Wragge Lawrence Graham &Co

"Be ye ever so high"

Gordon Harris, 2015

17th Annual Patent Seminar

CONTENTS

1 Introduction

I opened last year's talk with a brief description of where we had got to in most of the key areas of patent law along the lines of "*previously in patent seminar talks…*". The reason for that was that it certainly seemed as though a stable state had been reached and little more was being done than judges applying a small "touch on the tiller" in the majority of cases.

While it remains true 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, it is fair to say that there has been more by way of new developments this year. Our new generation of judges are finding their feet now and we have seen some very interesting decisions, some of which I will be describing below.

We also have a last blast from the long running *Virgin v Zodiac* case, which ties in with the Advocate General's opinion on the Spanish challenge to the Unified Patent Court and the Unitary Patent system.

I said last year that I was perhaps unusual in being very concerned not just with ensuring that the law is properly applied, but that justice is also done. I certainly adhere to the principle described by Dr Thomas Fuller that "*Be ye ever so high, the law is above ye*". It appears that does not apply to all institutions in the patent world.

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

2 Infringement

2.1 Construction

There has been a lot of consideration by the courts of the question of how to construe patents during the last 12 months. Perhaps the most significant single development came in the case of ***Actavis v Lilly***[1].

Prosecution history

It has been a long established principle that the courts, in seeking to construe the meaning of a patent, do not go into the prosecution history. The patent document is supposed to stand on its own. Lord Hoffmann reiterated this in the *Kirin Amgen* case[2], in which he said that "*Life was too short*" for people to spend time on the patent prosecution history when seeking to construe a patent. In ***Actavis v Lilly***, Arnold J sought to make a subtle adjustment to that general principle.

[1] Actavis UK Limited v Eli Lilly & Company [2014] EWHC 1511 (Pat) (15 May 2014)
[2] Kirin Amgen Inc and Ors v Hoechst Marion Roussel Limited & Ors [2004] UKHL 46, [2005] RPC 9, [2005] 1 All ER 667

The claimants were seeking a declaration of non-infringement in relation to a pharmaceutical patent. There was a counterclaim for threatened infringement in the United Kingdom. Arnold J commenced his consideration of the issue by acknowledging that there is no doctrine of "file wrapper estoppel" in the UK. However, he contended that it was already the case that prosecution history is admissible as an aid to construction. Arnold J summed up his take on the position in the following passage:

> "*I accept that …. courts should be cautious before relying upon prosecution history as an aid to construction. In the real world, however, anyone who is interested in ascertaining the scope of a patent and who is professionally advised will obtain a copy of the prosecution file (most, if not all, of which is generally open to public inspection) and will consider it to see if it sheds light on the matter. 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 ensuring the 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.*"[3]

Arnold J acknowledges that the original doctrine of "file wrapper estoppel" evolved in the USA because of the doctrine of equivalents, which encourages the broad construction of patent claims. Although he still avers that there is no doctrine of file wrapper estoppel in the UK, his explanation of why consideration of the patent history may be valid is tantamount to introducing file wrapper estoppel "through the back door". If the principle purpose for considering the prosecution history is 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?

We have been moving in this direction for a number of years now. Lord Justice Jacob (as he then was) in the *Virgin* case[4] talked about the skilled reader looking behind the patent itself, to consider the patent family in order to construe specific claims. That now appears to have been a step on the road to a new position adopted by Arnold J, taking the whole question of considering the context of the patent to a much broader level.

Protocol questions?

The case of ***Collingwood Lighting v Aurora***[5] sheds some further light on a similar issue. Collingwood contended that Aurora was infringing its patent for fire resistant LED downlighting. The primary non-infringement argument was that the Aurora

[3] Actavis UK Limited v Eli Lilly & Company [2014] EWHC 1511 (Pat) (15 May 2014) at [111]
[4] Virgin Atlantic Airways Limited v Premium Aircraft Interiors UK Limited [2009] EWCA 1062
[5] Collingwood Lighting Limited v Aurora Limited [2014] EWHC 228 (Pat) (10 February 2014)

products had a two part housing. However, there was no express limitation in the language of the claim to housing comprising of only one component. In this case, Mr Justice Roth, who is playing an increasing role in patent cases, referred back to the so called "Protocol Questions" formulated by Lord Hoffmann in the *Improver*[6] case back in 1990. Considering the guidelines based on the *Kirin Amgen*[7] decision, which were subsequently set out by Lord Justice Jacob in the *Virgin*[8] case, the judge questioned whether the tenth principle in the list proposed by Lord Justice Jacob was simply an encapsulation of the Protocol questions. The item in question reads as follows:

> "*On the other hand purposive construction can lead to the conclusion that a technically trivial or minor difference between an element of a claim and the corresponding element of the alleged infringement nonetheless falls within the meaning of the element when read purposively. This is not because there is a doctrine of equivalents: it is because that is the fair way to read the claim in context.*"

It is interesting that a new judge reconsiders previous basic principles. It would be no surprise to find that aspects of the *Kirin Amgen* reasoning, as set out in the *Virgin* case, merely reflect the previous position in the Protocol questions, which were, after all, drawn up by the same judge.

Immaterial variation

In ***Scopema v Scot Seat***[9], the Court of Appeal was asked to determine whether a seat with a tilting back infringed Scopema's European patent entitled "Tilting device for a seat back". The Patents County Court (as it was then known) had held[10] that it did not on the basis of a detailed construction of the patent. In order to succeed on appeal, Scopema needed to show that the judge was wrong on both points of construction. Scopema contended that the fact that the rod met a flat surface was an immaterial variation, which did not prevent infringement. Adopting a common sense approach, the Court of Appeal found:

> "*Whatever the precise meaning of "complementary" in the context of the patent in suit, it stretches the language of the claim beyond breaking point to say that a round rod meeting a flat surface can thus be described …. A flat surface against which a round rod bears cannot be said to "cap" the rod in any sense of that word.*"[11]

The principle underlying the Court of Appeal's decision was that the commonly used argument regarding "an immaterial variation" did not entitle the court to ignore whole integers of a claim, or to disregard obviously intentional limitations.

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[6] Improver Corporation v Remington Products Limited [1990] FSR 181
[7] Kirin-Amgen v Hoechst Marion Roussel [2005] RPC 9, [2004] UKHL 46, [2005] 1 All ER 667
[8] Virgin Atlantic Airways Limited v Premium Aircraft Interiors UK Limited [2009] EWCA Civ 1062 at [5]
[9] Scopema Sarl v Scot Seat Direct Limited [2014] EWCA Civ 187 (28 February 2014)
[10] Scopema Sarl v Scot Seat Direct Limited [2013] All ER (D) 152 (Sep), [2013] EWPCC 32
[11] Scopema Sarl v Scot Seat Direct Limited [2014] EWCA Civ 187 (28 February 2014) at [17]

Reference numerals

In ***Jarden Consumer Solutions v SEB***[12], the question of the significance of numbering in relation to the drawings in patents was considered again. This refers back once again to Lord Justice Jacob's judgment in the *Virgin* case where he held[13] that the skilled reader should be taken to know the purpose of including reference numerals, the purpose of dividing claims into pre-characterising and characterising portions, and the practice of filing divisional applications. Jacob LJ had gone on to conclude:

> "[*We] do not think that numerals should influence the construction of the claim at all – they do not illustrate whether the inventor intended a wide or narrow meaning. The patentee is told …. that if he puts numerals into his claim they will not be used to limit it. If the court subsequently pays attention to the numbers to limit the claim that is simply not fair*".[14]

In the *Jarden Consumer* case, SEB argued for a construction based on using the numbers to identify particular parts and construing a limitation on that basis. Arnold J felt that SEB's approach did not contravene the principles stated by Lord Justice Jacob. He said:

> "*Rather, it is taking proper account of the* system of numbering used in the specification*, and the message which that conveys about the relationship between the respective parts.*"[15]

The Court of Appeal disagreed. In the leading judgment, Vos LJ stated:

"This was not a use of numerals simply to identify the parts of the patented device, or, to use Jacob LJ's analogy, to enable the reader to get the map the right way up. It was the use of numerals to direct the skilled reader to which parts of the patented device were to be read in the claims as being included when a particular term was used. Whilst, as the judge said, the point was not used to "limit" the claims in direct violation of Rule 43(7), it was used to construe the claims and, in particular, to give an extended meaning to the term "main body" so as to include the lid, which increased the scope of the patentee's protection. That was in my judgment impermissible."[16]

Aside from this, the Court of Appeal held that the judge's construction of the claims of the patent (to a 'dry fryer') was incorrect. SEB's contended construction would ask the skilled reader to look at the cooking process and to ignore the clear language of the claims being construed, the only support in the specification being the numbering, which had to be disregarded for this purpose. Properly construed, in view of the language of the claims and the specification, the patent did not claim a device in

[12] Jarden Consumer Solutions (Europe) Limited v SEB SA & Anr [2014] EWHC 445 (Pat) (28 February 2014); Jarden Consumer Solutions (Europe) Limited v SEB SA & Anr [2014] EWCA Civ 1629 (17 December 2014)
[13] Virgin Atlantic Airways Limited v Premium Aircraft Interiors UK Limited [2009] EWCA Civ 1062 at [5] to [10]
[14] Virgin Atlantic Airways Limited v Premium Aircraft Interiors UK Limited [2009] EWCA Civ 1062 at [17]
[15] Jarden Consumer Solutions (Europe) Limited v SEB SA & Anr [2014] EWHC 445 (Pat) at [81]
[16] Jarden Consumer Solutions (Europe) Limited v SEB SA & Anr [2014] EWCA Civ 1629 at [33]

which the main heater means were mounted on the lid. Consequently Arnold J's finding of infringement was overturned. Vos LJ considered this case one in which a close study of the principles of construction was needed. Jacob LJ's judgment in the *Virgin* case was extensively referred to.

Do not read limitations into the language of the claim which are not there

In ***ASSIA v BT***[17], a claimant alleged that a defendant infringed two of its patents concerning the methods for controlling the way in which an asymmetric digital subscriber line operated. At first instance it was found that the patent had been infringed. The Court of Appeal not only upheld the original decision, but found another claim in the patent was also valid and infringed, overturning the first instance decision on that point. Floyd LJ summarised the construction issue saying:

> "*A number of BT's arguments on this appeal involve reading limitations into the claim which are not there as a matter of language, on the grounds that to do so would follow more closely that which is disclosed by way of example in the body of the specification. It must be remembered, however, that the specification and the claims of the patent serve different purposes. The specification describes and illustrates the invention, the claims set out the limits of the monopoly which the patentee claims. As with the interpretation of any document, it is conceivable that a certain, limited, meaning may be implicit in the language of a claim, if that is the meaning that it would convey to a skilled person, even if that meaning is not spelled out expressly in the language. However it is not appropriate to read limitations into the claim* solely *on the ground that examples in the body of the specification have this or that feature. The reason is that the patentee may have deliberately chosen to claim more broadly than the specific examples, as he is fully entitled to do*".[18]

The judge noted, and the Court of Appeal agreed, that as all the words in the claim were ordinary English words, the issue was "a pure question of construction". This meant that no expert evidence was required or relevant.

Floyd LJ went on to reject an argument by BT that the word "generate" should be given a narrow meaning. BT argued that it should be interpreted to exclude "selecting a profile from a pre-existing set" because including that construction within the meaning of the claim would render claim 1 obvious over a prior art citation which Birss had held embodied the common general knowledge. Lord Justice Floyd rejected the submission. He said there was no evidence that the patentee knew of the specific prior art reference, and in such a case the claim may well have been framed in ignorance of it. In such circumstances it would be wrong to impute to the patentee an intention to frame a claim so as to avoid attacks which could be based on it.

[17] Adaptive Spectrum and Signal Alignment Inc v British Telecommunications Plc [2014] EWCA 1462 (11 November 2014); Adaptive Spectrum and Signal Alignment Inc v British Telecommunications Plc [2013] EWHC 3768 (Pat)

[18] Adaptive Spectrum and Signal Alignment Inc v British Telecommunications Plc [2014] EWCA 1462 at [45]

Standardised technology

The patents in the *ASSIA v BT* case[19], whilst not declared essential to any standard, do sit within the context of a standardised technology. The court was asked to consider the impact of those standards on the construction that should be given to the claim language. Lord Justice Floyd said:

> "*The skilled person would understand that the patentee was intending to cover the use of his invention in connection with the relevant standards*".[20]

This reasoning may be of use generally in relation to the construction of patents in the context of standardised industries.

The language of the claims must be given proper effect

The new Intellectual Property and Enterprise Court judge, Richard Hacon, had his chance to consider the question of construction in the case of ***William Mark v Gift House International***[21]. The claimant devised and marketed a flying fish toy. The defendant imported other flying fish toys known as "Mega Fliers" into the UK. The toy is effectively a fish shaped balloon with a flapping tail!

The first integer of the patent describes "a flying toy". It goes on to describe a "lighter than air gas" in a body portion providing neutral buoyancy to the toy, and an actuator coupled to a moving surface to drive the toy forward.

The main issue on construction arose from the defendant's submission that the word "toy" had a broad construction in the sense that it covered embodiments other than products which children play with. The judge went on:

> "*The defendant's other submission on construction was that paragraph [28] contemplates the possibility of a toy UFO or airship within the claim and that therefore the claims should be broadly construed. A UFO could be anything one can think of and beyond, so that changes little. The reference to an airship is curious because one would not normally expect a toy airship to be propelled by a moving tail. It would be exotic.*"[22]

The judge concluded:

> "*It seems to me that the word "toy" in the claims must be given proper effect. It limits the scope of the claims to products of a scale that a child might be*

[19] Adaptive Spectrum and Signal Alignment Inc v British Telecommunications Plc [2014] EWCA 1462 (11 November 2014); Adaptive Spectrum and Signal Alignment Inc v British Telecommunications Plc [2013] EWHC 3768 (Pat)
[20] Adaptive Spectrum and Signal Alignment Inc v British Telecommunications Plc [2014] EWCA 1462 at [113]
[21] William Mark Corporation & Anr v Gift House International Limited [2014] EWHC 2845 (IPEC) (22 August 2014)
[22] William Mark Corporation & Anr v Gift House International Limited [2014] EWHC 2845 (IPEC) at [40]

expected to play with as a toy, even where its actual use is intended more for adults."[23]

Accordingly, prior art in the form of airship technology was not relevant prior art, and the patent survived.

One of the most difficult cases in relation to construction this year was the case of ***HTC v Gemalto***[24]. The principle issue concerned construction of the word "micro-controller". The case at first instance had been heard by Mr Justice Birss, who had summarised the parties' contentions as follows:

"*The parties' rival constructions of the term micro-controller advanced in closing were far apart. HTC submitted that to the skilled addressee what the patent means by the term micro-controller is a reference to a single chip which contained a CPU and also had all its memory resources on the chip. ….. Gemalto's case is summarised in … its closing argument saying that micro-controller is an ordinary word in this technical field, with no special meaning to be derived exclusively from the description of the patent or externally. It means simply a controller which contains a micro-processor - hence micro-controller. The "controller" element connotes that it is not just a micro-processor, but also contains the elements necessary for it to exercise control, and so includes other functional elements such as memory, input/output etc.*"[25]

On appeal Gemalto modified (it used the word "refined") its argument saying that "the micro-controller called for by the claim was any functional unit, of the kind *typically* used in embedded or dedicated systems".

Lord Justice Floyd, giving judgment on behalf of the Court of Appeal, summarised the first instance findings as follows:

"*The judge approached the issue, as the parties had, by considering first what the expression meant to the skilled addressee without reading the patent. The term was not an expression used in ordinary English outside the computer field and expert evidence was therefore admissible to determine its meaning. The judge recognised that this was not the end of the question, however, because, in the patent, "it may be that the skilled reader would understand the expression as having been used in its familiar sense or one of its familiar senses or perhaps in a different sense altogether". It was therefore vital to consider how the skilled addressee would understand that the term was being used in the patent.*"[26]

[23] William Mark Corporation & Anr v Gift House International Limited [2014] EWHC 2845 (IPEC) at [41]
[24] HTC Corporation v Gemalto SA [2014] EWCA Civ 1335 (22 October 2014)
[25] HTC Corporation v Gemalto SA [2013] EWHC 1876 (Pat) at [60]-[61]
[26] HTC Corporation v Gemalto SA [2014] EWCA Civ 1335 at [30]

The judge had gone on to find that the term "single chip micro-controller" was not a widely used term at the priority date of the patent. He said that the term micro-controller could also be used to describe an embedded or dedicated system:

> "[*I]f one pointed a skilled person to a washing machine and asked them what was inside controlling the machine, they might say a micro-controller. … That usage of the term micro-controller was not referring to a chip as such at all. This is the sense in which Gemalto contends the word should be interpreted, as a controller which contains a microprocessor. … [T]he weight of the evidence was that this usage was not common in 1996 but was one of the senses in which the word had been used.*"[27]

The judge consequently found that a skilled person would not have been comfortable calling a chip with no memory a micro-controller.

Gemalto criticised the judge's analysis, saying that he focused on "the chip" whereas the practical person would focus on "working systems". It claimed that his search for a precise definition of the term "micro-controller" was overly meticulous, and that he had consequently lost sight of the fact that it was merely an umbrella term covering the prevalent single chip micro-controller, but also the full spectrum of what was used in embedded and dedicated systems.

Lord Justice Floyd felt that the criticism had no substance. In the key paragraph in question the judge had been considering the use of the term micro-controller to refer to a chip. Accordingly, the judgment should not be read as saying that there were no examples of usage of the term micro-controller to refer to a system which included a chip with no memory on it. The judge was saying that, in those cases where the term micro-controller is used in the sense of a chip, the chip always has a memory on it. He went on to say:

> "*Moreover none of Gemalto's examples were of a case where the term micro-controller was used in what the judge called the normal or extended sense and where it was clearly established that there was no memory on chip at all.*"[28]

Lord Justice Floyd concluded:

> "*It has to be recalled that the enquiry on which the judge was engaged at this stage was essentially aimed at establishing the ways in which the technical term was used in the art. The judge was better placed than this court to conduct this exercise. Having rejected the position that the term has a precise, accepted meaning in the art, the value of the exercise became more questionable. However, unless it is clear that the judge ignored relevant evidence or took irrelevant evidence into account, or was plainly wrong, we should not interfere with his conclusions. I am unable to fault his conclusion*

[27] HTC Corporation v Gemalto SA [2013] EWHC 1876 (Pat) at [81]
[28] HTC Corporation v Gemalto SA [2014] EWCA Civ 1335 at [36]

that the term was used in the art in various ways, of which the normal or prevalent way was to refer to a chip."[29]

Swiss-form claims

Mr Justice Birss has been making a number of very significant judgments over the last year, none more so than in disputes between *Hospira and Genentech*.

The first decision between these parties ***(Hospira v Genentech (I))***[30] concerned two patents. EP (UK) 1 210 115 had claims in Swiss-form concerning a dosing regimen for the monoclonal antibody trastuzumab, which is the active ingredient in Genentech's Herceptin medicine.

The parties agreed and Birss J accepted the following points on construction:

- The claimed treatment of HER2 positive breast cancer was a "functional technical feature" of the claim i.e. the claim is to something which is indeed an effective treatment of the disease.

- As a Swiss-form claim, the word "for" means "suitable and intended for" i.e. Swiss-form claims are an exception to the general rule that "for" means "suitable for".

Although these points were common ground between the parties, Birss J took the opportunity to consider their implications. He said:

"…The effect of these points is that 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 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.

[29] HTC Corporation v Gemalto SA [2014] EWCA Civ 1335 at [38]
[30] Hospira UK Limited v Genentech Inc [2014] EWHC 1094 (Pat)

On the other hand, if all the patent contains is a mere proposal, then it has not made a contribution to the art in this example. 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 (**T609/02 Salk Institute**) and the UK (**Regeneron**). 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."*

Particularly for medical use inventions, there is a fine balance in hand involving claim construction, the need for any claimed priority filing to derive the subject matter of the claim, the need for plausibility in order to confer sufficiency and the need to file before the claimed invention is rendered anticipated or obvious by disclosures made in the course of or pursuant to clinical trials. It is important for innovation that the courts are sensitive to this and it is encouraging that the English court at least recognises the balance in play.

In the second decision between the same parties, *(**Hospira v Genentech (II)**)*[31], Birss J made an *obiter* comment that the infringement of Swiss-form claims is often argued only under section 60(2) (Infringement by supplying essential means), which avoids the problem of deciding whether it is a product or process claim. There remains, it seems, scope for arguing for either construction.

The EPO's Boards of Appeal have tackled the issue of the construction of Swiss-form claims and decision ***T 1780/12***[32] is noteworthy in this context. The question in issue was whether claims in a divisional application directed towards a second or third therapeutic use, formatted in accordance with Article 54(5) EPC, were prohibited as double patenting when the parent application had been granted with claims concerning the same invention in Swiss-form.

[31] Hospira UK Limited v Genentech Inc [2014] EWHC 3857 (Pat) (21 November 2014)
[32] T 1780/12 Cancer treatment/Board of Regents, The University of Texas (30 January 2014)

The TBA noted that prohibition of double patenting concerned the grant of a second patent for the same subject matter. Regarding the claims in question the TBA stated:

- The Swiss-form claims (i.e. "Use of X for the manufacture of a medicament for the treatment of Y") are purpose-limited process claims which comprise the manufacture of a medicament as a technical feature.
- The Article 54(5) claims are purpose-limited product claims which do not comprise the manufacturing feature.
- The subject matter of the claims was therefore different.

The TBA elaborated:

> *"It is generally accepted as a principle underlying the EPC that a claim to a particular activity (e.g. method, process, use) confers less protection than a claim to the physical entity* per se*, see decision G2/88. It follows that a purpose-limited process claim also confers less protection than a purpose-limited product claim. The scope of protection is…noticeably different…"*[33]

Hence the applicant's request did not fall foul of the prohibition on double patenting. It will be interesting to see how this will be incorporated into the English patent judges reasoning, as and when the need arises.

Product by process claims

Hospira v Genentech (II)[34] concerned patents relating the formulation of the trastuzumab antibody. Birss J was considering an application for amendment of product-by-process claims. He fairly described product-by-process claims as "tricky". Claim 1 of EP (UK) 2 275 199, as it was proposed to be amended, was for a product "obtainable by lyophilising a solution".

Birss J analysed the paradox presented by *Kirin Amgen*[35] for the construction of product-by-process claims: a product not made by the claimed process was found not to infringe because it was not made by the claimed process but another product not made by the claimed process rendered the claim lacking in novelty. Birss J therefore concluded that the House of Lord's point in *Kirin Amgen* was a rule of novelty, not one of construction.

Following the introduction of s.75(5) of the Patents Act, the court should follow the principles applied by the EPO in the context of considering whether to permit an amendment to create an overt product by process claim – and in that context treating the point as rule of novelty works. Birss J explained that European Patent Office practice is to permit "obtainable by" as wording in a patent claim only if there is no other way to describe a particular characteristic of the product in question. In order for that to work, one clearly must be aware of the characteristic in question, and it must be true that in fact process conditions can be specified which do produce the

[33] T 1780/12 Cancer treatment/Board of Regents, The University of Texas at [22]

[35] Kirin-Amgen v Hoechst Marion Roussel [2005] RPC 9, [2004] UKHL 46, [2005] 1 All ER 667

characteristic. Hence from a novelty perspective, according to EPO practice, "obtainable by" and "obtained by" are treated as the same.

However, Birss J then commented that *"it is hard to see how one can apply one of the key principles of construction emphasised by Kirin Amgen itself, that the reader considers what the draftsman was using the language of the claim to mean"*, unless the "obtained by" language excludes things never intended to be covered. So as a matter of construction (i.e. for infringement and sufficiency) the words chosen will form the relevant scope of the claim for the purposes of infringement and sufficiency: "obtained by" claims would only cover products obtained by the process; "obtainable by" claims present clarity problems. Genentech intended that the characteristic which the process language defined was the molar ratio of the four ingredients in the lyophilised material. However, the court held that proposed claim 1 did not expressly state which characteristic was referred to and therefore the only realistic conclusion was that every conceivable characteristic "obtainable by" would be caught by the definition, including but not limited to molar ratio. As such, the proposed product by process wording could not be allowed.

Also noteworthy in *Hospira v Genentech (II)* was Birss J's comment that although none of the claims in issue used words like 'stable', the skilled reader would understand that what was claimed was a stable lyophilised formulation, suitable for perenteral administration to humans.

It should be remembered therefore that more general rules of construction (e.g. not reading limitations into the claim which are not there, per Floyd LJ in *ASSIA v BT*[36]) should be used with caution in pharmaceutical claim language.

So there is much to ponder on developments in the law of claim construction in 2014. As I said at the outset, perhaps the most significant development is the availability of the patent prosecution history, and the subtle introduction of a form of prosecution history file wrapper estoppel by Mr Justice Arnold. We wait with interest to see how that develops in the coming year.

2.2 Defences, acts of infringement, stays and evidence

Over the last few years, and particularly since the Supreme Court decision in *Virgin v Zodiac*[37], the question of when it is appropriate to stay UK litigation has been considered in some detail.

Stays

In ***HTC Corporation v Nokia***[38], a High Court judge found that the claimant's products had infringed the defendant's patent and granted an injunction. However, he stayed

[36] Adaptive Spectrum and Signal Alignment Inc v British Telecommunications Plc [2014] EWCA 1462
[37] Virgin Atlantic Airways Limited v Zodiac Seats UK Limited [2013] UKSC 46
[38] HTC Corporation v Nokia Corporation [2013] EWHC 3247 (Pat) and HTC Corporation v Nokia Corporation [2013]; HTC Corporation v Nokia Corporation [2013] EWCA Civ 1759 (12 December 2013)

the injunction pending appeal in respect of the claimant's flagship product only. The claimant appealed against the limited stay.

Lord Justice Patten, giving judgment for the Court of Appeal, summarised the basic principles in relation to the grant of injunctions following a finding of infringement, in a quote from Mr Justice Floyd as he then was in *Novartis v Hospira*[39]. Floyd J said:

> "*(i) The court must be satisfied that the appeal has a real prospect of success.*
>
> *(ii) If the court is satisfied that there is a real prospect of success on appeal, it will not usually be useful to attempt to form a view as to how much stronger the prospects of appeal are, or to attempt to give weight to that view in assessing the balance of convenience.*
>
> *(iii) It does not follow automatically from the fact that an interim injunction has or would have been granted pre-trial that an injunction pending appeal should be granted. The court must assess all the relevant circumstances following judgment, including the period of time before any appeal is likely to be heard and the balance of hardship to each party if an injunction is refused or granted.*
>
> *(iv) The grant of an injunction is not limited to the case where its refusal would render an appeal nugatory. Such a case merely represents the extreme end of a spectrum of possible factual situations in which the injustice to one side is balanced against the injustice to the other.*
>
> *(v) As in the case of the stay of a permanent injunction which would otherwise be granted to a successor or claimant, the court should endeavour to arrange matters so that the Court of Appeal is best able to do justice between the parties once the appeal has been heard.*"

With that in mind, Lord Justice Patten went on to consider the circumstances of this particular case, and the first instance judge's decision to grant only a limited stay in relation to a single product. He found that the judge was wrong in principle, saying that he had lost sight of the basis on which a temporary stay of this kind is conventionally granted. Lord Justice Patten said:

> "*So far as HTC is concerned, there was no clear distinction in the evidence between the effect of the injunction on the One phone as opposed to the entire One range and, although stating that the two were not the same in his judgment, the judge gives no indication in that part of the judgment as to the facts or other matters which he relied upon in order to reach that conclusion.*"[40]

[39] Novartis AG v Hospira UK Limited [2013] EWCA Civ 583 at [41]
[40] HTC Corporation v Nokia Corporation [2013] EWCA Civ 1759 (12 December 2013) at [18]

Lord Justice Patten found that there was evidence that HTC's marketing approach had been broad, across the whole range of its products, rather than around a single phone. He noted that the judge appeared to have been tilted in favour of refusing the stay by the fact that one phone in the range had been launched more recently. He said:

> "*The difference in timing is said to be between March and August 2013, although HTC say that the One Mini was designed in January 2013… But if the decisive factor should be the amount of time available to HTC to make contingency plans for an alternative chip by reference to a start date beginning with the commencement of the German infringement proceedings then that would seem to apply as much, if not more, to the One phone, which was the earlier product. None of this is really explained in the judgment.*"[41]

Accordingly, Lord Justice Patten concluded that it was wrong that HTC should be penalised because it failed to use the time available since the claims of infringement were first made to provide a workaround in respect of the chips. A general stay of the injunction was awarded pending judgment in the main appeal.

Also on the subject of stays, and with more significance to the European element, Arnold J handed down a significant judgment in the case of ***Actavis v Pharmacia***[42].

The question of stays had been subject to various guidelines, but these were largely given on the basis of the Court of Appeal's decision in *Unilin v Berry*[43]. When that decision was reversed by the Supreme Court in *Virgin v Zodiac*[44] *(3 July 2013)*, Lord Sumption noted that "*If I had concluded that the defendant was estopped from relying on the revocation or amendment of the patent once the court had ajudged it to be valid… it would have been difficult to defend the guidance given by the Court of Appeal in Glaxo*". He therefore suggested that the guidance should be re-examined by the Patents Court and the Court of Appeal.

The Court of Appeal promptly gave a substantial 13-part analysis of the principles underlying the decision whether or not to grant a stay in *IPCom v HTC*[45] *(21 November 2013)*. I will not set out the full principles here, having dealt with them previously, but suffice to say that the Court of Appeal acknowledged that the discretion of the court is very wide indeed and should be exercised to achieve the balance of justice between the parties, having regard to all relevant circumstances of the particular case.

In the *Actavis* case[46], Arnold J, at the request of the patentee, stayed UK proceedings pending the outcome of opposition proceedings at the European Patent

[41] HTC Corporation v Nokia Corporation [2013] EWCA Civ 1759 (12 December 2013) at [19]
[42] Actavis Group PTC EF v Pharmacia LLC [2014] EWHC 2265 (Pat (11 July 2014) and Actavis Group PTC EF v Pharmacia LLC [2014] EWHC 2611 (Pat) (24 July 2014)
[43] Unilin Beheer BV v Berry Floor and Ors [2007] EWCA Civ 364; [2008] 1 All ER 156
[44] Virgin Atlantic Airways Limited v Zodiac Seats UK Limited [2013] UKSC 46 at [38]
[45] IPCom GmbH & Co KG v HTC Europe Co Limited and Ors [2013] EWCA Civ 1496
[46] Actavis Group PTC EF v Pharmacia LLC [2014] EWHC 2265 (Pat (11 July 2014) and Actavis Group PTC EF v Pharmacia LLC [2014] EWHC 2611 (Pat) (24 July 2014)

Office. This decision was based on specific undertakings eventually given by the patentee.

Pharmacia initially offered the following undertakings:

1 to seek expedition of the EPO opposition proceedings;

2 not to seek an injunction against the alleged infringer, Actavis, or its customers until the determination of the EPO proceedings; and

3 only to seek damages of 1% of Actavis' net sales taking place during the period from launch until the determination of the EPO proceedings, if the patent were to be held valid both by the EPO and by the English courts.

Arnold J refused to grant a stay based on those undertakings alone, saying that they did not address the "chilling effect on Actavis' investment decisions". After his first judgment was circulated Pharmacia suggested it might be willing to give the following additional undertakings:

4 not to seek an injunction in the UK against Actavis or its customers in relation to a particular product during the life of the patent; and

5 only to seek damages of 1% of Actavis' net sales in the UK during the life of the patent if the patent is ultimately held valid by the EPO and valid and infringed by the English courts.

Arnold J decided that the addition of the fourth and fifth undertakings "substantially eliminate[d] the commercial uncertainty to which Actavis will [otherwise] be exposed in the United Kingdom as a result of a stay".

He said that:

> "*[E]xpedition of the EPO proceedings is warranted not merely because of the existence of the English proceedings, which will include the counterclaim for infringement that Pharmacia has undertaken to bring. It seems to me plain from the current position of the parties that there is a strong likelihood of further proceedings elsewhere in Europe and, furthermore, a strong likelihood that those further proceedings will include infringement proceedings and one or more contracting states of the EPC."* [47]

This led Arnold J to express the hope that the EPO will accede to the joint request of the parties to accelerate the opposition proceedings. He also found that the damages assessed at 1% would be relatively modest.

While it is possible to understand that, in principle, the potential of an injunction at some future point might give rise to some commercial uncertainty, on the facts of this

[47] Actavis Group PTC EF v Pharmacia LLC [2014] EWHC 2611 (Pat) (24 July 2014) *at [7]. The UK was the second largest market for the drug, Germany having a larger market)*

case it is difficult to see why the first three undertakings did not grant sufficient certainty to justify a stay.

The UK market for the patented product is worth about £14 million per annum. Arnold J assumed that Actavis would obtain a 50% market share at 90% of Pharmacia's average price. This would make Actavis' market share worth £6.3 million per annum, or £3.15 million if parallel imports were removed from the equation.

The stay would have delayed procedures for between three and five years, giving Actavis time to receive revenue of between £9.45 million and £15.75 million. The stay potentially increases Actavis' costs by £63,000 a year (if the patent is valid and infringed at the end of the proceedings). This means their revenue might be reduced only by a small amount.

As with so many issues regarding intellectual property cases, there are potential anti-trust implications. Settlement agreements between patent holders and generics companies have been the subject of intent scrutiny by anti-trust authorities recently, both in the EU, the US and further afield. If Actavis and Pharmacia had agreed such a low licencing fee as part of settlement discussions, rather than as undertakings given to the court, it is possible that the settlement agreement would have been anti-competitive as an (effectively) royalty free licence which maintained a duopoly position for both companies.

Although this is not a classic "pay to delay" settlement agreement it would appear to have a very similar effect from the consumer perspective.

It is also clear that the current judges are attempting to limit the impact of Lord Sumption's judgment in the *Virgin* case. He said, in terms:

> "*Where judgment is given in an English court that a patent (whether English or European) is valid and infringed, and the patent is subsequently retrospectively revoked or amended (whether in England or at the EPO), the defendant is entitled to rely on the revocation or amendment on the enquiry as to damages.*"[48]

What he clearly appears to be intimating is that in England, an unsuccessful defendant should be able to rely on the revocation of a patent in subsequent patent litigation (i.e. if a third party subsequently successfully attacks the validity of the patent).

Since it is unlikely that an implied statutory right can be derived from the Act, it would seem that Lord Sumption might be arguing in favour of cross undertakings in damages and in respect of the adverse effects of an injunction, which extend until the expiry or lapse of the patent in the UK, or even six years beyond that (to cover any revocation actions brought in defence of infringement actions started after the expiry

[48] Virgin Atlantic Airways Limited v Zodiac Seats UK Limited [2013] UKSC 46 at [35]

of the patent but before the relevant limitation period expires). There is no suggestion of anything along those lines in the judgment of Arnold J in this case.

In ***ASSIA v BT***[49] the Court of Appeal reached the stage of giving judgment finding two ASSIA patents valid and infringed while opposition proceedings were still pending in the EPO. The Court of Appeal granted an injunction and authorised the commencement of an inquiry into damages. Floyd LJ made it clear that should damages be awarded they would have to be paid subject to a cross-undertaking to repay in the event that the opposition was successful. However, in relation to the injunction, he held that it should be granted with no cross-undertaking. Is that in line with the spirit, if not the letter, of Lord Sumption's judgment in *Virgin*[50]? Floyd LJ said that the injunction was "properly awarded", but what if the result of the opposition is that the patent as granted was invalid, and hence void *ab initio*? Of course, the grant of an injunction is a discretionary remedy and this is a case where the background facts are complex and difficult. That may well have been an influencing factor in the judge's decision to grant an unfettered injunction.

As I indicated above, it seems to me that the judges at High Court and Court of Appeal levels are unhappy with the Supreme Court's decision in *Virgin* and are taking every opportunity to limit its effect. BT have sought leave (strongly opposed by ASSIA) to appeal to the Supreme Court. We await developments with interest.

"Innocent infringement" regarding section 60(2)

The question of "innocent infringement" arose in ***Kennametal v Pramet Tools***[51]. Kennametal was the proprietor of a patent relating to metal inserts. The key feature of claim 1 was the substantially straight region of the cutting insert.

The defendants argued that they did not know that the inserts had a substantially straight region, had not intended it and it was not obvious to the skilled person. The claimant argued that if the defendant intends a particular use to be made of his product it should not matter whether he knows that the resulting combination actually infringes. That is for the court to decide objectively.

Henry Carr QC sitting as a deputy judge, agreed with the claimant's interpretation. He stated that:

> *"The knowledge/obviousness requirement is concerned with the use to which the means supplied by the defendant are to be put. Whether it is complicated or difficult to work out that the means has the features required by the claim is not the point…. Contributory infringement is an important aspect of the exclusive rights accorded to the patentee…. If the contributory infringer could claim in such cases that there was no infringement because the requisite*

[49] Adaptive Spectrum and Signal Alignment Inc v British Telecommunications Plc [2014] EWCA Civ 1462 (11 November 2014) and Adaptive Spectrum and Signal Alignment Inc v British Telecommunications Plc [2014] EWCA Civ 1513 (21 November 2014)
[50] Virgin Atlantic Airways Limited v Zodiac Seats UK Limited [2013] UKSC 46
[51] Kennametal Inc v Pramet Tools SRO & Anr [2014] EWHC 565 (Pat) (5 March 2014)

knowledge was lacking, then this would prevent enforcement in the case of complex inventions."[52]

Summary judgment

One of the cases which went through both first instance and the Court of Appeal in 2014 was ***Nampak v Alpla***[53]. This case concerned an application for summary judgment in relation to patent proceedings – a fairly rare event.

The case related to plastic milk bottles. Nampak has a patent for a plastic container which it asserted against Alpla's bottle called "ECO1". The trial of the infringement action was due in January 2015 (but has since settled). In the meantime Alpla designed a variant, the "ECO2", and issued proceedings for a declaration of non-infringement in respect of the ECO2 design, applying for a summary judgment in those proceedings.

Birss J noted as common ground that summary judgment is often not appropriate in patent cases. He referred to Arnold J's recent explanation, in ***Starsight v Virgin***[54] for the reason why it is difficult to grant summary judgment in patent cases. Arnold J found that:

> "[*I]n order to determine even issues of claim construction and infringement, it is necessary for the court to adopt the mantle of the person skilled in the art. For that purpose, the court needs to receive expert evidence as to the common general knowledge as to the art in question at the relevant date*".[55]

In the *Starsight* case, there were "powerful arguments which may well lead the court at trial to the conclusion that claim 1 of the patent as proposed to be amended is not infringed by any of the allegedly infringing devices". Despite this, in Arnold J's judgment it did not follow that it was an appropriate case for summary judgment. In addition to the considerations noted above, he was not persuaded that Virgin had no real prospect of success at trial, and the delay of at least a year in bringing the application meant that it was heard only shortly before the main trial. Perhaps noteworthy also is Arnold J's comment that he was "unconvinced" by Virgin's explanation that had they made the application earlier, it would have been met with the response that it was premature until expert evidence was served.

The claim language of Alpla's patent required the bottle to have two pairs of opposing sides of differing lengths, where the first pair was orthogonal to the second pair. It also required four "truncated corners" between the two pairs of sides and a pouring aperture. One integer of the claim required "the length of the first pair of opposing sides to be less than the diameter of the pouring aperture".

[52] Kennametal Inc v Pramet Tools SRO & Anr [2014] EWHC 565 (Pat) at [94]
[53] Nampak Plastics Europe Limited v Alpla UK Limited [EWHC] 2196 (Pat) (3 July 2014); Nampak Plastics Europe Limited v Alpla UK Limited [2014] EWCA Civ 1293 (9 October 2014)
[54] Starsight v Virgin [2014] EWHC 8 (Pat) (9 January 2014)
[55] Starsight v Virgin [2014] EWHC 8 (Pat) at [20]

Adopting a construction based on the simple language of the claim, Birss J held that the ECO2 design "does not infringe because it does not satisfy the feature in the claim. The length of the first pair of opposing sides is greater than the diameter of the pouring aperture".

Birss J held that the reasons for caution regarding summary judgment in patent matters "do not mean a patentee can resist an application for summary judgment simply by advancing unspecific assertions about the need for expert evidence". He awarded a declaration of non-infringement by way of summary judgment.

In the Court of Appeal, in giving his judgment in the *Nampak* case, Lord Justice Floyd reviewed previous case history. He noted the decision of Lord Justice Jacob in *Virgin v Delta*[56], where he said:

> "*Whilst the general rules as to summary judgment apply equally to patent cases as to other types of case, there can be difficulties, particularly in cases where the technology is complex. If it is, the court may not be able, on a summary application, to form a confident view about the claim or its construction, particularly about the understanding of the skilled man. On the other hand in a case such as the present, where the technology is relatively simple to understand, there is really no good reason why summary procedure cannot be invoked. No one should assume that summary judgment is not for patent disputes. It all depends on the nature of the dispute.*"[57]

That can cut both ways, of course. If the court is able to grasp the case well enough to resolve the point, then it can and should do so – whether in favour of the patentee or the alleged infringer.

However, Lord Justice Floyd found another quote from Lord Justice Jacob, this time in *Khatri v Co-operative Centrale Raiffeisen-Boerenleenbank*[58]. In that case Jacob LJ said:

> "*Although a case may turn out at trial not to be really complicated, it does not follow that it should be decided without a fuller investigation into the facts at trial than is possible or permissible on an application for summary judgment. Thus the court should hesitate about making a final decision without a trial, even where there is no obvious conflict of fact, where reasonable grounds exist for believing that a fuller investigation into the facts of the case would add to or alter the evidence available to a trial judge and so affect the outcome of the case.*"[59]

It is clear from those conflicting statements by the same judge that nothing is simple in this area. The principal authority, often quoted, is the case of *Three Rivers District*

[56] Virgin Atlantic Airways Ltd v Delta Air Lines Inc [2011] EWCA Civ 162
[57] Virgin Atlantic Airways Ltd v Delta Air Lines Inc [2011] EWCA Civ 162 at [13]
[58] Saleem Khatri v Cooperative Centrale Raiffeisen-Boerenleenbank BA [2010] EWCA Civ 397
[59] Saleem Khatri v Cooperative Centrale Raiffeisen-Boerenleenbank BA [2010] EWCA Civ 397 at [3]

Council v Bank of England[60]. The House of Lords (Lord Hobhouse of Woodborough) in that case said:

> "*The criterion which the judge has to apply in [order to grant summary judgment] is not one of probability: it is absence of reality. …the phrases "no realistic possibility" and "what is fanciful or inconceivable" appropriately express the same idea."*

It is clear from previous decisions of the Court of Appeal that it is for the applicant to prove it is entitled to have the other side's case dismissed.

In *Nampak v Alpla*, Lord Justice Floyd summed the position up for the Court of Appeal saying:

> "*It is clear that the fact that a dispute involves the resolution of an issue of construction of a patent does not automatically render it unsuitable for summary judgment. However it is necessary to proceed with caution given that the court is not being called upon, when construing a patent, to decide what the words of the patent mean to it, but what they would have been understood to mean by the person skilled in the art.*"[61]

He went on to say:

> "*It follows from what I have said that, on a summary judgment application such as this, it is necessary for a party who claims that the court is inadequately equipped to decide an issue of construction to identify, perhaps in only quite general terms, the nature of the evidence of the common general knowledge which he proposes to adduce, and to be in a position to explain why that evidence might reasonably be expected to have an impact on the issue of construction. If that party is not able to do so, it is open to the court to conclude that he is simply hoping that "something may turn up" and that his defence does not have the necessary "reality" to avoid summary judgment.*"[62]

The Court of Appeal disagreed with the test which Birss J had applied in construing the claim and reached its own conclusions on construction of the claim based on a reading of the specification. Jacob LJ said that he was "unable to see how they could be shown to be erroneous by subsequent evidence". Nevertheless, it was the Court of Appeal's view that the sides of the ECO2 design were longer than the diameter of the aperture and accordingly the feature of the claim was not satisfied. Even using Nampak's test, the ECO2 design did not infringe.

[60] Three Rivers District Council and Ors v Governor and Company of the Bank of England [2001] UKHL 16; [2001] 2 All ER 513
[61] Nampak Plastics Europe Limited v Alpla UK Limited [2014] EWCA Civ 1293 at [9]
[62] Nampak Plastics Europe Limited v Alpla UK Limited [2014] EWCA Civ 1293 at [11]

Accordingly, in the *Nampak v Alpla* case, the Court of Appeal held summary judgment to be appropriate because:

1 the technology was relatively simple to understand;

2 the words of the specification and the claims were simple to understand;

3 there was no suggestion from either side that there were any terms of art involved; and

4 there was no point arising from the common general knowledge which had a bearing on the issue which Alpla's declaration required to be decided.

Those guidelines are quite clear. It also seems clear from the Patent Court judge's decisions that an applicant for a summary judgment needs to move quickly following the commencement of proceedings. The court will not countenance an appeal of the summary application extending beyond the date of the main trial.

It is also clear from the judgments of Birss J and Floyd LJ that there is useful guidance as to what is required to overcome an application. A summary judgment application can be made on 14 days' notice. To mitigate against the risk of being incapable of answering a summary judgment application, patentees should search for an expert before commencing infringement proceedings, which could increase costs yet further. Ironically, of course, they would only need to do so in the more simple cases.

Since an application for summary judgment is likely to force patentees to front-load costs, it is easy to see why an application for summary judgment may be a useful tactic to force a recalcitrant claimant to crystallise its position on claim construction earlier than it might otherwise have done. The contrary risk is that a finding on construction at a summary judgment application can present *res judicata* in a subsequent trial, if a summary judgment application fails.

"ex turpi causa non oritur actio"

The Supreme Court has not been particularly busy in patent matters this year, but it was called into action to consider the interesting defence of illegality in the case of *Servier v Apotex*[63].

In 2006, Servier obtained an interim injunction restraining Apotex from making sales in the UK of a generic drug (perindopril) which, it was alleged, infringed Servier's formulation patent. The patent was later found to be invalid although it would have been infringed. Apotex claimed for damages under Servier's cross undertaking given to the court. Its position was that but for the interim injunction it would have sold an additional 3.6 million packs of tablets in the UK, the active ingredient for which would have been manufactured in Canada by a group company. Late in the High Court

[63] Les Laboratoires Servier and Anr v Apotex Inc and Ors [2014] UKSC 55

damages inquiry, Apotex was held in Canada to have infringed, by the manufacture of such tablets, Servier's Canadian patent for the compound which remained in force in Canada although it had expired in the UK.

Servier amended its defence to the claim for damages under the cross undertaking to argue that according to the doctrine of *ex turpi causa non oritur actio*, it was contrary to public policy for Apotex to recover damages for being prevented from selling a product whose manufacture in Canada would have been illegal as an infringement of Servier's Canadian patent.

In any event, Servier also argued that in assessing Apotex's loss of profit, the damages for infringement to which Servier would have been entitled in the Canadian proceedings should be treated as an additional cost of manufacture.

The second issue was stayed pending the assessment of damages in Canada and Apotex later conceded that any damages which would have been awarded in the Canadian proceedings should be deducted from the award payable in the UK irrespective of the fate of the first issue.

Servier's argument of illegality succeeded before Arnold J but failed in the Court of Appeal, and accordingly it proceeded to the Supreme Court.

Lord Sumption gave the leading judgment. He rejected the approaches of both the lower courts, noting that their differing answers both depended "not on the character of the illegality but on largely subjective judgments about how badly Apotex had behaved and how much it mattered".

The principle underlying the defence of illegality was set out in 1775 in *Holman v Johnson*[64] where Lord Mansfield said:

> "*No court will lend its aid to a man who founds his cause of action on an immoral or illegal act …..*".

The key question arising was what constituted "turpitude" (i.e. "illegality" for the purpose of the defence). Lord Mansfield had referred not only to criminal acts, but also immoral or illegal ones founded on acts which are contrary to the public law of the state and which engaged the public interest. Accordingly, offences of dishonesty or corruption have always been regarded as engaging the public interest even in the context of purely civil disputes. Lord Sumption held that a patent is a public grant of the state, but it does not follow that the public interest is engaged by a breach of the patentee's rights. The effect of the grant "is simply to give rise to private rights of a character no different in principle from contractual rights or rights founded on breach of statutory duty or other torts". He concluded:

> "*The only relevant interest affected is that of the patentee, and that is sufficiently vindicated by the availability of damages for the infringements in*

[64] Holman v Johnson (1775) 1 Cowp 341

Canada, which will be deducted from any recovery under Servier's undertaking in England. There is no public policy which would justify in addition the forfeiture of Apotex's rights."

It is now reasonably clear that acts of patent infringement will not amount to "illegality" for the purposes of this defence unless there is some additional criminal or quasi criminal activity. Exactly what the position might be had the right in question been copyright, or indeed a trade mark, is more problematic, as infringement of both can give rise to criminal proceedings.

2.3 Remedies and costs

Damages under a cross-undertaking

Having just considered potential defences against a claim under a cross undertaking for damages, there has been a significant case this year on the question of cross undertakings generally. In ***AstraZeneca v KRKA***[65], Mr Justice Sales made a number of findings in relation to the assessment of damages to be awarded to a generic drug manufacturer and distributor under a cross undertaking given by the patent owner in respect of an interim injunction which it later had to have withdrawn.

The judge confirmed the principles established in the 2008 case *of Servier v Apotex*[66] as regards the assessment of damages due under a cross undertaking. In that case, Norris J said this:

"*The principles of law sufficient to enable me to quantify compensation in this case may be shortly stated:*

(a) The undertaking is to be enforced according to its terms. In the instant case (as in many others) it is that Servier will comply with any order the court may make "if the court … finds that this Order has caused loss to the defendants". The question for me is therefore: what loss did the making of the Order and its continuation until discharge cause to Apotex?

(b) The approach is therefore essentially compensatory and not punitive.

(c) The approach to assessment is generally regarded as being that set out in the obiter *observation of Lord Diplock in Hoffmann-La Roche v Secretary of State for Trade [1975] AC 295 at 361E namely: -*

> *"The assessment is made upon the same basis as that upon which damages for breach of contract would be assessed if the undertaking had been a contract between the plaintiff and the defendant but the plaintiff would not prevent the defendant from doing that which he was restrained from doing by the terms of*

[65] Astrazeneca AB and Anr v Krka d.d. Novo Mesto and Anr [2014] EWHC 84 (Pat) (24 January 2014)
[66] Les Laboratoires Servier and Anr v Apotex Inc and Ors [2008] EWHC 2347 (Ch)

the injunction."

(d) *What Apotex was trying to do (and what the Order restrained it from doing) was to enter a new market for the sale of generic perindopril. It was denied exploitation of this opportunity. The outcome of such exploitation is attended by many contingencies but [previous case law] establishes that whilst "the presence of all the contingencies on which the gaining of the prize might depend makes the calculation not only difficult but incapable of being carried out with certainty of precision" damages for the lost opportunity are assessable.*

(e) *The fact that certainty or precision is not possible does not mean that a principled approach cannot be attempted. The profits that Apotex would have made from its exploitation of the opportunity to sell generic perindopril depend in part upon the hypothetical actions of third parties and in part upon Servier's response to them. A principled approach in such circumstances requires Apotex first to establish on the balance of probabilities that the chance of making a profit was real and not fanciful: if that threshold is crossed then the second stage of the enquiry is to evaluate that substantial chance.*"[67]

With those principles in mind, in *Astrazeneca v Krka*[68] the parties largely agreed on the approach to be adopted to assessing the value of the loss of the chance for the defendant to enter the market in October 2010. AstraZeneca accepted that the manufacturer and its distributor had shown on the balance of probabilities that, but for the grant of the injunction, they would have sought to enter the market from October 2010 with full force and effect, seeking to win as much market share as they could using the marketing resources in place. No distinct assessment was required of what might have happened in a different counterfactual scenario, for example if they had limited their marketing efforts out of fear of the damages they might have to pay AstraZeneca if it had transpired that they were infringing.

However, a significant factual dispute was whether AstraZeneca would at some point have sought to drop the price for its own product if Krka's product had made significant headway into the market.

On what would have happened in the hypothetical 'counterfactual' scenario in which the interim injunction had not been awarded, the judge preferred Krka's evidence, from experienced pharmacists employed as Medicine Managers to work with doctors to reduce the NHS's drugs bill, to the comparative evidence relied on by AZ. AZ's evidence concerned the following:

(i) What happened when Krka's product did eventually enter the market in September 2011 (when its penetration of the market was considerably less than that which Krka and its distributor said would have been achieved in October 2010, relying on the evidence of the

[67] Les Laboratoires Servier and Anr v Apotex Inc and Ors [2008] EWHC 2347 (Ch) at [5]
[68] Astrazeneca AB and Anr v Krka d.d. Novo Mesto and Anr [2014] EWHC 84 (Pat) (24 January 2014)

Medicine Managers); and

(ii) What happened when the branded generic anti-depressant Venlalic was launched in competition with Effexor in 2009 (when, again, the penetration of the market was considerably less than that which Krka and its distributor claimed would have been achieved if launch had occurred in October 2010).

This is a significant consideration and an interesting finding. The judge assessed the factual scenario as follows:

1 It was very likely that Krka and its distributor would have persuaded the NHS's Northern Ireland Board, under considerable pressure to reduce costs, to promote a switch to the generic drug soon after October 2010.

2 It is very likely that the distributor would have persuaded Primary Care Trusts with potential savings of £50,000 or more to promote a switch to the generic drug shortly after its launch in 2010.

3 It is likely that the distributor would have persuaded a substantial proportion of Primary Care Trusts with lower potential savings to promote a similar switch, though the proportion might have been lower.

4 It is likely that the distributor would have persuaded a substantial proportion of dispensing doctors to make the relevant switch to prescribe the generic drug within a period of about 6 months.

5 It is likely that the distributor would have succeeded in securing the contracts in the Secondary Care Sector which it hoped to bid for.

Armed with those factual assumptions, the assessment of damages payable under the cross undertaking can proceed. This case gives a very useful indication as to the thought processes adopted by the court in considering damages under a cross undertaking. This is something which may become more and more relevant given the regime on stays and the possibility of even final injunctions being subject to some form of cross undertaking where there are pending European opposition proceedings.

Costs

In ***Samsung v Apple***[69], the age old question of the apportionment of costs in relation to aspects of the case was considered.

At first instance the court held that Samsung's two patents were invalid.[70] The Court of Appeal agreed to stay the appeal pending a decision of the EPO on Samsung's

[69] Samsung Electronics Co. Limited v Apple Retail UK Limited [2013] and Anr EWHC 467 (Pat), Samsung Electronics Co. Limited v Apple Retail UK Limited and Anr [2014] EWCA Civ 376 (1 April 2014)
[70] Samsung Electronics Co. Limited v Apple Retail UK Limited and Anr [2013] EWHC 467 (Pat)

application for central amendments of the patents. The Court of Appeal rejected Apple's counter application which would have forced Samsung to choose between the English appeal and EPO amendment proceedings.[71]

Samsung argued that the appeals in relation to the two patents in suit should be split as they were materially different. They related to different technology, were addressed by different legal teams/experts at trial, and the judge gave separate judgments on them. The Court of Appeal felt that this was inappropriate as Samsung had sued Apple for infringement of both patents in one action and the judge made one final order in relation to it.

Samsung argued that its application had been allowed whereas Apple's was not, and so it should get all the costs. Apple argued that Samsung had been granted an indulgence and so should pay Apple's costs. The Court of Appeal saw merit in both arguments. Lord Justice Kitchin noted also that Samsung had sought an adjournment at a late stage and had failed to apply for the amendments now in issue before the trial or promptly afterwards. Apple had acted properly in resisting Samsung's application. Accordingly, the "just result" was to make no order in relation to the costs of either application.

This represents a very interesting progression in thinking. It is quite clear that Samsung made a successful application whereas Apple made an unsuccessful application. However, because of prior conduct, and the nature of the indulgence effectively being granted to Samsung, this more holistic consideration of the circumstances was considered the fair approach.

There are always a good number of interesting cost cases arising from the Intellectual Property and Enterprise Court (IPEC). One of the more extraordinary in 2014 was to be found in the case ***Brundle v Richard Perry and Others***[72]. The court was determining issues of costs after the claimant was successful on a claim of groundless threats[73]. The patent owner had also lost a counterclaim for infringement brought against a third party who had sold the allegedly infringing product to the claimant.

Judgment had been given after the change to Table A scale costs, but the claim form was issued before that change took place and it was agreed that both parties would have expected the old rules to apply regarding costs. The aggregate costs awarded to both successful parties totalled £49,645 – just below the £50,000 cap.

What marks this case out was that the patentee had behaved rather badly. He attempted to forge a letter from the trial judge to influence the cost proceedings. Under IPEC rules, the overall caps and scale costs are mandatory except where a party's behaviour amounts to an abuse of the process. Judge Hacon commented as follows:

[71] Samsung Electronics Co. Limited v Apple Retail UK Limited and Anr [2014] EWCA Civ 250 (11 March 2014)
[72] F H Brundle v Richard Perry [2014] EWHC 979 (IPEC) (2 April 2014)
[73] F H Brundle v Richard Perry [2014] EWHC 475 (IPEC) (6 March 2014)

> "*I accept that CPR 44.2(4)(a), as expanded upon in rule 44.2(5), allows the court to have regard to the conduct of the parties when assessing costs. Mr Perry's conduct has been strikingly unusual but not, in my view, truly exceptional on the scale of unsatisfactory behaviour. It is open to me in the present case to take Mr Perry's conduct into account if this does not give rise to a total award in costs above £50,000. I believe that in the light of Mr Perry's conduct of this action taken as a whole, culminating in the purported letter from me of 26 March 2014, it is appropriate to award an additional £2,000 in costs to be paid to each of the other parties.*"

If forging a letter from a judge does not amount to unreasonable behaviour, then I am not at all sure what does!

Another issue arising in the same case regarded the dissemination of the judgment. The judge held that although no IP right infringement had actually taken place, it was appropriate for the judgment to be disseminated at Mr Perry's expense in a relevant trade journal because his threats may have led to uncertainty in the market place, causing the other parties to suffer.[74]

Damages for groundless threats

Unusually the issue of threats raised its head again in the case of ***SDL Hair v Next Row***[75]. This was a judgment of Richard Meade QC sitting as a deputy judge in IPEC. The defendant was the proprietor of a patent for an induction heating unit for hair rollers. The defendant's solicitors wrote letters to the claimant, and a number of other parties including QVC (a television shopping channel) each of which was found by the judge to amount to a threat.

The claimant sought damages for loss of profit relating to the threat raised with QVC. There was evidence that QVC were going to sell the claimant's product under a promotion called "Today's Special Value" with enhanced marketing, but on receiving the threat they cancelled it.

The judge held that the claimant had lost sales through QVC via the cancelled promotion. He found there was also a 35% chance that it could have received a second "TSV" promotion. Accordingly, damages, assessed at just over £40,000, were awarded in relation to loss of sales through QVC.

The claimant failed in relation to another threat on the grounds that it had given unrealistic delivery times to its prospective customer which it had no real prospect of meeting. This had led the customer to lose faith in the claimant regardless of the threat and accordingly sales would have declined or stopped in any event.

[74] F H Brundle v Richard Perry [2014] EWHC 979 (IPEC) (2 April 2014)
[75] SDL Hair Limited v Next Row Limited & Ors [2014] EWHC 2084 (IPEC) (3 July 2014)

Norwich Pharmacal Order

Finally in relation to this section, 2014 saw a rare application under the *Norwich Pharmacal* jurisdiction. This occurred in the case of ***Wobben Properties v Siemens***[76].

The claimant sought a *Norwich Pharmacal* order for disclosure of Siemens' customers within the jurisdiction where the wind turbine technology alleged to infringe the claimant's patent had been activated, or would be activated by the time of the scheduled trial (June 2015). In addition to Siemens, the claimant had already sued at least three other entities for infringement of the patent by use of the Siemens' technology. The claimant argued that the end users of the technology are very substantial parties, the use of the technology is very profitable, and since the patent expires in August 2016 the delay which might be involved in bringing a second or subsequent action against an end user might result in the claimant not obtaining injunctive relief because of the expiry of the patent. It also argued that if an end user later challenged the patent and succeeded in obtaining revocation, any award of damages or account of profits would be overridden on the principle set out in *Virgin v Zodiac*[77].

Mr Justice Morgan held that a wrong had arguably been committed by Siemens' customers, that Siemens had facilitated this, that Siemens had the requested information, and that the claimant needed the requested information to enable it to bring proceedings against Siemens' customers. On that basis he considered that it was just to make the order sought and better for all concerned if Siemens reduced the number of customers who would be sued by the claimant to those who had actually used the technology. He said that in fact the reputational damage to Siemens would be reduced by this approach. Accordingly the *Norwich Pharmacal* order was duly granted.

3 Validity

3.1 Anticipation/Priority

I have often struggled to know where to put cases on priority in this framework, but since the normal implication of failed priority is anticipation, I have settled on this section. It is an increasingly important issue, with the fashionable argument based on "poisonous priority" being regularly deployed. I have never quite got this point. If the disclosure in the original document is not sufficient to support priority, how can it anticipate?

[76] Wobben Properties GmbH v Siemens Plc [2014] EWHC 3173 (Pat) (2 October 2014)
[77] Virgin Atlantic Airways Ltd v Zodiac Seats Ltd [2014] AC 160, [2013] UKSC 46

Priority

The question of priority was at large in the case of ***Hospira v Novartis***[78]. This was a Court of Appeal judgment on appeal from a decision of Mr Justice Arnold. Lord Justice Floyd delivered the main judgment.

Novartis was appealing against a decision that its patent for zoledronate was invalid. Claim 7 claimed the use of the drug for the treatment of osteoporosis, where the medicine was adapted for intravenous administration of about 2-10mg about once a year. Claim 7 claimed priority from documents including a US patent which explained that the dosage size would depend on the potency of the main ingredient and the dosing interval. Specifically in relation to more recent versions of the drug, such as Zoledronate, it said that "a unit dose from one up to ten milligrams might be used. For example, from about one to about five milligrams could be used for dosing once every six months; whereas a dose of about two up to about ten milligrams might be used for once a year dosing".

The issue was whether this American document disclosed the subject matter of Claim 7 of the patent.

In a nutshell, the Court of Appeal held that the disclosure of the US patent was either too general or too specific for the claimed invention to be "supported by matter disclosed" in it:

> *"If one focuses on the disclosure about zoledronate, the "2-10 mg once a year" passage tells the skilled reader nothing about dosage range for any particular method of administration. It also does not tell the reader about the dosage range for any particular condition, such as osteoporosis. Example 5, on the other hand, is specific to intravenous administration. It teaches that 4 mg, once a year, administered intravenously to patients with post-menopausal osteoporosis is effective, but nothing about what other doses could be used at that dosage interval."*[79]

The skilled person would know from their common general knowledge that dosage is critically dependent on condition and method of administration. Intravenous administration delivers the drug directly to the bloodstream without the loss of drug via excretion which would occur in oral administration. A lower dose would apply in such a case. Other dosage ranges are given in the patent. These examples could not be taken as disclosing that they are suitable for every condition and every means of administration. Accordingly this does not support the argument that the 2-10 mg administration is of general application.

As the patent could not therefore claim priority from the US application, it was rendered invalid by intervening prior art.

[78] Hospira UK Generics (UK) Limited trading as Mylan v Novartis AG [2013] EWCA Civ 1663 (19 December 2013)
[79] Hospira UK Generics (UK) Limited trading as Mylan v Novartis AG [2013] EWCA Civ 1663 (19 December 2013) at [32]

The Court of Appeal took a good look at the law on priority. Although the language of Article 87 of the European Patent Convention and Section 5 of the Patents Act, which provide for the entitlement to an earlier priority date, is different, the two formulations must be taken to mean the same thing. The language of the Convention was interpreted by the Enlarged Board of Appeal[80] as meaning that the priority of a previous application is to be acknowledged "only if the skilled person can derive the subject matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole".

Accordingly, priority can be lost by narrowing down the disclosure from the priority document in a manner which means that the invention could not be derived directly and ambiguously from it. Alternatively it could be lost by widening or generalising from the priority disclosure. This was the problem Novartis was faced with. The description of a dosage of "2-10mg once a year" did not teach the skilled person about the dosage range for any particular method of administration of the medicament, so in that respect the passage was too general. However, the example given in the patent was specific as to intravenous administration but only in patients with postmenopausal osteoporosis. In other words that passage was too narrow.

Concerns about poisonous priority and toxic divisionals derive from the interpretation of the Enlarged Board of Appeal's decision in G2/98. In that case the EBA said:

> *"The use of a generic term or formula in a claim for which multiple priorities are claimed in accordance with Article 88(2) EPC, second sentence, is perfectly acceptable under Articles 87(1) and 88(3) EPC, provided that it gives rise to the claiming of a limited number of clearly defined alternative subject-matters."*[81]

Several Boards of Appeal and judges have interpreted the words "limited number of clearly defined alternative subject -matters" as meaning that the claim of the subsequent application must itself define this limited number of clearly defined alternative subject-matters, whereas in decisions T 1222/11[82] and (recently) T 571/10[83] the Boards of Appeal (3.3.07 in each case) have departed from the strict and literal interpretation of the words. The inconsistency has led to a referral to the Enlarged Board of Appeal in case T 557/13, the outcome of which is awaited with interest.

Priority was also the issue in the case of ***HTC v Gemalto***[84].

The facts of this case are less interesting in this regard, but Lord Justice Kitchin sets out a useful summary of the law and how it should be applied. He reiterates that it is clear from Section 5 of the Patents Act 1977 that an invention is entitled to priority if it is supported by matter disclosed in the priority document. The earlier application

[80] in G2/98 "Same Invention" 2001 OJEPO 413
[81] G2/98 "Same Invention" 2001 OJEPO 413 at [6.7]
[82] T 1222/11 (4 December 2012)
[83] T 571/10 3 June 2014
[84] HTC Corporation v Gemalto SA [2014] EWCA Civ 1335 (22 October 2014)

must be in respect of the same invention, and the approach is not formulaic, but rather that priority is a question about technical disclosure – explicit or implicit. The question is: "is there enough in the priority document to give the skilled person essentially the same information as forms the subject of the claim and enables him to work the invention in accordance with that claim"?

Lord Justice Kitchin summed the position up as follows:

> "*The skilled person must be able to derive the subject matter of the claim directly and unambiguously from the disclosure of the priority document. The question was one of what was disclosed to the skilled person, not what was made obvious to him by the priority document, for example in the light of his common general knowledge. … That does not mean, however, that the priority documents should be read in a vacuum. The question of what a document discloses to a skilled person takes account of the knowledge and background of that person. A document may mean one thing to an equity lawyer and another to a computer engineer, because each has a different background. The document still only has one meaning because it is only the relevant skilled person's understanding which is relevant. What is not permissible is to go further than eliciting the explicit or implicit disclosure and take account of what a document might lead a skilled person to do or try, or what it might prompt him to think of.*"[85]

Accordingly it is clear that, for the purposes of priority, the principles in play are those of anticipation, not obviousness. It is not enough that it might be obvious to a skilled person to go from the priority document to the invention in the patent. It must be clearly and unambiguously disclosed. Lord Justice Kitchin makes that point quite clear. HTC contended that the first instance judge (Birss J) had erred in adopting this strict line, and in indicating that obviousness to the skilled person was not enough. Lord Justice Kitchin dealt with the point in these terms:

> "*On HTC's first point, I do not think it is right to suggest that the judge crossed the line between clear disclosure and obviousness. His reliance on the common general knowledge of the skilled team of other methods of compacting an application was not for the purpose of supplementing what was actually disclosed so as to include specific disclosures of those methods. He was explaining that, because the skilled team approached the priority document with their background knowledge of a wide variety of methods, they would understand that namespace mapping was being disclosed as an example of a suitable technique of compaction of the program.*"[86]

Accordingly, it is clear that the common general knowledge of the skilled reader is relevant, but only on a contextual basis. This is not a question of combining the disclosure with common general knowledge – that is not enough to establish priority.

[85] HTC Corporation v Gemalto SA [2014] EWCA Civ 1335 at [65]
[86] HTC Corporation v Gemalto SA [2014] EWCA Civ 1335 at [70]

Anticipation

Another basis on which a patentee may cause themselves difficulty, in relation to anticipation, is if there has been non-confidential disclosure of the invention prior to the priority date of the patent. In ***AGA Medical v Occlutech***[87] just such a situation arose.

AGA had a patent for a device for occluding defects in the atrial septum of the heart. The septal defect is often called a "hole in the heart" and is a relatively common birth defect generally fixed by surgery if it does not close by itself. The device comprised two cupped discs containing patches of fibre, connected by a short thin cylindrical waist, all made from woven strands of a "memory metal" which resumed its shape after being compressed. The advantage of this sort of device is that it could be used to close defects without the need for open heart surgery.

AGA's patent was granted in June 2011 and its priority date was 14 May 1996. However, in September 1995, AGA oversaw a clinical trial of three prototype devices at a hospital in Bratislava. The trial does not seem to have been especially formal and was arranged by the inventor of the device directly through a friend at the hospital. The inventor then attended the hospital and assisted using the devices in surgery on three children.

AGA claimed that Occlutech infringed the patent. Occlutech counterclaimed that AGA's patent had been anticipated due to the Bratislava disclosure and in any event was obvious over another prototype disclosed in a March 1996 presentation.

To cut a long story short, AGA lost. On the facts the judge held that at least some of the Bratislava prototypes potentially anticipated the patent. The issue was whether or not they had been disclosed confidentially.

Roth J confirmed that a disclosure will only form part of the state of the art if it was made available to the public; and for that purpose, it must have been made available to at least one person who was free in law and equity to use it. This brings the analysis into the English law of confidence. Roth J noted that the basis on which a duty of confidence arises in English law was expressed by Lord Goff as follows, in his speech in the *Spycatcher*[88] case:

> *"I start with the broad general principle (which I do not intend in any way to be definitive) that a duty of confidence arises when confidential information comes to the knowledge of a person … in circumstances where he has notice, or is held to have agreed, that the information is confidential, with the effect that it would be just in all the circumstances that he should be precluded from disclosing the information to others."*

[87] AGA Medical Corporation v Occlutech (UK) Limited [2014] EWHC 2506 (Pat) (22 July 2014)
[88] Spycatcher AG v Guardian Newspapers (No. 2) [1990] 1 AC 109 at [281]

Roth J. noted that this approach was cited with approval by Lord Nicholls in *Campbell v Mirror Group Newspapers*[89]:

> *"Now the law imposes a 'duty of confidence' whenever a person receives information he knows or ought to know is fairly and reasonably to be regarded as confidential."*

Roth J also noted the oft-cited explication by Megarry J in *Coco v AN Clark (Engineers) Ltd*[90]:

> *"It seems to me that if the circumstances are such that any reasonable man standing in the shoes of the recipient of the information would have realised that upon reasonable grounds the information was being given to him in confidence, then this should suffice to impose upon him the equitable obligation of confidence. In particular, where information of commercial or industrial value is given on a business-like basis and with some avowed common object in mind, such as a joint venture or the manufacture of articles by one party for the other, I would regard the recipient as carrying a heavy burden if he seeks to repel a contention that he was bound by an obligation of confidence."*

On the facts of the *AGA v Occlutech* case, the devices were found to have been provided to the medical personnel involved without any express obligation of confidence. Roth J held that there was no presumption of confidentiality simply because the devices were supplied as part of a clinical trial. The evidence of the doctors was that they had never been given any indication or impression that the details of the devices they used were to be kept confidential. Their subsequent behaviour, in sharing information with their medical teams and more widely at conferences, was consistent with that. Hence on the facts, Roth J. held that the disclosure to the doctors was without an obligation of confidence, whether this was assessed on a subjective or an objective basis. The patent was therefore invalid for anticipation.

There is a clear, salutary warning here that any prior disclosure must be in circumstances where the duty of confidence is expressly imposed. An assumption as to confidentiality would be a very dangerous thing.

Finally on anticipation, the judgment of Sales J in ***Teva v AstraZeneca***[91] is noteworthy for its confirmation of the different times at which prior art documents should be interpreted, depending upon whether the assessment concerns novelty or inventive step. Sales J said:

- For the purpose of anticipation, "the court dons the mantle of the relevant skilled person and reads the [prior art] 1993 Patent in the light of the CGK of such a person in 1993";

[89] Campbell v Mirror Group Newspapers [2004] UKHL 22, [2004] 2 AC 457 at [14]
[90] Coco v AN Clark (Engineers) Ltd [1969] RPC 41 at 47-48
[91] Teva UK Limited & Anr v AstraZeneca AB & Ors [2014] EWHC 2873 (Pat) (2 September 2014)

- For the purpose of obviousness, "the issue has to be addressed as at the priority date [of the patent in issue] in June 1998".

A useful reminder!

3.2 Obviousness

This year is no different from any other in that there are more cases where obviousness is a key factor than any other single topic. As usual, most involve a lot of findings and very little law, but there are some key points of interest this year.

"Could"/"would"

To set the scene it is worth considering the judgment of Mr Justice Roth in ***Collingwood Lighting v Aurora***[92].

Considering the question of obviousness, Mr Justice Roth referred to Jacob LJ's summary, in *Actavis v Novartis* (2010)[93] of the "could/would" approach to obviousness set out in the EPO's Examination Guidelines. The basis of this is that it was not enough to show that prior art teaching could have prompted the skilled person to arrive at the invention by adapting or modifying the closest prior art, but rather it must be shown that he would have done so in the hope of solving the objective technical problem[94]. Lord Justice Jacob concluded:

> "*I do not read this as involving a requirement that the notional skilled person would actually physically implement the idea. What the passage is saying, sensibly enough, is that it is not enough the skilled person could have arrived at the invention from the prior art, it must be shown that he would have done. Whether he would actually press ahead and implement the idea depends on a host of other commercial considerations.*"[95]

With that background in mind, I will move on to the interesting case of ***Hospira v Genentech (II)***[96] where Mr Justice Birss took a closer look at this issue in relation to two patents concerning the formulation of trastuzumab. Trastuzumab is the monoclonal antibody which is the active ingredient in Genentech's Herceptin cancer medication. Genentech proposed amendments to various claims of the patents.

Birss J opens with the classical approach to obviousness, confirming the structured approach set out by the Court of Appeal in *Pozzoli*[97], with qualifications from the

[92] Collingwood Lighting Limited v Aurora Limited [2014] EWHC 228 (Pat) (10 February 2014)
[93] Actavis UK Ltd v Novartis AG [2010] EWCA 82, [2010] FSR 18
[94] Collingwood Lighting Limited v Aurora Limited [2014] EWHC 228 (Pat) at [42]
[95] Actavis UK Ltd v Novartis AG [2010] EWCA 82, [2010] FSR 18 at [46]
[96] Hospira UK Limited v Genentech Inc [2014] EWHC 3857 (Pat) (21 November 2014)
[97] Pozzoli Spa v BDMO SA & Anr [2007] EWCA 588, [2007] FSR 37

House of Lords in *Conor v Angiotech*[98] and the often approved statement of Kitchen J (as he then was) in *Generics v Lundbeck*[99] where 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.*"

In recent years, the question of obviousness has been considered by the judges, more often than not, in relation to the very simple question – is it obvious?

The age old could/would dilemma arose again in the Hospira v Genentech (II) case. Hospira submitted, based on expert evidence, that the claimed formulation was one of the formulations that the skilled person could have derived by routine means. Genentech emphasised, by reference to established case law, that the question is whether the skilled person would have arrived at the claimed invention, not whether they could have. Birss J considered the issue and concluded as follows:

> "*My conclusions under the could/would argument are as follows. It is not true to say that a real team* would *arrive at a formulation consisting of [the patented combination]. It would be idle to pretend otherwise and Hospira do not do so. But what Hospira's submission is getting at is that the claimed result can be reached by the application of nothing other than routine approaches applied to excipients which were part of their common general knowledge. In my judgment on the facts of this case that is correct.*"[100]

Accordingly, although on its own submission, Hospira put its case, at its highest, that a skilled person could have derived the patent by routine means, Birss J found that the patent was indeed obvious and involved no inventive step over cited prior art. In doing so he touched on the "step by step" approach involving the established authority of the *Technograph*[101] case. Hospira alleged that this was a classic case of a step by step approach. The judge disagreed. He said that whilst the *Technograph* position was significant, other factors came into play. In this case those factors could be characterised as follows:

"*(i)* *Although a number of choices have to be made, the existence of these choices is not tainted with hindsight.*

(ii) *Although the point cannot be taken too far since the ingredients interact and have to work in combination, nevertheless a number of the choices here fall to be made in parallel not in series.*

[98] Conor Medsystems Inc v Angiotech Pharmaceuticals Inc & Ors [2008] UKHL 49, [2008] RPC 28
[99] Generics UK Limited & Ors v Lundbeck A/S [2007] EWHC 1040 (Pat), [2007] RPC 729,
[100] Hospira UK Limited v Genentech Inc [2014] EWHC 3857 (Pat) at [234]
[101] Technograph v Mills & Rockey [1972 RPC 346

(iii) This is a highly empirical field and is one in which the skilled team will without hindsight want to test a range of ingredients.

(iv) The tests themselves are run in parallel. The skilled team does not test one combination at a time. It tests a number together."[102]

It is arguable that, in this decision, Mr Justice Birss has done damage to two of the most hallowed principles underlining the law of obviousness. He appears to have cast doubt on the previously watertight "could/would" formulation, whilst at the same time questioning the general applicability of the *Technograph* test, and insisting that it is subject to the context in which it is to be applied, and in particular the question of whether the steps are to be taken consequentially or in parallel.

In relation to the "could/would" question, it has been argued that Birss' approach is altogether more logical. It is the nature of the skilled person to be an automaton who will do anything without invention. Accordingly, if the skilled person could make something without invention, effectively the formulation applied by the court previously means that he would do so in pursuit of the definite objective in view. I am not sure that Birss J actually goes that far, and it may be that the qualifications are limited to the detailed factual situation in this case. However, it certainly is a cause of widespread discussion and in all likelihood will be considered on appeal before too long.

Changing tone slightly, some interesting issues arose in the case of ***Phil & Ted's Most Excellent Buggy Company v TFK Trends for Kids***[103]. This was a Court of Appeal decision from a first instance finding that a patent for a transformable seat in a baby buggy was invalid for obviousness over a Chinese utility model patent published shortly before the patent in the UK.

The Court of Appeal upheld the first instance decision, finding that the skilled person would have been interested in putting the Chinese utility model into practice as it had been published shortly before the priority date and clearly indicated a clever design based on geometrics and fixed pivot points.

The skilled person was also deemed to understand that other elements of the design such as using fabric sidewalls would have to be present. Making the seat reversible was also part of general buggy knowledge at the time so this could be used as it was obvious to also apply it to the Chinese design.

A worthwhile starting point?

Mr Justice Arnold had to consider the question of obviousness in the case of ***Compactgtl v Velocys***[104]. The patents in question were amended to remove what was considered to be an "obvious mistake". Reference to "residence time" was

[102] Hospira UK Limited v Genentech Inc [2014] EWHC 3857 (Pat) at [241]
[103] Phil & Ted's Most Excellent Buggy Company Limited v TFK Trends for Kids GmbH & Ors [2014] EWCA Civ 469 (16 April 2014)
[104] Compactgtl Limited v Velocys Plc and Ors [2014] EWHC 2951 (Pat) (22 September 2014)

corrected to "contact time". Arnold J decided this was an obvious mistake based on the expert evidence and the way that a skilled person would read the patents. In normal circumstances the amendment would violate both the prohibitions of Section 76 of the Patents Act against added matter and extending protection. However, because the amendments were necessary as a result of a mistake, those considerations were not applied.

The amended patent survived, with all attacks based on anticipation and obviousness failing. There were a couple of particularly useful "take home" points made by the judge.

First, he said that disclosure of specific elements and combinations, and a more general disclosure of "platinum group metal or metals" did not anticipate the use of unspecified group metals in the claimed invention.

Secondly, he made it quite clear that numerical limits say what they mean. In this case, 5.2 seconds could not in any circumstances be construed as including "less than five seconds". Considering one particular piece of prior art - Schanke - he gave a pithy summary saying:

> "*Given (i) the scepticism with which the skilled person would approach Schanke, (ii) the absence of attention which it had received, (iii) the underwhelming results it reported, (iv) the fact that Schanke had not demonstrated that his solution to the heat transfer problem would work and (v) the fact that any attempt to make it work would involve a research project, I consider that the skilled person would conclude that Schanke did not represent a worthwhile starting point for development. It follows that it does not render any of the claims of the Patents obvious.*"[105]

That is a fairly comprehensive "put down" of cited prior art!

The Pozzoli approach

It is always interesting when new judges get to work on this issue, and this year, in the important case of ***Generics (UK) Limited v Richter Gedeon***,[106] Mr Justice Sales addressed the question of obviousness in detail.

Generics requested a declaration of invalidity in respect of the defendant's patent on the basis of obviousness. The patent was for a single dosage regimen for the use of a drug as an emergency contraception method.

Generics cited a World Health Organisation (WHO) report which highlighted the effectiveness of a single dosage regimen, and used the report to establish that the effectiveness of a single dose regimen as compared with the widely used two dose approach was common general knowledge. The court determined that the state of

[105] Compactgtl Limited v Velocys Plc and Ors [2014] EWHC 2951 at [148]
[106] Generics (UK) Limited (trading as Mylan) v Richter Gedeon Vegyeszeti Gyar RT [2014] 1666 (Pat) (22 May 2014)

the art at the priority date included the common general knowledge about existing emergency contraception methods as well as the WHO report.

Generics argued that the relevant expertise for the assessment of the issues in the case was that of a clinician with an interest in emergency contraception. The patentee argued that the relevant expertise was that of a medical statistician as only a statistician would understand the statistics around the efficacy of the dosage regimen.

The key finding by the judge was that the WHO study which evaluated the efficacy of a single dose approach was part of the common general knowledge as well as the state of the art. He also narrowed the relevant clinician to being a clinician working in the delivery of specialist contraception services who has been awarded the basic diploma on membership of the Faculty of Family Planning and Reproductive Healthcare. He thought they would have at least five years hands-on experience in the management of emergency contraception.

The question of prejudice raised its head again, and the old discussion about "lions in the path and paper tigers" arose. The patentee argued that there was a prejudice against a single dose approach. The judge found there was not.

He applied the classic formulation – the *Pozzoli*[107] analysis – to the case. He went through the four phases meticulously, before reaching his finding that the patent was indeed invalid as being obvious over the common general knowledge in the form of the WHO report.

We have already considered Birss J's take on the "would/could" issue and the "step by step" analysis. He does not appear to be a great fan of the established legal formulations in relation to obviousness, because in ***Teva v Leo Pharma***[108], he went 15 rounds with the *Pozzoli* approach, or rather chose to ignore it altogether.

The judge was being asked to consider whether two patents (one a divisional of the other) relating to a combined formulation for the treatment of psoriasis were valid and infringed. Teva adopted a somewhat unusual approach to its allegation of obviousness. The gist of it was as follows:

- The skilled addressee would be a team comprising at least a skilled clinician and a skilled formulator. The skilled clinician's common general knowledge would lead the skilled person to think of the combination. The skilled clinician would have liaised with the skilled formulator to produce an ointment containing the combination of active ingredients. When the skilled formulator was presented with a prior art citation (a US patent "Turi") it would have been obvious to use the non-aqueous solvent described in it as a solvent to combine betamethasone with calcipotriol.

[107] Pozzoli Spa v BDMO SA & Anr [2007] EWCA 588, [2007] FSR 37
[108] Teva UK Limited and Anr v Leo Pharma A/S and Anr [2014] EWHC 3096 (Pat) (6 October 2014)

This unusual way of stating the case on obviousness led to Birss J departing from the traditional way of assessing obviousness using the *Pozzoli* approach.

By way of reminder, the accepted formulation by the Court of Appeal in *Pozzoli*[109] is as follows:

> "*1(a) Identify the notional "persons skilled in the art";*
>
> *(b) Identify the relevant common general knowledge of that person;*
>
> *2. Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;*
>
> *3. Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;*
>
> *4. Viewed without any knowledge of the alleged invention as claimed, do these differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?*"

Birss J sets out the test in the judgment and the next four headings track the four parts of the test. He complies with the first two steps – he identifies the skilled person and their common general knowledge and identifies the inventive concept. However, when it comes to considering the third step, to identify the differences, Birss J does not identify the differences between the cited prior art and the claimed invention. This is because, in the judge's words, "Turi on its own does not lead a skilled person to the invention in this case". The judge elaborates as follows:

> "*Most obviousness attacks involve a primary documentary reference. The differences between the primary reference and the invention can be identified (*Pozzoli*). …*
>
> *Some attacks are based on common general knowledge alone, in which case all the elements of the invention are said to derive from common general knowledge alone. …*
>
> *TEVA's case is unusual in that it starts from common general knowledge and then involves adding information from a document (Turi) which is not part of the common general knowledge and which TEVA do not submit would be found on a literature search. TEVA rely on the principle that any document forming part of the state of the art must be placed before the skilled person. Turi on its own does not lead a skilled person to the invention in this case. Although Leo contend that the argument fails on the facts, they did not object to the argument in principle. I will return to this below. At this stage it means*

[109] Pozzoli Spa v BDMO SA & Anr [2007] EWCA 588, [2007] FSR 37 at [23]

that there is no point in identifying the differences between the invention and a primary reference."

Accordingly, it is quite clear that Birss J has not followed the standard *Pozzoli* formulation. He has not sought to identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed.

The next question is, does that matter?

There is no obligation on the court to follow the *Pozzoli* formulation. Section 3 of the Patents Act does not contain or refer to the test, and there is recent Court of Appeal authority (*Smith & Nephew v Convatec*[110]) that has stated clearly that while "it is often convenient, [it is] by no means essential, to consider an allegation of obviousness using the structured approach explained by this court in *Pozzoli*".

In this case, the crucial point appears to be the nature of the skilled person. The skilled addressee was agreed to be a team, and it was the judge's opinion that the common general knowledge of the clinician got him so far but then the prior art, Turi, was useful only to the formulator to get him to the invention. It is true that Turi is of no use to the clinician – its disclosure relates to the use of a solvent which is only of interest to the formulator. However, it is not clear why, even if Turi was given to the clinician, he would not simply pass it on to the formulator. It is not even clear that it needs to be obvious for him to give it to the formulator in order for the claimed invention as a whole to be obvious.

It seems to me that the judge has got himself into something of a pickle here. It is well established that the skilled person can constitute a team, the very purpose of that team being to include people with different skills. Further, the *Pozzoli* approach requires that the difference is identified between the inventive concept and the matter stated as forming part of the state of the art. It is of course acknowledged law that, for the purposes of obviousness, one can combine a specific item of prior art with common general knowledge. If that is the basis of an argument, then is it even true to say that part 3 of the *Pozzoli* formulation requires the differences between a specific item of prior art and the inventive concept to be identified?

This is the sort of trouble which arises when these standard formulations are not adopted. The judgment appears to have created something of a mess, and no doubt the Court of Appeal will turn its mind to it in due course.

Obvious to try

In the *Teva v Leo Pharma* case, the judge also addressed the question of "obvious to try". The key passage of the judgment on this point reads as follows:

[110] ConvaTec Limited and Ors v Smith and Nephew Healthcare Limited and Ors [2012] EWCA Civ 1638 at [36]

> "*Leo emphasised two judgments of Floyd J (as he then was) which considered the role of "obvious to try" in the assessment of inventive step. They were Leo Pharma v Sandoz [2009] EWHC 996 (Pat), and Omnipharm v Merial [2011] EWHC 3393. These judgments show that "obvious to try" is simply one of a variety of factors which fall to be considered. The significance of these factors varies from case to case and depends on the facts. Obvious to try cases usually involve consideration of the level of expectation of success but one cannot lay down a general characterisation of what the true level of expectation must be in every case beyond stating that it must be a fair one. In that way the differences between different cases is taken into account. It is wrong to ask whether something might achieve a particular desired effect. It is correct to ask whether it was obvious that it would achieve that effect.*"[111]

However it is not clear why the judge had adopted this form of analysis. The proper question of whether something is obvious is surely a question of whether, before doing anything else, it is obvious what will happen. Once the race is run, it is obvious who has won – the question is whether it is obvious who will win beforehand.

Birss J decided that it would be obvious for the skilled formulator to try the solvent, stating that "based on what the skilled formulator knew about it at the time there was a sufficient prospect of a positive result in the tests with this compound to make it worth testing. It was obvious to do so". Birss J concluded that the patents were obvious.

Accordingly in answering the question whether the solvent was "obvious to try" Birss J seems to be answering the very question ("whether something might achieve a particular desired effect") which he has previously stated it is "wrong to ask". What is quite clear is that it is perfectly possible that different results might arise depending on whether a judge choses to follow the *Pozzoli* approach or not. On that basis, although it is clear there was no legal obligation on Birss J to apply the test, the fact that he has partially done so and partially not, will certainly be considered on appeal. Birss J's "skilled team" appears to operate in a different way to a real life team. Both the finding that it was common general knowledge to combine calcipotriol and betamethasone and a finding that it was obvious to try the solvent Arlamol, were contrary to evidence regarding the actual behaviour of real life teams. Without these findings the claims would have been inventive.

It is also worth dwelling briefly on the case of ***Teva v Astrazeneca***[112], if only for an interesting passage which arose following the submission of the judgment.

Astrazeneca owned a second medical use European patent for an asthma treatment involving a composition comprising two active ingredients, formoterol and budesonide (an "ICS"). Teva argued the patent had been anticipated by prior art referred to as the "1993 Patent". The judge, Mr Justice Sales, found that the 1993 Patent disclosed that formoterol and an ICS could be used in combination, including in a combination

[111] Teva UK Limited and Anr v Leo Pharma A/S and Anr [2014] EWHC 3096 (Pat) at [53]
[112] Teva UK Limited & Anr v Astrzeneca AB [2014] EWHC 2873 (Pat) (2 September 2014)

inhaler, for maintenance therapy and that there could be a rescue effect. The significant difference between the disclosure in the 1993 Patent and the invention in the Patent in suit was the use of such a combination, including by way of a combination inhaler, for relief therapy at other times. Teva also contended that in any event the patent was obvious based on the common general knowledge. Sales J held that there was no anticipation, but when reviewed alongside the common general knowledge, the skilled man armed with the 1993 Patent would have considered that a combination would be worth trying for both maintenance and emergency relief.

When the judgment was handed down in draft, Astrazeneca objected on the basis that Teva had argued that it was the combination of the 1993 Patent and CGK that invalidated the patent, but that Mr Justice Sales had considered CGK alone. Teva had initially pleaded CGK alone but it had agreed not to rely on that at trial.

The judge admitted that in his trial judgment he had considered CGK alone to be enough. It had not been clear to him at trial that CGK alone was no longer being pursued because evidence ranged very widely over CGK and was not always tied to the 1993 Patent. The judge was then, post-trial, directed to correspondence showing that Teva's case was not CGK alone and he agreed that this was therefore an exceptional case and he should amend his judgment.

He considered if he was prejudicing either party by doing so but concluded that he was not. He said he had ample opportunity to hear Teva's case and the amendment was effectively just removing an intellectual shortcut he had applied.

It may be that it was clear at trial the judge just got his reasoning wrong, but the more likely outcome is that this case should serve as a reminder to parties to be clear about what is being pleaded and the basis of the case, especially when blurring prior art and CGK.

One should not be surprised that Astrazeneca has submitted that the outcome should be reversed following the judge's mistake. Equally and unsurprisingly, Teva took the opposite view.

The judge concluded that as he had considered the 1993 Patent very closely in the context of anticipation, it was not a problem for him to amend his judgment to apply the 1993 Patent together with the common general knowledge, to reach the same conclusion that he had previously done in relation to CGK alone.

Expert witnesses

Finally in this section, it is worth capturing some comments made in relation to expert evidence, which of course is very often crucial to the outcome of a validity challenge.

In ***Environmental Defence Systems v Synergy Health***[113], Judge Hacon in the IPEC, considered a case involving alleged infringement of a patent for flood

[113] Environmental Defence Systems Limited v Synergy Health Plc & Ors [2014] EWHC 1306 (IPEC) (1 May 2014)

defences. To say that the parties were in different fields of activity would be something of an understatement. Environmental Defence Systems were looking to protect the public from rising rivers, whereas Synergy Health were manufacturers of incontinence pads. There was a third defendant who was using the absorbent pads manufactured by Synergy Health as a flood protection method. The judge concluded that there was no inventive step as it would have appeared obvious to the skilled person to try the absorbent pads as fillers in flood defences. Of more importance is the question of the expert witnesses. The claimant adduced evidence from an expert in personal hygiene products whereas two of the defendants adduced evidence from an expert in flood risk management.

Judge Hacon was not happy with this situation. He said:

> "*What may not be done is to consider inventive step from the perspective of the two skilled persons jointly where one is drawn from the field of the prior art and the other from the technical field to which the patent is solely addressed. Invention may lie in joining two or more technical fields of expertise to address the problem. Creating an inventive step in that way would wrongly neutralise the possibility of the assembled skilled persons perceiving the inventive step.*"[114]

The judge identified that this was a particular issue in the Intellectual Property Enterprise Court where strict rules applied to the number of expert witnesses who could be called. He said that:

> "*A party seeking to invalidate a patent, generally the defendant, proposes a shortlist of prior art. According to English procedure (unlike that of the EPO) it is not for the court to say whether the shortlist contains the closest prior art – the defendant must decide on its best shots. Taking the simple case (no combinations of prior art relied on) each cited piece of prior art will at trial be taken to have been read with interest by the skilled person in the light of his common general knowledge. That common general knowledge will depend on the technical field from which the skilled person is drawn. Since potentially there are alternative sets of common general knowledge the defendant must say which technical field for the skilled person is being nominated and this must clearly be stated in the defendant's pleadings. The court may have to resolve certain characteristics of the skilled person, notably the level of his education and training and the precise content of his common general knowledge. But his technical field is a matter for the defendant to nominate in its pleadings so far as inventive step is concerned.*"[115]

The judge's practical advice to parties was as follows:

> "*It should then follow that by the time of the [case management conference], it is evident what sort of directions each of the parties is seeking and why, in particular with regard to expert evidence: how many experts need to give*

[114] Environmental Defence Systems Limited v Synergy Health Plc & Ors [2014] EWHC 1306 (IPEC) at [22]
[115] Environmental Defence Systems Limited v Synergy Health Plc & Ors [2014] EWHC 1306 (IPEC) at [25]

evidence and in which disciplines. I should say that even if the defendant pleads that skilled persons from more than one technical field are relevant due to a distinction between assessing inventive step and other matters, it does not at all automatically follow that more than one expert will be permitted."[116]

It is accordingly clear that defendants may have some interesting choices to make in pursuing proceedings in IPEC.

A small point relating to expert witnesses arose also in the case of ***Bugen Seitz v Corpoplast***[117]. Mr Justice Roth considered a dispute as to the validity of a patent relating to the valves used in machines for blowing plastic bottles. The claimant sought revocation of a patent held jointly by the first and second defendants on the grounds of novelty and obviousness.

The invention used plastic for the valves controlling the high pressure air used in the process and Roth J found that the skilled person at the priority date would have been prejudiced against the use of plastic for this equipment. Of general interest was his decision to give no weight to the expert evidence adduced by the claimant because that expert was much influenced in his views by his personal involvement in designing a blow moulding machine using plastic pistons, making it very difficult for him objectively to assess the position of the notional skilled person who lacked this quality of inventiveness.

The upshot is a practical one indicating the importance of carefully selecting an expert witness who can give objective evidence.

Selecting the right expert has been a theme in a number of this year's cases. The courts, usually polite to expert witnesses, have become somewhat more critical of experts whose job appears to have more to do with advocacy than informing and educating the court – the role for which the court finds experts useful.

3.3 Insufficiency

Although a number of cases make reference to the issue of insufficiency, there has been little by way of genuine legal advance this year. It is unusual for insufficiency to be the principal ground for allegations of invalidity, and consequently, with so many findings of obviousness, it is common in judgments to find that the insufficiency arguments are not fully addressed in the judgment. That was not the case in ***Idenix v Gilead Sciences Inc***[118]. At 621 paragraphs, this judgment of Arnold J is the longest of the year and deals with the full panoply of patent issues.

Idenix claimed that Gilead had infringed its patent by the keeping and disposal of Sofosbuvir, a breakthrough treatment for hepatitis C. Gilead denied infringement and counterclaimed for revocation on the grounds of anticipation, obviousness,

[116] Environmental Defence Systems Limited v Synergy Health Plc & Ors [2014] EWHC 1306 (IPEC) at [28]
[117] Eugen Sietz AG v KHS Corpoplast GmbH and Anr [2014] EWHC 14 (Ch) (15 January 2014)
[118] Idenix Pharmaceuticals Inc v Gilead Sciences Inc & Ors [2014] EWHC 3916 (Pat) (1 December 2014)

insufficiency and added matter – the full house! Arnold J found that the patent was indeed anticipated, obvious, insufficient and containing added matter. Further, proposed amendments were not allowable. However, had the patent been valid it would have been infringed – scant consolation to Idenix.

I could probably have prepared an entire paper based on this case, but will confine myself to the issue of insufficiency, which was dealt with in some detail.

Arnold J addressed the classic formulation of insufficiency, saying:

> "*Failure to enable the invention to be performed without undue burden is often referred to as "classical insufficiency" and failure to enable the invention to be performed over the whole scope of the claim is often referred to as "Biogen insufficiency" or "excessive claim", although these are aspects of the same objection and often fade into one another.*"[119]

Arnold J noted that he had reviewed the law that referred to classical insufficiency in *Sandvik v Kennametal*[120], and he had done the same for excessive claim breadth in *Medimmune v Novartis*[121]. He then summarised the position in the *Idenix* case as follows:

> "*For the reasons set out above, the court must undertake a two stage enquiry. The first stage is to determine whether the disclosure of the Patent, read in the light of the common general knowledge of the skilled team, makes it plausible that the invention will work across the scope of the claim. If the disclosure does make it plausible, the second stage is to consider whether the later evidence establishes that in fact the invention cannot be performed across the scope of the claim without undue burden. In some cases, it is convenient to divide the second stage into two, first considering whether the invention can be performed without undue burden at all and then whether the claim is of excessive breadth.*"[122]

There is, of course, considerable authority (*Halliburton v Smith*[123], *AHP v Novartis*[124], and other cases) to support the basic principle that a patent will be insufficient if the specification requires the skilled person to undertake a substantial research project in order to perform the invention.

In this case, for factual reasons set out in the judgment, Arnold J concluded that the disclosure of the patent, read in the light of the common general knowledge of the skilled team, did not make it plausible that the invention would work across the scope of the claims (whether as granted or as proposed to be amended). There was considerable argument and evidence on the question of whether the patent enabled the skilled team to perform the invention without undue burden. If Idenix's scientists

[119] Idenix Pharmaceuticals Inc v Gilead Sciences Inc & Ors [2014] EWHC 3916 (Pat) at [464]
[120] Sandvik Intellectual Property AB v Kennametal UK Limited and Anr [2011] EWHC 3311 (Pat)
[121] MedImmune Ltd v Novartis Pharmaceuticals UK Ltd [2011] EWHC 1699 (Pat) at [458]-[484]
[122] Idenix Pharmaceuticals Inc v Gilead Sciences Inc & Ors [2014] EWHC 3916 (Pat) at [467]
[123] Halliburton Energy Services Inc v Smith International (North Sea) Ltd [2006] EWCA Civ 1715 at [18]
[124] American Home Products Corp v Novartis Pharmaceuticals UK Ltd [2001] RPC 8 at [41]-[47]

had managed to do so, it was only after more than two and a half years of work. Gilead's scientists managed to do so more quickly, due to a combination of their skill and luck. The specification on its own neither enabled the skilled person to make the claimed compounds nor gave the skilled person any real assistance in doing so. Relying upon his common general knowledge, the skilled person might, with luck, or might not, if unlucky, after many months succeed in making the claimed compounds. That was way beyond what was acceptable for the purposes of sufficiency.

The judge concluded:

> "*Drawing these threads together, the conclusion I have reached is that the Patent does not enable the skilled person to make the claimed compounds without undue burden. The specification gives the skilled person no meaningful assistance, and so the skilled person has to rely upon his general knowledge. The skilled person would undertake a retrosynthetic analysis, and would be immediately confronted with the problem that his target compound contained a tertiary fluorine with a particular stereochemistry. He would appreciate that making such a compound would be difficult and challenging, and there would [be] a large number of potential routes to consider. The skilled person's prospects of success would depend on both skill and luck.*"[125]

Addressing the breadth of the claim, the judge identified Gilead's case as being that the patent does not enable the skilled team to perform the invention across the breadth of claim one without undue burden. He said:

> "*The basis for this contention is simple: even once the medicinal chemist has made one of the compounds, the virologist has to test it for anti-viral activity. There is no dispute that testing a compound for anti-*Flaviviridae *activity would be routine work which in itself would not be unduly burdensome. But the claim covers billions of compounds and the Patent gives the skilled team no clue as to where to start.*"[126]

Idenix's answer to this contention is that Gilead did not establish that any of the claimed compounds do not work. Accordingly, say Idenix, the invention can be performed across the breadth of the claims without undue burden, because the medicinal chemist can make the compounds without undue burden and the virologist can test them without undue burden.

Arnold J concluded that the patent does not suggest that all of the claimed compounds have an anti-viral activity.

> "*On the contrary, all it says is that they can be screened for such activity. Even if it is plausible that the claimed compounds do have such activity, it is clear from the evidence that they may turn out not to do so when tested. Accordingly I agree with Gilead that the patent does not enable the skilled team to perform the invention across the breadth of the claim without undue*

[125] Idenix Pharmaceuticals Inc v Gilead Sciences Inc & Ors [2014] EWHC 3916 (Pat) at [594]
[126] Idenix Pharmaceuticals Inc v Gilead Sciences Inc & Ors [2014] EWHC 3916 (Pat) at [596]

burden because it sets the skilled team a research project and claims the results."[127]

Earlier in the year, in ***Hospira v Genentech* (I)**[128], Hospira succeeded in a classical obviousness/sufficiency squeeze. Genentech's Swiss-form claim to the use of trastuzumab in a medicament related to the use of the following dosage schedule: 8mg/kg loading dose and subsequent doses of 6mg/kg on a three weekly schedule (which may be described as 8 + 6 q3w). Hospira alleged that the claim was obvious in light of an earlier US FDA label showing Herceptin administered on a different dosing regimen, 4 + 2 q1w. After considering the evidence, Birss J held:

"Having thought of the idea of three weekly dosing and approached a pharmacokinetics expert, the clinician would receive the expert's conclusion that there was no reason on pharmacokinetic grounds not to conduct the trial which would be supported by the detailed analysis described by Dr Earhart. The clinician would understand Dr Earhart's reasoning in general terms and would see that it supported three weekly dosing using doses in the relevant range. They would understand that nothing like an unequivocal assurance of success was being given but would have confidence in the reasoning given that the FDA had approved a label which indicated that there was a longer half life at higher doses and that a dose in the range contemplated could safely be administered. I find that the clinician in the team would go ahead and conduct the trial. They would treat a small number of metastatic breast cancer patients with a three weekly dosing regimen of trastuzumab. It would not be inventive to select 8 mg/kg as an initial dose and 6 mg/kg as a maintenance dose."[129]

Despite finding the claim obvious, Birss J considered Hospira's contention that if the claim was not obvious, then it was insufficient. He referred to the Court of Appeal's judgment in *Regeneron v Genentech*[130] as addressing the law relevant to sufficiency and said:

"[A]lthough proof that a medicine works for a particular therapeutic purpose is not required, the patent specification must show that the product has an effect on a disease process so as to make the claimed therapeutic effect plausible. The effect must be plausible to a person (or team) skilled in the art reading the patent with their common general knowledge."[131]

The patent did not contain any pharmacokinetic data from trials using the claimed regimen (only proposals for such a regimen), but an example did contain pharmacokinetic data from a 4 + 2 q1w study (i.e. the same regimen as that disclosed in the FDA label on which the obviousness challenge was based). Birss J held that if it would not be obvious to move from the prior art dosing regimen to the

[127] Idenix Pharmaceuticals Inc v Gilead Sciences Inc & Ors [2014] EWHC 3916 (Pat) at [598]
[128] Hospira UK Limited v Genentech [2014] EWHC 1094 (Pat)
[129] Hospira UK Limited v Genentech [2014] EWHC 1094 (Pat) at [117]
[130] Regeneron Pharmaceuticals Inc & Anr v Genetech Inc [2013] EWCA Civ 93, [2013] RPC 28
[131] Hospira UK Limited v Genentech [2014] EWHC 1094 (Pat) at [120]

claimed invention, then, based on the information in the patent read in the light of the common general knowledge, the skilled team would not conduct a clinical trial of the claimed three weekly dosing regimen. On that hypothesis the patent would not render the claimed effect plausible and the patent would be invalid for insufficiency. Despite this, he considered the extent to which the standard for plausibility differs from the standard for obviousness to be a "question for another day". Genentech's appeal of Birss J's decision is listed to be heard in mid-January.

3.4 **Added matter**

Perhaps the most significant decision in relation to added matter this year was in the case of ***AP Racing Limited v Alcon***[132], where the Court of Appeal reversed a decision of the IPEC that a patent for disc-brake callipers was invalid for added matter. The Court of Appeal stated that the judge had incorrectly concluded that the asymmetry in the claim integer that was accused of being added matter was not disclosed in the application as filed, although he agreed that a general asymmetry was implied and there was a specific embodiment described which came within the claims.

The patent relates to disc-brake callipers for motor vehicles and in particular racing cars.

Disc-brakes operate on a disc which rotates with the road wheels of the vehicle on a hub carried by the vehicle's chassis. The calliper is the body into which the brake pads are fitted and at which the brake pads can be activated to make contact with the disc. When so activated the pads slow down the disc and with it the road wheels. The patent involved the application of a peripheral stiffening band ("**PSB**"). It explains there may be at least one PSB extending about an outer lateral surface of the mounting side lift or there may be two PSBs. At first instance Judge Birss (as he then was) had found:

> "*A disclosure that something is asymmetric is a much broader concept than teaching that a thing has a particular shape. The fact that the shape is in fact asymmetric is necessary but is not sufficient to support the generalisation. The argument based on the figures suffers from the same difficulty".*[133]

Accordingly, although he had concluded that the peripheral stiffening bands disclosed in the application weren't necessarily asymmetrical, he concluded that when the patent was discussing asymmetry it was discussing the asymmetry of the body as a whole. It was not saying anything about the asymmetry of the individual PSBs. He doubted that the skilled person would analyse the document in the detail propounded by counsel, and concluded that without reading the patent the skilled person would not have derived from the application "*a concept at the same level of generality*" as the feature of claim 1.

[132] AP Racing Limited v Alcon Components Limited [2014] EWCA Civ 40 (28 January 2014)
[133] AP Racing Limited v Alcon Components Limited [2013] EWPCC 3 (5 February 2014) at [84]

Lord Justice Floyd gave judgment in the Court of Appeal. He reviewed the law relating to added matter, considering the traditional authorities, and decided that he did not agree with the finding of Judge Birss. He said:

> "*I do not agree. The skilled person would understand from the application as filed that the design of the PSBs, in particular the fact that they wrapped around corners of the calliper, was technically significant in imparting stiffness to the calliper. It is true to say that one advantage of adopting this configuration would be understood to be the saving of material elsewhere, but the skilled person would not understand that taking that step would be necessary. As the application explains at page 12, "the PSBs are configured to resist the bending moment generated during braking". That is a clear and independent disclosure of the technical significance of the configuration of the PSB."*[134]

The most significant statement of the law came in the following passage:

> "*In my judgment the judge's conclusion on this issue was wrong. Having correctly concluded that the description in the application of the hockey stick shaped PSBs was of something "necessarily asymmetrical" he should have gone on to ask himself whether there was any added disclosure in the granted specification. The description of the PSBs in claim 1 as "asymmetric" has to be read as part of the disclosure of the specification of the granted patent as a whole, taking account of the different function of the claims and the specification. When this is done the skilled person could understand that the patentee has drafted his claim so that it covers asymmetric PSBs generally. However I am not persuaded that the specification read as a whole discloses any configuration of PSB which is not disclosed in the application. The skilled person would understand from the granted patent, just as in the case of the application, that PSBs disclosed include those which follow a lateral and leading edge (and therefore are asymmetrical about the lateral axis). The skilled person would also understand that the PSBs are exemplified by the hockey stick shapes described in the specific embodiments. He or she would not, therefore, learn any new information about the invention".*[135]

It is quite clear from this judgment that the law does not prohibit the addition of claimed features which state in more general terms that which is described in the specification. It is the very same point which we saw in another context in *ASSIA v BT* above.

After having his knuckles rapped by the Court of Appeal from his time as IPEC judge, Mr Justice Birss, as he now is, considered the question of added matter in the case of ***Hospira v Genentech (II)***[136].

[134] AP Racing Limited v Alcon Components Limited [2014] EWCA Civ 40 at [36]
[135] AP Racing Limited v Alcon Components Limited [2014] EWCA Civ 40 at [30]
[136] Hospira UK Limited v Genentech Inc [2014] EWHC 3857 (Pat) (21 November 2014)

He identifies two lines of authority. The traditionally quoted cases on added matter are *Bonzel v Intervention*[137] and *Vector v Glatt*[138]. More recently the case of *European Central Bank v BSS*[139] has confirmed the general gist of the change of authority. These cases have given rise to the concept known as "intermediate generalisation" whereby, although seemingly based on an original disclosure, aspects of the claim cannot reasonably be said to have derived from that disclosure, and are consequently added matter for the purposes of patent law.

The other chain of authority, starting with *AC Edwards v Acme* in 1982[140] and culminating in the *AP Racing*[141] case in 2014, seems to show that, while it is true that a claim may cover a wider range of materials than are disclosed in the first example to the preferred embodiment, the amendment may not mean that the patent discloses new information.

Birss J notes that life is made more difficult because the EPO does not approach added matter in the same way as the English courts.

He notes that the *AC Edwards* and *AP Racing* cases are concerned with mechanical inventions in which a word or phrase has been used to identify or describe a structure in the application. In each of those cases the inevitable effect of using this new descriptive language is that the claim will not be limited to the particular arrangements described in the application. The claim will have a broader scope. But in each case the court found that no other construction or thing was disclosed by the patent in which this language appeared in the claim.

In *Hospira v Genentech* (II), before going on to consider the facts of the case, Birss J concludes:

> "*I can see that this result follows in cases about descriptive language like this. Plainly the law cannot be that any change in descriptive language will never add matter but these cases show that some kinds of change in descriptions do not. Of course there is no reason to limit this principle to mechanical inventions, it just comes up naturally in those cases. I have more difficulty applying that principle to a case in which the skilled reader knows that the art is empirical, that the disclosure is a form of recipe, and that the point of the exercise is to produce a material which has certain properties determined by carrying out tests on the material produced (e.g. stability).*"[142]

Accordingly, whilst specifically acknowledging that this is not really the case, Birss J appears to be indicating that mechanical cases may take a different path to pharmaceutical cases when it comes to added matter on the issue of intermediate generalisation.

[137] Bonzel v Intervention [1991] RPC 553
[138] Vector v Glatt [2007] EWCA Civ 805
[139] European Central Bank v DSS [2007] EWHC 600 (Pat)
[140] A.C. Edwards Ltd v Acme Signs & Displays Ltd [1992] RPC 131
[141] AP Racing Limited v Alcon Components Limited [2014] EWCA Civ 40 (28 January 2014)
[142] Hospira UK Limited v Genentech Inc [2014] EWHC 3857 (Pat) (21 November 2014) at [174]

As you have seen in other areas, it does appear that Mr Justice Birss is getting himself a little tied up in his attempts to rewrite or, at best, reorganise some of the pre-existing principles underpinning important aspects of patent law.

Notwithstanding the excessive length of the judgment overall, for a slightly more pithy interpretation of the underlying principles of added matter, Mr Justice Arnold in *Idenix v Gilead* merely said:

> "*The law with regard to added matter was explained by Lord Justice Jacob in Vector Corp v Glatt Air Techniques Ltd [2007] EWCA Civ 805, [2008] RPC 10 at [4]-[9]. The essential question is whether the skilled person or team would, upon reading the granted or amended patent, learn anything about the invention which he or they would not learn from the application or the unamended patent."*

I would respectfully suggest that that remains a straightforward and easily applicable test.

3.5 Patentable subject matter

There were a flurry of cases in this area a few years ago, but the principles have been largely established, and, for the time being, the number of cases has reduced significantly, particularly in the field of software patents.

Software

In ***Lantana v the Comptroller General of Patents***[143] the Court of Appeal upheld a decision of Mr Justice Birss dismissing an appeal against the Patent Office's refusal to grant a patent in accordance with section 1(2) of the 1977 Patents Act. The Court of Appeal, considering the critical question of technical contribution, approved its own previous judgment in *HTC v Apple*[144] where it gave guidance as to the answer to the question of whether an invention has made a technical contribution to the art.

Briefly summarising those findings, the position is as follows:

1. First, it is not possible to define a clear rule to determine whether or not a program is excluded and each case must be determined on its own facts.

2. The fact that improvements are made to the software programmed into the computer rather than hardware forming part of the computer does not make a difference. The analysis must be carried out as a matter of substance not form.

3. The exclusions operate cumulatively. So, for example, the invention in the *Gale*[145] case related to a new way of calculating a square root of a number with the aid of

[143] Lantana Limited v Comptroller General of Patents, Designs and Trade Marks [2014] EWCA Civ 1463 (13 November 2014)
[144] HTC Europe Co Ltd v Apple Inc [2013] EWCA Civ 451
[145] Gale's Application [1991] RPC 305 (CA)

a computer and that was not permissible. The incorporation of the program in a ROM did not alter its nature – it was still a computer program incorporating a mathematical method. Both are excluded matters.

4. It is helpful to ask what the invention contributes to the art as a matter of practical reality over and above the fact that it relates to a program for a computer. If the only contribution relies in excluded matter then it is not patentable.

5. Conversely it is also helpful to consider whether the invention may be regarded as solving a problem which is essentially technical and if that is so whether that problem lies inside or outside the computer.

In the *Lantana* case, the features of the invention were: firstly, a local datastore on a local computer including a list of documents located on a remote computer; secondly, the local computer being programmed to send an email to the remote computer specifying a file and its list of documents: and thirdly, the remote computer selecting the file specified in the email and generating an email by which it sends a copy of the file back to the local computer.

Birss J concluded that the second and third steps were not inventive. The transmission of data across the internet was part of the prior art. The Court of Appeal duly agreed. One aside of note was that Lantana sought to rely on a number of decisions of the European Patent Office. The Court of Appeal quite clearly stated that the decisions of the EPO provide only limited assistance to the court in determining whether the process adopted by the judge in this jurisdiction was flawed. The conclusion of the court was as follows:

> "*It is not the fact that the invention relates to a computer program that renders it un-patentable. The exclusion is not so worded. It is worded as a partial exclusion. The invention must make some technical contribution over and above that provided by the program itself, such as an improvement in the working of the computer. In this case there was no technical contribution outside the computer program. The transfer of data and recovery of the file by an automatic email were not inventive steps in themselves. Thus I conclude that the computer program does not relevantly operate as more than a program. Lantana may overcome the hurdle of achieving a novel and inventive step but it has not overcome the hurdle of being excluded matter under section 1(2) of the Patents Act 1977.*"[146]

Biotechnology

Patentable subject matter raises its head in another completely different sphere of activity in the case of *International Stem Cell Corporation v The Comptroller General of Patents*[147] – a decision of the Court of Justice of the European Union.

[146] Lantana Limited v Comptroller General of Patents, Designs and Trade Marks [2014] EWCA Civ 1463 at [53]
[147] International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks, Case C-364/13, CJEU, 18 December 2014

It is established in the Patent Act 1977 and its underlying European antecedents, that the use of human embryos for industrial or commercial purposes cannot give rise to a patentable invention.

ISCO submitted two applications for registration of national patents relating to the parthenogenetic activation of oocytes for the production of human embryonic stem cells, methods of producing synthetic cornea or corneal tissue which involve the isolation of stem cells from parthenogenetically activated oocytes and product by process claims to synthetic cornea or corneal tissue produced by these methods.

The hearing officer at the UKIPO refused to register the applications. The reasoning was that the inventions disclosed in the applications related to unfertilised human ova whose condition and further development had been stimulated by parthenogenesis and that such ova were capable of commencing the process of development of a human being just as an embryo created by fertilisation of an ovum can do so. This meant that, within the meaning of the CJEU's judgment in *Brüstle*[148], no patent should be granted. ISCO appealed claiming that the judgment in *Brüstle* intended only to exclude from patentability organisms capable of commencing the process of development which leads to a human being. It argued that the organisms such as those the subject of the applications for registration cannot undergo such a development process and consequently they should be capable of being patented. The Patents Court decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

> "*Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings, included in the terms "human embryos" in Article 6(2)(c) of Directive 98/44?*"

Noting that ISCO had amended its applications to exclude the prospect of the use of additional genetic manipulation, the CJEU then held:

> "*It is for the referring court to determine whether or not, in the light of knowledge which is sufficiently tried and tested by international medical science… human parthenotes, such as those which are the subject of the applications for registration in the case in the main proceedings, have the inherent capacity of developing into a human being.*
>
> *If the referring court were to find that those parthenotes do not have such a capacity, it should infer from this that they do not constitute "human embryos" within the meaning of Article 6(2)(c) of Directive 98/44.*
>
> *In view of the foregoing considerations, the answer to the question referred is that Article 6(2)(c) must be interpreted as meaning that an unfertilised human ovum whose division and further development have been stimulated by*

[148] *Brüstle* C-34/10, EU:C:2011:669

parthenogenesis does not constitute a "human embryo" within the meaning of that provision, if, in the light of current scientific knowledge, that ovum does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to determine."

For those many people who were appalled by the *Brüstle* judgment, this is a sound step in the right direction. This should help to stimulate considerable further research into stem cell treatments.

4 Technical Matters and Procedure

Non-designation

I am delighted that there should be one last hurrah for the seemingly never ending case of ***Virgin v Zodiac***.

I reported at length on this issue a couple of years ago, but the Court of Appeal has now had its say, so I will set out the background again partly because it is so incredible, and partly by way of revision.

This is the issue which has become known as the "non-designation point".

In short, in August 2002, Virgin filed an application under the Patent Convention Treaty. All available PCT contracting states were designated, including a GB national application and an EP (UK) designation through the EPO. The parent application entered the European regional phase on 1 March 2004.

On 23 April 2004, Virgin filed a divisional application at the EPO which ultimately became the patent which has been the subject matter of all the litigation. It is commonly known as the '908 patent. To create it, Virgin's patent attorneys used electronic form 1001E. On that form there is a box which was checked, corresponding to the statement "all states which are contracting states to the EPC at the time of filing this application are hereby designated". The box is pre-checked and applicants cannot uncheck it. Against a later box 6.1, is the statement "the applicant currently intends to pay designation fees for the following states". Virgin entered a list covering more than 20 member states of the EPC. GB was not included.

The form also contained a note to the effect that "re item 6.1: GB is expressly NOT designated in this application. Apart from GB, all other EPC contracting states which were designated in the parent application are designated in this application."

As the first instance judge, Floyd J, as he then was, put it:

"*The desire not to designate GB at all or to countermand immediately the mandatory designation, could scarcely have been clearer*".

In November 2004, the EPO issued a search report on the '908 application which included a reference to an intervening GB national application. As the judge put it,

such a reference would not have been necessary unless by this time the EPO was proceeding on the erroneous basis that GB was designated. When the application was published, in January 2005, the front page stated that all contracting states were designated. This was clearly not in conformance with the information in field 6.1 Form 1001E and the subsequent note on the form.

Nothing of use can be learnt from the payment of designation fees. These are capped at seven designations. 24 states were reported as designated on the published application and consequently it cannot be clear that a payment was intended for GB or not.

Back in the UK, the issue of double patenting raised its head. The UKIPO wrote to Virgin in relation to this issue. In October 2005, Virgin wrote to the EPO to withdraw the UK designation from the parent application. In November 2005, Virgin informed the UKIPO by letter that it had withdrawn the UK designation of the parent application and that it would withdraw the UK designation of the divisional prior to grant. Somewhere between then and August 2006, Virgin had a change of heart because at that point it submitted to the European Patent Office a request for accelerated prosecution of the divisional patent, 908, the patent in respect of which it had clearly indicated that GB was not to be designated, together with two sets of claims – one for all designated states and one for the UK only as a result of an intervening national publication.

In November 2008, Zodiac's German patent attorneys wrote to the EPO to request correction of the GB designation as "an obvious mistake". (The communication was in the name of Premium Aircraft Interiors Group Ltd, which at the time was a group company of Zodiac. Except where quoting from a judgment, I will use the name "Zodiac"). This communication was sent to the Opposition Division which replied informing Zodiac that the request for correction had been forwarded to the Examining Division which would "consider of its own motion, instigated by a letter from a third party, whether the decision should be corrected."

Immediately the EPO was delving into the realm of fiction. The Examining Division did not consider the issue "of its own motion" if it did so at all, it did so following a specific prompt by Zodiac's patent attorneys.

The Examining Division then produced a document expressing conclusions and presumably sent this to the Opposition Division at some time thereafter. It did not send the document to Zodiac. The Opposition Division communicated the contents of the document to Zodiac in April 2009.

The Examining Division effectively decided that it was not necessary to correct the decision with regard to the GB designation. It referred to "ambiguity" in Form 1001 which should have been clarified with the applicant but said that there was no "explicit and ambiguous withdrawal". It also claimed that designation is by payment, not by indication on Form 1001 and a designation fee for GB was paid.

In both respects it was, of course, completely wrong. There was no ambiguity on Form 1001 – Floyd J made that point quite clear. Secondly, designation is not by payment of fees. That cannot be the case when there is a cap at certain countries. There is no way of knowing from that payment alone which of the other potentially designated states were actually covered by the fees. In this case, on Form 1001 Virgin made it quite clear that GB was not intended to be paid for, excluding it from the list of countries at paragraph 6.1.

The Examining Division document, submitted to the Opposition Division but not Zodiac, makes reference to the principle of good faith, on the basis that having accepted the GB designation throughout the examination proceedings, it would be wrong to stop doing so at that stage. The document was signed by three patent examiners. It is not disputed that it was certainly an administrative, rather than a legal decision.

Zodiac duly appealed to the Technical Board of Appeal. It also raised the designation point in the context of ongoing opposition proceedings. After the operative part of its decision in June 2009, the Opposition Division stated that it "certainly regrets any adverse effect that might result for Zodiac or, more generally, for the public from the administrative mistake which occurred during the examination proceedings leading it to grant."

So there we have it. Everybody can see that a mistake was made. Floyd J saw it. The Opposition Division saw it. Zodiac certainly saw it and raised it in every conceivable venue. The matter made its way to the High Court where the case was heard by Floyd J. Zodiac's case was that EPO decisions are justiciable in the English courts under modern principles of private international law. This is because the EPO purports to grant domestic privately enforceable legal rights. Moreover, the nullity of the EPO's decision to grant flows through to the registration by the UKIPO of the '908 patent which is also of no effect. The court was being asked to do no more than to ensure that the formalities for a valid grant were properly observed.

Having provided that summary of the facts again, I will not delve into the legal reasoning for the first instance decision save as to repeat the key passage from Floyd J's judgment where he said:

> "*The restriction on the right to challenge the designation of the UK pursues the same legitimate aim as was in play in the* Lenzing *case. Not every decision in the grant procedure which may adversely affect the rights of an individual is capable of challenge: a line has to be drawn between those decisions which are to be capable of full challenge and those which are not, or which are simply to be subject to a review. The EPC as a whole has decided where those lines are to be drawn. The extent to which the designation of the UK may be challenged in proceedings before the EPO, namely by asking the appropriate division to review its decision, represents the agreement of the contracting states on where the line is to be drawn in that respect. I do not think that the inability to challenge the designation of the*

UK in the national court violates the defendant's Article 6 rights (under the Human Rights Act)."[149]

Inevitably, the matter proceeded to the Court of Appeal.[150]

In relation to the EPO opposition proceedings, the Court of Appeal found that Zodiac had no right to seek partial revocation of the patent in its opposition proceedings for non-designation of the UK designation. Further, as a non-party to the examination of the patent application, Zodiac had no *locus standi* to object to a grant which included the UK as a contracting state. The consequence was that the '908 patent was granted with a UK designation which had remained unaffected by anything in the opposition proceedings or by its subsequent amendment.

The Court of Appeal found that the effect of the grant of the '908 patent and its publication in the European Patent bulletin was that it obtained the legal status under section 77, of a patent granted on an application under the Patents Act. As such, the grounds upon which its validity could be put in issue in English proceedings were limited to those specified in section 74, which correspond to those contained in Articles 52 to 57 of the EPC. Section 74 was therefore, on its face, a complete answer to the admissibility of the defences based on non-designation and this was certainly the view of the Court of Appeal.

Lord Justice Patten concluded:

"Even if a right exists under domestic law to challenge the validity of a fraudulently granted UK patent, that arises.....as a substantive right under domestic law. In relation to the similarly granted European patent there is no asymmetry. The grant of the patent and its validity are governed by the terms of the EPC.....a combination of the provisions of sections 72 and 74 of the 1977 Act and the common law [mean that] a domestic court will not adjudicate upon the decisions of an international body such as the EPO."

The upshot of this, of course, is that administrative decisions of the EPO are incapable of judicial review. According to Mr Justice Floyd, endorsed by the Court of Appeal, the UK signed away the right to judicially review decisions of the EPO, conceding that the EPO itself was the only body capable of reviewing its own decisions. Bearing in mind that the EPO's own position is that only parties to the examination procedure, namely the EPO itself and the patentee, are privy to that process and capable of participating in it, third parties are excluded even from the meagre review system which the UK courts appear to believe is sufficient for proper administration of justice.

[149] Virgin Atlantic Airways Limited v Jet Airways (India) Limited and Ors [2012] EWHC 2153 (Pat) at [251]
[150] Virgin Atlantic Airways Ltd v Jet Airways (India) Ltd and Ors [2013] EWCA Civ 1713

This places the EPO above the law. A decision by the EPO, conceded by the EPO itself and found in judicial proceedings in the UK to have been an egregious mistake, is not capable of being judicially reviewed by the court, notwithstanding the enormously prejudicial consequences, and the fact that it gave rise to a patent – a privately enforceable right – which in turn prompted years of expensive litigation.

You will not be surprised to know that my sympathies were entirely with the Spanish Government when it sought to challenge the legality of the new proposed Unified Patent system, on the grounds that the EPO's decisions are incapable of judicial review. For my part, that is a blanket reason for the whole system needing to be stopped in its tracks. I said at the outset of this paper that it is my strongly held belief that Dr Thomas Fuller, latterly endorsed by the great Lord Denning, was entirely right. No-one and no thing should be above the law. It was, perhaps, inevitable that the self-serving processes of European institutions should generate an Advocate General's opinion which endorses the status quo, and confirms the supra-national and supra-legal status of the European Patent Office. Whilst I can see the benefits of the Unitary Patent system and the Unified Patents Court, it is impossible fully to support it, while this blatant lacuna remains open.

Burden of proof

In ***Andrew Cooke v Watermist Limited***[151] an IPO hearing officer was confronted with a very difficult situation when he did not find any of the evidence presented to him convincing. The case was a dispute over inventorship. He heard the evidence and cross-examination of the two contenders and concluded that they were both unreliable witnesses. He also heard the evidence of a third person, and although believing it to be reliable, did not consider that it contained sufficient information to enable him to make a decision between the competing claims. There was no documentary evidence of any note at all.

What he chose to do was to consider the burden of proof. That lay with the Claimant, to displace the *status quo* as regards to stated inventorship. He found that the Claimant had not satisfied the burden of proof, so he dismissed the claim.

The matter was appealed to the High Court and heard by Mr Justice Arnold. He found that in the circumstances, the hearing officer had correctly decided that he could not reach a decision on the basis of the evidence or the credibility of the witnesses. He had therefore acted correctly in reverting to deciding the case on the burden of proof, which lay with the Claimant, and he had therefore rightly decided that this burden had not been discharged.

This case brings back some bad memories of the long running litigation between Cinpres and Melea, all of which arose because a hearing officer failed to understand the proper nature of conditional evidence, and, in reaching the wrong conclusion, triggered many years of litigation, ultimately only resolved after a second visit to the Court of Appeal. I remain of the view that factual disputes of this nature are better

[151] Andrew Cooke v Watermist Limited BL O/275; Andrew Cooke v Watermist Limited [2014] EWHC 125 (Pat) (3 February 2014)

decided in Court, rather than before hearing officers, who are adept at deciding the technical issues of patentability, but less accustomed to deciding between rival witnesses of fact.

How threatening need a threat be?

I have already touched briefly on the case of ***FH Brundle v Perry***[152]. The Defendant was the proprietor of a patent relating to a fence bracket. He wrote a series of letters to the Claimant alleging infringement of his patent. The Claimant denied these allegations and bought a claim for groundless threats.

Judge Hacon, who, as we have seen, was at his most tolerant in this case, was called upon to decide whether a letter from Mr Perry constituted a threat. The letter included the following passages:

> *"It has now been brought to my attention that your Company has been selling a product of Betafence known as Nylofor 3D bracket that is used to install Nylofor fencing, for over at least five years, according to your Southampton office and you in fact still sell these products.*
>
> *This Nylofor product infringes my patent and I demand that you provide an Account of Profits of direct profit on [direct sales].*
>
> *I am legally entitled to a share of these profits whilst the Patent was in force and which is currently being restored to the register, as it had lapsed temporarily due to a Patent Office error in late 2011."*[153]

Mr Perry argued that although he had indicated his entitlement to recover damages, he had not made an actual threat of litigation. Judge Hacon did not agree. He said:

> *"It is not necessary for a claimant in a threats action to prove that the Defendant has in so many words said "I intend to issue proceedings against you for infringement …". It is sufficient if the defendant has asserted that he has legal rights in respect of intellectual property and that he intends, as against the claimant, to enforce those rights; the threat to do so may be veiled or covert, conditional or future."*[154]

Parallel UK and EPO proceedings: stay of UK appeal

A very interesting technical issue arose in the case of ***Samsung v Apple***[155]. At first instance the High Court held that two of Samsung's patents were invalid. This was then appealed. The Court of Appeal agreed to adjourn the appeal pending a decision

[152] F H Brundle v Richard Perry [2014] EWHC 475 (IPEC) (6 March 2014) and Brundle v F H Richard Perry [2014] EWHC 979 (IPEC) (2 April 2014)
[153] F H Brundle v Richard Perry [2014] EWHC 475 (IPEC) at [5]
[154] F H Brundle v Richard Perry [2014] EWHC 475 (IPEC) at [23]
[155] Samsung Electronics Co Ltd v Apple Retail Ltd & Anr [2013] EWHC 468 (Pat); Samsung Electronics Co Ltd v Apple Retail Ltd & Anr [2014] EWCA Civ 250 (11 March 2014)

of the European Patent Office in relation to an application by Samsung for central amendment of the patents.

Apple, which contested that application, also brought a counter application, the gist of which was to oblige Samsung to choose between the English appeal and the EPO amendment proceedings.

Referencing the Supreme Court decision in *Virgin v Zodiac*[156], the Court of Appeal dismissed Apple's application. Lord Justice Kitchin, giving judgment for the Court of Appeal, described Apple's application as follows:

> *"The relief which Apple sought on its application was, however, of a rather different kind. It sought an order that this appeal be struck out unless Samsung withdrew its central amendment applications, which it plainly has no intention of doing."*[157]

Noting that the central amendment procedure is efficient and takes relatively little time at the EPO, Lord Kitchin went on to conclude as follows:

> *"In these circumstances, it seemed to us we had to adjourn this appeal until the outcome of the central amendment applications is known. It was not suggested that an adjournment would in and of itself cause Apple any significant prejudice. Conversely, however, a refusal of the adjournment might have resulted in the appeal proceeding on what may turn out to have been a false basis, with all the consequential waste of costs and time that would entail.*
>
> *As for Apple's application, this fell to be dismissed because we do not believe it can be said at this stage that pursuit by Samsung of its central limitation applications necessarily means that these appeal proceedings constitute an abuse of the process of the Court. But as we make clear in our communication to the parties, this is entirely without prejudice to Apple's right to advance such submissions (and make such applications) as it may consider appropriate once the outcome of the central amendment applications is known."*[158]

What was clearly established in the *Virgin v Zodiac* case was that there are perfectly legitimate parallel channels of patent enforcement and litigation in the European system. It is however not possible for one to pay no heed to the other, particularly where decisions as to the amendment or potential invalidity of patents has a retrospective effect.

Disclosure to foreign lawyers

A potentially significant minor issue arose in the case of ***Wobben v Siemens***[159]. In patent proceedings, the claimant German company applied for permission to disclose

[156] Virgin Atlantic Airways Limited v Zodiac Seats UK Limited [2013] UKSC 46
[157] Samsung Electronics Co Ltd v Apple Retail Ltd & Anr [2014] EWCA Civ 250 at [40]
[158] Samsung Electronics Co Ltd v Apple Retail Ltd & Anr [2014] EWCA Civ 250 at [58]-[59]
[159] Wobben Properties GmbH v Siemens Plc [2014] EWHC 3173 (Pat) (2 October 2014)

to three of its German lawyers a product and process description prepared by the defendant for which a confidentiality club was required. The German lawyers had worked with Wobben for years in relation to patent matters, and instructed English lawyers on their behalf. They continued to advise substantially in relation to the action. Siemens argued that it was reasonable to expect Wobben to deal directly with English lawyers and did not want its confidential information being used in parallel German proceedings and other patent applications.

Wobben's application was granted. Mr Justice Mann held that the interests of Wobben and Siemens were finely balanced, but that as the PPD went to the heart of the infringement case, and the German lawyers were to be involved in advising on the claim, it would need to be disclosed to them so as not to be inappropriately disadvantageous.

Appropriately worded undertakings would, he said, be sufficient protection for safeguarding the information. The risk of subconscious use in German proceedings was not a weighty consideration. The presumption should be that respectable and responsible individuals in a respectable and responsible firm, in a well-established legal jurisdiction such as Germany, would comply with undertakings rather than deliberately breach them.

Employee compensation

Employee compensation cases have been thin on the ground, but (not so) hot on the heels of the last substantial case, the *Kelly* case[160], comes a new one in the shape of ***Shanks v Unilever***[161]. Shanks claimed to be the inventor of a set of biosensors for medical diagnostics which he claimed had been of "outstanding benefit". He had made an application to the UK IPO for an apportionment of profit in his favour pursuant to section 40 of the Patents Act. He was unhappy with the UKIPO's finding, and appealed to the High Court. Unilever argued for a reduction in the benefit figure to reflect tax and research and development costs. The case was heard by Arnold J, who dismissed Mr Shank's appeal and upheld the decision that the benefit achieved was not outstanding.

There were a number of important findings in the case. One was that the relevant benefit was the benefit obtained by the Unilever group as a whole, rather than the specific legal entity which had employed Mr Shanks.

This was a case in which Unilever did not exploit the patent itself, but profited from patent licences and assignments. That had the beneficial effect of making the financial benefit easier to quantify. However Arnold J noted that, in his view, the hearing officer had made an error in not taking into consideration that Unilever's size and resources allowed it to secure advantageous licensing deals and that Mr Shanks had not been effectively involved in the commercialisation of the patents.

[160] Kelly v GE Healthcare Ltd [2009] EWHC 181 (Pat), [2009] RPC 12
[161] Ian Alexander Shanks v Unilever Plc & Ors [2014] EWHC 1647 (Pat) (23 May 2014)

The judge agreed with Unilever that its tax position should be taken into consideration when calculating the benefit.

Arnold J said:

> *"Unilever challenge the hearing officer's conclusion … on a different basis. This is that the hearing officer wrongly failed to take account the critical role of Unilever's size and financial clout in extracting licence fees, particularly in circumstances where there was unchallenged evidence that the validity of the Shanks Patents was open to question. Counsel for Unilever submitted that this explained why most of the licensees had approached Unilever and why they were prepared to take licences at modest royalty rates in return for freedom to operate under the Shanks Patents.*
>
> *I accept this submission. So far as can be seen from his decision, the hearing officer limited his consideration to the skill, effort and money expended by Unilever in licensing the Shanks Patents and the risk and rate of return that this represented. I agree with Counsel for Unilever that it is clear that an important factor in Unilever's ability to extract licence fees was that fact that it could afford to bring proceedings for infringement and to pursue them to a conclusion."*[162]

Duration of proceedings in the UKIPO

Also in the ***Shanks v Unilever*** decision, in what the judge described as a "postscript" he said:

> *"It is clearly undesirable that a claim of this nature should take seven years to reach a first instance determination. The reasons for this were not explored before me, although it is clear that the interim decision and appeals were one factor, and I am not in a position to attribute blame. In future, however, the Intellectual Property Office should attempt to ensure that such claims are determined within a reasonable time of commencement".*[163]

I mention that in particular because of the last case which I am going to mention, ***Farrow Holdings v The Secretary of State for Defence***[164].

The appellant, Farrow Holdings, appealed against a hearing officer's decision[165] granting an application made by The Secretary of State for Defence for revocation of a patent on the grounds of invalidity. The patent related to a method for removing surface coatings from the hull of a boat, causing minimal damage. The patent had originally been held invalid due to lack of inventive step.

[162] Ian Alexander Shanks v Unilever Plc & Ors [2014] EWHC 1647 (Pat) at [108]-[109]
[163] Ian Alexander Shanks v Unilever Plc & Ors [2014] EWHC 1647 (Pat) at [124]
[164] Farrow Holdings Group Inc v Secretary of State for Defence [2014] EWHC 2047 (Pat) (27 June 2014)
[165] Secretary of State for Defence v Farrow Holdings Group, Inc. (Patent) [2013] UKIntelP o35313 (2 September 2013)

Mr Farrow was a litigant in person. He claimed that the hearing officer had failed to take important evidence into consideration in establishing whether a prejudice existed against the use of hot water. He also said there had been no proper cross examination of witnesses and was unhappy with the time pressure placed on the hearing by the hearing officer. He said that it was inappropriate that it was required to be finished within a day.

In his judgment Mr Justice Birss took the trouble to quote from the closing submission of Mr Farrow, the litigant in person, at the end of the case before the hearing officer. He said:

> *"I rest my case. I do not have anything else to say here. Do I want a recess? The answer here is no, I do not. I look at you, and I am that sort of guy. It is going to cost me to come in tomorrow. It is going to cost me accommodation. It is going to cost me all the way down the road. I will stay here until 5pm and I will answer your questions but I have nothing to say after today because it was my heart, my honesty and my belief."*[166]

Litigants in person always give us reasons to be cheerful!

The relevance of this case in relation to *Shanks v Unilever* is simply that the judge was once again critical of the length of time taken by UKIPO to deal with the case overall. In particular, he commented that it had, at one stage, taken UKIPO a year to publish a decision on an interim issue. Clearly, in the minds of our current patent judges, UKIPO's school report reads "must do better".

5 Summary and Conclusions

This has been a very active year of patent litigation. We may have lacked the blockbuster Supreme Court decisions of 2013, but there has been plenty of interest, not all of it positive.

Back in 2007 my equivalent paper was entitled "When is a patent not a patent?". The answer I gave at the end of the talk was "When it has been litigated in the UK Patents Courts". This was because, at that time, the patents courts judges were becoming notorious for invalidating patents. Their percentage pass rate for validity was very low, and they appeared to be ignoring even cogent expert evidence to find inventions obvious. The suggestion was that they had become "too clever for their own good".

Shortly afterwards, the House of Lords reached its decision in *Conor v Angiotech*[167]. After that, I commented that "the waters had receded from the earth" and the high water mark of obviousness was seen to be retreating. I have a slight fear that there are certain trends which are taking us back towards the bad old days of the UK being seen as an "anti-patent" jurisdiction.

[166] Farrow Holdings Group Inc v Secretary of State for Defence [2014] EWHC 2047 (Pat) at [9]
[167] Conor Medsystems Inc v Angiotech Pharmaceuticals Inc & Ors [2008] UK HL 49, [2008] RPC 28

What has happened this year to lead me toward that conclusion?

It is mainly the activity of the two main Patents Court judges. We have seen Birss J playing with well-known and established formulations, and in particular blurring the boundary between "could" and "would" in relation to the question of obviousness to try. I would not say that he is moving in the right direction.

Meanwhile, Arnold J appears to have fallen in love with the notion of poisonous priority, and an issue that was, only a few years ago, a mere side show, has become somewhat central to patent litigation in the UK. In fairness to Arnold J, this is partly prompted by some fairly extreme decisions from the European Patent Office, but it is an unwelcome trend as it is effectively a "trick" and to my mind does not have any place in a proper, mature, patent jurisdiction.

We need a system that is suitably fair to patentees and others alike. My next comment is often met with a sarcastic laugh, but it is firm in my view that patents which have been properly examined either in Munich or Newport, should start at least from the presumption that they are valid. My biggest criticism of the judges back in 2007, was that they appeared to be starting from the opposite position. Indeed, at a social occasion, the late Mr Justice Pumfrey actually said that if a patent got as far as being litigated in front of him, he tended to start from the view that it was probably invalid.

We must not get back into that mind-set. We have undoubtedly clever, and scientifically qualified, judges. That does not make them experts nor give them any particular insight into the mind-set of the person skilled in the art. They must be prepared to listen and learn.

It is probably clear from that last passage that neither Birss J nor Arnold J are in line for my "Judge of the Year" award!

Indeed, it has been something of a struggle this year. Absent any major decisions of great merit such as those emanating from the Supreme Court in 2013, I have been forced to look around for consistency or interest. As I have said previously, I do like it when new judges, not necessarily from the patents bar, find their way into our system. A few years ago I believe that the quality of judgments was improved when we saw an influx of judges of that nature, though they have mainly moved on now to the higher courts. However, in the interests of encouraging an honest and open approach, and because he has made a couple of significant contributions, I have decided to award, somewhat controversially, and possibly rather obscurely, the Judge of the Year award to Mr Justice Sales. In addition to making a couple of interesting and well thought through contributions to our *jurisprudence*, he also had the decency and honesty to admit when he had made a mistake, and to act on it appropriately.

We are told that, from October onwards, the listing office is behaving as though there were three full time Patents Court judges. We must therefore assume that an appointment will be made at some point in the first half of this year. Obviously this

always attracts interest and we very much look forward to seeing who joins the esteemed list of patent judges.

For each of the last three years I have made concluding remarks along the lines that, by this time next year we will know a lot more about the nature of the Unitary Patent system and the Unified Patents Court. In the year when I fail to say that, I expect there will be great progress, so perhaps this year I should not pass any comment. All I would say is that, when any new jurisdiction is established, it is important that it is placed properly in a constitutional framework. Since it is now clear, both from our own Court of Appeal and the Court of Justice of the European Union that the EPO is "above the law", I very much hope that those perfecting the Unitary Patent system will bear in mind the need to acknowledge that all institutions and individuals should be subject to the scrutiny of a valid legal system.

Gordon D. Harris
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