Wragge Lawrence Graham &Co

"And then there were three…"

Gordon Harris, 2016

18th Annual Patent Seminar

Dedicated to the memory of David Keltie 1938 – 2016

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1 INTRODUCTION

After a few relatively quiet years, with some very specific issues being decided, but little activity on "general principles", 2015 turned out to be a bumper year. We found 75 reported decisions on patent matters in the United Kingdom – easily the most in the 19 years I have been presenting this paper.

Last year I commented that "most of the key principles are stable and most of the tests which are applied in the operation of those principles remain the same". I am far from sure that I could say the same this year, and an outbreak of inter-judiciary squabbling has not assisted in finding consistent threads.

Last year I also speculated as to whether we were returning to the "bad old days" of the UK being seen as an anti-patent jurisdiction. I expressed concern that the two Patents Court judges were leaning towards meddling with well-established principles. Arnold J seemed to be importing file wrapper estoppel through the back door, while Birss J was confusing "could" and "would" in the vexed area of obviousness to try.

And then there were three… The well-deserved elevation of Henry Carr QC to Mr Justice Carr has added a new dimension, and in a few short months he has started to make an impression – and as we will see, in my view, a favourable one.

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

2 INFRINGEMENT

2.1 Construction

It always surprises me that there is so much to say about construction each year, but it goes on, and 2015 has seen a lot of noteworthy contributions.

Prosecution history estoppel

Last year I was critical of Arnold J's decision in ***Actavis v Lilly*** **(pemetrexed case)[1],** where he appeared to introduce a form of file wrapper estoppel. He said:

> *"In some cases, perhaps not very many, the prosecution history is short, simple and shows clearly why the claims are expressed in the manner in which they are to be found in the granted patent and not in some broader manner. In such a situation, there is no good reason why the court should shut its eyes to the story told by the prosecution file. On the contrary, consideration of the prosecution file may assist in*

[1] *Actavis UK Limited & Ors v Eli Lilly & Company* [2014] EWHC 1511 (Pat) (15 May 2014, pemetrexed case)

ensuring that patentees do not abuse the system by accepting narrow claims during prosecution and then arguing for a broad construction of those claims for the purpose of infringement."[2]

Although he said that there was no such doctrine in the UK, I concluded that if the principle purpose for considering the prosecution history was to ensure that the patentee does not seek to make broader claims than he is really entitled to on the basis of assertions made during the prosecution process, what else is that but a form of file wrapper estoppel?

The Court of Appeal[3] was unimpressed. Floyd LJ delivered a substantial lecture on the law relating to construction, reviewing both the "Protocol Questions" and the *Kirin Amgen* decision at length. He said:

"The difficulty I feel with endorsing this reasoning is as follows. Firstly it assumes that the skilled reader will always read the prosecution history. I do not see why this should be so, given the limited value which, at least before the judgment in this case, it was generally recognised to have. Secondly, and more importantly, it suggests that the story told by the prosecution history of how the claims came to be drafted as they were will assist the court in preventing abuse of the system. To my mind this will be a very rare case indeed. Unless the acceptance of a restriction in a claim is to operate as some kind of estoppel against the patentee arguing for wider claims (a proposition for which neither side contended…) there will always remain an issue as to whether the applicant needed to accept the restriction notwithstanding that he did so. In those circumstances, the light which the prosecution history sheds on the ultimate question of construction is likely to be extremely limited."[4]

He went on:

"I therefore do not regard it as useful to go to the prosecution history in order to discover that the patentee accepted a restriction to his claim against an objection of lack of support in the specification. It is always open to a party attacking the patent to argue that the claims as sought to be construed by the patentee lack support in the specification… What purpose does it serve to illustrate this point by showing that the patentee was faced with an official objection to that effect and amended his claims in the light of it? It is still open to the patentee to say that he need not have done so, and the apparent concession he made in prosecution was wrongly made. If it is not open to the patentee so to contend, then the prosecution history is indeed creating a form of estoppel".[5]

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[2] *Actavis & Ors v Eli Lilly* [2014] EWHC 1511 (Pat) (15 May 2014, pemetrexed case) at [11]

[3] *Actavis UK Limited & Ors v Eli Lilly & Company* [2015] EWCA Civ 555 (25 June 2015, pemetrexed case)

[4] *Actavis & Ors v Eli Lilly* [2015] EWCA Civ 555 (25 June 2015, pemetrexed case) at [58]

[5] *Actavis v Eli Lilly* [2015] EWCA Civ 555 (25 June 2015, pemetrexed case) at [59]

He concluded:

> *"In any event, patent offices are usually concerned with patentability, not scope of protection. If an applicant were to conclude every letter by saying that he did not accept that by accepting this or that limitation he was necessarily restricting the scope of protection, no inference could be drawn from his conduct in accepting it. I would be reluctant to put the patent attorney's profession to this unnecessary trouble."*[6]

This was a case involving "Swiss form" claims.

Swiss form claim construction

By way of revision, a "Swiss form" claim is a patent claim expressed as:

> *"The use of (a) in the manufacture of a medicament for the treatment of disease (b)"*[7].

It is a way around the general exclusion from patentability of methods of medical treatment contained in the European Patent Convention and the UK Patents Act 1977. There has been a considerable amount of activity regarding the construction of Swiss form claims in 2015. Following the EPC 2000 and the Enlarged Board of Appeal's decision in G2/08 (ABBOTT RESPIRATORY/dosage regimes, 19 February 2010), Swiss form claims are no longer granted, 'EPC 2000' format being the appropriate structure, but the last Swiss form claim will not expire until 2030, so we will continue to be concerned with them for some time to come.

The construction of Swiss form claims has been a particularly contentious subject this year in litigation in the English courts.

In extensive litigation involving **Warner-Lambert,** the subject of matter of the patent was the drug known as pregabalin. This is a drug marketed by Warner-Lambert/Pfizer with approval for the treatment of epilepsy, generalised anxiety disorder and neuropathic pain. Warner-Lambert sell the original version under the name Lyrica and it is a very substantial selling drug in the United Kingdom. At least at the early stages of the litigation in the UK in 2015, up to 44% of sales of Lyrica were thought to be for the relief of neuropathic pain. Patent protection for the pregabalin compound had expired, but Warner-Lambert continued to have patent protection in Swiss form directed to pregabalin for treating pain (claim 1), with dependent claims to more limited pain categories, including neuropathic pain (claim 3).

Generics (trading as Mylan) sought revocation of Warner-Lambert's patent, as did Actavis. In the meantime, Actavis applied for, and became close to obtaining marketing authorisation for, a generic pregabalin medicine with 'approval' limited to epilepsy and GAD. Once they obtained marketing authorisation they planned to launch their 'skinny label' pregabalin medicine in the UK under the trademark Lecaent.

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[6] *Actavis v Eli Lilly* [2015] EWCA Civ 555 (25 June 2015, pemetrexed case) at [60]

[7] G5/85 EISAI/second medical indication, 5 December 1984 [1985 OJ EPO 64]

In the UK, where a doctor's prescription specifies a particular brand of medicine, the pharmacist must dispense that brand. However the overwhelming majority of prescriptions are written by reference to the international non-proprietary name of the active ingredients. At present, prescriptions tend rarely to specify, and a dispensing pharmacist only rarely knows, the indication for which a drug has been prescribed.

In the circumstances, and in view of the pricing mechanisms governing pharmaceutical products in the UK, Warner-Lambert contended that without taking appropriate steps to ensure that Actavis' generic pregabalin medicine was not dispensed for neuropathic pain, Actavis' launch of its skinny label medicine would infringe the patent and cause irreparable harm to Warner-Lambert before trial of the main action. Actavis disagreed. Actavis had taken, or offered to take, some steps to try to ensure that generic pregabalin would be neither prescribed nor dispensed for pain treatment, but Warner-Lambert did not consider these sufficient and sought an order for an interim injunction in mandatory form to place further positive obligations on Actavis.

In ***Warner-Lambert v Actavis (*21 January 2015)**[8] Arnold J refused to award Warner-Lambert the interim injunctive relief sought. Before addressing the usual commercial aspects relevant to an application for an interim injunction, a key question was whether there was a serious issue to be tried. In this context an issue arose as to the construction of the word "for" in the Swiss form claim in issue.

Arnold J said:

> *"Counsel for Actavis submitted that the word "for" in claims 1 and 3 of the Patent should be given a purposive construction, and that the only construction which gave effect to the purpose of Swiss form claims, and the policies underlying the granting of such claims, was to interpret "for" as meaning "suitable and (subjectively) intended for". Furthermore, he argued that Warner-Lambert's construction failed to achieve this. In this regard, he drew attention to the position of an inventor who patents a first medical use for a compound and markets the compound for that use. Subsequently a second inventor patents a second medical use for the same compound and markets the compound for that use. The first inventor carries on marketing the compound for the first use. For reasons such as those discussed in this judgment, it is foreseeable that the first inventor's product will in fact be dispensed for the second use. If foreseeability is enough, the first inventor will infringe the second patent simply by carrying on doing what he was doing before the second patent was applied for. The same is true if foreseeability is not enough, but actual knowledge that the first inventor's product is being dispensed for the second use is enough. Nothing less than a requirement of subjective intention will protect the first inventor from infringement. The same applies to a third party who sells the same product for the same purpose as the first inventor."*[9]

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[8] *Warner-Lambert Company LLC v Actavis Group PTC EHF & Ors* [2015] EWHC 72 (Pat) (21 January 2015)

[9] *Warner-Lambert v Actavis & Ors* [2015] EWHC 72 (Pat) (21 January 2015) at [109]

Arnold J considered various authorities then concluded:

> *"Counsel for Warner-Lambert had no cogent answer to this argument, and I accept it. Accordingly, I would hold that the word "for" in Swiss form claims imports a requirement of subjective intention on the part of the manufacturer that the medicament or pharmaceutical composition will be used for treating the specified condition."*[10]

The case duly headed off to the Court of Appeal[11] in quick time. Although the decision to refuse an injunction was upheld on the balance of commercial convenience, the Court of Appeal took a wholly different approach to the construction of Swiss form claims ***(Warner-Lambert v Actavis* (28 May 2015)).**

Giving a general critique of the whole notion of Swiss form claims, Lord Justice Floyd concluded:

> *"Legal rules which are not soundly based resemble proverbial bad pennies: they turn up again and again."*[12]

That is certainly true in relation to matters involving Swiss form claims in 2015!

Turning to the case in hand, Floyd LJ described the issues in front of him as follows:

> *"In a commendably succinct judgment on what is a very difficult question Arnold J started by recording that it was common ground that the word "for" in claims such as those in the patent were to be understood as "suitable and intended for". It was further common ground that pregabalin was suitable for treating neuropathic pain. The questions were twofold: whose intention was relevant, and what was comprised in the requirement of intention? Warner-Lambert said it was sufficient if Actavis intended to sell pregabalin and knew that pharmacists were likely to dispense it for treating neuropathic pain if positive steps were not taken to prevent this. Actavis contended that such knowledge was not sufficient and that what was required was a subjective intention on their part that Lecaent should be used for treating pain. The judge accepted Actavis' argument that subjective intention on the part of the manufacturer was required."*[13]

The first big conclusion was to establish once and for all that Swiss form claims are "process" not "product" claims:

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[10] *Warner-Lambert v Actavis & Ors* [2015] EWHC 72 (Pat) (21 January 2015) at [111]

[11] *Warner-Lambert Company LLC v Actavis Group PTC EHF & Ors* [2015] EWCA Civ 556 (Pat) (28 May 2015)

[12] *Warner-Lambert v Actavis & Ors* [2015] EWCA Civ 556 (Pat) (28 May 2015) at [54]

[13] *Warner-Lambert v Actavis & Ors* [2015] EWCA Civ 556 (Pat) (28 May 2015) at [99]

> *"Thus the first question is to determine the category of claim and its technical features: the technical subject matter of the claim. We know from the authorities cited above that the claim is a process claim. The skilled person would understand that the technical features of the present claim extend beyond making pregabalin, yet fall short of including the step of actually using pregabalin for treating pain. Instead it includes a feature concerned with the ultimate purpose of the product manufactured, namely the intentional treatment of pain. I would describe the subject matter of the claim, therefore, as making pregabalin for patients to whom it will be intentionally administered for treating pain. Making pregabalin for patients to whom it is to be administered for the non-patented indications is not within the technical subject matter of the claim. Only the former category of manufacture makes use of the technical contribution of the patentee."*[14]

He elaborated further saying:

> *"The skilled person would understand that the claim in question owes its novelty to the discovery of the new therapeutic use of the medicament. This emerges from a number of cases."*[15]

He then went on to recite the formulation of Swiss form claims set out by Jacob LJ in *Actavis v Merck*[16] where he said:

> *"The novelty of the process (i.e. use of X in the manufacture of a medicament for Y) comes from the "new therapeutic use"."*[17]

Floyd LJ then moved on to the crucial issue of the meaning in this context of the word "for". He said:

> *"Against that background the skilled person would understand the word "for" in the claim to be providing a link between the act of manufacture using pregabalin and the ultimate intentional use of the drug by the end user to treat pain. The critical issue for me to decide is what is sufficient to constitute that link. An extreme view might be that if the drug is in fact used for the patented indication then it has been made "for" that indication, whatever the manufacturer's intention might be…*
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> *It would mean that a manufacturer could not tell whether he had made use of the subject matter until after, and perhaps a long time after, he had disposed of the product. The realistic candidates are therefore (a) foreseeability that the drug will*

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[14] *Warner-Lambert v Actavis & Ors* [2015] EWCA Civ 556 (Pat) (28 May 2015) at [118]

[15] *Warner-Lambert v Actavis & Ors* [2015] EWCA Civ 556 (Pat) (28 May 2015) at [120]

[16] *Actavis UK Ltd v Merck & Co. Inc* [2008] EWCA Civ 444 at [27]

[17] *Warner-Lambert v Actavis & Ors* [2015] EWCA Civ 556 (Pat) (28 May 2015) at [120]

intentionally be used for the patented indication and (b) a subjective intention to that effect."[18]

He then answered his own question as to the preference between those two candidates, saying:

"…as this court made clear in Actavis v Merck, the objection of lack of patentable subject matter is overcome by the fact that the claim is a manufacturing process claim. The skilled person would thus appreciate that there is no reason to imply a narrow or strict mental element in order to ensure that this peril is avoided."[19]

Summing up and concluding Floyd LJ said:

"I can therefore see no reason why the skilled person would conclude that the word "for" implied subjective intent. He would understand that the manufacturer who knows (and for this purpose constructive knowledge is enough) or could reasonably foresee that some of his drug will intentionally be used for pain is making use of the patentee's inventive contribution, in the same way as a manufacturer who actively desires that result. In my judgment, therefore, the skilled person would understand that the patentee was using the word "for" in the claim to require that the manufacturer knows (in the above sense) or can reasonably foresee the ultimate intentional use for pain, not that he have that specific intention or desire himself."[20]

The judge went on to note that section 60(1)(b) of the Patents Act 1977 makes it an infringement to use the process. There is no mental requirement: liability is strict. Floyd LJ concluded:

"How does one tell whether a manufacturer is using the manufacturing process of the claim, and therefore rendering himself liable for patent infringement? The answer must be when he manufactures pregabalin when he knows or foresees that users will intentionally administer it for pain."[21]

Even the use of the "intentionally" in that last sentence opens up a multitude of issues. Intention continues to be a relevant consideration, but the relevant intention is passed further down the line to the user. To infringe the patent, the manufacturer using the process must either know or foresee that those further down the chain will "intentionally" administer it for the purpose protected by the Swiss form claim.

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[18] *Warner-Lambert v Actavis & Ors* [2015] EWCA Civ 556 (Pat) (28 May 2015) at [122]

[19] *Warner-Lambert v Actavis & Ors* [2015] EWCA Civ 556 (Pat) (28 May 2015) at [123]

[20] *Warner-Lambert v Actavis & Ors* [2015] EWCA Civ 556 (Pat) (28 May 2015) at [127]

[21] *Warner-Lambert v Actavis & Ors* [2015] EWCA Civ 556 (Pat) (28 May 2015) at [129]

Even Floyd LJ himself identified that there were a number of "hard cases" arising from his conclusion. What if a manufacturer has been selling the medicine in question before the priority date? Is it fair that he be made an infringer when his sales increase because of the uptake of the old product for the new use, and when he has done nothing to solicit this new business? Floyd LJ felt that the answer to any potential unfairness may lie in the relief to be granted. He recognised that a general injunction prohibiting the sale of the product itself would plainly not be justifiable, and that it may in fact be unjust and inconvenient to grant an injunction at all. He went further and said that it may be that the grant of an injunction would be inappropriate even if the manufacturer was not a prior user, where to grant an unqualified injunction would unfairly prejudice his right to sell the drug for the non-patented indications.

The interim issues having been dispensed with, the substantive issues arose in a trial before Arnold J later in 2015. Having praised Arnold for his "succinct" judgment in the interim injunction dispute, I wonder what Floyd J will make of the substantive judgment! Arnold J's 10 September 2015 decision in the Warner-Lambert pregabalin litigation concerned the revocation actions (and claims for threats) brought by Generics (trading as Mylan) and Actavis and Warner-Lambert's claims for infringement against those parties. The title of the decision accords with the senior revocation claim: ***Generics (t/a Mylan) v Warner-Lambert (10 September 2015)***[22]. The decision is compendious in its consideration of virtually every issue in patent law and we will be meeting it again repeatedly during this paper. It runs to over 80,000 words and 727 paragraphs.

Arnold J made a series of key rulings on construction. These were:

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

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

- Claim three was its use for treating "neuropathic pain", which Arnold J ruled encompassed both central and peripheral types of neuropathic pain and was not (as Warner-Lambert contended that the skilled person would understand it) limited to peripheral neuropathic pain. Arnold J reasoned that the term appeared to be used in the patent quite generally, and with no reference to "peripheral neuropathic pain", nor any indication that central neuropathic pain was not intended to be included.

Arnold J held that, as the Court of Appeal had not overruled the decision to refuse an injunction, any comments they made on the question of construction were merely *obiter*, and

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[22] *Generics (UK) Limited (trading as Mylan) & Ors v Warner-Lambert Company LLC* [2015] EWHC 2548 (Pat) (10 September 2015)

not binding on the lower court. He promptly went on to disagree with many of the Court of Appeal's findings on construction.

For example, Arnold J found that Lord Justice Floyd's construction of "for" had the consequence:

> *"…that, if it was foreseeable to an unlicensed manufacturer of pregabalin that "*some *of his drug" … would be intentionally administered for the treatment of pain, then all of that manufacturer's acts of manufacture of pregabalin would be infringing acts even though it was foreseeable that the remainder of its pregabalin would be administered for the treatment of non-patented indications… Further, all of the pregabalin would be infringing product, and thus anyone who subsequently dealt in it would also infringe on a strict liability basis."*[23]

Arnold J commented that he thought it was "reasonably clear" from Lord Justice Floyd's judgment that he did not intend his interpretation to have this consequence. However, the only indication he could see as to how Floyd LJ thought it was to be avoided was in the discussion of the question of remedies.

He said he had "*considerable doubts*" as to the correctness of Floyd LJ's interpretation, though he said that as he was not "*entirely convinced*" that Floyd LJ was wrong, he did not want to depart too far from his reasonings.

Instead, he chose to interpret the Court of Appeal's judgment in a creative manner:

> *"There are two main aspects of the dispute. First, counsel for Pfizer submitted that there was no real difference between Floyd LJ's interpretation of the word "for" and a pure test of foreseeability on the part of the manufacturer that its pregabalin would in fact be used for the treatment of pain. I do not accept this submission. Floyd LJ made it clear … that intentional administration was at the heart of the invention, that … the word "for" provided the link between the manufacture of pregabalin and the intentional use of the drug, … that the word "for" required knowledge or foresight of the ultimate intentional use, … that there were two mental states involved and … that a manufacturer infringes when he knows or foresees that users will intentionally administer pregabalin for the treatment of pain. Thus the requirement of intention is central to his interpretation. It is plainly not a pure test of foreseeability. Furthermore, I agree with counsel for Actavis that a pure test of foreseeability would not be enough to confer novelty on the claim. It is the element of intention which ensures novelty."*[24]

It is easy to see where Arnold J is going in that passage, though it is interesting that he seems to impute two mental states. The first is the manufacturer's foresight that infringement will occur further down the chain, and the second is the intentional administration by users for the treatment of pain, in other words the purpose protected by the patent. It is equally arguable,

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[23] *Generics (t/a Mylan) v Warner-Lambert* [2015] EWHC 2548 (Pat) (10 September 2015) at [627]

[24] *Generics (t/a Mylan) v Warner-Lambert* [2015] EWHC 2548 (Pat) (10 September 2015) at [634]

in my view, that you can conflate those two areas to a single mental state. It is the manufacturer's foresight of intentional use which really matters.

In any event, Arnold J certainly appears to be differing from the reasoning of Lord Justice Floyd who, in the Court of Appeal's interim injunction decision said:

> *"If [counsel] were correct that a subjective mental element on the part of the manufacturer were necessary in order to provide the claim with novelty, there would be powerful reasons for adopting it. However, I do not see how that can in fact be so. If a product is "for" a particular therapeutic indication if it is reasonably foreseeable that it will be used intentionally for the treatment of pain, then it will not be rendered lacking in novelty by showing that products in the prior art have been manufactured in circumstances when it was not possible to foresee such a result."*[25]

An alternative interpretation of Floyd LJ's guidance could be that the "intention" he referred to is the inherent intent to administer for pain which arises on any occasion a patient takes a pill to relieve his pain (as opposed to for a non-pain indication). This interpretation would not require specific intent in the mind of one individual (i.e. doctor, pharmacist) or team that Lecaent in particular be handed to a particular patient for the treatment of pain. It would mean that such administration was (in almost all cases) foreseeable – unless steps had been taken to seek to avoid dispensing the generic product for the patented indication. The assessment would then turn on what steps had, in fact, been taken and whether they were sufficient to abrogate that foreseeability. Is a "skinny label" an absolute defence?

I think it is safe to say that we have not heard the last of this case. The matter will undoubtedly be reviewed once again by the Court of Appeal and it will be for that court to make sense of the apparent discrepancy in reasoning between Floyd LJ at the injunction hearing, and Arnold J at the trial.

Moving on, in ***Merck v Ono***[26], Merck sought the revocation of the patent in suit owned by Ono, with Bristol Myers Squibb as their exclusive licensee.

Both Merck and BMS had developed antibodies and obtained approval for their use for the treatment of some cancers; both parties' antibodies remained in clinical trials in relation to other cancer indications.

Merck did not defend the infringement claim beyond its assertion that the patent was invalid. Ono's position was that in this jurisdiction, if its infringement claim was successful, given the life-saving nature of the therapy it would not seek an injunction provided an appropriate royalty was agreed or awarded by the court for future infringement. Birss J noted that Ono's stance did not mean that the patent was to be judged by a different standard to any other.

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[25] *Generics (t/a Mylan) v Warner-Lambert* [2015] EWHC 2548 (Pat) (10 September 2015) at [124]

[26] *Merck Sharp & Dohme Ltd v Ono Pharmaceutical Co Ltd & Anr* [2015] EWHC 2973 (Pat) (22 October 2015)

In relation to the question of construction, there was a dispute as to whether "cancer treatment" meant that no cancer was excluded or whether it would be understood as limited in some way. Birss J stated that it plainly was not limited. He explained:

> *"This question is of most significance in the context of sufficiency of disclosure, priority and plausibility. With an eye on these arguments, it is worth noting that cancers can be divided up in numerous ways. There is no simple list of types of cancer. For example although in some contexts one can refer simply to lung cancer, in other contexts one distinguishes between non-small cell lung cancer and other kinds of lung cancer. The fact that the skilled reader knows and understands this does not alter the conclusion on construction. The claim is as wide as possible.*
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> *Very few drugs work in every single patient to whom they are administered, for a variety of reasons. The fact that no skilled reader of the patent would expect this drug to work in every patient does not alter the point on claim construction either."*[27]

Late in the year, more litigation between Actavis and Lilly came before the newly appointed Mr Justice Carr **(*Actavis v Lilly* (tomoxetine)).**[28]

This was a "clearing the way" action in which Actavis failed to revoke Ely Lilly's second medical use patent for atomoxetine (also known as tomoxetine) for the treatment of ADHD. This was the first substantive judgment from Henry Carr and it represented a promising start. Recognising that he was dealing with another Swiss form claim, Carr J adopted the reasoning on construction of Floyd LJ in the *Warner-Lambert v Actavis* litigation. Bear in mind that Arnold J had considered this ruling to be merely *obiter*; Carr J appeared to take a different approach. He adopted the conclusion of Floyd that the word "for" in medical use claims meant "suitable and intended for" in the sense that such use was known or reasonably foreseeable by the manufacturer. He also adopted the thinking which we have seen from Birss J in the *Merck v Ono* case. He said:

> *"It is also clear that the words 'for treating attention deficit/hyperactivity disorder' do not mean that the treatment has to be successful in every patient. Obviously, as patients respond differently to treatments, this will never be the case for any medical use claim."*[29]

Accordingly, he reasoned that the words "for treating" have to be construed in context. He adopted previous authority indicating that the skilled addressee would realise that drugs which were perfectly suitable for treatment would not always be successful. However, if the drugs had no effect, then they were clearly not suitable. The phrase therefore meant "suitable for trying to treat…", what is suitable being a question of fact, not one of perception. This is what

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[27] *Merck v Ono & Anr* [2015] EWHC 2973 (Pat) (22 October 2015) at [116]-[117]

[28] *Actavis Group PTC EHF & Anr v Eli Lilly and Company* [2015] EWHC 3294 (Pat) (16 November 2015, tomoxetine case)

[29] *Actavis & Anr v Eli Lilly* [2015] EWHC 3294 (Pat) (16 November 2015, tomoxetine case) at [93]

the phrase "suitable for" means in this context. If the drug has a beneficial effect it will be suitable. If not, it will not be.

In this paper I usually shy away from an overly detailed analysis of life sciences related cases, leaving that to my colleagues more scientifically adept at analysis. However, the issues which I have been considering in the last few cases are, although in the life sciences sector, of broader application. The word "for" has been at the heart of many patent cases over the years, across a range of technologies. The current squabble over the meaning of "for" in relation to Swiss form claims has wider implications and this will no doubt play out in other fields of technology in the years to come.

Numerical limits

Moving on to another old favourite in the field of claim construction, the case of ***Smith & Nephew v ConvaTec***[30] dealt with the age old issue of numerical limits.

I first encountered this in one of my very first patent seminar talks back in 1997 when Peter Prescott QC, sitting as a deputy judge, delivered judgment in the case of ***Auchinloss v AVS***[31]. After noting the general concept of "immaterial variants" and indicating that that stems from the use of descriptive words or phrases, Peter Prescott QC said:

> *"Where the patentee has expressed himself in terms of a descriptive word or phrase there may be room for supposing that he was using language figuratively, and did not intend to restrict himself to the purely literal meaning. But where the patentee has defined an integer on his claim in terms of a range with specified numerical limits at each end, his purpose must be taken to have been to claim thus far and no further. His reason for doing so may not be apparent, but it may exist all the same, for instance it may lie "buried in the prior art". Further, in this case I believe that there are evident reasons of convenience and certainty which would have led him to claim in this way."*[32]

At first instance in *Smith & Nephew v ConvaTec*[33], Birss J had concluded that you should use the concept of "significant figures" so, for example, a range of 1-25 would mean 0.95-25.5. As mathematicians will be aware, this is based on the rules of rounding, which lead to unequal error margins at factors of 10 with the significant figures approach: 0.5 is already rounded to one significant figure; the result would only be 1 if you began with 0.95 or greater. In contrast, rounding leads to 25 for all numbers equal to or greater than 24.5 and less than 25.5.

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[30] *Smith & Nephew plc v ConvaTec Technologies Inc* [2015] EWCA Civ 607 (24 June 2015)

[31] *Auchinloss & Anr v Agricultural & Veterinary Supplies Ltd & Ors* [1997] RPC 649

[32] *Auchinloss & Anr v Agricultural & Veterinary Supplies Ltd & Ors* [1997] RPC 649, pages 689-690

[33] *Smith & Nephew plc v ConvaTec Technologies Inc* [2013] EWHC 3953 (Pat) (12 December 2013)

The Court of Appeal disagreed with Birss J's approach. Giving the primary judgment, Lord Justice Kitchin said:

> *"In my judgment there can be no logical basis for preferring the significant numbers approach over the whole number (or zero decimal places) approach in construing the claim in issue. The purpose of expressing numbers to a particular degree of precision may be to convey to the reader the degree of accuracy with which he needs to make a particular measurement or carry out a calculation. In the context of the claimed method, it is to convey to the reader the range of permissible binding agent concentrations and the accuracy with which those concentrations need to be determined. There is no reason to suppose that this can vary depending on whether the bottom of the range is 1%, 2% or 5% or whether 10% is at the top or bottom of the range. It seems to me that Professor Kennedy [the expert] therefore put it entirely correctly in saying as he did in his first expert report that it is not the number of significant figures that is important in this context, and instead it is the precision with which a number is written. I consider that Professor Kennedy was also right to say that the skilled person would understand the 1% and 25% limits to have been expressed to the nearest whole number."*[34]

Kitchin LJ went on to say:

> *"The judge appears to have attached some importance to the relative error margins at the top and bottom of the range. As he explained, the whole numbers approach means that at the bottom of the range the error margin is as high as 50% whereas at the top of the range it is only 2%. I accept that this is so, but the skilled reader would appreciate that this is the inevitable consequence of the adoption by the patentee of such a wide range of permissible concentrations. Accordingly it is not a matter which carries much weight in favour of the significant figures approach."*[35]

The 'Modified Process' adopted by Smith & Nephew comprised the steps of the patented method save that the concentration of the binding agent was no more than 0.77%. On Birss J's construction that was outside the scope of the patent, but the Court of Appeal's construction brought it within the infringing range.

Time for pleading arguments on construction

Finally in relation to construction, in the case of ***Glass v Freyssinet***[36], the claimants complained that the defendant, Freyssinet, was running an argument on construction at trial that had not been pleaded.

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[34] *Smith & Nephew v ConvaTec* [2015] EWCA Civ 607 (24 June 2015) at [60]

[35] *Smith & Nephew v ConvaTec* [2015] EWCA Civ 607 (24 June 2015) at [63]

[36] *Glass v Freyssinet Limited* [2015] EWHC 2972 (IPEC) (21 October 2015)

While the judge expressed sympathy with the claimants' position, in his view the question of construction was "liable to remain open up to and throughout the trial". His Honour Judge Hacon concluded:

> *"I agree that it is possible for a party to be disadvantaged by a new argument on construction to the extent that they can claim to have been taken unawares and deprived of the opportunity to file evidence that would have been relevant to the opponent's case now being advanced on a new construction of the claim. Parties in the Intellectual Property Enterprise Court would be very well advised to include all arguments in their pleading, including those on construction, to avoid any risk of having part of their case disregarded. Moreover, deliberately conceding an argument for tactical advantage is liable to be met with a severe sanction. But so far as construction is concerned, provided there is no deliberate concealment and the opposite party is unable to prove significant prejudice caused by a failure to plead the argument, parties are unlikely to meet with any resistance from the court as to the arguments they wish to advance."*[37]

The issue in question in this case was the question of whether it is a convention that a subordinate claim will, by its nature, be narrower than a previous claim. The new argument proposed at the trial, on construction, was that claim 1 needed to be broader than dependent claim 9. The upshot of the judge's finding on the issue was that claims 1 and 9 had the same scope. Judge Hacon noted that this did not accord with the convention that a subordinate claim will be narrower than an antecedent claim on which it is dependent and that this convention can be used as guidance as to the construction of the antecedent claim. However, the convention is not conclusive. Judge Hacon said:

> *"But this is a convention, not an inflexible rule and can be ignored where the words of the antecedent claim or other matters suggest that it should be."*[38]

2.2 Infringement

Swiss form claims – direct infringement

There is a considerable overlap between infringement and construction issues in the ongoing ***Warner-Lambert*** saga.

Faced with difficulties with enforcing Swiss form claims Arnold J took the creative, if somewhat surprising, step of ordering that the NHS issue guidance on the prescribing and

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[37] *Glass v Freyssinet* [2015] EWHC 2972 (IPEC) (21 October 2015) at [21]

[38] *Glass v Freyssinet* [2015] EWHC 2972 (IPEC) (21 October 2015) at [29]

dispensing of pregabalin in ***Warner-Lambert v Actavis* (2 March 2015)**[39]. As already discussed, Warner-Lambert's Swiss form patent concerns pregabalin for the treatment of pain, including neuropathic pain. Accordingly, when used for the treatment of neuropathic pain, it is Warner-Lambert's branded medicine, Lyrica which should be prescribed and dispensed. In making this direction, Arnold J has created a practical solution drawing on his previous reasoning concerning website blocking orders.

The legal basis for making such an order was to be found at section 37(1) of the Senior Courts Act 1981. Both NHS England and Warner-Lambert's lawyers agreed that the present situation was similar to that in the *Norwich Pharmacal* cases.

Norwich Pharmacal concerned orders made against parties for disclosure of documents where the party is not likely to be involved in the claim but is mixed up in the factual background, whether innocently or not. The suggested analogy in the present case was that NHS England was an innocent party mixed up in the alleged wrongdoing of others. Arnold J did not necessarily agree with the analogy, but for the present purposes he said that he was "*prepared to assume that the equitable protective duty and duties analogous thereto can be enforced by injunction in parallel circumstances*".

The judge also noted that before he could make the order against NHS England, he would need to be satisfied that it complied with Article 3 of the Enforcement Directive (2004/48/EC), and in particular that "the order is proportionate, does not create barriers to legitimate trade and contains safeguards against abuse". He considered the following factors to be relevant to his conclusion that the order sought by Warner-Lambert was proportionate:

- a patent is an IP right which is to be protected in accordance with article 17(2) of the Charter of Fundamental Rights of the European Union;
- the freedom of generic suppliers to conduct business would be protected by a cross undertaking in damages;
- the impact on dispensing by pharmacists, and the potential for the order to cause them to make lower profits, was justified by the existence of the patent in suit (assuming it was valid).

Arnold J was therefore satisfied that he could grant the order sought against NHS England. He was satisfied that the order contained appropriate safeguards, in particular the fact that it would cease to apply if the patent was revoked or expired, and that it included the cross undertaking in damages and the liberty to apply. Arnold J summarised the rationale behind his decision as being that "*the issuing of guidance by NHS England is the most efficacious, dissuasive and cheapest solution to the problem which confronts Warner-Lambert*".[40] He also explained that he had followed the same approach as in his decision in *Cartier v B Sky B*[41] regarding the granting of website blocking orders.

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[39] *Warner-Lambert Company LLC v Actavis Group PTC EHF & Ors* [2015] EWHC 485 (Pat) (2 March 2015)

[40] *Warner-Lambert v Actavis & Ors* [2015] EWHC 485 (Pat) (2 March 2015) at [22]

[41] *Cartier International v British Sky Broadcasting* [2014] EWHC 3354 (Ch) (17 October 2014)

The decision represents a bold and pragmatic step by Arnold J in addressing the enforcement of second medical use claims. It was considered to reduce the likelihood of generic pregabalin being prescribed for the patented indication in a practical way, thereby enforcing the patent. By doing so it offered comfort to the generic manufacturers as regards their potential liability for infringement. The breadth of the cross undertaking also reduced the prospect that Warner-Lambert would "profit" from the order, in the event that the patent was later found invalid.

However, eyebrows might be raised among doctors and pharmacists who find themselves at the frontline of patent enforcement. Questions have also since arisen as to the effectiveness of the measure.

The decision nevertheless indicates that the courts are not afraid to extend the use of the inherent jurisdiction beyond the traditional contexts, to deliver a practical solution to a commercial dispute. The decision may mark a change in how second medical use claims will be enforced in England and Wales, but there is likely to be more to come, which may yet steer the courts away from this path.

Indeed, when the question of the interim injunction application reached the Court of Appeal, Warner-Lambert attempted to open the issue again, saying that there was evidence that the guidance directed towards the medical profession had not worked. Floyd LJ refused Warner-Lambert permission to adduce evidence to that effect. He explained that the purpose of the appeal was to review the judge's exercise of discretion on the material before him and not to permit a "free for all". (Several months later though, in ***Warner-Lambert v Sandoz***[42] (in which interim relief was granted restraining launch of 'full-label' generic pregabalin by Sandoz), Arnold J noted that the guidance issued by NHS England regarding pregabalin was "proving less effective than was anticipated", and that equivalent guidance had not been issued in Scotland).

Concerned by the issues in general, the Secretary of State for Health took the unusual step of intervening in the appeal hearing. The basis of the intervention appeared to be in support of Arnold J's first instance finding on the construction of the Swiss form claim. (The approach advocated by the Secretary of State would in practice have essentially absolved NHS bodies from potential liability for infringement of patents with claims in Swiss form).

As well as pointing out the deficiencies in the Secretary of State's suggestion on construction, Lord Justice Floyd politely informed him that he "*was not persuaded*" that the court needed assistance from the Secretary of State on what was "*essentially an issue of substantive patent law*". Whilst Arnold J had allowed the Secretary of State to appear at the hearing before him, this was because issues arose as to the guidance which might be given by NHS England to prescribing doctors. No such requirement for assistance had arisen on the appeal.

Indirect infringement under section 60(2)

[42] *Warner-Lambert Company LLC v Sandoz GmbH & Ors* [2015] EWHC (Pat) (4 November 2015)

The whole issue of indirect infringement under section 60(2) is vexed. It has been dealt with this year, inter alia, in the case of ***Actavis v Lilly (*pemetrexed case)**[43].

In accordance with section 60(2) of the Patents Act it is an act of indirect infringement to supply or offer to supply in the UK the means relating to an essential element of the invention, for putting the invention into effect, where the requisite knowledge element is present.

In *Actavis v Lilly* (pemetrexed case), the facts gave rise to an indirect infringement argument because, although Actavis' medicament did not contain the sodium ions required by the language of the claim, in the ordinary course, Actavis' medicament would be dissolved and/or diluted in saline, a source of abundant sodium ions, before administration to the patient.

Arnold J ruled that this did not give rise to contributory infringement because sodium was not used in the manufacture of Actavis' solid form medicament. However, following its ruling on construction, the Court of Appeal disagreed with the judge on infringement. Floyd LJ said:

> *"A means for releasing pemetrexed ions into solution relates to an essential element of the invention where the invention calls for pemetrexed ions and sodium ions in solution, particularly as it is the presence of the pemetrexed ions in the manufactured medicament which is essential for its efficacy as a medicament. The invention is then put into effect when the pharmacist makes up the solution using pemetrexed dipotassium … because there comes a stage in the course of that activity when pemetrexed disodium is present and used."*[44]

The gist of the finding is that the essential means did not have to be something which could be used without alteration by the buyer. The Court of Appeal's conclusion on indirect infringement directly contradicted an equivalent decision by a German court in Düsseldorf. Floyd LJ commented:

> *"Whilst the decision of the [Düsseldorf appeal court] is entitled to great respect, including as it does distinguished patent judges, I am not persuaded by its reasoning to change the view which I have formed on the issue of contributory infringement. Firstly, if by its requirement that "the means must be configured in such a way that a direct use of the invention is possible" it is indicating that pemetrexed dipotassium cannot be an essential means, then that result is inconsistent with [previous case law] and it is not open to us to follow it. Secondly, it seems to me that the [Düsseldorf appeal court] has failed to give sufficient recognition to the fact that, applying the teaching of the patent, it is sufficient if one finds in the medicament in question sodium ions and pemetrexed ions in solution in a ratio of at least 2:1. Rather, as I read the judgment, the court appears to understand "pemetrexed disodium" as*

[43] *Actavis UK Limited & Ors v Eli Lilly & Company* [2015] EWCA Civ 555 (25 June 2015, pemetrexed case)

[44] *Actavis & Ors v Eli Lilly* [2015] EWCA Civ 555 (25 June 2015, pemetrexed case) at [89]

describing only that substance in solid form. I have explained why I do not agree with that conclusion."[45]

I did caution that Arnold J's compendious judgment in ***Generics (t/a Mylan) v Warner-Lambert (10 September 2015)***[46] would arise time and again so here it comes for the second time. In dismissing one of the arguments raised by Warner-Lambert in relation to the interim injunction application, Arnold J went further and struck out Warner-Lambert's claim for indirect infringement under s.60(2)[47].

The Court of Appeal reversed the strike out.[48] As an aside, it is worth noting that, in doing so, it made a positive decision. How this could be characterised by Arnold J at the full trial as "obiter" is hard to see.

When the issue returned to Arnold J at the substantive hearing, he revisited the point once again. Despite the Court of Appeal having overturned his first instance decision striking out Warner-Lambert's arguments under section 60(2) on indirect infringement, Arnold J gave short shrift to the argument for a second time.

Where Floyd had referred to the European Patent Convention, Arnold J said that that was puzzling as the law regarding infringement was in fact derived from the Community Patent Convention, not the EPC. He was "baffled" by Floyd LJ's comment that while the claim under section 60(2) might not add anything to the direct infringement claim it was wrong to strike it out. He said that he simply "did not understand" Floyd LJ's third reason, which suggested that the phrase "putting the invention into effect" may need closer scrutiny. Having made those comments, he dealt with the allegation very briefly, effectively just confirming his interim view as follows:

"The fundamental difficulty with Pfizer's claim under section 60(2) remains, as it has always done, that claims one and three of the patent are claims to processes of manufacture, but there is no act of manufacture by any party downstream from Actavis, nor even the prospect of an act… [A]lthough there is no difficulty in concluding that Lecaent's active ingredient is "means relating to an essential element of the invention for putting the invention into effect", Lecaent is not suitable for putting, or intended to put, the invention into effect: either the invention has already been put into effect by the time that Lecaent leaves Actavis' hands or it is not put into effect at all."[49]

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[45] *Actavis & Ors v Eli Lilly* [2015] EWCA Civ 555 (25 June 2015, pemetrexed case) at [99]

[46] *Generics (t/a Mylan) v Warner-Lambert* [2015] EWHC 2548 (Pat) (10 September 2015)

[47] *Warner-Lambert Company LLC v Actavis Group PTC EHF* [2015] EWHC 249 (Pat) (6 February 2015)

[48] *Warner-Lambert v Actavis & Ors* [2015] EWCA Civ 556 (Pat) (28 May 2015)

[49] *Generics (t/a Mylan) v Warner-Lambert* [2015] EWHC 2548 (Pat) (10 September 2015) at [684]

On that basis he found that there was no indirect infringement.

Where does that leave us? While the *Generics (t/a Mylan) v Warner-Lambert* case now leaves the first instance court, at least on the question of liability, I suspect that there will be much more to come from the pregabalin saga, including from the higher UK courts. On the question of indirect infringement, it would seem that the Court of Appeal's decision in the interim injunction case was *ratio* (i.e. a genuine decision), rather than *obiter*, and therefore should have been binding on Arnold J. When the case returns to the Court of Appeal, it will be interesting to see if the court takes any substantive note of Arnold J's comments, or merely dismisses them as inappropriate given that he was effectively contradicting superior authority. He may have been puzzled, baffled, and lacking in understanding, but there is no question that he made a finding in contradiction of what appears to be Court of Appeal authority. The key passage from the Court of Appeal came in Floyd LJ's judgment where he said:

> *"[W]hen section 60(2) speaks of "putting the invention into effect" it may be legitimate to look not just at whether any one person is carrying out the invention in a sense which would give rise to liability of that person for an act of infringement. It may be that the invention is put into effect if pregabalin is manufactured by one person and supplied to another who intentionally uses it for the treatment of pain. In those circumstances, a person who supplies pregabalin with the requisite knowledge (i.e. that prescribed in section 60(2) itself) does provide means suitable and intended to put the invention into effect, albeit by the combination of manufacturer and user, rather than by one person alone."*[50]

What constitutes an 'offer'?

An interesting small issue regarding the "offer" act of infringement arose in the IPEC case of *Glass v Freyssinet*[51]. Judge Hacon referred to *Gerber v Lectra*[52] as authority for the concept that the word "offer" in section 60(1) of the Patents Act 1977 does not have the general meaning applicable in English contract law.

In *Gerber v Lectra*, Jacob J found that the approach to the construction of section 60 should be purposive. In that case "early advertisements were infringements not mere threats". He summarised the law as follows:

> *"A party who approaches potential customers individually or by advertisement saying he is willing to supply a machine, terms to be agreed, is offering it or putting it on the market".*[53]

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[50] *Warner-Lambert v Actavis & Ors* [2015] EWCA Civ 556 (Pat) (28 May 2015) at [138]

[51] *Glass v Freyssinet* [2015] EWHC 2972 (IPEC) (21 October 2015)

[52] *Gerber v Lectra* [1995] RPC 383

[53] *Gerber v Lectra* [1995] RPC 383 at page 411

Such an act would not, of course, constitute an "offer" for the purposes of English contract law. However, Judge Hacon noted:

> *"All relevant factors are to be taken into account to the end of assessing whether there was an offer as a matter of commercial substance. Such factors will certainly include the perception of the putative offeree."*[54]

In this case, Freyssinet had sent to one of the claimants a copy of a data sheet which set out a galvanic protection system falling within claim 1 of the patent. It was actually sent by a marketing administrator without line manager authorisation, following an enquiry made by the claimant in relation to an advertisement for a different product. There was an accompanying communication which said:

> *"Please see attached the only two data sheets regarding anode systems. Let me know if these are any use, if not I will ask our expert on this subject to call you."*

Judge Hacon found as a matter of fact that Freyssinet never intended that the data sheet should constitute any kind of offer to anyone, and Dr Glass did not appear to have interpreted the data sheet as an offer to supply a hybrid system to him or his company.

Burden of proof in certain cases

Finally in this section, an interesting point concerning a little known provision arose in the case of ***Magnesium Elektron v Molycorp***[55].

Birss J provided the first interpretation of section 100 of the Patents Act, which concerns the burden of proof in the context of products alleged to be produced directly by means of the patented process.

Section 100 states:

> "Burden of proof in certain cases.
>
> (1) If the invention for which a patent is granted is a process for obtaining a new product, the same product produced by a person other than the proprietor of the patent or a licensee of his shall, unless the contrary is proved, be taken in any proceedings to have been obtained by that process.
>
> (2) In considering whether a party has discharged the burden imposed upon him by this section, the court shall not require him to disclose any manufacturing or commercial secrets if it appears to the court that it would be unreasonable to do so."

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[54] *Glass v Freyssinet* [2015] EWHC 2972 (IPEC) (21 October 2015) at [94]

[55] *Magnesium Elektron Limited v Molycorp Chemicals & Oxides (Europe) Limited* [2015] EWHC 3596 (Pat) (15 December 2015)

The first obvious question arising is what is meant by the expression 'new product'? Does the word 'new' have the same meaning as in section 1 of the Patents Act, i.e. something not forming part of the state of the art? That would narrow the scope of section 100 materially.

Birss J commented that if a product defined in a general way was novel, then the inventor would have been able to claim it, the patent would most likely contain a product claim as well as a process claim, and the problem faced as regards proof that the product was the direct product of the claimed process would not arise. Accordingly, on that basis, there would effectively be no need for section 100. Birss J therefore concluded that what was meant by "new product" in section 100 was different and did not have the same meaning as "new" in the context of section 1 of the Patents Act.

Birss J noted that there was nothing in section 100 which required that the product which must be "new", be a thing defined at the same level of generality as the words used in the process claim, and this case illustrated the difference.

In the context of the interim hearing (regarding permission for service outside the jurisdiction), Birss J found that there was a serious issue to be tried as to whether the product in question was obtained directly by means of the patented process, and consequently that the burden of proof was reversed.

2.3 Defences, Stays and Evidence

Expert evidence

It is often said that cases are won and lost on expert evidence. Accordingly, the whole issue of finding, briefing and compiling the report of the expert witness(es) is a crucial part of the job of preparing a patent case for court. Things do not always go well, and Birss J gave a strong message to expert witnesses in the case of ***Synthon v Teva***[56].

The judge made it clear that Synthon's legal advisers had fallen short of their duties in respect of the preparation of their expert witness. Professor Tabor gave a single expert report. Her written evidence was criticised in many ways: the report was at times too generalised, over stated and in need of qualification; extracts were included without their full context and sources for quotes were not exhibited; it failed to mention that she had searched text books to support her view on common general knowledge but not found support; or that she had found other relevant prior art; and she served no reply evidence qualifying her statement on points where it was appropriate to do so and where she agreed with Teva's experts.

For most of these deficiencies the "real cause" of the problem was the advice she received from the legal team. She had not acted as an expert witness before and so was reliant on the legal team with regard to her responsibilities, and she over-relied on the advice they gave.

Birss J said:

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[56] *Synthon B.V. v Teva Pharmaceutical Industries Limited* [2015] EWHC 1395 (Pat) (21 May 2015)

"Expert witnesses owe a duty to the court... This duty overrides any duty they have to the party and its team of legal advisers and CPR r35.3(2) makes that expressly clear.

…The qualifications were given readily when the questions were put and I am quite certain Professor Tabor in no sense set out to mislead. However Professor Tabor should have exercised her own judgment on the matter. It hardly needs saying that experts bear a personal responsibility for their evidence. If she had then I am sure a reply report would have been written and when Professor Tabor swore to the truth of the two reports, what she was swearing to would have fairly represented her actual opinions."[57]

Despite all of this, Birss J's view was that Professor Tabor was "*clearly an expert in her chosen field, gave candid evidence and answered questions without equivocation*" and he considered her oral evidence to be fair.

There is a clear lesson there for legal advisers preparing evidence for court.

Previous settlement agreement

In the case of ***Stretchline v H&M***[58], the evidential issue concerned an application for the strike out of the defence and counterclaim.

The patent in suit concerned an invention for making fabric tubes which are used to encase underwires used in garments such as bras and swimming costumes. An initial dispute was settled by an agreement reached in May 2011, but in 2012 Stretchline became suspicious that H&M was once again infringing the patent. It brought new proceedings in 2013 with inconsistent claims. Following some disclosure these were refined to an alleged breach of the settlement agreement, and infringement of the patent. Only later activities, from after the date of the settlement agreement, were relied upon in relation to patent infringement.

H&M responded to these claims by way of defence and counterclaim. It contended that it had not acted in breach of the settlement agreement or committed an infringement of the patent for two reasons: (a) its bras did not fall within the scope of the patent, and (b) the patent was invalid.

Stretchline sought to strike out those parts of the pleaded case which raised the issue of the validity of the patent, whether by way of defence or counterclaim.

Mr Justice Sales agreed with Stretchline that pursuant to the settlement agreement, all issues raised by H&M in relation to the validity of the patent were settled definitively between the parties by the terms of that agreement. The case was appealed, and Lord Justice Kitchin gave the only reasoned judgment.

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[57] *Synthon v Teva* [2015] EWHC 1395 (Pat) (21 May 2015) at [16]-[17]

[58] *Stretchline Intellectual Properties Ltd v H&M Hennes & Mauritz UK Ltd* [2015] EWCA Civ 516 (22 May 2015)

He was puzzled as to why H&M had not sought to strike out Stretchline's claims of infringement. Referring to the terms of the settlement agreement he said that it was clear that:

> *"Its scope extends a good deal further and reflects the intention of the parties that henceforth any dealings by H&M in products falling within the scope of the patent and its equivalents in other jurisdictions should be regulated by the agreement and not by resort in all of those jurisdictions to claims of infringement, which claims would no doubt be met with defences of invalidity and counterclaims for revocation. Such an array of claims and counterclaims is precisely what the parties intended to avoid by entering into this agreement.*
>
> *For all of these reasons I would therefore hold that the present proceedings do not relate to or arise out of the original claims and that Stretchline is precluded by the settlement agreement from pursuing its claim for infringement of the patent in parallel with its claim for breach of contract."*[59]

Interestingly, the question of Stretchline's claim was not an issue which either party had asked the court to decide.

Competition law defence

It is a sad year when the question of a defence under the terms of European law is not raised, and fortunately we have one this year. In ***Huawei v ZTE***[60], the defence of abuse of dominance arose. In 2009 Huawei notified the European Telecommunications Standards Institute (ETSI) that its patent was essential or potentially essential to the standard for Long Term Evolution (LTE). At the same time it undertook to grant licences to third parties on fair, reasonable and non-discriminatory terms (FRAND).

Between November 2010 and the end of March 2011, Huawei approached ZTE and sought to licence the patent in question, among others. ZTE engaged, to a degree, in the licencing discussions with both parties making offers and counter offers including offers of cross licences. However no licence was concluded.

Subsequently Huawei brought proceedings against ZTE for patent infringement in Germany. In doing so it sought an injunction, delivery up and damages. In its defence ZTE asserted among other things that Huawei, in pursuing the relief sought, was abusing its dominant position contrary to Article 102 of the Treaty on the Functioning of the European Union (TFEU).

The German court held that the patent was essential to the standard and therefore was infringed by ZTE. Given the inconsistent approaches, however, the court referred certain questions to the Court of Justice of the European Union (CJEU).

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[59] *Stretchline v H&M* [2015] EWCA Civ 516 (22 May 2015) at [38]-[39]

[60] *Huawei Technologies Co Ltd v ZTE Corp & Anr*, case C-170/13, CJEU (16 July 2015)

The CJEU declined to address directly whether ownership of a Standard Essential Patent (SEP) automatically results in the proprietor being in a dominant position. However the judgment appears to make clear that for there to be abuse of a dominant position something more will be required, such as the patentee refusing to offer a licence in circumstances where it has previously made a FRAND declaration.

The court went on to describe a framework for determining abuse, saying, in terms:

- the patentee must notify the prospective licensee of the infringement by designating that SEP and specifying the way in which it has been infringed;

- after the prospective licensee has indicated its willingness to conclude a licence on FRAND terms, it is incumbent on the patentee to make a written offer of a licence on those FRAND terms. The CJEU has ruled that this offer should specify the amount and method of calculation of the royalties;

- the prospective licensee should respond to the offer. Here the court emphasised that the prospective licensee should "diligently" respond to the offer, in accordance with "recognised commercial practices in the field and in good faith" (which implies that there should not be any delaying tactics);

- should the prospective licensee not accept the offer, it should "promptly" make a counter offer; and

- crucially, if the prospective licensee is using the teachings of the SEP, it should provide "appropriate security in accordance with recognised commercial practices in the field, for example by providing a bank guarantee or by placing the amounts necessary on deposit".

In implementing this approach the court emphasised that it should always remain open for the prospective licensee to challenge the validity or essentiality of the patent and for the parties to remit the issue of FRAND to an independent third party. It also drew a distinction between seeking injunctive relief or delivery up (which could result in an abuse of a dominant position) and damages (which could not).

The decision does appear to redress the imbalance between the patentee and prospective licensee resulting from previous decisions including the *Motorola* case. By virtue of requiring the payment of security, the court has helped to clarify what constitutes an "unwilling" licensee. It also provides the parties with improved guidance as to the way that negotiations should be conducted.

That is not the end of the issue, clearly, but it is a helpful step in creating a sensible commercial environment.

Stay of injunctive relief

The question of stays arose in the case of ***Smith & Nephew v ConvaTec***[61].

I have already referred to this case in relation to construction and the question of numerical limits. Smith & Nephew, the unsuccessful party following the Court of Appeal's substantive decision, made it clear that it intended to apply to the Supreme Court for permission to appeal. The patent was also the subject of on-going opposition proceedings: it was revoked by the Opposition Division in December 2014, but ConvaTec had appealed and Smith & Nephew had asked for acceleration of the appeal.

Smith & Nephew sought a stay of the final injunction and orders for delivery up to which ConvaTec was entitled, pending the outcome of their application for permission to appeal to the Supreme Court, and pending the outcome of the opposition proceedings. Smith & Nephew argued that if the stay was not granted, it would suffer severe and irreparable harm to its market, and that would be so even if it subsequently won before the Technical Board of Appeal or on appeal to the Supreme Court.

Recognising that the Supreme Court could take a different view on permission, the Court of Appeal ruled that there was a "real prospect" of a further appeal. In the circumstances the "balance of justice" favoured suspending the injunction at least until the Supreme Court decided whether to grant permission to appeal. The question whether to grant any further stay would be a matter for the Supreme Court. In reaching this conclusion the particularly important factors were:

- The Court of Appeal did not believe that Smith & Nephew could be criticised for first seeking and failing to revoke the patent and then seeking a declaration of non-infringement. They had merely sought to clear the way.

- If the injunction was suspended for a relatively short time but was ultimately granted, ConvaTec would recover its monopoly position in the market and any damage it suffered in the meantime would likely be wholly or largely quantifiable by reference to the quantity and value of Durafiber product made and sold in the meantime. There was little evidence of it being a real possibility that Smith & Nephew would take the opportunity to design around the patent.

- On the other hand, if the injunction was ordered immediately, the consequences to Smith & Nephew were likely to be severe and irreparable.

- Smith & Nephew had been pressing for the accelerated disposal of the opposition proceedings.

- ConvaTec had not offered a cross-undertaking in damages. However Kitchin LJ noted that in the light of the matters referred to, were ConvaTec now to offer such a cross-undertaking the Court of Appeal would not reverse its decision on the stay.

[61] Smith & Nephew plc v ConvaTec Technologies Inc [2015] EWCA Civ 803 (30 July 2015)

The Court of Appeal also considered the position regarding a stay pending the decision of the Technical Board of Appeal. This raised different considerations and the court had "well in mind the decision and reasoning" in recent cases such as *ASSIA v BT*[62]. However, the present case was "unusual" in that the patent had been revoked by the opposition division and the decision of the TBA was likely to be at most only a few months after the decision of the Supreme Court in relation to the application for leave to appeal.

The injunction would therefore be stayed pending the decision of the Supreme Court on permission or, if later, the decision of the TBA. However, subject to any further stay which the Supreme Court may grant, the Court of Appeal did not envisage this stay extending beyond April 2016. Should this appear likely, the parties were at liberty to apply to a single judge of the Patents Court.

That decision seems far more in line with key recent authorities, including *Virgin v Zodiac*[63], and represents a sensible and pragmatic approach by the Court of Appeal in the light of the specific facts and timetables in the case in hand.

2.4 Remedies and Costs

Scope of an account of profits / damages enquiry

In ***AP Racing v Alcon Components***[64], an interesting issue arose concerning an application to strike out as an abuse of process, new allegations of infringement brought following the conclusion of the original action.

In 2014 the Court of Appeal overturned a judgment by Birss J, who had found that AP Racing's patent was invalid for added matter. As Alcon had conceded that the patent was infringed if it was valid, in relation to four out of five pleaded shapes of calipers, the Court of Appeal merely referred the matter to an election by AP Racing as to whether there should be an account of profits or an enquiry as to damages.

There then followed various exchanges of correspondence while AP Racing decided what it wanted to do about a number of further calipers which were not the subject of its earlier infringement claim, but which it now contended also infringed the patent. Eventually AP Racing filed a fresh claim for infringement and Alcon applied for it to be struck out.

This introduced the case of *Henderson v Henderson*[65], which has been the subject of much discussion in patent litigation in recent years. This 1843 decision is the basis on which it is a

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[62] *Adaptive Spectrum and Signal Alignment Inc v British Telecommunications plc* [2014] EWCA Civ 1513 (21 November 2014)

[63] *Virgin Atlantic Airways Ltd v Zodiac Seats UK Ltd* [2013] UKSC 46 (3 July 2013)

[64] *AP Racing Ltd v Alcon Components Ltd* [2015] EWHC 1371 (IPEC) (15 May 2015)

[65] *Henderson v Henderson* [1843] 67 E.R. 313

general rule that the parties to litigation are to bring forward their whole case, and the court will not permit the same parties to open the same subject of litigation in respect of a matter which might have been brought forward as part of the original case. The question of *res judicata* applies not only to points upon which the court was actually required by the parties to form an opinion and pronounce a judgment but to every point which properly belonged to the subject of the litigation and which the parties, exercising reasonable diligence, might have brought forward at the time.

Judge Hacon considered the applicability of that rule in the current case. He said that a claimant is under no general duty to exercise reasonable diligence to ascertain whether he has a potential further cause of action. He went on to say:

> *"On the other hand, in some cases the defendant may be able to show that the claimant knew enough to put him on enquiry to find out more. Even then, it does not follow that there was an abuse on the part of the claimant, but it is relevant to the overall assessment and at a certain point the claimant's knowledge may help to tip his behaviour into abuse."*[66]

Way back in the 1970's in the well-known patent case of *General Tire v Firestone*[67], Graham J permitted relief to be claimed in relation to a number of tyres, although the case on liability was fought by reference to a single tyre. There have been a number of cases down the years in which that principle has general been applied, and, at an enquiry or account of damages, consideration has been given to alleged acts of infringement which the trial judge had not specifically addressed.

Judge Hacon believed that the *General Tire* case was the default position in patent cases and upon the facts of the case in hand, was of the view that AP Racing should be permitted to continue with their case. He went as far as to say that they had shown a "casual disregard of any need to sort out precisely which calipers it wished to complain about", but said that the new allegations could still be considered as part of the enquiry in the first action if needs be, and this would not unjustly harass or repress Alcon. The strike out application was duly refused and Judge Hacon invited submissions from the parties on what might be the best procedural way forward.

Interestingly in his judgment, Judge Hacon did not quote from *Henderson v Henderson*. It seems that, in his view at least, the practice of permitted inclusion, at the quantum stage, of claims for relief regarding similar but previously un-pleaded infringements, gives a helpful shortcut around the rule in *Henderson v Henderson*.

Interim injunctions

In relation to the issue of remedies and costs, I frequently refer at length to applications for interim injunctions.

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[66] *AP Racing v Alcon Components* [2015] EWHC 1371 (IPEC) (15 May 2015) at [15]

[67] *General Tyre & Rubber Company v Firestone Tyre & Rubber Company Limited* [1975] RPC 203

This year we have seen the significant interim injunction issues arising in ***Warner-Lambert v Actavis*** **(21 January 2015)**[68]. The decision concerned Warner-Lambert's application for interim relief, in mandatory form, against Actavis.

It is established law in relation to injunctions that there are two steps to be overcome. The first is that there should be a serious issue to be tried, and the second is that the balance of harm – commonly known as the balance of convenience – should weigh in favour of granting an injunction. In the current case, Arnold J found that there was neither a serious issue to be tried, nor any significant balance of harm operating in favour of Warner-Lambert, and he refused the injunction. The Court of Appeal differed from him in relation to the serious issue to be tried, but accepted the reasoning in relation to the balance of harm, and consequently the interim relief sought was not awarded.

Arnold J also concluded, on the basis of Supreme Court authority (*OBG v Allan*[69], per Lord Hoffmann), that whether they be prohibitory or mandatory, the same principles applied to granting injunctions. Accepting that mandatory injunctions can sometimes affect parties who are not actually party to the litigation, he emphasised that greater care generally needs to be taken, but the basic two-part test applies in all cases.

As we have seen, following the refusal of the interim relief sought against Actavis, Warner-Lambert, through its parent company Pfizer, wrote to the National Health Service Commissioning Board asking it to issue guidance in relation to the prescription of pregabalin for use in the treatment of neuropathic pain. The NHS replied saying that it was an innocent bystander in the present dispute, that it was unwilling to issue guidance of its own motion, but that it would not oppose an application by Warner-Lambert for an order requiring the NHS to issue guidance provided certain conditions were met. Warner-Lambert duly applied to the court for such an order and the case was heard by Arnold J.

As we have already seen, having satisfied itself of its jurisdiction to act under the Senior Courts Act 1981, the court duly issued the order sought by Warner-Lambert on the basis that a cross undertaking in damages would be given by Warner-Lambert to NHS England, The Department of Health, Actavis and other parties. The terms of the order were that NHS England was to issue guidance in prescribed terms essentially saying that, for the treatment of pain, Warner-Lambert's Lyrica should be prescribed by brand and for other indications prescriptions should be done by reference to the generic name pregabalin.

I have to say that I find the legal premise for this decision somewhat shaky, and it will be interesting to see if it is the subject of an appeal at any stage. That seems unlikely in this case, as the parties have all consented to the form of order.

Damages under a cross undertaking

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[68] *Warner-Lambert v Actavis & Ors* [2015] EWHC 72 (Pat) (21 January 2015)

[69] *OBG v Allan* [2007] UKHL 21, [2008] 1 AC 1

The perils of seeking an interim injunction were made all too clear in the case of ***AstraZeneca v KRKA***[70].

AstraZeneca had a patent for the manufacture of a medicament for the inhibition of gastric acid secretion. In September 2010 the defendants, KRKA, sought to bring to the market a generic equivalent to AstraZeneca's drug.

AstraZeneca issued proceedings for infringement of the patent and sought an interim injunction to restrain marketing of the generic drug. KRKA agreed to submit to AstraZeneca's application on the basis that a full cross-undertaking in damages was given.

At around the same time another generic company, Ranbaxy, began proceedings in respect of the same patent. A trial took place on the issue of infringement only, and in 2011 Kitchin J (as he then was) held that Ranbaxy's product did not infringe. Shortly afterwards the injunction on KRKA was lifted.

The declaration of non-infringement awarded to Ranbaxy opened the door to the marketing of generic products by a series of other companies including Arrow, Mylan and Teva. KRKA argued that it had therefore been deprived of their "first mover" advantage. It claimed damages under the cross undertaking given by AstraZeneca, seeking £32m in respect of its losses.

One of the arguments deployed by AstraZeneca was that it was extremely complex to work out the actual damages incurred, especially in relation to the loss of first mover advantage, and consequently the court should take a very cautious and conservative approach to the issue of damages. The matter ended up in the Court of Appeal, which did not adopt AstraZeneca's position.

The Court of Appeal made it clear that where a claimant has obtained interim relief by persuading the court that it would be easier to calculate the defendant's loss than his own, the claimant should not say later that the task of calculating damages is of such extreme complexity that a cautious approach is justified. There should be "symmetry". Lord Justice Kitchin accepted that evidence of "true comparable" is likely to be of great assistance to the court in assessing what would have happened but for the grant of an injunction.

[70] *AstraZeneca AB & Anr v Krka dd Novo Mesto & Anr* [2015] EWCA Civ 484 (21 May 2015)

This is a salutary message from the Court of Appeal. A claimant who obtains interim relief in a process involving a limited consideration of the merits should similarly expect a "liberal assessment" of damages under the cross undertaking in the event that it is unsuccessful in its substantive claim.

Although interim injunctions can be obtained with little regard to the merits of the case, needing only evidence of a "serious issue to be tried", claimants would do well to conduct their own assessment in some detail to avoid this sort of situation. It is always likely to be the case that when an injunction is granted which prevents a party from starting out in the market, losses can be substantial as a result of the delay in market position as well as pure loss of sales.

Expert evidence on an urgent interim injunction application

In ***Teva v Actavis***[71], Teva applied for permission to rely on an expert report in its urgent application for an interim injunction against Actavis.

Actavis argued that the report was inadmissible because it failed to comply with civil procedure rules requiring the report to contain a statement that the expert has understood and complied with his duty to the court.

Arnold J ruled that the evidence was admissible. He said:

> *"In my judgment Teva should be given permission to rely on Dr Wu's report for the purposes of the present application. I accept that the mere fact that the application before the court is one for an interim injunction, which has been made as a matter or urgency, does not mean that the court should simply disregard the requirements of [the civil procedure rules]. Nevertheless, one has to be realistic and recognise that it is simply not feasible for parties applying to the court on an urgent basis to dot the i's and cross the t's in the way that is expected when experts' reports are being prepared in advance of trial. What matters is whether, in substance, the evidence appears to be expert evidence which it would be proper to admit at trial if the formalities were attended to."*[72]

In that case, Arnold J went on to grant the interim injunction.[73] In relation to the serious issue to be tried, Arnold J agreed with Teva that the court had to be particularly cautious before concluding that the case on invalidity was so strong that Teva could be said to have no real prospect of success. He said that the dispute was not capable of resolution without the

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[71] *Teva Pharmaceutical Industries Limited v Actavis UK Limited* [2015] EWHC 2605 (Pat) (9 September 2015)

[72] *Teva v Actavis* [2015] EWHC 2605 (Pat) (9 September 2015) at [15]

[73] *Teva Pharmaceutical Industries Limited v Actavis UK Limited* [2015] EWHC 2604 (Pat) (9 September 2015)

benefit of full expert evidence and proper consideration at trial. In those circumstances, it was clear that there was a serious question to be tried.

Moving on to the balance of harm, Teva had been selling its product for 10 years and had a track record of sales and an established monopoly price. On that basis, the loss of sales ought to be easily quantifiable. However, Teva raised the familiar concern as to the prospect of a price spiral once more than one generic company enters the market. Arnold J noted:

> *"The problem from Teva's perspective is that, even if it is successful at trial, it does not follow that it will be able to put its prices back up to the previous monopoly price level."*[74]

Arnold J noted that the Managing Director of Actavis had given evidence that he was "not aware of any instance where a pharmaceutical company has tried to raise prices to their previous patented level following successes at trial and met resistance to that". However the judge said:

> *"As counsel for Teva pointed out that is consistent with the proposition that no pharmaceutical company in that position has ever tried to raise their prices at all. Certainly there is no evidence of any instance where a pharmaceutical company which has sought an interim injunction in circumstances such as these has been successful in raising its prices after refusal of the interim injunction but success at trial.*
>
> *In addition one must also take into account such questions as the uncertainty as to the extent of the price depression, how long it would last beyond trial and what other factors might impact on it, such as alternatives to the infringing product becoming available."*[75]

Arnold J therefore concluded that damages would not be an adequate remedy for Teva if no injunction was granted now but it was successful at trial in due course and obtained a final injunction.

Looking at the opposite side of the case, Arnold J considered whether damages would be an adequate remedy for Actavis if they were wrongly injuncted. He said that so far as loss of sales were concerned, it was not impossible for the court to make some kind of reasonable estimate. However, he thought the more important form of unquantifiable harm from Actavis' perspective was the loss of the first mover advantage. On the facts of this case it was an advantage that was "likely to be short lived in any event".

Accordingly, on weighing up the balance of harm, the judge decided to grant the injunction.

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[74] *Teva v Actavis* [2015] EWHC 2604 (Pat) (9 September 2015) at [30]

[75] *Teva v Actavis* [2015] EWHC 2605 (Pat) (9 September 2015) at [32]-[33]

This is a somewhat surprising judgment from Arnold J. His reasoning acknowledges the historical failure of pharmaceutical companies to raise prices after a finding of infringement. It is interesting to note that the patentee is Teva, which more frequently crops up in disputes playing the role of the generic.

Teva's claim was in EPC 2000 form rather than Swiss form. However a key factual difference to note between Arnold J's decision in this case and his earlier decision refusing to award an interim injunction in mandatory form in *Warner-Lambert v Actavis (21 January 2015)*, was that Parkinson's Disease was the only therapeutic indication for which Teva's originator product was approved – this is not noted in the judgment but it is apparent from a check of Teva's product.

The strikingly different outcome invites question as to why the enforcement of a second medical use patent should be so much more difficult according to whether the active ingredient has been approved for any other therapeutic indication. The dichotomies would appear to raise questions as to compliance with TRIPS and the Community Patent Convention in the context of patents for inventions residing in a second or subsequent medical use.

2.5 Threats

The proposals for the changes in the law relating to groundless threats are dealt with elsewhere. However, one issue has arisen this year which is worthy of note.

In ***Generics (t/a Mylan) v Warner-Lambert (10 September 2015)***, the never ending judgment of Arnold J, it was perhaps inevitable that the issue of groundless threats would arise.

Several communications sent by Pfizer in parallel with the ongoing litigation were considered to fall foul of the provisions of the Patents Act prohibiting threats, including a letter sent to superintendent pharmacists, a letter to sent to clinical commissioning groups and a letter sent to the British Medical Association.

Arnold J's findings on threats may well undergo further review in the higher courts in due course. In the meantime, anyone considering written communications regarding patent defence in the pharmaceutical sector, particularly entities or individuals in the public sphere, would do well to pay heed to his comments.

He said that whether a communication amounts to a threat depends on how it would be understood by an ordinary reasonable person in the position of the actual recipient. The ordinary reader will take into account all the relevant circumstances known to the parties at the date of the communication. A communication may amount to a threat even it is veiled, covert, conditional or future in nature. A general warning not to infringe a patent is not a threat, but it is otherwise if the warning would be understood to refer to the products of a specific manufacturer, importer or vendor.

In the current case, Warner-Lambert's parent company, Pfizer, wrote to the Department of Health in 2014 in the following terms:

> *"Pfizer believes that the current prescription, dispensing and reimbursement framework is likely to contribute to infringement of the pain patent. This may occur if generic pregabalin products are prescribed, dispensed and used to treat neuropathic pain – as opposed to epilepsy or generalised anxiety disorder. Therefore we believe that certain players in the prescription, dispensing and reimbursement chain may, albeit potentially unwittingly, be involved in such infringing activities."*[76]

That was the nature of the majority of the correspondence which was sent. There is too much to list out in this paper, but the general gist was along those lines.

Arnold J's approach was to look at each of the letters in turn, and consider who had actually received them and what their state of mind was. Some of the recipients gave evidence and others did not. Accordingly, some letters were deemed to constitute threats and others not, more on the basis of the state of mind of the recipient, than the contents of the letter itself. For example, one letter was sent to superintendent pharmacists. It was received by a Ms Wright who gave clear and convincing evidence that she interpreted the letter as a threat, not least because it was received by recorded delivery. In that case the letter included lines such as "this is a legal matter" and made specific reference to Actavis. The judge found that it did constitute a threat.

Pending the change in the law, letters of this nature should be handled with extreme caution.

3 VALIDITY

Before embarking on my usual trawl through the grounds of invalidity of a patent, I want to introduce a new section this year which will operate, to some extent, as general background across all the other categories. The section deals with the question of common general knowledge and of skilled persons. It arises from a couple of decisions which are worthy of note.

3.1 Common general knowledge and the skilled person

In ***VPG Systems v Air-Weigh Europe***[77], Judge Hacon had to rule on claims for measuring the state of loading of a vehicle. As usual, in considering the law on obviousness, Judge Hacon had to consider the common general knowledge and the identity of the person skilled in the art.

There was a dispute between the parties about the field from which the skilled person would be drawn in that case. Judge Hacon gave a useful background statement of the position, and the law.

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[76] *Generics (t/a Mylan) v Warner-Lambert* [2015] EWHC 2548 (Pat) (10 September 2015 at [696]

[77] *VPG Systems UK Ltd v Air-Weigh Europe Ltd* [2015] EWHC 1862 (IPEC) (1 July 2015)

One party suggested that the relevant field of the skilled person, or possibly team, was the on-board weighing industry and the automotive industry generally. The other party thought that the skilled person should come from the vehicle on-board weighing industry.

Citing *Catnic v Hill & Smith*[78], the judge said:

> *"Generally it is sufficient to identify the skilled person as the person who is likely to have a practical interest in the subject matter of the invention and practical knowledge and experience of the kind of work in which the invention is intended to be used."*[79]

The judge noted that pursuant to *Schlumberger v Electromagnetic Geoservices*[80], this characterisation will always apply where the court is considering the construction of the patent for an allegation of insufficiency, but on certain facts such a characterisation will be inappropriate for the skilled person enrolled to assess inventive step. He went on to say:

> *"In the present case I see no real difficulties that need teasing out. The technical field of the invention claimed and that of the prior art are the same."*[81]

He then went on to assess what the skilled person's common general knowledge would be, as usually occurs.

I cannot describe my joy to have come across the case of ***Teva v LEO***[82] where my old friend Sir Robin Jacob (as he is now described) was sitting in the Court of Appeal. I am not sure how many more times we will have the benefit of his experience, but it was good to see him back in form in this case.

The Court of Appeal reversed findings by Birss J that two of LEO's patents were obvious. We will return to this case in relation to the question of "obvious to try" below, but for the time being there were some pertinent comments from Sir Robin in relation to the person skilled in the art.

He said that some of the judge's reasoning was "rather odd" in particular the judge's suggestion that the notional skilled person in the art would be different from the real skilled person. Birss J had said:

> *"The skilled formulator would decide what compounds to test based on the properties of the compounds. LEO emphasised Professor Brown's evidence that familiarity with*

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[78] *Catnic Components Ltd v Hill & Smith* [1982] RPC 183 at 242-3

[79] *VPG Systems v Air-Weigh Europe* [2015] EWHC 1862 (IPEC) (1 July 2015) at [28]

[80] *Schlumberger Holdings Ltd v Electromagnetic Geoservices AS* [2010] EWCA Civ 819; [2010] RPC 23

[81] *VPG Systems v Air-Weigh Europe* [2015] EWHC 1862 (IPEC) (1 July 2015) at [29]

[82] *Teva UK Ltd & Anr v LEO Pharma A/S* [2015] EWCA Civ 779 (28 July 2015)

such compounds would be a critical element in the skilled formulator's thinking. I accept that familiarity would always play a part in the choices made by real formulators working in real organisations since it maximises the chances of success by using tried and tested compounds which are often found to work. However I find that the notional skilled formulator would not be as conservative in his or her thinking as that evidence might suggest…"[83]

Sir Robin Jacob did not like this. He said:

"But the law of obviousness attributes to the notional person the real prejudices and practices of persons skilled in the art. For instance the "bag ridden" mind set of real vacuum cleaner designers was attributed to the person skilled in the art in Dyson v Hoover."[84]

In this case, Sir Robin Jacob felt that the judge's approach regarding the skilled person had important consequences, and the decision was ultimately reversed.

It was always a strong principal of Sir Robin Jacob to try to keep the often theoretical law of patents in the real world. His approach to the nature and identity of the skilled person reflects this. He requires that they have the real prejudices and practices of persons skilled in the art – not a theoretical mind set.

3.2 Anticipation/priority

I normally have little to say on this – the law is established and the tests are by their nature largely objective.

However, priority has become more of an issue in recent years, and the European Patent Office has been to the fore, so it is perhaps appropriate to look at a Technical Board of Appeal decision in this area.

Poisonous priority

In the case of Infineum/Partial Priority T557/13, issues relating to the difficult issue of poisonous priority have been referred to an Enlarged Board of Appeal.

The Traveaux Preparatoires to the European Patent Convention 1973 distinguished between claims called "and" type claims, where feature A is disclosed in one priority document and B is disclosed in another priority document, and the claim to the combined features is too narrow to be supported by the first priority, as against "or" claims, where the claim is too broad to be supported by the disclosure of the first priority document.

The relevant provisions within the European Patent Convention are:

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[83] *Teva UK Ltd & Anr v LEO Pharma A/S* [2014] EWHC 3096 (6 October 2014) at [79]

[84] *Teva & Anr v LEO* [2015] EWCA Civ 779 (28 July 2015) at [29]

- Article 88(2): where appropriate multiple priorities may be claimed for any one claim;

- Article 88(3): if one or more priorities are claimed in respect of a European patent application, the right of priority shall cover only those elements of the patent application which are included in the application or applications whose priority is claimed;

- Article 769(1): which lays down that a divisional application "may be filed only in respect of subject matter which does not extend beyond the content of the earlier application as filed; insofar as this requirement is complied with, the divisional application shall be deemed to have been filed on the date of filing of the earlier application and shall enjoy any right of priority".

The case in the UK in which this issue has perhaps been most clearly set out in recent years is that of *Nestec v Dualit*[85] regarding coffee machines. There, the English Patents Court applied the proviso as a pre-condition to be met in order to accord partial priority. Partial priority was denied because the further alternatives encompassed by the claim but not disclosed in the priority document could not be distinguished clearly enough. Consequently claim 1 was found to lack novelty over the subject matter disclosed in the priority document which was the prior art pursuant to section 2(3) of the Patents Act.

Acknowledging that these issues are difficult, the following questions have been referred :

"1. Where a claim of a European patent application or patent encompasses alternative subject matters by virtue of one or more generic expressions or otherwise (generic "or" claim), may entitlement to partial priority be refused under the EPC for that claim in respect of alternative subject matter disclosed (in an enabling manner) for the first time, directly, or at least implicitly and unambiguously, in the priority document?

2. If the answer is yes, subject to certain conditions, is the proviso "provided that it gives rise to the claiming of a limited number of clearly defined alternative subject matters" to be taken as the legal test for assessing entitlement to partial priority for a generic "or" claim?

3. If the answer to question 2 is yes, how are the criteria "limited number" and "clearly defined alternative subject matters" to be interpreted and applied?

4. If the answer to question 2 is no, how is entitlement to partial priority to be assessed for a generic "or" claim?"

We will await enlightenment on these difficult issues.

[85] *Nestec S.A. & Ors v Dualit Limited & Ors* [2013] EWHC 923 (Pat) (22 April 2013)

Disclosure' as a requirement for anticipation

In the case of ***Synthon v Teva***[86], Birss J ran a cursory rule over the background law of anticipation. In a useful summary he said:

> *"The House of Lords in Synthon v Smithkline Beecham held that for an item of prior art to deprive a claim of novelty, two requirements must be satisfied: disclosure and enablement. First, the prior art must disclose subject matter which, if performed, would necessarily infringe that claim. As it was said in General Tire v Firestone, "the prior inventor must be shown to have planted his flag at the precise destination before the patentee". The second requirement identified in Synthon is that the prior art must disclosure the subject matter sufficiently to enable the skilled person to perform it."*[87]

In the current *Synthon* case, the judge felt that there was no issue about enablement – the prior art certainly provided enough information for the enablement test to be satisfied. The issue was whether, as a matter of disclosure, the prior art would fall within the claims. The judge repeated that the test is a very strict one. He said that the "flag planting" metaphor employed in previous authorities was intended to indicate the strictness of the test. He said that the test is one of necessity and inevitability. He went on:

> *"If a prior document leaves open a choice for the skilled person and if the result only falls within the patent claim if the skilled person adopts one way forward and not the other, then there is no lack of novelty. In that circumstance evidence that a skilled person "would" do something when faced with that choice, is evidence relevant to obviousness, not novelty. The claim may lack inventive step but it has not been anticipated. On the other hand patentees will sometimes argue that a choice exists but in fact there is no genuine choice and in fact the patented way forward really is inevitable. If those are the facts then the claim lacks novelty but that is not because the skilled person had to make a choice, it is because there really was no choice at all. Fanciful supposed choices do not count."*[88]

That is as clear and firm a statement of the law as we have seen.

When is 'made available to the public before the priority date'?

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[86] *Synthon B.V. v Teva Pharmaceutical Industries Limited* [2015] EWHC 1395 (Pat) (21 May 2015)

[87] *Synthon v Teva* [2015] EWHC 1395 (Pat) (21 May 2015) at [88]

[88] *Synthon v Teva* [2015] EWHC 1395 (Pat) (21 May 2015) at [89]

It is rare that a complex technology patent case can be described as "fun" but those of us so inclined certainly derive some entertainment from the case of ***Unwired Planet v Huawei***[89] in the context of anticipation.

The case involved a patent belonging to Unwired Planet relating to a polling system for a wireless telecommunications network. The patent is essential to a particular standard, and that in itself has given rise to part of the problem in this case.

The defendants' challenge of lack of novelty relied upon an Ericsson document. This document was uploaded to a publically accessible server for consideration at an ETSI working group meeting. As soon as it was uploaded the document was freely available on the internet to anyone anywhere in the world. It was not in dispute that the Eriksson document amounted to an enabling disclosure of the invention. But did it form part of the state of the art?

Birss J started by looking at the law – always a helpful step. He paraphrased section 2 of the Patents Act and article 54 of the EPC as follows:

> *"The state of the art shall be held to comprise everything made available to the public before the priority date."*[90]

The judge stressed that the words refer to things made available *before* a date. The date mentioned is the priority date. There is no reference to ascribing a calendar date to an item of prior art.

There were two questions in this case. What was the priority date, and was the prior art made available before that date?

At any given moment, the time and date around the world are different. In order to give it meaning the priority date has to be based on some frame of reference. The only frame of reference which makes sense, said the judge, is the one at the patent office at which the priority document was filed. Using any other approach would mean that an event which happened after the priority document was filed could count as prior art. That would be a "very odd result".

Birss J noted that this view was consistent with at least one decision of the EPO, though inconsistent with a different decision concerning a Huawei application, which Unwired Planet contended was wrong.

Having characterised the priority date as the date of the document's filing in the USPTO (8 January 2008), the judge then considered whether the Ericsson document was made available before that date. The uploading occurred at 7.36am GMT on 8 January 2008. In Hawaii the time and date at this point was 21:36 on 7 January 2008.

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[89] *Unwired Planet International Limited v Huawei Technologies Co Ltd & Ors* [2015] EWHC 3366 (Pat) (23 November 2015)

[90] *Unwired Planet v Huawei & Ors* [2015] EWHC 3366 (Pat) (23 November 2015) at [157]

The key point was that because the priority document was filed in the USPTO, it was necessary to consider whether from the perspective of the USPTO, in the EST time zone, the Ericsson document was made available before 8 January 2008. From the perspective of that time zone, the upload occurred at 2.36am on 8 January 2008. This was not before the priority date, but rather on the priority date, so the Ericsson document was not state of the art for the purposes of the patent and could not form the basis of a challenge to novelty.

This might seem harsh for the defendants in the present case because the Ericsson document was in fact made available to the public before the moment in time that the priority document was filed. The judge noted the "justice" in the defendants' submissions. However, if the law was as the defendants wished it to be, it would catch as prior art things made available to the public at a time after the priority document was filed. Birss J said:

> *"The facts in this case flatter the defendants' argument. Consider what would happen if the content of a priority document filed at the Japanese patent office early in the morning was then placed on the internet one hour later. It would be available all over the world and at that moment the date in the USA would be the day before. On the defendants' submission this would be prior art because it is to be regarded as having taken place before the priority date. I do not agree."*[91]

The judge also provided a useful table illustrating the times that events occurred in the time zones considered in the present case:

	CET (GMT +1)	GMT	EST (GMT - 5)	Hawaii (GMT - 10)
Ericsson Doc uploaded to ETSI server	8 Jan 08:36	8 Jan 07:36	8 Jan 02:36	7 Jan 21:36
Ericsson Doc downloaded by Mr Lieshout	8 Jan 09:45	8 Jan 08:45	8 Jan 03:45	7 Jan 22:45
Priority Doc filed at USPTO	8 Jan 22:59	8 Jan 21:59	8 Jan 16:59	8 Jan 11:59

'Enablement' as a requirement for anticipation

Finally in relation to anticipation, I want to consider briefly the case of ***Merck v Ono***[92].

Having already learned that one part of the anticipation test – that related to the actual equivalence between the anticipation and the claims in the patent – is very strict, this case deals more with the question of enablement and the notion of plausibility.

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[91] *Unwired Planet v Huawei & Ors* [2015] EWHC 3366 (Pat) (23 November 2015) at [169]

[92] *Merck Sharp & Dohme Ltd v Ono Pharmaceutical Co Limited & Anr* [2015] EWHC 2973 (Pat) (22 October 2015)

Birss J noted that the question of whether a patent or priority document makes something plausible has come up in the cases in the context of industrial application, sufficiency, priority and obviousness. In this case, it was argued to play a part in novelty as well.

To date, the highest UK courts have addressed questions regarding plausibility in *Conor v Angiotech (House of Lords)*[93] and *HGS v Lilly (Supreme Court)*[94]. The Supreme Court held that the sense that the word "plausible" conveys is that there must be some real reason for supposing that the statement is true, but the standard is not any higher than that.

In *Merck v Ono*, Birss J noted that, although the word is increasingly used across a range of patent issues, it is not found in the relevant parts of the European Patent Convention or the Patents Act 1977 – there is no law of plausibility as such. He said:

> *"It has proved to be a useful concept in various factual situations but just because that has proved to be true in one case does not mean that everything said in that context applies in a very different context. There is no law of plausibility as such."*[95]

Recapping, once again, on the general law of novelty, Birss J reiterated that for anticipation to be established there must be disclosure of the invention by the prior art and that disclosure must be enabling – it must properly enable a person skilled in the art to work something which falls within the scope of the claim.

The *Merck* case involved Swiss form claims, and the parties agreed that an enabling disclosure of the same therapeutic effect in the prior art was necessary since the claims derive their novelty from the intended medical use.

The judge noted that this reflects the fact that in medical use claims, the new use is a critical feature of the claims. The use provides the novelty to the invention since the substance itself and its medical use are previously known. He noted that in the European Patent Office, the view is taken that with claims in either Swiss form or EPC 2000 form, the actual achievement of the therapeutic effect is a functional technical feature of the claim, as opposed to a mere statement of purpose or intention.

Drawing this together in relation to the current case he said:

> *"Ono submitted that plausibility was an aspect of the law of novelty. When the draft judgment was prepared I attributed the same submission to Merck too, but then received notes on that point from the parties. Merck submitted it had not made the submission but Ono submitted that it had. No matter. In my judgment there is no distinct requirement for plausibility in the law of novelty, over and above disclosure and enablement, but in a proper case plausibility is an aspect of enablement. In order*

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[93] *Conor Medsystems Incorporated v Angiotech Pharmaceuticals Incorporated & Ors* [2008] UKHL 49

[94] *Human Genome Sciences Inc v Eli Lilly & Company* [2011] UKSC 51

[95] *Merck v Ono & Anr* [2015] EWHC 2973 (Pat) (22 October 2015) at [137]

to amount to an enabling disclosure of a medical use claim and thereby deprive the claim of novelty, the prior art has to make the therapeutic effect plausible."[96]

Bearing in mind that the judge had already acknowledged the Supreme Court's finding in *HGS v Lilly* that the standard for plausibility is not particularly high, this raises interesting questions about the enablement test in relation to anticipation. It would be a curious outcome if one part of the test for anticipation was, on Birss J's own finding, very strict, and the other was somewhat looser.

3.3 Obviousness

Year after year we are presented with supposedly "new" thinking on obviousness. In truth we learn little. Judges come and judges go and they all want to have their say, but in the end they never provide any enlightenment beyond the basic question – is it obvious?

There is still no better statement of the law than that set out by Kitchin J as he then was in *Generics v Lundbeck*[97] when he said:

"The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success."[98]

In other words, it is a multifactorial issue. There is no individual test which can be applied, and drawing principles is very hard.

Each year I weigh through case after case and find myself frustrated that as practitioners we end the year no better able to give firm advice on inventive step than before. However, let us dip into this year's offerings and see where we get to.

"Fair expectation of success"?

In ***Hospira v Genentech (III)***[99], Arnold J delivered the latest blow in the ongoing saga surrounding trastuzumab (the monoclonal antibody in Herceptin) and Hospira's continued efforts to knock out Genentech's patents and clear the way for the launch of a generic version of the medicine.

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[96] *Merck v Ono & Anr* [2015] EWHC 2973 (Pat) (22 October 2015) at [175]

[97] *Generics UK Limited & Ors v H. Lundbeck A/S* [2007] EWHC 1040 (Pat)

[98] *Generics UK Limited & Ors v H. Lundbeck A/S* [2007] EWHC 1040 (Pat) at [74]

[99] *Hospira UK Limited v Genentech Inc* [2015] EWHC 1796 (Pat) (24 June 2015)

The key issue in relation to inventive step was whether, based on a particular item of prior art, it would have been obvious for the person skilled in the art to try to perform Genentech's invention.

Genentech, relying on the House of Lords' decision in *Conor v Angiotech*[100], argued that the correct question was whether it was obvious that the claimed technical effect *would* be achieved by the skilled person, not merely that he might achieve it.

However, Arnold J thought that Genentech's reliance on *Conor* was misplaced. He said that what that case was really saying was that what matters is whether the person skilled in the art would have had an expectation of success sufficient to induce him to perform the invention. He summarised in these terms:

> *"Accordingly, I consider that the correct test is whether the skilled person would have a "fair expectation of success" if he were to try the claimed product or process. As the Court of Appeal has held in MedImmune and other cases, what amounts to "fair expectation of success" depends on all the circumstances."*[101]

That means that in any given case, the judge has to establish what amounts to "a fair expectation of success". Arnold J, assessing the facts of this case, considered the following items:

- How motivated would the skilled man have been to try to find such a treatment?
- Would the trial be a routine one?
- Would the trial be burdensome?
- Would the trial present a risk to patients?
- What alternative options were there?
- Were there any "lions in the path" that would deter the skilled man from performing the invention?
- Failure rates in phase III trials: the skilled man would know that trials of the nature required would not necessarily succeed.

Arnold J found on the facts that the skilled person would have been highly motivated to discover the invention, would have carried out a routine trial that was not overly burdensome, would have expected a low risk to patients, would have seen only a limited number of alternatives, would have known that combinations of this type were a well-established way to treat cancer, would not have perceived any serious reasons why he should not proceed, and

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[100] *Conor Medsystems v Angiotech & Ors* [2008] UKHL 49; [2008] RPC 218

[101] *Hospira v Genentech* [2015] EWHC 1796 (Pat) (24 June 2015) at [115]

would have viewed the prior art as the result of over a decade of study by distinguished scientists in the field.

On that basis, he found the patent invalid for lack of inventive step.

In ***Teva v LEO***[102], Birss J, at first instance, adopted an unusual approach to the assessment of obviousness. He held that, based on the common general knowledge alone, the skilled person would think of combining the active ingredients the subject of the claim in issue and would be motivated to combine them in a way which created a non-aqueous ointment formulation. He said that based on what the skilled formulator knew about it at the time there was sufficient prospect of a positive result in the tests with this compound to make it worth testing and that it was obvious to do so. The consequence was that the patent was invalid.

When this got to the Court of Appeal, Sir Robin Jacob gave the leading judgment.[103] He thought that Birss J had got the "obvious to try" standard wrong. He said:

> *"In effect the judge was saying that the idea of including this solvent as part of a research project amounted to obviousness. The "obvious to try" standard requires a higher expectation of success than that. Otherwise, as I observed in St Gobain:*
>
> > *"Mere possible inclusion of something within a research programme on the basis you will find out more and something might turn up is not enough. If it were otherwise there would be few inventions which were patentable. The only research which would be worthwhile would be in areas totally devoid of prospect.""*[104]

The Court of Appeal felt that the error resulted from the judge missing the real significance of the evidence and his own findings of fact. The judge had accepted evidence that to the skilled person, identifying a non-aqueous solvent which would actually work to produce a stable ointment was not easy.

The judge had found that the formulator would test a number of solvents, about 10-20, and it was implied that the expectation of success with any one of them was not high. Sir Robin Jacob said that the fact that the field was empirical and such testing was "entirely routine" did not alter the expectation of success.

This represents a certain reining in of the "obvious to try" principle.

It was of course inevitable that obviousness would be discussed in the vast judgment of Arnold J in ***Generics (t/a Mylan) v Warner-Lambert (10 September 2015)***[105]. The judgment,

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[102] *Teva UK Limited & Anr v LEO Pharma A/S* [2014] EWHC 3096 (Pat) (6 October 2014)

[103] *Teva UK Limited v LEO Pharma A/S* [2015] EWCA Civ 779 (28 July 2015)

[104] *Teva v LEO* [2015] EWCA Civ 779 (28 July 2015) at [32]

[105] *Generics (t/a Mylan) v Warner-Lambert* [2015] EWHC 2548 (Pat) (10 September 2015)

handed down some six weeks or so after the Court of Appeal's decision in *Teva v LEO*, made no mention of the guidance given by the Court of Appeal in that case. Instead, Arnold referred to his judgment in *Hospira v Genentech (III)* and said that the correct test was whether the skilled team would have a fair expectation of success if it were to try pregabalin for the treatment of pain.

The question of the expectations of the skilled person arose once again in ***Merck v Ono***[106]. Birss J acknowledged that the Court of Appeal had told him, in its recent *Teva v LEO* decision, that he had got the 'obvious to try' test "wrong" in that case. In the *Merck v Ono* decision, he appeard to apply the Court of Appeal's guidance on the test:

> "*A skilled person reading the Latchman paper in the light of their common general knowledge, might conceive of carrying out a mouse tumour model test of PD-1 blockade. However if they did think about performing the test, they would be doing so hoping that the test might succeed, not expecting that it would. There would not be a sufficient expectation that the outcome would be successful to render the invention obvious. I find that the invention involved an inventive step over the Latchman paper.*"[107]

Then, in In ***Actavis v Lilly*** **(tomoxetine case)**[108], Mr Justice Carr got to have his first material look at the law of obviousness. He issued a clear warning against what he described as a "mechanistic application" of the "obvious to try" approach in this context. He said:

> *"The potential difficulty that would be caused by a mechanistic application of the "obvious to try" approach … was explained by Professor Sir Hugh Laddie in "Patents – what's invention got to do with it?" (Chapter 6 in Intellectual Property in the New Millennium):*
>
> > *"The problem can be approached by considering first the concept of 'obvious to try'. The classic statement of this principle is set out in the judgment of the Court of Appeal in Johns-Manville Corporation's Patent. It was said that a development should be treated as obvious if 'the person versed in the art would assess the likelihood of success as sufficient to warrant actual trial'. Statements to similar effect have been made by the [European Patent Office].*
> >
> > *On its face, this produces an unworkable or irrational test. If the reward for finding a solution to a problem and securing a monopoly for that solution is very high, then it may well be worthwhile for large players to examine all potential avenues to see if one gives the right result, even though the prospects of any one of them succeeding are much less than 50/50. What makes something worth trying is the outcome of a simple risk to reward calculation. Yet, if the reward is very large, the avenues worth trying will be*

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[106] *Merck v Ono & Anr* [2015] EWHC 2973 (Pat) (22 October 2015)

[107] *Merck v Ono & Anr* [2015] EWHC 2973 (Pat) (22 October 2015) at [273]

[108] *Actavis & Anr v Eli Lilly* [2015] EWHC 3294 (Pat) (16 November 2015, tomoxetine case)

expanded accordingly. So, the more commercially attractive the solution and the more pressing the public clamour for it, the harder it will be to avoid an obviousness attack. In those circumstances a solution which is quite low down a list of alternatives, all of which are more or less worth trying, will fail for obviousness.'"[109]

How is the 'invention' defined?

Also notable is the emerging difference between the judges of the Patents Court as to how the invention of the patent should be defined when considering a challenge of lack of inventive step.

Did you think the courts had already settled on the answer to this?

In ***Generics (t/a Mylan) v Warner-Lambert (10 September 2015)***[110], Arnold J made the following observation on the law regarding inventive step:

"Counsel for Warner-Lambert submitted that Mylan and Actavis must show that it would have been obvious to the skilled team that pregabalin would be effective to treat pain, but he nevertheless accepted that it was relevant to consider whether the skilled team would have a fair expectation of success if it were to try pregabalin for the treatment of pain. In my judgment this is the correct test…"[111]

In the context of construing the Swiss form claim language the judge had noted that the word "treating" was "a functional technical feature of the claim i.e. the actual attaining of the therapeutic benefit is a technical feature of the claimed invention". However, the judge also ruled that the criterion for determining the actual attaining of clinical benefit was a positive result in one of three animal models used in the patent (as argued by Actavis), rather than positive results in a (phase II) clinical trial (as argued by Warner-Lambert).

Following on from this, Arnold J considered Mylan and Actavis' obviousness challenge by asking whether it would have been obvious to the skilled person to test pregabalin in one of the three animal models used in the patent with a fair expectation of success.

In taking this approach Arnold J defined the 'invention' for the purposes of the assessment of inventive step by reference to the support provided in the specification, rather than by considering whether the attaining of the claimed therapeutic benefit (treatment of pain) would have been obvious.

Nevertheless the judge observed that Mylan and Actavis' case suffered from a basic difficulty – none of the prior art relied upon disclosed both pregabalin and use for the treatment of neuropathic pain. Their case relied upon combinations of prior art documents being read by

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[109] *Actavis & Anr v Eli Lilly* [2015] EWHC 3294 (Pat) (16 November 2015, tomoxetine case) at [106]

[110] *Generics (t/a Mylan) v Warner-Lambert* [2015] EWHC 2548 (Pat) (10 September 2015)

[111] *Generics (t/a Mylan) v Warner-Lambert* [2015] EWHC 2548 (Pat) (10 September 2015) at [292]

the skilled person together. For each combination the judge considered that Mylan and Actavis had asserted a step by step argument to suggest that the skilled team would reach the invention, which he found was based on hindsight. Consequently, the invention was not obvious.

In keeping with Arnold J's approach in the *Warner-Lambert* case, in ***Merck v Ono***[112] Birss J considered the 'invention', for the purpose of the obviousness assessment, as defined by the level of support provided in the specification (a mouse model), rather than by the therapeutic purpose defined in the claim "cancer treatment".

In ***Actavis v Lilly*** **(tomoxetine case)**[113], Carr J stepped away from the approach adopted by Arnold J and Birss J. He started with a bold statement of intent. He said that it is the claimed invention that is to be assessed, not the "invention" as defined by the data provided in the specification. He said:

> *"What must be obvious?*
>
> *It may appear that the answer to this question is so self-evident that it is not worth asking. However it is important not to become confused between the extent of disclosure of the specification and the invention specified in the claims. The appropriate question for the court to ask itself is whether, in the light of the state of the art, the invention specified in the claims is obvious."*[114]

He went on to say:

> *"Of course, the extent of disclosure of the specification, and the absence of experimental data, is a matter of relevance to the plausibility of the patent for the claimed therapeutic purpose. However, when considering the cited prior art, the correct question is whether the alleged invention defined in the claim was obvious."*[115]

Carr J's conclusions on the law meant that the invention was defined according to the functional technical feature of therapeutic efficacy, not in accordance with the level of supporting data contained in the specification. It was not obvious that that claimed invention (tomoxetine in ADHD) would work, nor would the skilled person have had a 'fair expectation of success'. So the patent was inventive.

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[112] *Merck v Ono & Anr* [2015] EWHC 2973 (Pat) (22 October 2015)

[113] *Actavis & Anr v Eli Lilly* [2015] EWHC 3294 (Pat) (16 November 2015, tomoxetine case)

[114] *Actavis & Anr v Eli Lilly* [2015] EWHC 3294 (Pat) (16 November 2015, tomoxetine case) at [100]

[115] *Actavis & Anr v Eli Lilly* [2015] EWHC 3294 (Pat) (16 November 2015, tomoxetine case) at [101]

Secondary evidence of inventive step/obviousness

In ***Unwired Planet v Huawei***[116]**,** the question of inventive step arose, along with an old favourite – the role of secondary evidence.

On the law regarding inventive step, Birss J adopted the Court of Appeal's structured approach to the assessment of obviousness – the *Pozzoli* test, and approved Mr Justice Kitchin's statement of the law in *Generics v Lundbeck* which I have already set out above.

Having duly given himself the proper warning that secondary evidence had a role to play but must be "kept in its place" Birss J went on to consider inventive step in relation to three prior art documents.

Unwired Planet argued that it was important to consider what actually happened when the documents in question were made available. They said that the evidence showed that over a short period of time there was a technical debate involving intense effort and focus by engineers from numerous leading firms in the field. None of the skilled people appeared to have spotted the idea in the document which, it was argued, represented prior art.

When all the evidence was considered, it was this secondary evidence which proved decisive in favour of Unwired Planet, and the patent was found not to be obvious.

Drawing the strands together…

What the collective judges appear to be saying is that even a general analysis of the situation suggests that there is usually an element of "obviousness to try" in any research endeavour that is not undertaken with complete blindness but rather with some semblance of a chance of success. If the question of patentability is determined on that basis, that would not only be contrary to statute, but would result in a marked deterioration of the whole patent system as an incentive to invest in those efforts and attempts which go by the name of "research".

The safeguard is the standard set for the expectation of success. The fact that it may be commercially attractive to try every possible avenue of research, in the light of the potential rewards if success is achieved, does not mean that it is "obvious to try". Obviousness cannot relate to commerciality – it must relate to a reasonable technical expectation of success. That is the clear message, and it appears that Carr J, like Sir Robin Jacob, is seeking to apply limits to the "obvious to try" principle which risks undermining the entire patent system.

Secondary evidence can be important – even in defeating a claim of obviousness. The "step by step" approach and the mosaicing of prior art are still wrong.

However, there is clear discrepancy between the judges of the Patents Court as to how the 'invention' of the patent should be defined when assessing an obviousness challenge. Carr J

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[116] *Unwired Planet v Huawei & Ors* [2015] EWHC 3366 (Pat) (23 November 2015)

has asserted that it is the claimed invention which sets the bar; Arnold J & Birss J have set the target rather lower, by reference to the support provided in the specification.

The same three Patents Court judges also disagree as to the relationship between the concept of 'plausibility' in the context of sufficiency and the standard for assessment of inventive step. Are they equivalent? Or is one hurdle higher than the other? If so, which is the higher standard? This is discussed further following a consideration of their rulings on sufficiency.

It is to be expected that the Court of Appeal will be kept busy in 2016 sorting out these inconsistent approaches. However, I do feel that in 2015 limits have clearly been applied to the use of the "obvious to try" test which could be useful in reversing the trend, emerging in recent years, of this country being a graveyard for patents on the grounds of inventive step.

3.4 Insufficiency

The cases on insufficiency will feature the three current Patents Court judges – Arnold J, Birss J, and Carr J – in that order. The conclusion at the end of the three cases may be interesting!

Turning first to the magnum opus of Arnold J in ***Generics (t/a Mylan) v Warner-Lambert (*****10 September 2015)**, Mylan and Actavis challenged the sufficiency of a number of the claims in the patent, and in particular claims 1 and 3.

Arnold J recognised that two types of insufficiency have emerged over the years. The first is the "classical" type (i.e. where the specification does not enable the skilled person to perform the invention across the scope of the claim), and the other relates to what has become known as "Biogen" insufficiency (i.e. where the claim is excessively broad because the same result can be achieved by the skilled person by different means which make no use of the invention). This was a case more closely related to the *Biogen* type of insufficiency.

Arnold J quoted Lord Justice Kitchin in the ***Regeneron***[117] case. Kitchin LJ said:

> *"It must … be possible to make a reasonable prediction that the invention will work with substantially everything falling within the scope of the claim or, put another way, the assertion that the invention will work across the scope of the claim must be plausible or credible. The products and methods within the claim are then tied together by a unifying characteristic or a common principle. If it is possible to make such a prediction then it cannot be said the claim is insufficient simply because the patentee has not demonstrated the invention works in every case."*[118]

[117] *Regeneron Pharmaceuticals Inc & Anr v Genentech Inc* [2013] EWCA Civ 93 (21 February 2013)

[118] *Regeneron v Genentech* [2013] EWCA Civ 93 (21 February 2013) [100]

So here we have the word "plausible" once again in issue, this time in the context of insufficiency. I have already referred to Lord Hope's reference to the meaning of the word 'plausible' in *HGS v Lilly*[119]. Lord Hope said:

> *"I would not quarrel with Jacob LJ's comment, after consulting the Shorter Oxford English Dictionary, that the sense that word conveys is that there must be some real reason for supposing that the statement is true. The important point, however, is that the standard is not any higher than that."*[120]

Arnold J said that the same sense is conveyed by some of the other expressions which can be found in the case law, for example on industrial applicability, which were mentioned by Lord Neuberger in his judgment in *HGS v Lilly*, such as "reasonably credible".

I do not propose to go into the facts of the pregabalin case in detail – that will not be helpful. However, it is important to note that Warner-Lambert argued that it was relevant that pregabalin had subsequently been authorised for central (as well as peripheral) neuropathic pain. Accordingly, they argued that this added weight to the plausibility argument with regard to the sufficiency of claim 3, which concerned 'neuropathic pain'. However, Arnold J adopted the argument of counsel for Mylan and Actavis, asserting that "later work does not justify a claim which was speculative when it was made".

Further, said Arnold J, even if there was, as Warner-Lambert asserted, sufficient data in the patent to make it obvious to try pregabalin for neuropathic pain, that was not enough for sufficiency.

Consequently, claims 1 (to pain) and 3 (to neuropathic pain) of the patent, and certain other claims, were found to be insufficient. However dependent claims directed to subsets of 'pain' and 'neuropathic pain' which were rendered plausible by the disclosures contained in the specification (for example in the context of peripheral neuropathic pain), were not found to be insufficient.

Turning now to Birss J, he had his say on the subject in the case of ***Merck v Ono***[121]. It will be recalled that in this case Birss J noted the apparent applicability of the concept of 'plausibility' across the full range of patent issues. Insufficiency was one of them. Birss J referred to his commentary in ***Hospira v Genentech (I)***[122], where, with reference to second medical use claims, he summarised the law as he saw it as follows:

> "*…. such claims are generally regarded as novel over a mere proposal to administer the drug to patients in the manner claimed. That is because the mere proposal does*

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[119] *Human Genome Sciences v Eli Lilly* [2011] UKSC 51

[120] *Human Genome Sciences v Eli Lilly* [2011] UKSC 51 at [149]

[121] *Merck v Ono & Anr* [2015] EWHC 2973 (Pat) (22 October 2015)

[122] *Hospira UK Limited v Genentech Inc* [2014] EWHC 1094 (Pat) (10 April 2014)

not disclose that the treatment is indeed efficacious. If it was obvious that the treatment would be efficacious, or at least it was obvious to conduct a trial of the treatment which would involve treating patients, then the claim is likely to lack inventive step but that is another matter.

One might say therefore that the patent specification must contain the results of a clinical trial in order to prove efficacy, since the claims contain this element as a feature. But to require that at least in all circumstances may cause another problem. Finding new treatments for disease is highly desirable. Clinical trials are a necessary but very expensive and complex part of that process. The existence of a patent (or application) may facilitate investment in the clinical trial which might not otherwise take place but that means that the patent has to be applied for before the results are known. So a rule which demanded clinical results could cause real difficulties.

On the other hand, if all the patent contains is a mere proposal, then it has not made a contribution to the art. One has now come full circle. A mere proposal is not a disclosure of the claim, properly construed. But the patentee can hardly argue, and the court or patent office is unlikely to accept, that a mere prior proposal is not enough to invalidate the claim if all that is present in the specification of the patent is a mere proposal followed by a use claim.

Moreover it would be a recipe for abuse if all that was required in order to obtain a patent in this field was a proposal, without any basis, to use drug A to treat disease B.

Patent law seeks to address these factors balancing the requirements for sufficiency of disclosure against the rules of novelty and inventive step. But the conventional sufficiency test of asking whether the claimed invention works does not help. The treatment does work but what if the patent does not say so?

For these reasons the idea of "plausibility" as part of the law of sufficiency of disclosure has been developed both in the EPO and in the UK. The term "plausibility" has been coined to characterise what it is that a patent specification must provide in order to be sufficient, short of full clinical proof of efficacy."[123]

One of Merck's submissions was that the 'research programme' required to put the invention into practice was unduly burdensome and that this was illustrated by the fact that, almost a decade after the start of clinical studies, research to find an efficacious therapy even in the most important and lethal cancers is continuing.

Birss J said:

"I do not accept that submission, for the following reasons. First, no undue burden for a skilled person is involved in creating a suitable inhibitory … antibody in the first place. Second, no undue burden is involved in finding an antibody which is useful in cancer treatment and which successfully treats many cancers. It is true that these

[123] *Hospira UK Limited v Genentech Inc* [2014] EWHC 1094 (Pat) (10 April 2014) at [57]-[64]

steps all involve very considerable work and very substantial cost but they are not of a quality which undermines the sufficiency of the patent's disclosure. It is true that the clinical research into antibodies is continuing but ten years is not a long time in the context of this sort of clinical research. The fact that clinical trials in many cancers are continuing does not count against sufficiency."[124]

Noting that the claim in the *Merck* case was a Swiss form claim, Birss J sought to emphasise the distinction in such cases from classic cases like *HGS v Lilly* (which concerned a product claim). He said:

"The principle applicable to purpose limited medical use claims must be that the material relied on to establish plausibility must be both sufficiently specific, and have a sufficient breadth of application, to fairly support the claim both in terms of the nature of the agent claimed to have an effect, and in terms of the effect claimed."[125]

In other words, what he is saying is that, in the context of Swiss form (and EPC 2000) claims, the plausibility must extend both to the medicament, and its success as a treatment.

On the facts of the case, Birss J concluded that the information in the specification of the patent (being (i) *in vivo* data from mouse models (x2) for cancer, combined with (ii) a selective presentation of information that was within, but not a comprehensive reflection of, the common general knowledge) ensured that the claim to priority was sound, and the claims were (apparently) plausible. Sufficiency was supported also by later published data demonstrating efficacy and/or continued research interest for a range of cancer indications.

Next we turn to Carr J, who considered the question of insufficiency in ***Actavis v Lilly* (tomoxetine case)**[126].

Carr J noted that for the purpose of obviousness, the skilled person should be able to make a fair prediction that the alleged trial will, not might, succeed. Is the same true in relation to sufficiency, or is the standard of plausibility different?

Actavis contended that the tests were essentially the same. Lilly contended that the tests were different. Essentially, Lilly argued that plausibility, in the context of sufficiency, is merely a threshold test restraining excessive claim scope, and that it is irrelevant if the invention can, in fact, be performed across the scope of the claim.

Having rejected a submission that the imposition of a test for plausibility would be contrary to established law – TRIPS, the EPC, or the 1977 Act, Carr J said that plausibility had been referred to by courts at the highest level as one factor that should be taken into account in the assessment of industrial application, sufficiency and inventive step, which are all parts of the

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[124] *Merck v Ono & Anr* [2015] EWHC 2973 (Pat) (22 October 2015) at [170]

[125] *Merck v Ono & Anr* [2015] EWHC 2973 (Pat) (22 October 2015) at [139]

[126] *Actavis & Anr v Eli Lilly* [2015] EWHC 3294 (Pat) (16 November 2015, tomoxetine case)

requirements of the relevant treaties and legislation. However, his conclusion was that the standard for assessment of plausibility in the context of sufficiency is not the same as the standard for assessment of expectation of success in the context of obviousness. He said:

> *"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 programme 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."*[127]

He went on to conclude that, in the context of insufficiency, plausibility is a "threshold test" which is satisfied by a disclosure which is "credible" as opposed to speculative. He said:

> *"That disclosure may subsequently 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 standard for assessment of expectation of success in the context of obviousness."*[128]

Rather than taking the part of either Arnold J or Birss J in their apparently differing decisions on this issue, Carr J has chosen to plough a completely different furrow of his own.

In contrast to Arnold J (in the *Warner-Lambert* case), and in a much more decisive statement of the law than provided by Birss J (in the *Merck* case), he said that in the context of insufficiency, "plausibility" is only a threshold test; it is not the same as the standard for assessment of an expectation of success in the context of obviousness.

The judge's conclusions on the law meant that the claimed invention was credible and therefore plausible, despite supporting data not being provided. So the patent was not insufficient.

The consequence of the different approach taken by Carr J appears to be beneficial to patentees. Had he considered the concept of plausibility to equate to the test of "fair

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[127] *Actavis & Anr v Eli Lilly* [2015] EWHC 3294 (Pat) (16 November 2015, tomoxetine case) at [177]

[128] *Actavis & Anr v Eli Lilly* [2015] EWHC 3294 (Pat) (16 November 2015, tomoxetine case) at [178]

expectation of success", an obviousness/insufficiency squeeze would seem to have come into play in that case with Actavis succeeding on insufficiency.

A plausible difference in judicial approach?

It would appear, therefore, that there is a discrepancy between the Patents Court judges as regards the standard for assessment of a challenge of insufficiency.

Arnold J's decision, handed down in September 2015, appeared to put in place something approaching a two stage test. In consequence, although there was no dispute in the *Warner-Lambert* case that the invention could, in fact, be performed across the scope of the Swiss form claim (in particular claim 3), the judge found the claim invalid for insufficiency because the data contained in the specification, combined with the common general knowledge, did not render it 'plausible' that pregabalin would be effective to treat central neuropathic pain (a subset of the scope of the claimed indication). If the specification rendered the invention obvious to try for neuropathic pain, that was not enough.

In October 2015, Birss J appeared to step away from such a strict approach. Noting that there is no law of plausibility as such and noting the importance of considering the context of any particular invention, he indicated that there was no need for the court to apply previous wording incorporating a "requirement" for plausibility as a test to be met in later cases. Although Ono's medicament did not have efficacy across all "cancer" indications the claim was nevertheless sufficient.

Completing the trilogy, in November 2015 Carr J sought to reduce the hurdle presented by the growing concept of 'plausibility', ruling that it was merely a "threshold test". His reasoning suggests that the standard for plausibility/credibility is not as high a test as the standard for assessment of inventive step.

In view of the inconsistencies, it is to be expected that there will be appeals in this trilogy of cases. We will await with interest the outcome as the year progresses.

Nevertheless, it is fair to say that, from an early start, Carr J's judgments may justifiably be considered as a positive development for innovative industries.

Second medical use inventions generally

It is the clear intention of legislatures around the world that the patent system incentivises investment in research, including into innovative medical uses of known drugs. However, medical research is heavily regulated. By necessity it involves patients, doctors, hospitals and academic institutions. The patent system has not really been designed to accommodate this.

Patents are jurisdiction-specific but filing may be coordinated and streamlined to some degree. A portfolio of patents is needed for effective "global" coverage. There are different requirements for sufficiency/plausibility in different jurisdictions. In the course of collaborative

multicentre medical research, information on the existence of clinical trials will often reach the public domain before data demonstrating efficacy has been obtained and/or published.

So when do you file? Do you wait until you have enough data to that you can be sure that you can demonstrate sufficiency/plausibility for all relevant jurisdictions, risking the emergence of information on a trial which demonstrates activity and renders the invention obvious (eg *Hospira v Genentech (III)*)? Or do you file earlier, with the risk that the patent/application is invalid for insufficiency (eg *Generics (t/a Mylan) v Warner-Lambert* (10 September 2015)?

Arnold J's decision in the *Hospira v Genentech (III)* and *Warner-Lambert* cases serve as a stark reminder of the difficult choice currently faced by the innovative pharmaceutical industry. Higher court guidance would be welcomed and would preferably follow consideration of the balance between the patent law requirements for sufficiency and inventive step, and the regulatory requirements for safety and efficacy testing and the ethical conduct of clinical trials, not just in the context of the UK, but reflecting the global environment in which medical research is conducted.

3.5 Added Matter

In ***IPCom v HTC Europe***[129], Birss J had to consider the question of added matter in the context of applications to amend IPCom's patent in the course of an infringement action.

This was one of those difficult cases where, the patent having been through an opposition procedure resulting in amendment, and the subject of an ongoing appeal, the suspensive effect of appeals meant that the patent remained in its form as granted, but that would possibly be only a temporary state of affairs. In order to equalise the position between the EPO and the UK court, IPCom made an application to amend the patent to the form accepted by the Board of Appeal of the EPO.

HTC submitted that if the proposed amended claim was construed as IPCom contended for, then the claim would be bad for added matter as an intermediate generalisation.

Birss J agreed that in terms of its coverage the claim did indeed cover something more general than the second embodiment. In that sense, as a matter of coverage, the claim was an intermediate generalisation. But this did not decide the point. Birss J stated:

> *"As the line of cases … explains, 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. In other words to characterise a claim as an intermediate generalisation is not sufficient to establish the presence of added matter. Proving that a claim is an intermediate generalisation in terms of coverage does not establish added matter.*

[129] *IPCom GmbH & Co KG v HTC Europe Co. Ltd & Ors* [2015] EWHC 1034 (Pat) (24 April 2015)

> *It is on the distinction between coverage and disclosure that the argument founders. The claim refers to transmission "as a bit pattern" and to an "access class bit". 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."*[130]

In ***Novartis v Focus***[131], it is perhaps no surprise that Arnold J found another pharmaceutical patent invalid.

Novartis alleged that its European patent was infringed by the defendants' various products, all of which were generic versions of a Novartis patch. The purpose of the patch was to deliver a drug for preventing, treating or delaying progression of dementia or Alzheimer's disease. The defendants, Focus, Actavis and Teva, challenged validity. The patent was held to be invalid for added matter and for lack of inventive step.

Arnold J reviewed the law on added matter, summarising that:

> *"The key question is whether the patent presented the skilled team with information about the invention which was not directly and unambiguously derivable from the application."*[132]

I will not go through the facts in detail – they do not add much – but in the end Arnold J concluded that there was considerable new information in the patent, which could not be reasonably derived from the priority document. He said that Novartis really had no answer to these points.

The description of what amounted to intermediate generalisation appears to adopt a different test to that applied by Birss J, and consequently a tougher line for the patentee. Regular readers of the judgments of Arnold J will not be surprised by this.

In ***Teva v LEO***[133], having found the patent invalid for obviousness, Birss J did not address the question of added matter. The decision on obviousness having been reversed, Sir Robin Jacob took a succinct look at the issue in the Court of Appeal.[134]

Teva alleged that the original wide disclosure of the application was so wide that it even included the use of solvents and long lists of ingredients. The narrow particular disclosure of

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[130] *IPCom v HTC Europe & Ors* [2015] EWHC 1034 (Pat) (24 April 2015) at [125]-[126]

[131] *Novartis AG & Ors v Focus Pharmaceuticals Limited & Ors* [2015] EWHC 1068 (Pat) (27 April 2015)

[132] *Novartis & Ors v Focus & Ors* [2015] EWHC 1068 (Pat) (27 April 2015) at [103]

[133] *Teva UK Limited & Anr v LEO Pharma A/S* [2014] EWHC 3096 (Pat) (6 October 2014)

[134] *Teva UK Ltd & Anr v LEO Pharma A/S* [2015] EWCA Civ 779 (28 July 2015)

the proposed amended patents, asserted Teva, consequently amounted to a later "pick and mix" operation which in substance added new information by discarding much that would not work or might not work.

Sir Robin Jacob disagreed. He said that the "pick and mix" could be found in the application itself and therefore could not fairly be characterised as an intermediate generalisation. In effect, the application was inviting its reader to operate a "pick and mix" approach, so that the patentee did so in the context of drawing up the final version of the patent did not constitute intermediate generalisation. The patent survived.

3.6 Patentable Subject Matter

There is mercifully little to say on this in 2015. However, there is an interesting decision from an EPO Enlarged Board of Appeal in relation to biological processes for the production of plants, in particular tomatoes and broccoli!

The exclusion of essentially biological processes for the production of plants does not, according to the EPO, have a negative effect on the allowability of a product claim directed to plants or plant material such as fruit.

The fact that the only method available at the filing date for generating the claimed subject matter was an essentially biological process for the production of plants disclosed in the patent application did not render a claim directed to plants or plant material other than a plant variety unallowable.

Further, the fact that the patent featured a product by process claim directed to plants or plant material defined by an essentially biological process for the production of plants did not render the claim unallowable. It is not relevant that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process.

4 TECHNICAL MATTERS AND PROCEDURE

There are usually a lot of disputes arising in the cases concerning minor technical issues. In view of the sheer volume of the case law in relation to the major points, I have settled on just a handful of issues to deal with under this heading this year.

Transfer between patent courts

The first concern is the important issue of the transfer of cases between courts. In ***Canon Kabushiki v Badger***[135], Canon claimed that the defendants had infringed its patent involving printer cartridges. The defendants accepted that their cartridges fell within the scope of Canon's patent but defended their actions by asserting invalidity.

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[135] *Canon Kabushiki Kaisha v Badger Office Supplies Ltd & Ors* [2015] EWHC 259 (Pat) (6 February 2015)

Canon commenced the action in the High Court and the defendants applied to transfer the matter to IPEC.

In the last financial year, the largest of the defendants, Badger, had had 87 employees, a turnover of £8 million and a profit after tax of only £2,639. The second defendant had had a profit after tax of £94,000. In contrast, of course, Canon is a very large company with very substantial sales and profits.

Based on their relevant sales, the defendants estimated the value of Canon's claim to be approximately £141,000 – a figure well within the IPEC damages cap. Canon, on the other hand, argued that the patent in suit protected sales of products worth in the region of €70 million each year – well in excess of the £1 million rule of thumb guide on matters suitable for IPEC. Canon argued that although the case against the particular defendants was only relatively small, the patent in question had much wider repercussions for the market generally, and consequently this was not a case that was appropriate for IPEC.

Among the issues emerging in the case was the question of whether the activities of Badger's supplier, Ninestar amounted to "making" within section 60(1)(a) of the Patents Act. It will be recalled that this can be a highly contentious and "fact heavy" issue which found its way to the Supreme Court in *Schütz v Werit*.[136]

In the context of Badger's validity challenge, three pieces of prior art were raised.

Arnold J considered that the complexity of the issues presently raised made the case not well suited for trial within IPEC. Although the case could be tried there, squeezing it into a two day trial (as is required for IPEC matters) would be difficult.

Further, there was something to be said on Canon's part for the concern that it should not be unduly constrained in its approach to this case by the scale costs regime in the IPEC given the issues raised by the defendants.

Arnold J noted that the obvious consequence of the court ordering a transfer of a case to the IPEC is to subject the resisting party, against its will, to the scale costs regime of the IPEC. He said that need not be decisive, and it will be for the court to decide on a case by case basis whether the transfer is in the interests of justice overall, but it is an important consideration.

The application was unsuccessful, but Arnold J felt that the defendants had raised real concerns as to the proportionality of a trial in the High Court. He indicated that the court would therefore actively manage both the case and the costs in these proceedings, along the lines of the policies adopted in IPEC.

Pre-action disclosure

[136] *Schütz (UK) Limited v Werit (UK) Limited* [2013] UKSC 16 (13 March 2013)

The question of pre-action disclosure can be of considerable interest in some cases. This year, the case of ***The Big Bus Company v Ticketogo***[137] dealt with this issue.

The respondent Ticketogo owns a UK patent for a ticketing system using the internet. The company's business is in patent licensing.

Ticketogo approached The Big Bus Company, an operator of open top buses, alleging that it had infringed the patent and inviting it to take a licence. In the course of correspondence, Ticketogo referred to numerous licences agreed with third parties regarding the same patent but refused to provide copies of them.

Without admitting patent infringement, The Big Bus Company applied to the court for pre-action disclosure of the licences. Conscious of the expense of patent infringement proceedings and the prospect of incurring irrecoverable costs, The Big Bus Company argued that the requested disclosure would enable it to quantify the value of Ticketogo's claim, and so either facilitate the resolution of the dispute by informed settlement or, at the least, assist with proportionate conduct of the claim.

The question of granting pre-action disclosure is one in the complete discretion of the court.

First, the court must satisfy itself that the parties to the application are likely to be parties to subsequent proceedings. This requirement is considered on the basis that such proceedings are brought, and was clearly met in the present dispute.

The next requirement is that the respondent's duty by way of "standard disclosure" would extend to the documents for which pre-action disclosure is being sought. Ticketogo argued that the licences went only to the question of quantum, and that that would not be considered at a trial, but rather at a bifurcated hearing on quantum falling after the trial had been completed. Arnold J disagreed. Citing previous case law he held that it was in the court's discretion whether to split the trial of liability and quantum; and the obligation to give "standard disclosure" extended to documents relating to quantum even where there was a split trial, unless the court made an order to limit discovery. A number of the licences in question would therefore fall within the scope of standard disclosure since they would be relevant to the calculation of any award as to damages.

The final requirement is that disclosure before proceedings is desirable in order to dispose fairly of the anticipated proceedings, assist the dispute to be resolved without proceedings, or save costs. Ticketogo argued that pre-action disclosure would not necessarily dispose fairly of the proceedings or save costs. Since The Big Bus Company had not accepted liability, it did not follow that disclosure would automatically result in settlement. Further, in the event that the licences were disclosed but the patents found not to be infringed or to be invalid, or Ticketogo succeeded on liability and elected for an account of profits, the costs of disclosing the licences would have been incurred unnecessarily.

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[137] *The Big Bus Company Limited v Ticketogo Limited* [2015] EWHC 1094 (Pat) (28 April 2015)

Once again, Arnold J disagreed. He said that all too often the costs of intellectual property litigation are disproportionate to the damages recovered, and he referred to recent court cases as examples. In the present case, where the key information concerning the value of the claim was held by one party, it was desirable for that party to be required to disclose that information by way of pre-action disclosure. That would place the parties on an equal footing, and enable both parties to make an informed assessment of whether the claim was worth litigating at all, and so would promote settlement without resort to proceedings.

Having satisfied itself of the jurisdictional tests, the court then had to make a decision as to whether it was appropriate to exercise its discretion to make an order for pre-action disclosure. The discretion must be exercised in accordance with the overriding objective of dealing with the case justly and at a proportionate cost.

Arnold J concluded that an order for pre-action disclosure of licences granted under the patent in the transport sector should be made. He noted a letter of request by Ticketogo for disclosure of The Big Bus Company's online ticket sales and profits. The Big Bus Company accepted that "what was sauce for the goose was sauce for the gander" and agreed to make the disclosure. The judge encouraged the parties to try to reach an agreement.

In most patent licensing negotiations at present the prospective licensee has little or no knowledge of the terms that others have signed up to. The market seems to work perfectly well on that basis, and further, the party offering the licence often has no knowledge as to whether its prospective licensee has taken licences from other patentees or, if so, on what terms.

Will this decision lead to a change in current practice? It certainly seems likely to prove significant for many prospective litigants' negotiation and case management strategies. However, it is worth noting that Arnold J went through an arduous procedure before reaching his decision. The result should certainly not be seen as opening the door to a huge influx of applications for pre-action disclosure. In every case the jurisdictional and discretionary test will need to be met before the court will make an award and we expect future decisions to remain very fact specific.

Extended civil restraint order

It would have been sad if we had seen the last of the entertaining litigation involving Mr Richard Perry. In ***Perry v Brundle***, the story rumbles on.

You may recall that this was the case in which Mr Perry faked a letter from Judge Hacon in which the judge was represented to reverse his judgment and award Mr Perry £5 million in damages – an interesting notion in the IPEC. Now Mr Perry is back!

Following Judge Hacon's judgment in March 2014, Mr Perry was liable for threats, his own claim for infringement having failed. Following the infamous letter, Judge Hacon awarded Brundle a costs order for a little under £50,000. Mr Perry was unable to pay it and became the subject of a bankruptcy order.

Perry tried and failed to obtain permission to appeal Judge Hacon's decision. He tried and failed to obtain permission to continue acting as a company director notwithstanding his

undischarged bankruptcy. He tried and failed to obtain permission to appeal against the bankruptcy order. Judge Hacon observed a "note of exasperation" in the judicial finding of the last of these issues.

Mr Perry then commenced the current proceedings. He was informed by the examiner of the Official Receiver's office in Bristol that the cause of action in the present proceedings (if any) rested in the Official Receiver and that he had no right to take the proceedings any further. In those proceedings he alleged infringement of his patent by each of the defendants by reason of their dealings in a fence bracket. The defendants applied to strike out the claim on two grounds: first that any cause of action vested in the Official Receiver, and secondly that the claim in any event was *res judicata* following the judgment in the first action.

The defendant succeeded in September 2015 when Judge Hacon struck out the proceedings on both counts.[138] Subsequently Mr Perry made four further applications. Aside from their procedural shortcomings, since Mr Perry had no course of action in the proceedings as a whole, they did not succeed. Judge Hacon then considered whether it was appropriate to make an extended civil restraint order.

I do not propose to consider the law on extended CROs at this point. Suffice to say that Mr Perry met the general requirement that three or more claims or applications totally without merit had been made.[139] Further, his conduct as a whole suggested that he was likely to persist in the future with unmeritorious claims or applications.

Throughout the case, Judge Hacon did his best to be reasonable and considerate to Mr Perry, and even at the end, was polite to a fault in his judgment. Whether the whole set of issues might have been circumvented had he adopted a harder line earlier on, remains to be seen.

Product and process descriptions

In ***Stretchline v H&M***[140], the question of the usefulness of product and process descriptions arose. The defendant, H&M is a retailer and the products the subject of the infringement claim were manufactured by third parties. In English patent proceedings, parties alleged to infringe a patent who provide a product and process description (PPD) meeting certain requirements are not required to give disclosure on the issue of infringement. H&M purported to adopt this course, but appears not to have had the necessary technical expertise to provide factual information at the appropriate level of detail. This added to the costs of the litigation and led, in the end, to samples being disclosed at a late stage which were then analysed by Stretchline – a manufacturer with better technical expertise.

Mr Justice Carr had this to say on the issue generally:

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[138] *F.H. Brundle & Ors v Perry* [2015] EWHC 3056 (25 September 2015)

[139] *Perry v Brundle & Ors* [2015] EWHC 2737 (IPEC) (2 October 2015)

[140] *Stretchline Intellectual Properties Ltd v H&M Hennes & Mauritz UK Ltd* [2015] EWHC 3298 (Pat) (20 November 2015)

"Where a defendant elects to serve a PPD instead of providing disclosure, the courts have stated on a number of occasions that it is essential that it provides true information, sufficient to enable all issues of infringement to be resolved. The PPD must be complete in all relevant areas…

The facts of this case show, yet again, the importance of adherence to this duty. I accept that H&M, as a retailer, did not know the relevant facts about the composition of the alleged infringements. However, if a defendant does not admit infringement and elects to pursue a positive case of non-infringement, for example by performing its own experiments, as H&M did in the present case, it needs to find out the relevant facts. It was sensible to request and obtain samples of the allegedly infringing material, with and without fusible yarn. Such samples should have been disclosed at an early stage in the proceedings. A PPD would then have been unnecessary, or limited to information relevant to infringement which could not have been ascertained from the samples."[141]

The judge went on to say that, in many cases, the adequacy of a PPD may be questionable in the light of the construction placed upon the claim. In those circumstances, it would always be preferable to aid the description furnished to the patentee by a sample of the alleged infringement, or by drawings. He said that "had samples been provided at an early stage, much time and money spent arguing about the adequacy of the PPD would have been saved".

It is important to note Carr J's comments on the use of PPDs. The decision is one particularly to remember when involved in a patent dispute with a retailer who does not manufacture the product complained of.

Permission to serve proceedings in China

The final case I will refer to is included for reference only. I do not propose to go into the details of the issue in question but would merely flag it up given the increasing significance of trade with China, and the likelihood of allegations of infringement against Chinese companies selling products in the United Kingdom. In ***Magnesium Elektron v Molycorp***[142], Birss J gave permission to serve proceedings for patent infringement against a Chinese defendant based in China. His decision provides guidance on how to prepare an application for permission to serve outside the jurisdiction. As I indicated, I do not propose to go into the rules in detail. They are to be found in the Civil Procedure Rules at part 6.36 and following. However, I draw them to the reader's attention as this is a potentially important issue.

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[141] *Stretchline v H&M* [2015] EWHC 3298 (Pat) (20 November 2015) at [77]-[78]

[142] *Magnesium Elektron Limited v Molycorp Chemicals & Oxides (Europe) Limited & Anr* [2015] EWHC 3596 (Pat) (15 December 2015)

5 SUMMARY AND CONCLUSION

There are fine minds operating at every level of the UK jurisdiction now. No one can doubt the intelligence and experience of Birss J, Arnold J and Carr J at first instance. They are supported by some very capable judges who can turn their hands to relatively non-technical patent disputes.

Floyd LJ, Kitchin LJ and Lewison LJ provide an equally formidable team of intellect and experience in the Court of Appeal, while waiting in the Supreme Court are Lord Neuberger and Lord Sumption – the latter by no means a specialist patent judge, but possessed of a brain the size of Jupiter to deal with any issue.

Have we ever been better off?

Well, the problem seems to be that to adjectives like intelligent and experienced, you have to add "independent". What we are not seeing is any degree of consistency. There are big issues in the patent world where the current judges just cannot seem to see eye to eye – either at the same level or between stratas.

Why is this important? Well there is obviously the factor of "judge risk". When you commence an action you may do so in the hope that the case will (or will not) be heard by a particular judge and that may impact on the result. The Court of Appeal is there to smooth things out, but that represents another expensive layer of litigation, and not all cases are appropriate for appeal, especially if there have been significant findings of fact.

As I said at the outset, there has been a growing perception in recent years that the UK is becoming a place where patents go to die. Back in 2007 the title of my talk was "When is a patent not a patent?", and the answer was, when it has been litigated in the Patents Court. Are we back there again?

I would suggest that there might just have been a slight improvement in the last year. Sir Robin Jacob made a welcome come-back to pour some cold water on the ever expanding doctrine of "obvious to try". Carr J has made his first major interventions and has shown an initial inclination to give patentees a fair crack of the whip. Arnold J continues to slaughter pharmaceutical patents at an alarming rate, but close analysis reveals that he is probably normally right.

The perception must be addressed. We are losing cases to Germany where the bifurcated system and the ready availability of interim injunctions makes for an attractive environment for patentees.

This time next year, barring an unfortunate turn of events in a summer referendum, or further unforeseen delay, we will be considering the preparation for our first cases in the Unified Patents Court. That is an exciting prospect in many respects, but it opens the door to more inconsistency, more forum shopping, and more difficult decisions for prospective litigants.

Those who choose to opt out of the Unitary System, or indeed choose to opt out of Europe wide patenting altogether and opt for a few national patents, will need the UK courts to be

functioning at their best. We have the personnel, the experience and the brain power to deliver great justice now we just need the teamwork.

My choice of "judge of the year" this time round has been an easy one. While Carr J has made a great start, it is too soon for him. Birss J and Arnold J will be considered when they start agreeing on things, and in the case of Arnold J, as I said a few years ago, he will be considered when his average judgment length goes below 300 paragraphs.

There have been good contributions from the Court of Appeal this year, but nothing that stands out, so this year's award goes to Judge Hacon in the IPEC. He has given some solid practical judgments, but more importantly his continued adherence to strong case management has consolidated the work of Birss J. The only risk to IPEC now is that it becomes a victim (a) of its own success, and (b) the ongoing one man war being waged by George Osborne on public services. A few deputy judges would not go amiss in ensuring that the speed of the IPEC is maintained, and preferably improved.

And then there were three… Let us hope that the output of our triumvirate of patent judges amounts to a lot more than Wind and Wuthering!

Gordon D Harris
January 2016