company alleged to infringe, asserts that it will commence expensive patent litigation proceedings if a licence is not taken, and includes a list of other companies that have chosen to take a licence. The recipient of the letter may then elect to take a licence to avoid the costs and risks of litigation. However, the rules of engagement for companies that license their patents may have to be viewed in a slightly different light as a result of **Arnold J**'s decision in *Big Bus Company v Ticketogo*[81] regarding pre-action disclosure under **CPR r.31.16. Arnold J** granted an unprecedented application for pre-action disclosure of licence agreements previously concluded by the patentee, at least insofar as they related to the same field of business. The most interesting aspect of the Judge's analysis of the test for pre-action disclosure comes under the heading *"Discretion"*. Ticketogo argued that Big Bus Company should make its own determination of the claim's value, as others had done before it. It also argued that granting Big Bus Company's application for pre-action disclosure would deprive Ticketogo of the ability to continue to conduct its business of entering licence agreements in the same manner. This latter point was what **Arnold J** called *"the real point of principle raised by this application".* In granting the application, he decided that the negotiations for licences were a market, that price information was fundamental to the proper functioning of a market and that transparency was a virtue in any market.

More and more issues are beginning to arise in the English Courts regarding standard essential patents (or SEPs), i.e., patents that claim inventions that the proprietor has declared as necessary to use in order to comply with one or more technical standards. In *Vringo v ZTE*[82], **Birss J** made it clear that in a case concerning SEPs, and particularly when an infringement case has been based only on references to technical standards, the patentee should identify which standards he is relying on at an early stage in proceedings.

In a further *Vringo v ZTE*[83] judgment, **Birss J** held that licences for SEPs entered into by any entity in any party to the litigation's group of companies or any party's predecessor in title were relevant to the assessment of the royalty rate of a specific SEP, particularly with regard to whether or not there is a going rate for the licensing of SEPs in a defined technological area. He did, however, draw the line at details of licensing negotiations which he stated did not need to be disclosed.

An application made by Warner-Lambert for disclosure of certain documents relating to sales of Actavis' generic pregabalin medicine towards the end of the trial on the merits was refused[84]. **Arnold J** considered that the documents requested would likely be of marginal relevance and that the cost of obtaining them would be disproportionate. The Judge also held that the application was made too late because Warner-Lambert's legal team had been in possession of the information on which the application was based two to three weeks prior to the application. The lesson here is clear – applications for disclosure should be made as early as possible or the Court is likely to exercise its discretion not to make the order requested.

"The facts of this case show, yet again, the importance of adherence to [the duty of the parties in relation to a product description]" said **Carr J** in *Stretchline v H&M*[85], re-emphasising the duty stated by **Pumfrey J** in *Taylor v Ishida*[86]. **Carr J** found that both parties were at fault in their handling of the product and

[79] *Johnson v Gore Wood* [2002] AC 1; *Nikken v Pioneer* [2005] EWCA Civ 908
[80] *Warner-Lambert v Actavis* [2015] EWHC 3370 (Pat), at §148
[81] [2015] EWHC 1094 (Pat)
[82] [2015] EWHC 818 (Pat)
[83] [2015] EWHC 1704 (Pat)
[84] [2015] EWHC 2123 (Pat)
[85] [2015] EWHC 3298 (Pat), at §78
[86] [2000] FSR 224

process description (PPD) – H&M for allowing its expert to attest to the veracity of the PPD without having a full grasp of the facts or checking the data provided to him, and Stretchline for not having requested samples of the infringing fabric mentioned in a witness statement served months before trial. The Judge also made reference to the statement of **Pumfrey J** in *Minnesota Mining & Manufacturing Co.'s (Suspension Aerosol Formulation) Patent*[87] on the desirability of providing samples when providing particulars of the acts against which a declaration of non-infringement is sought, stating that in many cases samples should be provided alongside PPDs.

It is becoming a main theme of telecommunications patent litigation that phone manufacturers buy their chips from third parties who guard the secrecy of how their chips operate very carefully. In *TCT v Ericsson*[88], **Birss J** confirmed that the High Court has jurisdiction to issue Letters of Request to foreign courts seeking the production of documents despite the **CPR r.34.13** only contemplating such letters seeking the deposition of witnesses, thus allowing patentees such as Ericsson to have disclosure of the details of how chipsets work allowing them to assess infringement of their patents. In doing so, the Judge applied **Sir Donald Nicholls VC**'s reasoning in *Panayiotiu v Sony Music Entertainment*[89] where, having heard full argument, he decided that as a matter of its inherent jurisdiction the Court did have the jurisdiction to issue a Letter of Request relating only to the production of documents. An important element in the reasoning of **Nicholls VC** was that incoming Letters of Request could be in this form. As such, it did not seem sensible or realistic to think that, if a UK court would give effect to incoming Letters of Request for the production of documents alone from a foreign court, that somehow a UK court did not have the authority or jurisdiction to issue such Letters of Request to a foreign court. **Birss J** noted that, even though this case was decided under the **RSC**, it was clear that nothing in the **CPR** has made any difference to the reasoning in *Panayiotou*.

In *Regeneron v Kymab*[90] **Arnold J** restated that the key question to be asked in an application to use a confidential document that has been disclosed in English proceedings in parallel foreign proceedings was whether it is in the interests of justice to allow the party seeking to use the document to use it in the parallel proceedings, having regard to the interests of the opposing party in maintaining the confidentiality and restrictions on the use of the document. Regeneron's document went to the sufficiency of the patent in suit and, therefore, **Arnold J** held that the EPO should not reach a decision on insufficiency without the benefit of what appears to be an important document when an English Court has taken that document into account, particularly when the EPO and English Court hearings are close together.

Experiments

A party ignores the rules on experiments at its own risk. When time is short and agreement cannot be reached, a party may take the view that it is better to act now and argue later the admissibility of the experiments undertaken. However, a Judge may take the view that the prejudice caused by admitting the experiments outweighs their probative value. This was the situation in *Stretchline v H&M*[91], where Stretchline decided to run certain experiments not included in its original notice of experiments and argued that, because the experiments were of an elementary nature, there would be no prejudice to H&M if they were admitted. Perhaps unsurprisingly, H&M's expert did not agree and the matter came before **Morgan J** just four weeks before trial. He put a choice to Stretchline of whether to hold the trial date and forego the experiments, or adjourn and have them admitted. Stretchline chose the former.

Interim injunctions

As noted above, an interim injunction was refused against Actavis by **Arnold J** in respect of its skinny-label medicine in the Lyrica litigation on the basis that, not only was there no serious issue to be tried, but the balance of convenience also weighed in favour of there being no interim injunction. **Floyd LJ** agreed with **Arnold J** on the latter point on appeal.

In contrast, when Sandoz attempted to launch a full-label generic medicine in the autumn, it was restrained by an interim injunction – first temporarily by **Birss J** and then by **Arnold J**[92]. **Arnold J** did not accept Sandoz's argument that its case on the merits was

[87] [1999] RPC 135
[88] [2015] EWHC 938 (Pat)
[89] [1994] Ch 142
[90] [2015] EWHC 2580 (Pat)
[91] [2015] EWHC 2873 (Pat)
[92] [2015] EWHC 2919 (Pat); [2015] EWHC 3153 (Pat)

stronger than in Actavis' case and that this should be taken into account when assessing the balance of convenience. However, in a similar way to the case in *Smithkline Beecham v Apotex*[93] and *Novartis v Hospira*[94], **Arnold J** held that the harm to Warner-Lambert was unquantifiable and irreparable and that the balance of injustice favoured the imposition of an injunction. A cross-undertaking was made in favour of the NHS as well as Sandoz, but the Judge refused to order that Sandoz should benefit retrospectively from the cross-undertaking given to various generics at the time the NHS guidance was put in place in March, finding that if Sandoz wanted to benefit from this undertaking, they should have applied for it at the time.

An interim injunction was granted to Teva in respect of its patent directed to the use of rasagiline citrate in the treatment of Parkinson's disease[95]. Despite argument from Actavis that it had a *Gillette*[96] defence, i.e., that if there was infringement the patent was inevitably invalid over the prior art, **Arnold J** found that there was a serious issue to be tried and that although Actavis would lose the benefit of *"first mover advantage"*, the unquantifiable harm that Teva would suffer, combined with Actavis' failure to clear the way, tipped the scales in favour of granting an injunction.

Final injunctions

The question of the appropriate relief to be given when a second medical use patent is held valid and infringed remains a challenge for the English Courts. Everyone is clear that the goal should be to enable the patentee to retain the exclusivity for the patented indication whilst enabling free competition in the market for the non-patented indications. However, the landscape is complicated by the disconnect between the prescribing physician, the dispensing pharmacist and the payor (usually the government in the UK). In the application for interim relief in the pregabalin case, **Arnold J** described *"the best solution"* as physicians prescribing "Lyrica" for the patented pain indication and "pregabalin" for other indications[97]. Although physicians in the UK are strongly encouraged to prescribe with reference to the International Non-proprietary Name (or "INN") for the drug and not by brand, the pharmacist is legally obliged to dispense the branded medicine if the brand is specified on the prescription. This "best solution" was implemented later in the spring using the principles laid out in *Norwich Pharmacal*[98] and *Cartier v BSkyB*[99], although given that the Judge had already held that there was no serious issue to be tried on the issue of infringement, the ruling might be regarded as an extension of the *Norwich Pharmacal* principles[100]. The effectiveness of the NHS guidance is not entirely clear, it being contended by Warner-Lambert in the autumn that it *"had been less effective than [Arnold J] intended"*[101], but it is clear that **Arnold J** considers that early interaction with the NHS by a second medical use patent holder is important. As the Judge observed in the final part of his judgment following the main trial:

> *"I remain more convinced than ever that the best solution to the problem of protecting the monopoly conferred by a second medical use patent while allowing lawful generic competition for non-patented indications of the substance in question is to separate the patented market for the substance from the non-patented market by ensuring that prescribers write prescriptions for the patented indication by reference to the patentee's brand name and write prescriptions for non-patented indications by reference to the generic name of the substance (the INN) ... What is needed is for centralised and authoritative guidance to be given to prescribers as to when this practice should be adopted. ... I consider that it behoves patentees who want their second medical use patents enforced to provide NHS England with all the information and assistance it requires to enable it to issue appropriate guidance as and when required. I also consider that it behoves generic companies who want their interests in obtaining untroubled access to lawful markets protected to cooperate with NHS England as well. ... I therefore trust that the Secretary of State will take steps to ensure that a suitable system is put in place in England. I also trust that he will liaise with his counterparts in the Welsh, Scottish and Northern Irish administrations to try to ensure that the system operates across the whole of the UK"*[102].

Readers may recall *Adaptive Spectrum v BT*[103], from last year's review, as the case in which the Court of Appeal rejected BT's request for a cross-

[93] [2003] EWCA Civ 137
[94] [2013] EWCA Civ 583
[95] *Teva v Actavis* [2015] EWHC 2604 (Pat)
[96] *Gillette Safety Razor Company v Anglo-American Trading Company* (1913) 30 RPC 465
[97] [2015] EWHC 72 (Pat), at §73
[98] *Norwich Pharmacal v Customs and Excise Commissioners* [1973] FSR 365
[99] [2014] EWHC 3354 (Ch)
[100] [2015] EWHC 485 (Pat)
[101] *Warner-Lambert v Sandoz and Lloyds* [2015] EWHC 3153 (Pat), at §72
[102] [2015] EWHC 2548 (Pat), at §724
[103] [2014] EWCA Civ 1513

undertaking under a final injunction pending the outcome of EPO proceedings. With **Floyd LJ** giving the leading judgment, the Court of Appeal rejected the request because a final determination on validity had already been made in the English proceedings. Notwithstanding this precedent, the Court of Appeal did grant a stay of a final injunction pending EPO proceedings in *Smith & Nephew v Convatec*[104]. It did so in part because Smith & Nephew were seeking permission to appeal the claim construction issue on numerical ranges to the Supreme Court and partly because the extra time to the likely hearing date before the Technical Board of Appeal was very short. Furthermore, the balance of interests strongly favoured Smith & Nephew in that evidence was heard that its business would be irreparably damaged by the removal of its product from the market in circumstances where a related product had already been wrongly removed from the market in earlier proceedings. Although the merits of the EPO case were not a factor said to be taken into consideration, the Court did at least remark that the patent had already been revoked once by the TBA and the subsequently amended patent had already been revoked by the Opposition Division upon remittal.

Unjustified threats

As readers will know, it is possible to fall foul of the provisions relating to groundless threats of patent infringement even in relation to a patent application that has yet to grant. This was established by the Court of Appeal in *Brain*[105]. It was also established that in order for the owner of a patent application to rely on the defence of justification (i.e., that the threats were not groundless because the acts complained of would constitute infringement of a valid patent), he must: (i) ensure the patent is granted before trial; (ii) establish that the acts would have infringed the patent had it been granted on the date the patent application was published; and (iii) show that the acts would have infringed one or more claims of the application in the form they took immediately before preparations for its publication were completed.

In light of *Brain*, **HHJ Hacon** was invited to grant summary judgment in the case of *Global Flood Defence v Van Den Noort*[106] against the owner of a patent application concerned with flood defence systems on the basis that the owner had no realistic defence of justification. The reasoning of the claimant was that: (i) there was no prospect of patent grant before trial; (ii) the infringement proceedings were threatened imminently (not after grant); and (iii) they included products which fell outside the scope of the application. The Judge declined to grant summary judgment on the basis that the second argument failed: it was not the immediacy of the proceedings that was being communicated but that of the acts of the claimant, which if done or continued would have infringed the owner's rights under **section 69** of the **Act**.

Unjustified threats were also an issue in the pregabalin litigation[107], it being held that some of the communications Warner-Lambert had sent to pharmacists and other healthcare professionals would have been understood as a threat of litigation.

Application to re-open trial post-judgment

In *Vringo v ZTE*[108], ZTE found new prior art after judgment had been handed down but before the order had been sealed. **Birss J** rejected ZTE's application to re-open the trial, applying the conditions set out in *Ladd v Marshall*[109] for leave to adduce further evidence on appeal: (i) could the evidence have been obtained with reasonable diligence for use at trial?; (ii) would the evidence have an important influence on the case (though it need not be decisive)?; and (iii) is the evidence credible? Although he noted that a first instance trial judge ought to apply the *Ladd v Marshall* factors more leniently than would an appellate court, on any analysis of the factors, powerful reasons would be needed to justify the application. No such reasons could be found. Upon standing back, looking at the matter overall and applying the overriding objective, the Judge considered that ZTE's application could and should have been made before trial. To re-open the trial would have serious consequences for the Court's resources and the finality of the decision, as well as a serious impact on other court users.

Assignment

An interesting point of law was decided in a rather unexpected forum when **Cooke J**, sitting in the

[104] [2015] EWCA Civ 803
[105] *Brain v Ingledew Brown Bennison & Garrett* [1996] FSR 341
[106] [2015] EWHC 2087 (IPEC)
[107] See footnote 12, *ante*
[108] [2015] EWHC 214 (Pat)
[109] [1954] 1 WLR 1489

Queen's Bench Division and dealing with a claim for unpaid solicitors' fees in *Wright Hassall LLP v Horton*[110], found that there was no clear authority on whether the assignment of a patent requires consideration or not to be valid. The Judge held that no authority existed and that an instrument in writing satisfying the requirements of the **Act** is effective as a legal assignment, without any additional requirement for consideration.

Issues from the IPEC

HHJ Hacon continues to build on the reputation of the IPEC established by **Birss J** as a forum for sensibly managed smaller disputes heard within a shorter timeframe at lower cost. **Carr J**, in granting permission to appeal in the IPEC case of *Pacific Rim v PKF*[111], expressed dissatisfaction that a two hour application to amend a defence had been listed for a hearing some seven months after its listing appointment and suggested increased use of deputy judges within the IPEC to address this situation. In dealing with the appeal, he upheld the first instance decision, refusing permission to amend on the basis that the amendment introduced a pleading of prior use which should have been made at the case management conference some six months before the application was made. Interestingly, he also allowed Pacific Rim to withdraw its consent to the amendment, made in a signed consent order, where that order had not yet been sealed by the Court. He did so on the basis that, since consent was first given, PKF had made further applications for third party disclosure which came as a surprise to Pacific Rim and would have a bearing on the issue of prior use.

Readers will be aware that the IPEC exists as a specialist list within the Chancery Division of the High Court, having jurisdiction that is co-extensive with that of the rest of the Chancery Division. An interesting point of law concerning this jurisdiction arose before **HHJ Hacon** in unfortunate circumstances. The context is *Brundle v Perry*[112] (readers are referred to our Quotation of the Year in last year's review). Mr Perry had been made bankrupt following a £50,000 costs order made against him in previous proceedings in which he was held liable for making groundless threats of patent infringement[113]. Not wishing to be defeated, Mr Perry then embarked upon a succession of further actions. He unsuccessfully appealed the first instance decision against him on threats and non-infringement and, in an unsuccessful application described as *"almost incomprehensible"*[114], he sought permission to continue acting as a director of his company notwithstanding the bankruptcy order. He also unsuccessfully appealed the order for bankruptcy itself. He then returned to the IPEC to sue the original defendants again for patent infringement raising an allegation of fraud. During the course of these new proceedings, he made four further applications dealing with "theft" of his patent, permission to amend his claim based on criminal activity, the lifting of the IPEC damages cap and allegations against the defendants' solicitors for collusion, malicious prosecution and concealment of criminal activity. **HHJ Hacon** observed that *"once left to consider his position afterwards, [Mr Perry's] attitude hardens and his behaviour can become unrestrained and frequently abusive"*[115]. Accordingly, and perhaps unsurprisingly, the Judge considered whether he had the jurisdiction to make an extended Civil Restraining Order against Mr Perry. The Judge decided the question in the affirmative, holding that he was effectively sitting as *"a judge of the High Court"* for the purpose of **CPR PD3C §3.1B**. As such, in addition to striking out Mr Perry's new claim under the bar of *res judicata*, **HHJ Hacon** imposed an extended Civil Restraining Order quashing all future claims by Mr Perry.

The principles to be applied to applications for the transfer of proceedings from the Patents Court to the IPEC are well established[116]. It was the complexity of the issues that tipped the balance in favour of the rejection of an application for transfer to the IPEC made by the defendants in *Canon v Badger*[117], a case concerning printer cartridges that involved what promised to be an intricate inquiry into the facts relating to infringement, as well as a revocation case involving three pieces of prior art. **Arnold J** decided that this could not be accommodated within the two days of an IPEC trial but that he would bring to bear some active case management so as not to prejudice unduly the interests of the three defendants, all of which were SMEs.

[110] [2015] EWHC 3716 (QB)
[111] [2015] EWHC 3735 (Ch)
[112] [2015] EWHC 3056 (IPEC); [2015] EWHC 2737 (IPEC)
[113] [2014] EWHC 475 (IPEC)
[114] Application before District Judge Britton in Bristol County Court (8 July 2015)
[115] [2015] EWHC 2737 (IPEC), at §33
[116] *Comic Enterprises v Fox* [2012] FSR 30
[117] [2015] EWHC 259 (Pat)

Unitary patent / Unified Patent Court

In his introduction last year, your author admonished himself for being a little too optimistic about the pace of progress for the dossier in 2014. This year he is feeling distinctly smug that his predictions were almost entirely correct, and his best guess of the UPC starting up in 2017, possibly the second half, remains pretty reasonable. In fact, it is actually a little pessimistic with the first half of 2017 now being a very good bet. That this is so is a huge compliment to the Preparatory Committee which, despite limited resources, has done a fabulous job in dealing with what was frankly rather a mess left by the politicians who handed the practicalities over to them back in February 2013: getting a brand new multi-national judicial system up and running in little more than four years is a great achievement.

2015 in a nutshell

The major event of the year was perhaps the dismissal in May by the CJEU of the so-called "second Spanish Challenge" to the legality of the Unitary patent and language Regulations. Even though this strictly related to the Regulations, its effect was to clear away the last remaining legal hurdle to the new Court coming into existence, since as we know, the UPC and the Unitary patent are conjoined projects: no Unitary patents, no UPC; and no UPC, no Unitary patents.

The other really significant development was the EPO reaching agreement on the renewal fees and distribution key. Your author confesses that he harboured real doubts that this would be agreed at all given that it was a major reason the predecessor project stalled in 2004. At that time 15 countries were trying to reach agreement, and where they failed, 26 have now succeeded. (It is 26 rather than 25 because, significantly, Italy has now signed up fully to the project.)

On the domestic front, there was a delay in the UK's ratification progress. There is nothing sinister in this, however, since the UK's commitment to the project is not in doubt, and insofar as confirmation were needed, it was given by the announcement in August that the seat of the London branch of the Central Division and Local Division would be in a brand new building in Aldgate, near the heart of London's financial and legal district.

Other matters of importance during the year included:

- Publication in September of the rules of the European Patent Litigation Certificate.
- Signature in October of a new Protocol by many of the signatories to the UPC Agreement meaning that a new Provisional Authority can be created to take over the role of the Preparatory Committee by about mid-2016 and accept opt outs in advance of the Court opening.
- Publication of the 18th (and near final) draft of the Rules of Procedure in October.

Don't mention "Brexit"

So what could now possibly go wrong?

Perhaps Germany will, contrary to expectations, not proceed with ratification? This seems unlikely, however, and recent news suggests ratification is likely by the end of the year, and only marginally after the UK. If so, and given the strong likelihood that the remaining required number of states will also have ratified by then, it seems inevitable that the politicians will have done their bit by the autumn, or at least by the end of the calendar year. Of course, one or both of Germany and the UK will hold back from depositing their instrument of ratification so as to bring the new system into force at a time when everything is ready, notably the IT system, the Court structure and not least of all, a body of judges.

So if it is not Germany, could it be the UK? As mentioned above, the UK Government seems committed to the UPC. But is the UK populace committed to the EU? As is universally known, there will be a UK in-out referendum on 23 June 2016. Hence, the question arises: what if there is a vote to leave, and in particular:

1. Could the UK enter into the new system nonetheless?

2. If not, what then?

To answer these questions, one must first 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. On the first question, it may at first blush seem unthinkable to go ahead with the UPC which included the UK in the face of an "out" vote. However, on deeper consideration it is at least possible to contemplate the UK joining the UPC in the sure and certain knowledge that it would have to leave later. The reason is that on any estimate, untangling the UK from the EU would not be short task. Article 50 of the Treaty on European Union (as amended by the Lisbon Treaty) dictates that this should be complete within two years, but even if only that short a period, there may be good reason to allow the UPC to proceed, whilst permitting the other parties a period to transition to a UK-less system.

With regard to the second question, the key issue if that Article 89(1) of the UPC Agreement provides: *"This Agreement shall enter into force ... on the first day of the fourth month after the deposit of the thirteenth instrument of ratification or accession in accordance with Article 84, …..including the three Member States in which the highest number of European patents had effect in the year preceding the year in which the signature of the Agreement takes place ..."* (emphasis added). The three relevant countries included the UK. Hence, if the UK leaves the EU, Italy would replace it to join France and Germany as the three mandatory ratifying countries. This is because it was the fourth most popular country for validation in 2012. (The Netherlands was in fifth place, but was included in the Unitary patent "True Top 4" list because, at the time, Italy was not intending to join the Unitary patent part of the system.) But the key point here is that if there is an "out" vote, unless and until the UK actually leaves the EU, the UPC will be stalled – but probably only for two years.

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

Other matters for 2016

Finally, what other points should we look out for in 2016?

One especially contentious issue has been the opt-out fee. Pressure was applied to reduce this from the proposed €80, preferably to zero, and this was indeed the decision of the Preparatory Committee when it met on 24 and 25 February. Well done to all who lobbied for that change.

There are also some points which are important but which may not catch the public imagination. These include the precise arrangements for filing opt- outs. On this, the current suggestion on the table is for filing one opt-out at a time. This would be an administrator's nightmare and pressure is being applied to change this too. Another is the rules (more accurately guidelines) for assessing value and hence Court fees, as well as a final decision on the level of Court fees themselves. Again, a decision was reached at the February Preparatory Committee meeting. More details are available on the Bristows UPC site.

But there is one really significant issue which needs attention. It is the question of judges. There remains considerable uncertainty as to who they will be. Will the salary and other conditions of employment be sufficient to attract the best candidates? We now know from the February Preparatory Committee meeting that the first instance judges will be paid €132,000 per year and the Court of Appeal judges €144,000. Even though tax free, will that attract the best candidates, notably from the UK? Judicial training (including international secondments) commenced in 2015 and, indeed, Mr Justice Birss was spotted in November sitting in trial with a Czech judge at his side. But the application process has yet to begin - early summer is now a good guess. Further, despite speculation, no-one knows who the first President of the Court will be, beyond that he or she will be French because that is part of the deal that Paris hosts the seat of the Central Division. Likewise, no-one knows who will be the first President of the Court of Appeal:

that person can be of any nationality, but English, German, or maybe Dutch would be most likely. These are important matters. The success of the system depends not only upon the Court structure and its rules, but also – and perhaps mainly – its judges. We must all hope that they are of the highest quality.

Looking Ahead to 2016

2016 already looks set to be a busy year with significant disputes in all sectors being heard. The substantive issues in the pregabalin litigation are fixed to be heard by the Court of Appeal in late May. This litigation is surely destined for the Supreme Court. On the TMT side, the *Unwired Planet* litigation will be very active in 2016 with a further three technical trials listed in 2016 to go with the two trials heard in 2015 as well as the mammoth non-technical trial to be heard in October 2016 by **Birss J**. As noted above, **Carr J** has made a predictably strong start as a Judge and we are confident that he will continue to adopt a fair and pragmatic approach to his cases. Most importantly of all, the UPC will gear up for its opening scheduled for 2017 and we hope to be able to report on the final preparatory steps, including the take-up of the opt-out provisions, in next year's review.

The Authors

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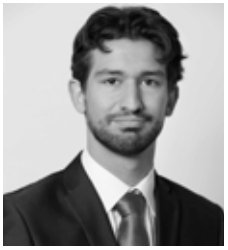

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01

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04

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