# AIPPI MEET

# DECEMBER 2018

# PATENT ROUND UP

# CHRISTMAS 2018


**ANDREW LYKIARDOPOULOS QC**

**8 NEW SQUARE**

**LINCOLN'S INN**


**10th DECEMBER 2018**

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**N.B. In all the following quotations from judgments the underlining has been added for emphasis and is not in the original judgments.**


**With many thanks to the team at Herbert Smith Freehills LLP who assisted in collating the cases.**

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## PATENTS COURT JUDGMENTS FOLLOWING TRIAL 2018

| CASE | ABOUT? | JUDGE | RESULT |
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| L'Oreal v RN Ventures<br><br>(5th Feb 2018) | ST Scheme case (including experiments)<br><br>Concerned electronic facial skin care devices | Henry Carr J | Valid and infringed |
| Cantel Medical v ARC Medical Design<br><br>(23rd Feb 2018) | Two patents (EP and UK) to a cover for a colonoscope shaft | Hacon HHJ | valid and infringed (as amended) |
| Anan Kasei v Molycorp Chemicals<br><br>(23rd April 2018) | Patent for vehicle exhausts (method for production of Ceric Oxide and catalyst for exhaust gas clarification) | Roger Wyand QC | Valid and infringed |
| Bose Corp v Freebit<br><br>(24th April 2018) | Patent for an improved earpiece "in ear" device. | Roger Wyand QC | Invalid (prior use/added matter) and not infringed |
| Philips v Asustek & HTC<br><br>(23 May 2018) | 1st trial of 3 trials for SEPs for UMTS, in particular for HSPA. | Arnold J | Valid and infringed |
| Liqwd Inc v L'Oreal | Patent concerning hair care products (method for | Birss J | Claim 11 (as amended) valid and infringed. |

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| (11 June 2018) | providing bleached hair) | | |
| Philips v Asustek & HTC<br><br>(10 July 2018) | 2nd trial of 3 trials for SEPs for UMTS, in particular for HSPA. | Arnold J | Invalid for obviousness |
| Philips v Asustek & HTC<br><br>(19 July 2018) | 3rd trial of 3 trials for SEPs for UMTS, in particular for HSPA. | Arnold J | Valid and infringed |
| Chugai v UCB<br><br>(24 August 2018) | Claim construction of a US patent for tocilizumab for rheumatoid arthritis | Birss J | Not infringed |
| Teva & Accord v Gilead<br><br>(18 September 2018) | SPC for tenofovir disoproxil with emtricitabine (covering Truvada used for HIV treatment). | Arnold J | SPC invalid |
| Glasswall v Clearswift Ltd<br><br>(28 September 2008) | Validity of a patent concerned with malware protection | David Stone | Invalidity attack dismissed. |
| Parainen Pearl Shipping v Kristian Gerhard Jebsen Skipsrederi AS<br><br>(11 October 2018) | DNI for use of a method of discharging a vessel based on doctrine of exhaustion or implied licence | Arnold J | Repair not manufacture; rights exhausted<br><br>No infringement |

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| Hospira v Cubist<br><br>(18 January 2018) | Method of purifying antibiotic daptomycin.<br><br>Held by Henry Carr J to be obvious | Kitchin LJ<br><br>(Lewison LJ agreeing) | Appeal dismissed |
| Sandoz & Hexal v Searle & Janssen Sicences<br><br>25 Jan 2018) | SPC for Darunavir marketed as Prezista (for HIV and AIDS) | Floyd LJ<br><br>(Kitchin LJ and Lewison LJ agreeing) | Preliminary view in favour of the Respondent,<br><br>Reference to the CJEU |
| Edwards LifeSciences v Boston Scientific<br><br>(28 March 2018) | Patents for heart valves.<br><br>Hacon HHJ held one patent invalid and one valid and infringed | Floyd LJ<br><br>(Kitchin LJ & McCombe LJ agreed) | Both appeals dismissed |
| Regeneron v Kymab<br><br>(28 March 2018) | Patents for production of human antibodies using transgenic mice.<br><br>Henry Carr J found infringement but the patents invalid | Kitchin LJ<br><br>(for the Court – Floyd LJ & Mccombe LJ) | Regeneron's appeal on validity allowed<br><br>Kymab's appeal on infringement dismissed. |
| Jushi v OCV Intellectual Capital<br><br>(19 June 2018) | Appeal from Hacon HHJ finding a patent for a glass fibre for reinforcing plastic to be valid and infringed. | Floyd LJ<br><br>(Kitchin LJ & Henderson LJ agreed) | Appeal dismissed |

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| AP Racing v Alcon<br><br>(21 June 2018) | Appeal from Hacon HHJ in an action concerning disc brak calipers.<br><br>The judge held one infringed and 6 did not. | Lewison LJ<br><br>(Lindblom LJ & Flaux LJ agreed) | Appeal dismissed |
| Glaxo v Vectura<br><br>(28 June 2018) | Appeal from a strike out of a claim for "Arrow relief" from Hacon HHJ | Floyd LJ<br><br>(Birss J agreed) | Appeal allowed |
| Curt Joa v Fameccanica<br><br>(30 July 2018) | Appeal from Hacon HHJ refusing a validating amendment for a patent concerned with diaper manufacture | Floyd LJ<br><br>(Patten LJ & Kitchin LJ agreed) | Appeal dismissed |
| Icescape v Ice-World<br><br>(10 Oct 2018) | Appeal from John Baldwin QC revoking a patent covering cooling members for ice rinks. | Kitchin LJ & Floyd LJ<br>(Longmore LJ agreed with both) | Appeal dismissed |
| SSH Communications v Sony<br><br>(11 Oct 2018) | Appeal from Roger Wyand QC revoking a patent concerned with communications in a data network. | Lord Kitchin<br><br>(Patten LJ & Floyd LJ agreed) | Appeal dismissed |
| Unwired Planet v Huawei<br><br>(23 Oct 2018) | Appeal from Birss J on whether UK Court can set global FRAND rates, correct application of FRAND injunctive relief and meaning of non-discrimination in | Lord Kitchin, Floyd LJ & Asplin LJ. | Appeal dismissed |

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|---|---|---|---|
| | FRAND context. | | |
| Warner Lambert v Generics | Appeal on plausibility and infringement of Swiss Form claims in respect of pregabalin | Lords Mance, Sumption, Reed, Hodge & Briggs | Appeal dismissed, cross-appeal allowed. |

## THE STARTER: ACTAVIS BEDS DOWN

### *Actavis v Lilly [2017] UKSC 48*

**Lord Neuberger:**

66. […] While the language of some or all of the questions may sometimes have to be adapted to apply more aptly to the specific facts of a particular case, the three reformulated questions are as follows:

    i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, ie the inventive concept revealed by the patent?

    ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?

    iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

    In order to establish infringement in a case where there is no literal infringement, a patentee would have to establish that the answer to the first two questions was "yes" and that the answer to the third question was "no"

### *Liqwd & Olaplex v L'Oreal – normal means purposive*

### *Birss J - 11 June 2018*

58 So far the judges of the Patents Court who have had the opportunity to express themselves on the point have unanimously held that the normal interpretation stage required by *Actavis* is the same as purposive construction (Arnold J in *Generics v Yeda [2017] EWHC 2629 (Pat)* , Richard Meade QC in *Fisher & Paykel v Resmed [2017] EWHC 2748* and Henry Carr J in *Illumina v Premaitha [2017] EWHC 2930 (Pat)* ). I agree for the reasons given by those judges. As Henry Carr J put it in paragraph 202 of *Illumina* , normal interpretation means purposive construction.

59 I will add two further observations. They are points which at least on one view of the issues in this case might have mattered but in the end did not. The first is about taking equivalents into account in the process of construction. One consequence of *Kirin-Amgen* was that account was taken of equivalents in the process of determining what the true purposive construction of the claim was. I will say only that I can see scope

for debate about whether, following *Actavis* , that sort of approach might or might not produce the same result at the normal interpretation stage as would have been arrived at following *Kirin Amgen* . In other words, construing a patent purposively to identify the normal interpretation in the manner described in those first instance decisions which I do agree with, may not be precisely the same as every nuance of the process of the determination of claim scope which was mandated by *Kirin-Amgen* prior to *Actavis* .

60 The second point is about validity and claim scope. One of the issues involves whether an amendment might extend the scope of protection and therefore be impermissible (or if it had been made already, invalid). This has caused me to think about the relationship between validity and the *Actavis* approach to claim scope (including the scope determined by the second stage of *Actavis* as well as the scope produced by the process of normal interpretation). I will say only that I can see room for arguing that for validity purposes some account ought to be taken of the wider scope.

[*For impact on novelty see for instance Arnold J in Generics, Synthon & Yeda [2017] EWHC 2629 at [159]-[167]]*

***Icescape Limited v Ice-World International – normal means purposive***

***Lord Kitchin and Floyd LJ – 10 October 2018***

***Lord Kitchin:***

59 It is, in my view, clear that this approach is markedly different from that which the courts in this country have adopted since *Catnic* . Any doubt about the matter is resolved by Lord Neuberger's judgment at [55] where he explained that Lord Hoffmann had effectively conflated the two issues into one single issue of construction. Lord Neuberger continued that he had considerable difficulties with the notion that there was a single conflated, or compound, issue and that, even if this notion were correct, that the issue was one of interpretation. In his view this was wrong in principle and could lead to error.

60 Lord Neuberger proceeded to elaborate (at [58]) the correct approach to issue (i). It is, he explained, a problem of interpretation to which the applicable principles are tolerably clear and were affirmed by Lord Hodge in *Wood v Capita Insurance Services Ltd [2017] UKSC 24, [2017] 2 WLR 1095* at [8] to [15]. But of course patents are different from contracts. Patents are addressed to all persons skilled in the art and describe and claim an invention for the purposes of securing a monopoly. […] Unlike a contract and as Lord Diplock emphasised in *Catnic* , a patent is a unilateral statement by the patentee, in words of his own choosing, addressed to persons skilled in the art, by which he informs them what he claims to be the essential features of his invention.

Indeed Lord Neuberger himself made clear at [54] that issue (i) must be considered through the eyes of the skilled addressee, and at [56] that issue (ii) involves not merely identifying what the words of the claim would mean in their context to the addressee (in other words, I interpolate, issue (i)), but also considering the extent to which the scope of protection should extend beyond that meaning. So I have no doubt that (despite Lord Neuberger's use of the term "literal" in considering issue (ii) and to which I will come in a moment) issue (i) involves purposive interpretation. I note this was also the view of Arnold J in *Mylan v Yeda [2017] EWHC 2629* (at [138]) and of Carr J in *Illumina Inc and ors v Premaitha Health Plc and anor [2017] EWHC 2930* at [201]. But I would add this: the question of equivalence is now addressed in issue (ii), as I will now explain.

61 Lord Neuberger considered issue (ii), namely what it is that makes a variant immaterial, from [59] to [65]. He thought that the three questions formulated by Hoffmann J in *Improver* were helpful but needed some elaboration and, particularly the second question, some reformulation.

62 The first *Improver* question, whether the variant has a material effect on the way the invention works, was addressed by Lord Neuberger at [60]. He thought this was generally satisfactory but the court must focus on "the problem underlying the invention", "the inventive core", or the "inventive concept". In effect the question is whether the variant achieves the same result in substantially the same way as the invention.

63 Lord Neuberger considered the second *Improver* question from [61] to [64]. He considered this was unsatisfactory because it imposed too high a burden on the patentee to ask whether it would have been obvious to the notional addressee that the variant would have no material effect on the way in which the invention worked, given that it required the addressee to figure out for himself whether the variant would work. The second question was better expressed as asking whether, on being told what the variant does, the notional addressee would consider it obvious that it achieved substantially the same result in substantially the same way as the invention. It should therefore be asked on the assumption that the notional addressee knows that the variant works to the extent that it actually does work. This question also applies to variants which rely on, or are based on, developments which have occurred since the priority date. Lord Neuberger left open the question whether or not the variant should not itself be inventive but found it hard to see why that alone should prevent the variant from infringing the original invention.

64 The third *Improver* question, namely whether the notional addressee would have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention, was considered by Lord Neuberger at [65]. He thought this was acceptable provided it was properly applied. Here he made four points:

i) Although "the language of the claim is important", consideration of this question does not exclude the specification of the patent and all the knowledge and expertise which the notional addressee is assumed to have.

ii) The fact that the language of the claim does not on any sensible reading cover the variant is certainly not enough to justify holding that the patentee does not satisfy the third question.

iii) It is appropriate to ask whether the component at issue is an "essential" part of the invention, but that that is not the same thing as asking if it is an "essential" part of the overall product or process of which the inventive concept is part. Here regard must be had to the inventive concept or the inventive core of the patent.

iv) When one is considering a variant which would have been obvious at the date of infringement rather than at the priority date, it is necessary to imbue the notional addressee with rather more information than he might have had at the priority date. Here Lord Neuberger had in mind the assumption that the notional addressee knows that the variant works.

***Floyd LJ:***

96 It is now clear from the Supreme Court's decision in *Actavis* that purposive construction forms but the first stage in the determination of the scope of protection conferred by the claims. In a sense, the first extreme referred to in Article 1 of the Protocol has been replaced by purposive construction, because it now represents the minimum protection afforded by the patent. There is a second, non-interpretative exercise which allows the patentee a degree of protection outside the normal, purposive meaning of the claims where the variant from the claim achieves substantially the same effect in substantially the same way.

97 It should not be thought, however, that the claims do not continue to have an important function. It is variants from the claim which have to achieve substantially the same effect in substantially same way as the invention. The claims remain the starting point for the subsequent analysis of variants. Although we may have edged closer to it, the new approach does not transgress the second of the outlawed approaches in the Protocol, which treats the claim merely as a somewhat vague guideline.

98 Although a number of issues remain unresolved, such as the approach the court must take to the scope of protection when considering validity as opposed to infringement, and the approach to inventive variants, the application of these new principles does not create any difficulty in the present case.

***Regeneron v Kymab –evidence for equivalents***

***Kitchin LJ – 28 March 2018***

90 […] We have considered the first issue, and have concluded as a matter of normal interpretation that the Kymab mice infringe. It follows that it is not necessary for us to consider the second issue. Had it been necessary, we would have been troubled by the suggestion that we could have approached this issue for the first time on this appeal. The case was not advanced on this basis before Henry Carr J. On balance we would have remitted the matter to him to consider the second *Actavis v Lilly* issue, had it been necessary for us to do so.

***Numerical ranges?***

***Jushi Group v OCV Intellectual Capital***

***Floyd LJ - 19 June 2018***

36 The principles applicable to the construction of numerical limits were recently reviewed by this court in *Smith & Nephew Plc v Convatec Technologies Inc [2015] R.P.C. 32* . Kitchin LJ (with whom Briggs and Christopher Clarke LJJ agreed) summarised them as follows at [38]:

"…the approach to be adopted to the interpretation of claims containing a numerical range is no different from that to be adopted in relation to any other claim. But certain points of particular relevance to claims of this kind do emerge from the authorities to which I have referred and which are worth emphasising. First, the scope of any such claim must be exactly the same whether one is considering infringement or validity. Secondly, there can be no justification for using rounding or any other kind of approximation to change the disclosure of the prior art or to modify the alleged infringement. Thirdly, the meaning and scope of a numerical range in a patent claim must be ascertained in light of the common general knowledge and in the context of the specification as a whole. Fourthly, it may be the case that, in light of the common general knowledge and the teaching of the specification, the skilled person would understand that the patentee has chosen to express the numerals in the claim to a particular but limited degree of precision and so intends the claim to include all values which fall within the claimed range when stated with the same degree of precision. Fifthly, whether that is so or not will depend upon all the circumstances including the number of decimal places or significant figures to which the numerals in the claim appear to have been expressed."

37 In any particular case, therefore, it is necessary to consider the relevant integer of the claim in the light of the disclosure of the patent, the common general knowledge and all other relevant circumstances. It is clear that the court was not laying down a rule of law as to how numerical ranges should be interpreted in all cases.

***Use of prosecution history?***

***L'Oreal v RN Ventures***

***Henry Carr J – 5 February 2018***

77 It should be emphasised that reference to the prosecution history is the exception, and not the rule. I understand why it was relied upon in the present case, although I have not accepted RN Ventures' submissions about it. Parties should think carefully in future

***Icescape v IceWorld***

***Lord Kitchin – 10 October 2018***

79 In my judgment this argument has no merit. It is impossible to determine whether the objection raised by the Examiner was a sound one or whether it was necessary to delete claim 7 to meet the objection. More importantly, it is impossible to discern in the correspondence any suggestion that Ice-World was surrendering an ability to argue that features D and E were inessential or that Ice-World was accepting that the scope of the claims did not extend to a system in which the feed and discharge manifolds were connected in parallel rather than in series. The correspondence falls well below the threshold set by the Supreme Court in *Actavis* . The contents of the file do not unambiguously resolve the point with which we have to deal as to the scope of protection conferred by claim 1 of the patent, and it would not be contrary to the public interest for the contents of the file to be ignored. In my view this is a very good illustration of why it is generally so unprofitable to explore the prosecution history.

## THE MAIN COURSE

## FRAND

***Unwired Planet v Huawei***

***Lord Kitchin (for the Court) – 23 October 2018***

### Ground 1 – Global licensing

52 We should say straight away that we accept without question that a UK SEP has limited territorial scope and that courts in this jurisdiction will generally only determine disputes concerning the infringement and validity of UK or EP UK patents. If a UK SEP is found valid and infringed, a UK court will only grant relief in respect of the infringement of that patent. As Aldous LJ explained in *Coflexip SA v Stolt Comex [2001] RPC 9* at [18], the injunction must equate to the statutory right given; a right which has been held to have been validly granted and infringed. So the court will only grant an injunction to restrain infringement of the SEP in issue in the proceedings. The same applies to a claim for damages: they will only be awarded for infringement of that SEP.

53 The position in relation to a FRAND undertaking is rather different, however. As we have seen, ETSI is the SSO for the EU but its standards are of international effect. So too, the FRAND undertaking given by a patent owner to ETSI in return for the incorporation into the standard of the technology protected by the patent is also of international effect. […]

54 But there is another side to the coin which needs some elaboration at this point. Just as implementers need protection, so too do the SEP owners. They are entitled to an appropriate reward for carrying out their research and development activities and for engaging with the standardisation process, and they must be able to prevent technology users from free-riding on their innovations. It is therefore important that implementers engage constructively in any FRAND negotiation and, where necessary, agree to submit to the outcome of an appropriate FRAND determination.

55 It therefore comes as no surprise to us that Huawei accepts, through counsel, that, outside the litigation process, SEP owners and implementers will often negotiate a licence which best suits their respective needs in accordance with FRAND principles and further, that this licence will often be global or at least cover a number of different territories. It may be wholly impractical for a SEP owner to seek to negotiate a licence of its patent rights country by country, just as it may be prohibitively expensive for it to seek to enforce those rights by litigating in each country in which they subsist. This latter point was accepted by Mr Cheng in the course of his evidence: he agreed that the costs of such litigation for UP would be impossibly high.

56 In our judgment these considerations point strongly to the conclusion that, depending on all the relevant circumstances, a global licence between a SEP owner and an implementer may be FRAND. Indeed, on the face of it, it is very hard to see how a

contrary view could be justified. Assuming such a licence is not discriminatory, it would be the product of two undertakings acting fairly and reasonably. What is more, it seems to us, at least as a matter of principle, that there may be circumstances in which it would not be fair and reasonable to expect a SEP owner to negotiate a licence or bring proceedings territory by territory and that in those circumstances *only* a global licence or at least a multi-territorial licence would be FRAND.

[…]

74 […] So we must now turn to the other criticisms of the judge's approach and the practical difficulties to which it is said to give rise.

[…]

79 In our judgment, these submissions confuse and elide two separate but related matters: first, the scope of these proceedings for patent infringement, and secondly, the scope and effect of the undertaking UP has given to ETSI. The only patent rights in issue in these proceedings have been SEPs that UP owns in this jurisdiction. The judge has found in the technical trials that two of those SEPs are valid and essential and it follows that Huawei's activities in this jurisdiction have amounted to an infringement of them. The judge has made no finding as to the validity or essentiality of any SEP in any other jurisdiction.

80 The next matter is the meaning and effect of the undertaking that UP has given to ETSI in relation to the SEPs in its patent portfolio, wherever those rights may be situated. This is a single undertaking, the construction, validity and enforcement of which are governed by French law. As we have explained, the judge decided, as he was entitled to decide, that this undertaking is enforceable by third party implementers and it requires a SEP owner to grant a licence to any such implementer under its SEPs on FRAND terms. One of the critical questions for the judge in this trial was what those FRAND terms were for a licence by UP to Huawei and, in particular, whether UP was required by its undertaking to grant to Huawei a licence under its SEPs territory by territory or whether it could meet its obligations to ETSI by offering to Huawei a worldwide licence. The judge decided this issue in favour of UP. In doing so he was not adjudicating on issues of infringement or validity concerning any foreign SEPs. Nor was he deciding what the appropriate relief for infringement of any foreign SEPs might be. He was simply determining the terms of the licence that UP was required to offer to Huawei pursuant to its undertaking to ETSI. It was then a matter for Huawei whether it was prepared to take that licence, and to do so in its full scope. It could not be compelled to do so, and if it chose not to, the only relief to which UP would be entitled would be relief for infringement of the two UK SEPs the judge had found to be valid and essential.

81 We therefore reject the submission that the judge has in some way usurped the right of foreign courts to decide issues of infringement and validity of patent rights subsisting in their respective territories, or of the appropriate relief to be granted if infringement is established. Similarly, we do not accept that the judge's approach pays insufficient heed to the principle of comity.

[…]

104 […] The judge was required to determine the meaning and effect of the FRAND undertaking which UP had given and Huawei was seeking to enforce. That is what he proceeded to do. He found that, having regard to the parties and in all the circumstances of this case, UP's undertaking to ETSI would be met by offering Huawei a global licence in respect of all of its SEPs on the terms he settled. We do not accept that this approach is likely to cause any problems of a kind with which commercial courts around the world are not familiar or which might impact upon the meaning and effect of the undertaking UP has given to ETSI. It is true that a court in one country will decide, as between the parties, whether a global or multi-territorial licence is FRAND but that is inevitable and we see nothing unfair about it, and it most certainly does not deprive a licensee from challenging the validity and essentiality of the SEPs in any jurisdiction where it may choose to do so.

[…]

121 We have come to a different conclusion from that of the judge on the question whether there can be only one set of FRAND terms for any given set of circumstances. Patent licences are complex and, having regard to the commercial priorities of the participating undertakings and the experience and preferences of the individuals involved, may be structured in different ways in terms of, for example, the particular contracting parties, the rights to be included in the licence, the geographical scope of the licence, the products to be licensed, royalty rates and how they are to be assessed, and payment terms. Further, concepts such as fairness and reasonableness do not sit easily with such a rigid approach. In our judgment it is unreal to suggest that two parties, acting fairly and reasonably, will necessarily arrive at precisely the same set of licence terms as two other parties, also acting fairly and reasonably and faced with the same set of circumstances. To the contrary, the reality is that a number of sets of terms may all be fair and reasonable in a given set of circumstances.

125 In our judgment this is more of a theoretical problem than a real one. If the SEP owner and prospective licensee cannot agree upon the terms and royalty rates of a FRAND licence and the question of what is FRAND falls to be decided by a tribunal, whether a court or an arbitrator, then the tribunal will normally declare one set of terms as FRAND and that will be the set of terms the SEP owner must offer to the prospective licensee. If, however, the outcome of the proceedings is that two different sets of terms are each found to be FRAND then in our judgment the SEP owner will satisfy its obligation to ETSI if it offers either one of them. It will in that way be offering an irrevocable licence of its SEPs on FRAND terms.

126 Counsel for Huawei submit this outcome will create injustice in a case where, as here, the real difference between the parties is whether a global or a national licence is FRAND. If both are FRAND then, counsel continue, the tribunal should limit its consideration to the particular jurisdiction where it is situated. Further, it would be unjust for the SEP owner to be given the opportunity to use the threat of a national injunction to require the prospective licensee to take the global licence for this would amount to a form of international coercion.

127 We disagree. For the reasons we have given earlier in this judgment, this submission involves an elision of two separate but related matters: first the relief to which a SEP

owner is entitled if it establishes infringement of its monopoly right, and secondly, what the SEP owner must do to satisfy the undertaking it has given to ETSI. Moreover, the term coercion is used in this context to imply improper duress or compulsion. But, if both the global and the national licence were FRAND, the SEP owner would be guilty of no such behaviour by offering the global licence. That global licence would, on this hypothesis, be fair, reasonable and non-discriminatory. It would then be a matter for the prospective licensee whether to accept it.

**Ground 2 - Non-discrimination**

195 On its face, the difficulty with the "general" non-discrimination approach is that it operates in an asymmetric fashion. On this approach, once a benchmark rate is identified, the SEP owner is precluded by the undertaking from attempting to secure higher rates from licensees, but there is nothing to prevent it from granting licences at lower rates. A proposed licensee who points to a prior comparable licence granted at a lower rate is not able to force down the rate on offer to match this lower rate.

196 The "general" approach does, however, gain support from the object and purpose of the FRAND undertaking. These are to ensure that the SEP owner is not able to "hold-up" implementation by demanding more than its patent or patent portfolio is worth. The undertaking therefore requires it to offer to license the portfolio on terms which reflect the proper valuation of the portfolio, and to offer those terms generally (i.e. in a non-discriminatory manner) to all implementers seeking a licence. The objective of the undertaking is not to level down the royalty to a point where it no longer represents a fair return for the SEP owner's portfolio, or to remove its discretion to agree lower royalty rates if it chooses to do so. It is inherently unlikely that a proposal presented in such terms would have gained support from innovators.

[…]

198 In that connection we consider that a non-discrimination rule has the potential to harm the technological development of standards if it has the effect of compelling the SEP owner to accept a level of compensation for the use of its invention which does not reflect the value of the licensed technology. It is true that it is not compelled to grant any licence, and may hold out for a return which is commensurate with the value of the portfolio, but such an approach is not always commercially possible. The undertaking should be construed in a way which strikes a proper balance between a fair return to the SEP owner and universal access to the technology without threat of injunction. We consider that a hard-edged approach is excessively strict, and fails to achieve that balance, whereas the general approach achieves the objective of the undertaking by making the technology accessible to all licensees at a fair price.

199 It is difficult to identify any underlying purpose which would support the hard-edged discrimination rule contended for by Huawei. Its effect is akin to the insertion of the rejected "most favoured licensee" clause in the FRAND undertaking. It is of course possible that those behind formulating the undertaking thought that the same effect as a most favoured licensee term could be achieved by the "ND" limb of FRAND, but we consider that it is far more likely that the industry would have regarded such a term as inconsistent with the overall objective of the undertaking.

200 Huawei is correct that the potential exists for discrimination below the benchmark rate. Such discrimination is not, however, without the potential for redress through the application of competition law. We can see no reason why the authors of the undertaking should have been concerned to constrain the ability of the SEP owner to grant licences at lower rates if these cause no competitive harm.

201 Whilst Huawei is right to point out that the effect of the general approach is to limit the impact of the non-discrimination limb of the undertaking, it may also fairly be said that the hard-edged approach gives unwarranted primacy to that limb, in that a licence granted at a lower rate, no matter how low, will always trump the benchmark fair and reasonable rate.

204 It is true that the parties who seek to negotiate a licence on FRAND terms will not have the benefit of a court-determined benchmark rate. We do not see this as a real practical difficulty with the judge's approach, however. If the correct approach in law is as we have determined, then it will mean that the focus of the negotiations will be on determining a fair and reasonable rate for the portfolio, an exercise which is familiar in the patent licensing world. It is true that this will not be as simple as merely identifying the lowest rate which the SEP owner has offered in the past, but that is a consequence of adopting an approach which does not abandon the principle of fair reward to the SEP owner.

## Ground 3 – Huawei v ZTE and proportionality

240 The CJEU continued (at [53]) that, in these circumstances, a refusal to grant licences on FRAND terms might in principle be raised by way of defence to an injunction or for the recall of products but the difficulty came where the parties could not agree what FRAND terms were. This discussion is followed by these two paragraphs:

> "55. In such a situation, in order to prevent an action for a prohibitory injunction or for the recall of products from being regarded as abusive, the proprietor of an SEP must comply with conditions which seek to ensure a fair balance between the interests concerned.
>
> 56. In this connection, due account must be taken of the specific legal and factual circumstances in the case (see, to that effect, judgment in *Post Danmark* , C-209/10, EU:C:2012:172, paragraph 26 and the case-law cited)."

242 Then, at paragraph [60], the CJEU stated the proprietor of a SEP cannot, without infringing Article 102 TFEU , bring an action against an alleged infringer seeking an injunction or the recall of products without notice or prior consultation with the alleged infringer, and that is so even if the SEP has already been used by the alleged infringer:

> "60. Accordingly, the proprietor of an SEP which considers that that SEP is the subject of an infringement cannot, without infringing Article 102 TFEU , bring an action for a prohibitory injunction or for the recall of products against the alleged infringer

without notice or prior consultation with the alleged infringer, even if the SEP has already been used by the alleged infringer."

243 The CJEU continued that, prior to proceedings, it is thus for the proprietor of the SEP, first, to:

"61. … alert the alleged infringer of the infringement complained about by designating that SEP and specifying the way in which it has been infringed."

244 Secondly, after the alleged infringer has expressed a willingness to conclude a licensing agreement on FRAND terms, it is for the proprietor of the SEP to:

"63. … present to that alleged infringer a specific, written offer for a licence on FRAND terms, in accordance with the undertaking given to the standardisation body, specifying, in particular, the amount of the royalty and the way in which that royalty is to be calculated."

245 Then, it is for the alleged infringer to:

"65. … respond to that offer, in accordance with recognised commercial practices in the field and in good faith, a point which must be established on the basis of objective factors and which implies, in particular, that there are no delaying tactics."

246 The sanction upon the alleged infringer if it fails to respond appropriately is explained by the CJEU at [66]. If it does not accept the offer which has been made to it, it may rely upon the abusive behaviour of an action for an injunction or for the recall of products *only* if it has submitted to the proprietor of the SEP in question, promptly and in writing, a specific counter-offer that corresponds to FRAND terms.

247 A further obligation is imposed on the alleged infringer at [67]. Where that undertaking is using the teaching of the SEP before the conclusion of a licence, it is for it, from the point that its counter-offer is rejected, to provide appropriate security in accordance with recognised commercial practices in the field.

248 Two other points should be mentioned at this stage. First, if no agreement is reached after the counter-offer, the parties may request that the amount of the royalty be determined by an independent third party without delay (see at [68]). Secondly, an alleged infringer cannot be criticised for challenging, in parallel to the negotiations of the grant of a licence, the validity or the essentiality of the SEPs in issue, or for reserving the right to do so in the future (see at [69]).

249 The conclusion of the CJEU on these points is then set out at [71] which we should set out in full:

"71. […] Article 102 TFEU must be interpreted as meaning that the proprietor of an SEP, which has given an irrevocable undertaking to a standardisation body to grant a licence to third parties on FRAND

terms, does not abuse its dominant position, within the meaning of Article 102 TFEU , by bringing an action for infringement seeking an injunction prohibiting the infringement of its patent or seeking the recall of products for the manufacture of which that patent has been used, as long as:

– prior to bringing that action, the proprietor has, first, alerted the alleged infringer of the infringement complained about by designating that patent and specifying the way in which it has been infringed, and, secondly, after the alleged infringer has expressed its willingness to conclude a licensing agreement on FRAND terms, presented to that infringer a specific, written offer for a licence on such terms, specifying, in particular, the royalty and the way in which it is to be calculated, and

– where the alleged infringer continues to use the patent in question, the alleged infringer has not diligently responded to that offer, in accordance with recognised commercial practices in the field and in good faith, this being a matter which must be established on the basis of objective factors and which implies, in particular, that there are no delaying tactics."

[…]

269 We have come to the firm conclusion that the CJEU was not laying down mandatory conditions at [70] of its judgment such that non-compliance will render the proceedings a breach of Article 102 TFEU and that the judge's interpretation of the CJEU's judgment is in this respect entirely correct.

***OTHER FRAND CASES:***

***Conversant v Huawei & ZTE [2018] EWHC 1216***
***Henry Car J - 8 May 2018 :***

Application before Henry Carr J to challenge jurisdiction on a claim (on the grounds that the claims are in substance claims for infringement of foreign patents whose validity is in dispute) or decline to exercise jurisdiction on the grounds of *forum non conveniens,* particularly in light of proceedings in China.

Henry Carr J held that the UK had jurisdiction to hear the case and that the case should continue in this jurisdiction. The Judge expressed the view that Birss J was correct in *Unwired Planet.* The appeal has been heard and judgment on appeal pending.

***Apple v Qualcomm [2018] EWHC 1188***
***Morgan J – 22 May 2018***

The claim was brought by Apple against Qualcomm (UK) Ltd (D1) that D1 was in breach of contract due to the fact that as a member of ETSI it was required to offer a FRAND licence under certain Qualcomm patents. Claims were also made against Qualcomm Inc. (D2) that 5 UK patents were invalid or not essential and that D2's rights in all of its EP patents (including the 5 UK patents in issue) were exhausted. Finally, claims were made against D2 that it had abused its dominant position and breached the ETSI IPR policy.

Qualcomm applied for an Order striking out or obtaining summary judgment on the claim against D1 on the basis that it was not the SEP owner. Proper service and jurisdiction over D2 was also disputed.

The Court considered the meaning of the ETSI undertaking and held it only applies to owners of SEPs (and not to corporate groups generally). Accordingly, summary judgment was granted to D1 on the claim against it.

As regards D2, the claims relating to the 5 UK SEPs were validly served in the UK. For the claims for which service out was required, the Court considered the various gateways. Further evidence was required for Gateway 9. The Court held in the interim that the UK was clearly and distinctly the proper forum for the claim for breach of Art. 102 TFEU, notwithstanding the fact that there were similar proceedings in the US.

## THE DESSERT

## Plausibility and infringement of Swiss Form claims

***Warner-Lambert v Generics (t/a Mylan)***
***Lord Mance, Lord Sumption, Lord Reed, Lord Hodge & Lord Briggs***
***14 November 2018***

***Plausibility***

***Lord Sumption, Lord Reed and Lord Briggs***

1. These proceedings raise, for the first time in the courts of the United Kingdom, the question how the concepts of sufficiency and infringement are to be applied to a patent relating to a specified medical use of a known pharmaceutical compound.

2. […] Swiss-form patents were not product patents, but purpose-limited process patents. They surmounted both obstacles because the invention is identified as neither a product nor a method of treatment but a manufacturing process for a novel purpose.

3. […] Once these changes came into effect, in 2011, Swiss-form patents ceased to be issued by the European Patent Office. EPC 2000 patents give rise to difficulties of their own, some of which are very similar. But this appeal is not concerned with them.

[…]

19 Lord Mance has expressed the view that sufficiency is a rule of judge-made law. It would I think be more exact to say that it is a statutory rule, which is fundamental to the public interest that justifies the issue of the patent. The contribution of judges has been to work out principles on which it can be applied to Swiss-form patents. Section 14 of the Patents Act and the corresponding provisions of the EPC assume that an invention will be sufficiently disclosed if the specification enables it to be "performed". In the case of a patent for a new product or process, that assumption is almost always correct. The skilled person will discover that it works by replicating it in accordance with the specification. But the assumption is not correct in the case of a second use patent. The invention is not the compound or the process of its manufacture. The skilled person already knows how to make the product from the prior art disclosed in the original patent. The invention consists in the new purpose for which the product is to be manufactured. If sections 14(3) and 72(1)(c) are read literally and as an exhaustive statement of the requirement of sufficiency, all that needs to be disclosed is the new purpose, which is enough to enable it to be administered to a patient suffering from the relevant condition. The skilled person does not need to know how or why the invention works in order to replicate it. The result would be that the knowledge which made the identification of the new purpose inventive need not be disclosed at all.

20 The main problem about this result is that it would enable a patent to be obtained on a wholly speculative basis. […] The patentee must disclose some reason for regarding this assertion as "plausible".

[…]

23 The concept of plausibility originates in the case law of the EPO as a response to over-broad claims, in particular claims to whole classes of chemical compounds supported by a description which fails to show which compounds can be expected to work. The Technical Board of Appeal treats the condition of sufficiency under EPC article 83 as satisfied if it is possible to work the invention across the scope of the claim from the information in the specification, interpreted in the light of common general knowledge at the priority date.

[…]

26 The answer to this anomaly in the case of Swiss-form patents was supplied by a series of decisions in which the EPO Technical Board of Appeal held that there was to be implied into a purpose-limited claim an assertion of efficacy for the designated purpose, and that this was an intrinsic technical feature of the claim.

[…]

35 All of these judgments deal with highly fact-specific issues arising from objections or potential objections on the ground of insufficiency. When reading them, it is important not to miss the wood for the trees. The fundamental principle which they illustrate is that the patentee cannot claim a monopoly of a new use for an existing compound unless he not only makes but discloses a contribution to the art. None of them casts doubt on the proposition that the disclosure in the patent must demonstrate in the light of the common general knowledge at the priority date that the claimed therapeutic effect is plausible. On the contrary, they affirm it: see *ALLERGAN* at paras 26, 37, and *BRISTOL* at para 3.2.

36 The Court of Appeal's statement of the effect of the plausibility test has already been quoted (para 20 above). They considered that the threshold was not only low, but that the test could be satisfied by a "prediction … based on the slimmest of evidence" or one based on material which was "manifestly incomplete". Consistently with that approach, they considered (paras 40, 130) that the Board's observations in *SALK* laid down no general principle. I respectfully disagree. The principle is that the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true. Plausibility is not a distinct condition of validity with a life of its own, but a standard against which that must be demonstrated. Its adoption is a mitigation of the principle in favour of patentability. It reflects the practical difficulty of demonstrating therapeutic efficacy to any higher standard at the stage when the patent application must in practice be made. The test is relatively undemanding. But it cannot be deprived of all meaning or reduced, as Floyd LJ's statement does, to little more than a test of good faith. Indeed, if the threshold were as low as he suggests, it would be unlikely to serve even the limited purpose that he assigns to it of barring speculative or armchair claims.

37 Plausibility is not a term of art, and its content is inevitably influenced by the legal context. In the present context, the following points should be made. First, the proposition that a product is efficacious for the treatment of a given condition must be plausible. Second, it is not made plausible by a bare assertion to that effect, and the disclosure of a mere possibility that it will work is no better than a bare assertion. As Lord Hoffmann observed in *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc [2008] RPC 28* , para 28, "it is hard to see how the notion that something is worth trying or might have some effect can be described as an invention in respect of which anyone would be entitled to a monopoly". But, third, the claimed therapeutic effect may well be rendered plausible by a specification showing that something was worth trying for a reason, ie not just because there was an abstract possibility that it would work but because reasonable scientific grounds were disclosed for expecting that it might well work. The disclosure of those grounds marks the difference between a speculation and a contribution to the art. This is in substance what the Technical Board of Appeal has held in the context of article 56 , when addressing the sufficiency of disclosure made in support of claims extending beyond the teaching of the patent. In my opinion, there is no reason to apply a lower standard of plausibility when the sufficiency of disclosure arises in the context of EPC articles 83 and 84 and their analogues in section 14 of the Patents Act . In both contexts, the test has the same purpose. Fourth, although the disclosure need not definitively prove the assertion that the product works for the designated purpose, there must be something that would cause the skilled person to think that there was a reasonable prospect that the assertion would prove to be true. Fifth, that reasonable prospect must be based on what the TBA in *SALK* (para 9) called "a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se." Sixth, in *SALK* , this point was made in the context of experimental data. But the effect on the disease process need not necessarily be demonstrated by experimental data. It can be demonstrated by *a priori* reasoning. For example, and it is no more than an example, the specification may point to some property of the product which would lead the skilled person to expect that it might well produce the claimed therapeutic effect; or to some unifying principle that relates the product or the proposed use to something else which would suggest as much to the skilled person. Seventh, sufficiency is a characteristic of the disclosure, and these matters must appear from the patent. The disclosure may be supplemented or explained by the common general knowledge of the skilled person. But it is not enough that the patentee can prove that the product can reasonably be expected to work in the designated use, if the skilled person would not derive this from the teaching of the patent.

[…]

39 The first argument is that whatever standard of plausibility is applied, the Court of Appeal were wrong to say that it had to be demonstrated across the whole scope of the claim. In my opinion, they were not wrong. As I have said, plausibility is not a distinct condition of validity, but one element in the test of sufficiency. As such, its application is governed by the same principles which apply to sufficiency generally. In a case such as this, where the claim is said to exceed the disclosed contribution to the art, it is of the essence that the specification must justify the full extent of the claim to the requisite standard. Where a feature of the claim is an assertion of therapeutic efficacy for a given condition, a monopoly is being claimed for the

process of manufacturing the compound for the treatment of that condition. This does not mean that it must work for all patients suffering from that condition, or work on every occasion when it is applied by way of treatment. But it does mean that where the condition identified embraces a number of different pathologies, and the claim is construed as asserting the efficacy of the product for each of them, the assertion must be plausible in relation to them all.

[….]

40 […] This does not mean that subsequent data is never admissible in a dispute about sufficiency, but the purpose for which it is admitted is strictly limited. Where the asserted therapeutic effect is plausible in the light of the disclosure in the patent, subsequent data may sometimes be admissible either to confirm that or else to refute a challenger's contention that it does not actually work: see, for example, *ASTRAZENECA/Omeprazole Na* (T 1677/11) (27 November 2012, unpublished), *MERCK, SHARP & DOHME/Pharmaceutical nanoparticulate composition of a Tachykinin receptor antagonist* (T 0210/11) (17 July 2014, unpublished). But it cannot be a substitute for sufficient disclosure in the specification. As the EPO Technical Board of Appeal observed in *JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE/Growth differentiation factor-9* (T 1329/04) [2006] EPOR 8 at para 12, (cited above), it cannot be a substitute for sufficient disclosure in the specification.

[…]

48 An appellate court should not normally interfere with conclusions of a trial judge which depend on his evaluation of a substantial body of expert evidence: see*Biogen Inc v Medeva Plc [1997] RPC 1* , 50 (Lord Hoffmann). I consider, however, that Actavis and Mylan are entitled to succeed on their cross-appeal, not because there was anything wrong with the judge's findings, but because those findings do not support his conclusion that the specification makes it plausible to predict that pregabalin will be efficacious for treating neuropathic pain. The question, it must be remembered, is not whether it is plausible but whether the specification discloses something that would make it so in the eyes of the skilled person.

49 The starting point was pointed out by the judge himself (para 255) in the context of the challenge based on obviousness. Because the only evidence of therapeutic efficacy presented in the specification is the results of the four animal models, the skilled person would understand that the patentee was relying on these as being predictive of efficacy. Those results were, however, predictive only of efficacy for inflammatory pain. The specification does not in terms claim more than this. No data are presented for the two recognised models of neuropathic pain, the Bennett model and the Kim and Chung model. There is no mention of central sensitisation, or indeed of any unifying principle that might embrace any condition other than inflammatory pain. This is an unpromising basis for a submission that there is a unifying principle which enables any kind of conclusion about efficacy for neuropathic pain to be derived from results of the animal models.

50 The judge's analysis of the implications for peripheral neuropathic pain of the data presented in the specification was based entirely on the common general knowledge

that central sensitisation was "involved" in both inflammatory and peripheral neuropathic pain.

[…]

52 More generally, it cannot in my view be enough to justify a monopoly that it is "possible" a priori that a drug which was effective for inflammatory pain would also be effective for neuropathic pain, in the absence of any reason to suppose that the possibility had some scientific basis or that it was more than speculative. Everything is possible that is not impossible, but "not impossible" is very far from being an acceptable test for sufficiency. Plausibility may be easy to demonstrate, but it calls for more than that.

***Lord Hodge – plausibility dissent***

180 Where I differ from Lord Sumption is that, in agreement with Lord Mance, who has analysed the three cases of *ALLERGAN* , *IPSEN* and *BRISTOL MYERS SQUIBB* , I do not interpret those principles as requiring the patentee to demonstrate within its patent a prima facie case of therapeutic efficacy.

181 In my view the recent decisions of the Board (a) require that the therapeutic effect of the medication appears plausible from the data in the patent interpreted in the light of the common general knowledge, (b) do not require that the patent discloses experimental evidence to demonstrate that plausibility unless there is an allegation, supported by sufficient evidence, that the invention does not work, but (c) allow the plausibility to be reinforced by considering evidence which post-dates the patent (although later-published data are not admissible if they alone render the therapeutic effect plausible), (d) take account of the ease with which the therapeutic effect can be ascertained using straightforward tests which are known in the prior art, and (e) where the data in the specification have made the claimed therapeutic effect plausible, place a burden on an objector to substantiate doubt that the desired effect can be achieved.

182 Adopting the lower standard of plausibility which the recent decisions support, I am inclined to think that Arnold J, who heard and analysed the expert evidence on this matter, including that of Professor Woolf, Dr Scadding and Professor Wood, did not err in his evaluation of that evidence when he concluded that Warner-Lambert had done just enough to satisfy the plausibility test in relation to peripheral neuropathic pain. The result of the rat paw formalin test demonstrated that pregabalin reduced inflammatory pain at phase 2. There was expert evidence which treated as credible the suggestion that the efficacy of pregabalin in reducing pain which that test revealed would not be confined to inflammatory pain and that the medication would also be effective in relation to peripheral neuropathic pain. As Arnold J stated (para 351), it was common general knowledge that central sensitisation was involved (at least as an amplifying mechanism) both in relation to inflammatory pain and in relation to peripheral neuropathic pain and that it played a role in the rat paw formalin test. The patent had not demonstrated that pregabalin had an effect on central sensitisation and a prima facie case had not been made out. But the plausibility test does not require that standard.

***Lord Mance – plausibility dissent***

193 In my view, Lord Sumption's analysis imposes too high a threshold, and imposes a burden on a patentee which the case law of the Board of Appeal of the European Patent Office does not justify.

[…]

195 For these reasons, I consider that it puts the test too high to suggest that "the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true" (Lord Sumption's judgment, para 36). That amounts on its face to, or certainly risks being read as, a requirement that the plausibility of the claim must appear to be established prima facie through scientifically cogent reasoning or experimental evidence set out in the specification.

[…]

Despite the use of phrases such as "reasonable prospect" and "might well produce", there is a real risk that the test as described by Lord Sumption would amount to, or be understood as, involving a requirement to establish a *prima facie* case on the material contained in the specification. In my opinion, the authorities analysed above do not put the standard so high. They certainly reject speculative or wide-ranging unsubstantiated claims. But they accept as sufficient a tailored claim which appears scientifically possible, even though it cannot be said to be even prima facie established, without for example testing or assays according to the state of the art. Only if a person skilled in the art would have significant doubts about the workability of the invention would it, in such a case, fail for insufficiency of disclosure.

196 I therefore consider that Lord Sumption's judgment puts the test of sufficiency of disclosure too high. I agree with the way in which Lord Hodge puts the position in para 181 of his judgment. I am also persuaded that, applying the correct test, Arnold J cannot be said to have erred in concluding there was enough material "just [to] make it plausible that pregabalin would be effective to treat peripheral neuropathic pain" (para 351). My reasons correspond with those given more fully by Lord Hodge in paras 182 to 184 of his judgment, which I have had the benefit of reading since writing a first draft of my own.

***Infringement***

***Lord Sumption (and Lord Reed) – outward presentation test for infringement***

68 The Court of Appeal broadly accepted Warner-Lambert's submission subject to two qualifications. First, the downstream use for treating pain had to be intentional rather than accidental. By this they meant only that patients would receive the drug for treating their pain, rather than for example for treating epilepsy, with a coincidentally

beneficial effect upon pain from which they happened also to suffer. The second qualification was more important. Floyd LJ held that the requisite mental element could be negatived if the manufacturer had taken all reasonable steps to prevent the downstream use of his drug for treating pain.

[…]

71 It is clearly correct that this issue depends not on the meaning of section 60(1)(c) of the Patents Act but on the construction of the relevant claims in the patent. The question is what, as a matter of construction, does it mean to claim in a patent the use of pregabalin for the preparation of a medicament "for" treating neuropathic pain. In my view, most of the difficulty in answering this question arises from the view of both courts below that Claim 3 (and any other purpose-limited claim in Swiss-form) includes a mental element, namely the intention of the manufacturer, as part of the definition of the monopoly. This view is perhaps invited by the common use of the phrase "purpose-limited" to describe a claim in Swiss-form. The expression is convenient, but it elides a number of different concepts, not all of which involve a mental element. I think that a test for infringement which depended on intention, whether objective or subjective, would be contrary to principle and productive of arbitrary and absurd results.

[…]

84 In my opinion, in a purpose-limited process claim, the badge of purpose is the physical characteristics of the product as it emerges from the relevant process, including its formulation and dosage, packaging and labelling and the patient information leaflet which in EU (and other) countries will identify the conditions for whose treatment the product is intended. I shall call this, for want of a better phrase, the "outward presentation" test. […].

[…]

86 However, whether or not it is soundly based on German law, Floyd LJ's objection to the "only packaging will do" test deserves to be considered on its merits. His main point was that once it was accepted (as it was, by both parties before him) that there was a mental element in a purpose-limited claim, there was no reason to limit the evidence of the manufacturer's intention to the physical presentation of the product. As he pointed out (para 191), "packaging may be a means of demonstrating the necessary mental element, whatever that is, but it cannot possibly be the only means of doing so." I accept that there is force in this point, which is one reason why I reject the importation of a mental element in the claim. It falls away if the mental element is discarded. […] It may be thought anomalous that the manufacturer of the generic product should be free of liability if he markets it for a patent-protected use provided that he labels it as being for a non-protected use. But to my mind it is a far greater anomaly that in a "charade" case the generic manufacturer's intention exposes to liability not just himself but any pharmacist who handles his product even if he scrupulously supplies it only for a non-protected use. Secondly, the imperfect nature of the protection conferred by an outward presentation test arises, as it seems to me, from a limitation inherent in a Swiss-form patent. A person's exposure to liability for infringement depends on the purpose for which the patent-protected product was

manufactured. The patentee's protection is therefore necessarily incomplete. A test which treated the claim as extending to the promotion of the product after its manufacture appears on the face of it to ignore this limitation. There is no perfect solution to this problem in the absence of a general defence of good faith available to third parties, such as exists in Germany in the case of claims to monetary remedies. But we are not in a position to add such a defence to the UK Patents Act. I consider that the outward presentation test is less imperfect than any other. The evidence does not enable us to say how serious the problem identified by Floyd LJ really is. The legislation was not drafted with purpose-limited products in mind, and if it proves to be serious it must be for the legislature to address it.

## Indirect infringement: section 60(2)

87 Warner-Lambert's alternative case of infringement, based on section 60(2) can be shortly dealt with. Section 60(2) is concerned with indirect infringement, ie with cases where a person incurs liability for infringement by knowingly supplying to a primary infringer the means of putting the invention into effect. There is a mental element in indirect infringement, for knowledge is expressly required. But it is unnecessary on this appeal to explore what that entails. […]

88 The short answer to this is that the invention protected by Claim 3 is the manufacture of pregabalin for the designated use, and not the subsequent use of the product for treating patients. [….] In my view Arnold J was right about this. The whole purpose of the Swiss-form for purpose-limited medical use claims is to avoid the problem of lack of novelty associated with product claims and the statutory provision which makes a method of treatment unpatentable. It is well understood that the degree of protection available from a Swiss-form claim may be more limited than that available from standard product claims. These essential features of purpose-limited patents are fatal to any attempt to construe Claim 3 as extending to steps taken by the pharmacist.

***Lord Mance***
***Outward presentation alone may not be sufficient***

206 In the case of a Swiss-form patent, it would be far from obvious or easily ascertainable whether there had been infringement, if the test were whether manufacture ("use for the preparation") of the composition had taken place by the manufacturer with the subjective intention that the composition be used for the specific purpose identified in the claim (ie here, "for treating neuropathic pain"). Further, if subjective intention were the test, what would this mean? Suppose that a manufacturer were deliberately to make more pregabalin than could be required for patent-free uses, there would be no means of saying whether any particular batch would be used for patented or for patent-free use. Would this mean that all manufactured batches infringed? So it would seem. These and other consequences are discussed by Lord Sumption and, I understand, recognised by Lord Briggs (see his para 171). They are to my mind powerful reasons for rejecting subjective intention as the test in any form.

207 What then of a test focused on the way in which the pharmaceutical composition is prepared, presented and marketed? This must include in particular its packaging and the instructions given for its use, since the actual pharmaceutical composition is by

definition identical to that produced by the patented process which it is said to infringe. Again, it is necessary to consider what such a test would mean. Here, some guidance is, in my view, available from German authority, identified by Lord Sumption in para 85 and by Lord Briggs in para 149. The German authority must be read with the understanding that a Swiss-form patent is under German law regarded as protecting a purpose-limited product, not (as under English law) a purpose-limited process. […]

213 In my view, the preferable starting point under English law is to view a Swiss-form claim in the second way identified in para 201 above. In other words, it protects the process of manufacturing a composition or product, which, as prepared, presented and put on the market, can be said objectively to be "for" the patent-protected use. A process leading to a composition or product, which does not make clear that its permitted use is limited will infringe. In the light of submissions received from counsel on this judgment as circulated in draft in the usual way before issue, I prefer however to leave open whether there might be some circumstances in which a generic manufacturer could or should be expected to go further, by a notice positively excluding the patent-protected use. […]

214 The delicate and difficult question is how far surrounding circumstances or general knowledge may be relevant, if in their light it is obvious or easily ascertainable that the process results in a product which, despite packaging and instructions making clear that it is for the non-patent-protected use, is destined for such use. For reasons already given, neither foreseeability nor subjective intention can be accepted as appropriate tests of liability.

215 The recent German authorities do not appear to give any direct answer to the question what a manufacturer is supposed to do, if it acquires the awareness of a "practice" of the sort mentioned in para 212 above. *Dexmedetomidin* (BeckRS 2018, 2410, para 44) says that it will be justified to hold it liable if "it still exploits this practice for itself by supplying its distributors". If that means that it must stop manufacturing and supplying any generic product, it involves an extreme solution which is too favourable to the patent-holder, since it excludes competition by the generic product even in patent-free areas of use. Another possibility is to read the German authorities as implying tacitly that the generic manufacturer should take (presumably, reasonable) steps to ensure that pharmacists and end users do not use the generic product for patented use. That would equate with the Court of Appeal's approach in this case, which constructs a pre-condition to legitimate manufacture and trade for which no basis, in my view, exists.

216 There is however a further possibility, which appears to have the support of paras 351 and 353 of Kühnen's work already cited, namely that, since a generic manufacturer has no contractual relationship with and cannot give directions to a third party such as a doctor prescribing drugs, the most that can be expected of such a manufacturer is that it makes clear on the product that it is not for the patent-protected use. It would seem to me also appropriate under English law to hold a generic manufacturer responsible in similar circumstances, if it was not made clear, in one way or another, that the product resulting from its manufacturing process was for the non-patent-protected use. […]

217 Because context is all in the law, I also think that we should be careful about committing ourselves in obiter remarks in relation to other extreme cases not now before us. It may be going too far in favour of generic manufacturers to suggest as an absolute rule that a generic product, prepared, presented and put on the market, must always be viewed in isolation by reference only to its own packaging and instructions, and without regard to the realities or of the market for which it is prepared and into which it is being released. […]

218 I prefer to say no more, and to leave open, the position in this type of remote situation. Normally, a generic manufacturer, and it follows others such as doctors, pharmacists and end users, should be protected from infringement of a Swiss-form patent if the manufacturer ensures that the generic product resulting from its manufacturing process is produced, prepared and marketed with a clear limitation to patent-free uses. As Kühnen observes, a generic manufacturer cannot control the activities of doctors, pharmacists and end users, with which it is in no contractual relationship. The protection afforded by a Swiss-form patent, analysed as protecting a process in the way that English law analyses it, is valuable, but necessarily limited.

***Lord Briggs***
***Subjective intent for infringement***

137 I can therefore return to the issues about mental element which arise from the infringement case under section 60(1)(c) . I have explained my view that this has nothing to do with the question whether section 60(1)(c) itself imposes a mental element as a requirement for infringement liability. It plainly does not. The real question is: what, if any, mental element is built into this purpose-limited process claim? That is a question of construction of the claim, not a question about UK patent infringement law. I have summarised the rival contentions of intention, foreseeability and (now) no mental element at all, but it is necessary to describe them, and their potential consequences, in more detail.

[...]

149 The Court of Appeal conducted its own review of the relevant European authorities about infringement of Swiss-form patents, first during the interim appeal in May 2015 and again during the appeal from the trial judgment, in October 2016. Floyd LJ concluded, correctly in my view, that they provide no clear or settled answer to the problem. But they do tend to show that a broad foreseeability test of the kind proposed by Warner-Lambert has not found favour. In summary, the German courts have concluded that the patentee will only be able to show that an alleged infringer's process is "for" the patented use if there is some outward manifestation of that purpose in the presentation of the manufactured product, for example in its packaging: […] Floyd LJ called it the "only packaging will do" approach. He noted that the recent decision of the EPO in T 1673/11 *GENZYME/Treatment of Pompe's disease [2016] EPOR 33* appeared to follow the German lead. The underlying rationale of those decisions appears to be that the "purpose" designated by a Swiss-form patent was an inherent property of the product which emerged from the manufacturing process, rather than something to be found in the mind-set of the manufacturer. In recent written submissions Warner-Lambert point out that the latest decisions of the

German courts have modified this rigorous focus upon the packaging by admitting proof of infringement by reference to foreseeability, for example in*Östrogenblocker* (Case I-2 W 6/17) (5 May 2017), para 39, and *Dexmedetomidin* (Case I-2 U 30/17) (1 March 2018), (BeckRS 2018, 2410, paras 42-44).

156 I am satisfied by the evidence, and by the submissions of the parties and the interveners, that the simple foreseeability test primarily contended for by Warner-Lambert would prioritise the first policy objective at an unacceptable cost to the achievement of the second objective. […]

160 Warner-Lambert's secondary case, namely foreseeability tempered by negativing intent by the taking of all reasonable steps, is the compromise solution preferred by the Court of Appeal.[…].

[…]

163 Following the hearing we considered whether an alternative approach would be to abandon the search for an appropriate mental element altogether. […]

[…]

165 I have, not without some reluctance, come to the conclusion that this is not an available alternative. My reasons follow. First and foremost, I think that the original concession that the purpose limitation in a Swiss-form claim necessarily involves a mental element of some kind on the part of the manufacturer was rightly made. When we speak of someone making something "for" a particular use, and conclude as we must that "for" means something more than "suitable for", it must point to something in the mind of the manufacturer. […]

166 By contrast I do not think that treating the purpose for which something is manufactured as inherent in the physical characteristics of the resulting product, truly reflects the role which the purpose limitation plays in defining the monopoly created by a Swiss-form patent. The fact is that, in its essentials, the Pregabalin-based medicament sought to be protected by the Patent has exactly the same physical characteristics as Pregabalin-based medicaments used to treat epilepsy and GAD.

167 That is not to say that the form in which the product of a manufacturing process is presented to the market will not often, or indeed usually, be decisive evidence, one way or the other, of the manufacturer's intended purpose, leaving aside the occasional cases where other evidence may prove that the presentation is in fact a charade. Subjective intent is routinely proved by objective evidence of conduct.

168 Secondly, I do not consider it safe to conclude that the apparent German lead in this direction can simply be followed in this different jurisdiction. I agree with Lord Sumption's analysis of the way in which German law differs from UK law in making a less significant distinction between purpose and product claims. I have not been able to agree with Lord Mance's analysis, which seems to me to follow the German lead in treating the purpose as limiting the product, by focusing solely on the way it is

packaged and marketed, while at the same time acknowledging that, in English law, the patent protects the process. […]

[…]

172 The so-called subjective intent test favoured by Actavis would I think accommodate all forensic means whereby a purpose of the generic manufacturer to serve (and profit from) the market for neuropathic pain could be proved, including but not limited to the packaging on the product. Anything from which the court could properly find that the manufacturer had such a purpose could be relied upon, including targeted disclosure, during litigation, of documentary records of the manufacturer's decision-making processes. I call it a "so-called" subjective test because a person's intention is as much a matter of fact as the state of his digestion, and this is true of corporate persons as much as of individuals. It may be proved objectively by words, conduct and even inactivity, and the court is well versed in treating a decision not to enquire about something suspected as probative of blind-eye knowledge.

***Lord Hodge***
***subjective intent for infringement***

188 I agree that the test of foreseeability which Warner-Lambert promote and the qualified version of foreseeability which the Court of Appeal favoured should not be adopted for the reasons which both Lord Sumption and Lord Briggs advance. The disagreement between Lord Sumption and Lord Briggs is whether, as Lord Sumption advocates, to adopt an approach, which has (at least until recently) found favour in the German courts, confining evidence of the purpose of an alleged infringing manufacturer's process to the outward manifestation of that purpose on the product itself, including its packaging, labelling or in an accompanying patient information leaflet, or, as Lord Briggs suggests, to assess that manufacturer's actual intention in producing the medicament by taking account also of other manifestations of that manufacturer's purpose. The approach of the German courts has the serious disadvantage of giving inadequate protection to the patentee of the Swiss-form patent against a generic manufacturer who uses "skinny labels" and patient information as a charade behind which it exploits the second use market. The approach which Lord Briggs favours may expose dealers in the generic product and dispensing pharmacists to strict liability for infringement as a result of matters over which they may have neither knowledge nor control. Both approaches are far from perfect. I confess to having been strongly attracted by the tidiness and consistency with the principles of tort law which Lord Sumption's approach involves. That approach also reduces the risk that suppliers and pharmacists will decline to deal in generic products after a patent has expired if there is a second medical use patent. But in my view Lord Briggs' approach creates a fairer balance between the central policy objectives which he sets out in para 160 of his judgment. Principally for that reason but also for the other reasons which he advances, I agree with Lord Briggs' judgment on this matter. If, on this approach, section 60(1)(c) were to cause serious problems to operators in the downstream market for generic products or to pharmacists, which in turn cause them to refuse to handle such generic products, it will be for the legislature to address those problems.

4. In order to allow the possibility of a generic medicinal product being placed on the market only for indications and dosage forms of the reference medicinal product which are no longer patented, Directive 2001/83 permits an exception to the principle of the uniformity of the reference medicinal product and the generic medicinal product: manufacturers of generic medicinal products can introduce a 'carve-out', whereby still patented indications or dosage forms of the reference medicinal product are deleted from the summary of characteristics of the generic medicinal product. The summary of characteristics is part of the authorisation documentation and contains information inter alia on applications and dosage of the medicinal product. It is aimed primarily at healthcare professionals, but also forms the basis for the package leaflet. A carve-out therefore means, in particular, that the still patented indications or dosage forms of the reference medicinal product do not appear in the package leaflet for the generic medicinal product, even though, from a purely medical point of view, that product — which is identical to the reference medicinal product — can also be used and thus prescribed for the indications in question and in the dosage forms in question.

5. It is not expressly regulated what effects the introduction of a carve-out in the summary of characteristics of a generic medicinal product has on the scope of the marketing authorisation for that generic medicinal product. In particular, it is unclear whether, if a carve-out is introduced after a marketing authorisation has already been granted for the generic medicinal product concerned, this marketing authorisation still applies to the indications or dosage forms which were deleted from the summary of characteristics by the carve-out or whether, in contrast, the subsequent notification of a carve-out means that the marketing authorisation must be limited to the remaining indications and dosage forms not affected by the carve-out.

6. That is the central question in this request for a preliminary ruling. […]

[…]

60. Against this background, it seems logical to interpret the second sentence of Article 11 of Directive 2001/83 to the effect that it is also possible to introduce a carve-out after the marketing authorisation has been granted for a medicinal product. In order to ensure that the authorised version of a medicinal product corresponds to the version placed on the market (a), a subsequent carve-out of this nature must be regarded as an application to limit the marketing authorisation (b).

[…]

66. The notification of a subsequent carve-out must therefore be regarded as an application to limit the previously granted marketing authorisation for a medicinal product. It is irrelevant in this connection whether by the carve-out the authorisation holder merely wishes to avoid infringements of patent rights or is intentionally seeking to limit the marketing authorisation. The deletion of an indication or dosage form from the summary of product characteristics objectively limits the scope of that

summary. As the latter determines the scope of the marketing authorisation, the carve-out must therefore also result in the limitation of that authorisation.

67. In accordance with this interpretation, both holders of marketing authorisations for generic medicinal products and national health authorities must accept that, after the introduction of a carve-out and the related limitation of the marketing authorisation, generic medicinal products will not be prescribed, or at least will no longer be prescribed as often, for the still patented indications or dosage forms of the reference medicinal product which are now no longer covered by the authorisation.

82. In the light of the foregoing, Articles 10 and 11 of Directive 2001/83 must be interpreted as meaning that a communication whereby the marketing authorisation applicant or holder for a generic medicine, within the meaning of Article 10, notifies the authority that he is not including in the summary of product characteristics and the package leaflet, pursuant to the second sentence of Article 11, those parts of the summary of product characteristics for the reference medicine referring to indications or dosage forms covered by the patent right of a third party should be considered as a request to limit the marketing authorisation for that generic medicinal product to the remaining indications or dosage forms.

86. Accordingly, Article 11 and Article 21(3) of Directive 2001/83 must be interpreted as precluding the competent authority from making public the summary of characteristics and the package leaflet of a medicinal product, including those parts referring to indications or dosage forms which are covered by patent law, in a situation where the marketing authorisation applicant or holder has notified the authority that, in accordance with the second sentence of Article 11 of the directive, he is not including such indications or dosage forms in the summary of characteristics and the package leaflet.

## A FEW MINCE PIES

### SPCs

### *Sandoz v Janssen*

### *Floyd LJ – 25 January 2018*

1 This appeal concerns the meaning of "the product is protected by a basic patent in force" in Article 3(a) of Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products ("the SPC Regulation").

[…]

4 In a decision dated 3 May 2017, Arnold J decided that darunavir was a product protected by the patent. He declined to refer questions to the CJEU on the interpretation of Article 3(a) of the SPC Regulation because he considered that, on all tenable constructions of Article 3(a), darunavir was protected by the patent. This is an appeal from that decision and his consequent order.

[…]

27 The appellants contend that for the product to be protected by a basic patent for the purposes of Article 3(a) it must be shown that "the skilled team would recognise the product as forming a part of the subject matter of the patent by reference to a careful reading of the patent based on the common general knowledge at the priority date". They submit that, given the large number of compounds covered by the claim and the unusual nature of the P1 substituent on darunavir, that test is not satisfied in the present case. The respondents disagree and contend that darunavir will be protected by the patent if it is one of the class of products defined and claimed in the claims of the patent by reference to the Markush formulae.

[…]

106 If it is right that there is a general requirement that the active ingredient which is the subject of the SPC must be identified, the question arises of how specific the claims must be. I agree with Mr Mitcheson that there is a spectrum of specificity indicated by the factual scenarios in the various decided cases and references. I would regard it as plain that a *Markush* claim can in some circumstances amount to a sufficiently precise claim for the purposes of Article 3(a), for example where individual substituents are identified in the specification, or where classes of such substituents are set out, and the skilled person would be able to determine the extent of those classes. However I do not think one can extract from the reasoning in *Eli Lilly* the proposition that an active ingredient is adequately identified by a Markush formula however broadly that formula is framed and however obscure the particular substituent required to form the active ingredient the subject of the SPC. […]

109 Like the judge, however, I am concerned with what I see as a fundamental defect with the "identification" test. The CJEU jurisprudence to date seems to take it as read that a claim can identify active ingredients with specificity. However that is not the function of claims in patents. Instead, claims are concerned with setting the limits to the monopoly. A further defect of the focus on the claim is that claims can be manipulated by skilful drafting to protect combinations, without distinguishing between genuine combinations of products which work together in a new and advantageous way so as to constitute an inventive advance, and mere collocations of products giving rise to their separate individual effects. I agree with the judge that a far better test would be to ask whether the product the subject of the SPC embodies the core inventive advance of the basic patent.

110 I think Ms May is wrong when she submits that the core inventive advance test is inadequate because it imposes no greater requirement in the case of a Markush claim than would be imposed by an infringement test. That submission is based on the false premise that any test one proposes, when applied to a particular type of claim, must add something to a test of infringement. I do not follow why that should be so. If the objective behind the *Lilly* requirement is understood to be that the active ingredient must embody the inventive advance, then that objective is satisfied by a valid Markush claim. Every compound encompassed by the claim delivers the core inventive advance. In other types of claim the test will not be satisfied. To take an example based on the facts of *Medeva* , if the vaccine the subject of the SPC did not take advantage of the synergistic effect in vaccine potency of the combination, for example by using normal doses, then it would not embody the core inventive advance.

111 The adoption of the core inventive advance test remains a possibility given the pending references from in *Sitagliptin* and *Teva v Gilead* , and the fact that it is becoming clear (see *Actavis v Novartis* , *Actavis v Boehringer* ) that the possible abuse identified by the Advocate General in *Medeva* can be dealt with through Article 3(c). If that test were adopted across the board and applied here, despite Ms May's submissions concerning its application (which I reject), I have no doubt that the SPC would satisfy Article 3(a).

115 I would therefore propose that this court should stay the present appeal proceedings and refer the following question to the CJEU:

> "Where the sole active ingredient the subject of a supplementary protection certificate issued under [the SPC Regulation ] is a member of a class of compounds which fall within a Markush definition in a claim of the patent, all of which class members embody the core inventive technical advance of the patent, is it sufficient for the purposes of Article 3(a) of the SPC Regulation that the compound would, upon examination of its structure, immediately be recognised as one which falls within the class (and therefore would be protected by the patent as a matter of national patent law) or must the specific substituents necessary to form the active ingredient be amongst those which the skilled person could derive, based on their common general knowledge, from a reading of the patent claims?"

3 On 25 July 2018 the Grand Chamber of the CJEU handed down its judgment in Case C-121/17 [EU:C:2018:585].

[…]

6 In its judgment the Court of Justice confirms that, in order to be "protected by a basic patent in force" within the meaning of Article 3(a) of the SPC Regulation, it is necessary, but not sufficient, that the product falls within the scope of protection of the basic patent applying what I called in my first judgment the Extent of Protection Rules, which in the case of a European patent are those contained in Article 69 EPC and the Protocol on the Interpretation of Article 69 . More is required, as the Court explains.

[…]

10 In a nutshell, what the Court is saying is that the purpose of the SPC Regulation is to enable the holder of the basic patent to obtain supplementary protection for what the patentee actually invented and not for what the patentee did not invent.

15 Counsel for Gilead submitted that this test was a pure extent of protection test. I do not accept that submission. The Court is clearly saying that more is required than that the product should fall within the scope of the claim: the skilled person must understand that the product is "a specification required for the solution of the technical problem". Again, this is not as pellucid as one would hope, because the Court is again using terminology derived from patent law inaccurately. Nevertheless, the sense is tolerably clear: the product must be one that the skilled person would understand, on the basis of the description and drawings and their common general knowledge, as embodying the technical contribution made by the patent. This is confirmed by what the Court says later in the judgment at [56].

[…]

17 Thus the product must be specifically identifiable by the person skilled in the art in the light of the description and drawings and the prior art, which must mean their common general knowledge, as at the filing date or priority date of the patent, and not merely in the light of information which becomes available later.

[…]

37 The first test is that, from the point of view of a person skilled in the art and on the basis of the prior art at the priority date, the combination of active ingredients must necessarily, in the light of the description and drawings of the patent, fall under the invention covered by that patent. As explained above, this is not a simple extent of protection test. Rather, the combination must be one that the skilled person would understand, on the basis of the description and drawings and their common general knowledge, to embody the technical contribution made by the patent.

[…]

39 The second test is that, from the point of view of a person skilled in the art and on the basis of the prior art at the priority date, each of the active ingredients must be specifically identifiable, in the light of all the information disclosed by the patent. There is no dispute that TD is specifically identifiable. In my view it is clear that emtricitabine is not specifically identifiable.

40 As counsel for the Claimants submitted, this result is perfectly consistent with the objectives of the SPC Regulation. As noted in my first judgment at [24], Gilead obtained a marketing authorisation in respect of Viread, which contains TDF, on 5 February 2002, less than five years after the application for the Patent was filed. Thus Gilead did not suffer sufficient regulatory delay in exploiting the Patent to warrant the grant of an SPC in respect of Viread. Moreover, although Gilead applied for and was granted a patent for the combination in Truvada, that patent was revoked by the Opposition Division of the European Patent Office and Gilead's appeal against that decision was dismissed. Thus Gilead made no invention in devising the combination which warranted the grant of a patent, let alone an SPC.

## *ABUSE OF PROCESS/LATE RAISED POINTS*

### *Teva v Gilead – post CJEU evidence?*

### *Arnold J – 18 September 2018*

26 Gilead further contends that it should be given permission to adduce further evidence because the CJEU has articulated a new test which was not anticipated as a possible test by the parties, and therefore it is fair for the parties to be given the opportunity to adduce evidence directed to the new test and for there to be a second trial to consider such evidence. More specifically, Gilead contends that the second of the two tests articulated by the CJEU is new, and one which depends on expert evidence as to the prior art and the common general knowledge of the person skilled in the art to whom the Patent is addressed as at the priority date.

27 In my judgment it is not appropriate to give the parties permission to adduce further evidence at this stage precisely because it would necessitate a second trial.

28 It seems to me that there is a strong analogy between Gilead's application and an application by a patentee to amend the claims of its patent so as to attempt to validate the claims after trial and the rendering by the court of a judgment concluding that the existing claims are invalid. If this would require a second trial, it will usually amount to an abuse of process and therefore will not be permitted: see *Nikken Kosakusho Works v Pioneer Trading Co [2005] EWCA Civ 906, [2006] FSR 4* , *Vector Corp v Glatt Air Techniques Ltd [2007] EWCA Civ 805, [2008] RPC 10* and *Nokia GmbH v IPCom GmbH [2011] EWCA Civ 6, [201l] FSR 15* and *Generics (UK) Ltd v Warner-Lambert Co LLC [2016] EWCA Civ 1006, [2017] RPC 1* .

29 Counsel for Gilead pointed out that this issue is currently before the Supreme Court in *Generics v Warner-Lambert* . That is so, but I must take the law as it presently stands.

***Liqwd Inc v L'Oreal – new experiments post judgment?***

***Birss J – 19 July 2018***

2 L'Oréal has now brought an application to admit further evidence, reopen the trial and decide one of the issues afresh taking into account the new evidence. The new evidence is a third report of Professor Law, one of the expert witnesses relied on by L'Oréal for the trial. Professor Law's third report sets out the results of an experiment he conducted in June 2018 after the judgment was handed down.

[…]

5 It is manifest that each side is playing for high stakes. Coming into this hearing, both sides were seeking to use it as a kind of free hit to argue out the application but, if their submission is not accepted, come back and have another go on another occasion. […]

[…]

27 The applicable legal principle is the one set out in *In Re L (Children)* . The judgment is one of Baroness Hale with whom the other members of the Supreme Court agreed. Baroness Hale dealt with the jurisdiction at paragraphs 16-19 and confirmed that the jurisdiction exists until the order is perfected by being sealed by the court. The principles governing the exercise of the jurisdiction were considered at paragraphs 21-27. Baroness Hale expressly considered *In re Barrell Enterprises [1973] 1 WLR 19* and the authorities following it which grappled with the idea that exceptional circumstances were required. She held that exceptional circumstances were not required […]

28 I take it therefore that the decision is one made by applying the overriding objective as set out in CPR Part 1 r1.1 . Every case will depend on its particular circumstances. A relevant factor must be whether any party has acted upon the decision to his detriment before the order has been formally drawn up.

29 In support of their case on abuse of process, Olaplex cited the judgment of the Court of Appeal in *Warner-Lambert v Generics (UK) [2016] EWCA Civ 1006* . […] Nevertheless neither side invited me to wait for the outcome in the Supreme Court.

[…]

48 The overriding objective is to deal with cases justly and at proportionate cost. L'Oréal's case is that the heart of the overriding objective is to get the right answer. However, as explained above, the new evidence does not give L'Oréal a knock out

point. Each side has an arguable case and if the new evidence is admitted then there is likely to be a further two or three day trial, and a further judgment.

49 Of course the court adjudicating any dispute strives to get the right answer. However, the overriding objective cannot be summarised in that way. Put in L'Oréal's terms, the overriding objective is more accurately summarised as being to get the right answer in the right way. That is why CPR r1.1 refers to factors such as proportionate cost, ensuring parties are on an equal footing, dealing with matters expeditiously and fairly, allotting an appropriate share of the court's resources, and procedural compliance. These procedural factors are there to do justice between the parties and to administer justice as a whole.

[…]

58 Putting it the other way round, the reason L'Oréal lost the substantive priority issue at trial was not merely because of the lack of the new experimental evidence. Rather it lost because the evidence it chose to acquire and advance to prove that case at trial and the arguments deployed in support of the point, did not succeed. Now L'Oréal seeks to deploy more evidence on the same point.

59 To make an order requiring the court to redecide an issue on the basis of fresh evidence, when the issue to which it is relevant was addressed and decided, does not require exceptional circumstances ( *Re L (Children)* ), it requires the application of the overriding objective. For such an order to be in accordance with the overriding objective there must be something about the circumstances to justify that course given its inevitable consequences in terms of cost and trouble to the parties of a further trial but also the allocation of the court's resources to these litigants as opposed to others. Although it recognises the impact on costs on Olaplex, L'Oréal's approach to this application ignores the impact on the court's resources and other litigants.

60 The fact that the counterparty has not acted to their detriment in response to the judgment is very important in the sense that if they have done, then it will make such an application all the harder, but that factor alone cannot justify making the order in this case. No doubt the circumstances will vary infinitely but obvious factors are the strength of the case taking into account the new evidence and reasons why the new evidence was not deployed at trial. I also bear in mind that this is a commercial dispute between substantial undertakings (I know Olaplex complain that their resources are stretched) in which finality may well have more weight than, for example, a case concerning the long term welfare of a child.

63 I am entirely confident that if L'Oréal had thought of this priority point months before trial, it could have acquired this experimental evidence well in advance (subject to the Patents Court's usual safeguards concerning experimental evidence) and could have put forward Professor Law's opinions about inevitability at the same time.

[…]

66 L'Oréal argues that there will be no delay in the overall scheme of the litigation if a provisional order is made on the other issues now such that the appeal process can be set in motion, or alternatively that a few months delay is a relatively small prejudice

compared to the risk of reaching the incorrect result. If the new evidence made all the difference between success and failure on the issue of priority itself and therefore on validity of claim 11 and if it was something which came out of the blue after trial when the priority point had been in issue for months, then I would take a different view. Many litigants, having chosen to advance their case in a particular way, then lost at trial, would like to call further evidence. […]

67 I recognise that this is not a case in which the winning party has acted to their detriment in reliance on the judgment. Nevertheless an order to direct a reconsideration of the issue of priority of Example 8 of WO 768 over US 239 would not be in accordance with the overriding objective. The application is dismissed.

## ***Warner Lambert v Generics – post trial amendment?***

## ***Lord Briggs – 14 November 2018***

118 It is of course open to this court to adopt a different position on this question than either the series of decisions in the Court of Appeal, or the views of the Supreme Court of the Netherlands. But I can see no good reason why we should do. First, no authority to the contrary, here or elsewhere in Europe, was cited to us. Secondly, I find the analysis of Arnold J of the reasons why different contracting states should have different procedural rules and principles about amendment, cited above, to be compelling. Thirdly, nothing in the language of article 138 suggests that the Court of Appeal and the Supreme Court of the Netherlands have got its purpose and effect wrong. Finally, matters of procedure are pre-eminently a matter for the Court of Appeal, and this court is slow to interfere in a consistent development of procedural principle by that court unless persuaded that it is clearly wrong.

119 I can deal briefly with the second ground, namely that this was an amendment to a partly valid patent. That is literally true, even given our conclusions on insufficiency, since the claims relating to different types of inflammatory pain have survived. But it misses the point of the *Nikken* principles. They distinguish between (i) amendments merely to delete claims and related material which have been found to be invalid, and (ii) amendments designed to make good a claim not thus far advanced in the amended form. The proposed amendment of Claim 3 is not to excise parts found to be invalid. The whole of Claim 3 was held invalid. Furthermore it is common ground that it would require a further trial to test the validity of the amended Claim 3.

120 The submission that the refusal was disproportionate, even applying the *Nikken* principles and *Johnson v Gore Wood* , was based on the assumption (shared by the judge) that a further trial need not take longer than two days, that the cost of this would be modest compared with the value of the amended Claim 3, that an order for costs would deal with any prejudice to Actavis and Mylan, and that the amendment, even if late, was a response to a late raising by Actavis and Mylan, shortly before trial, of an invalidity argument based upon the absence of sufficiency in a claim for central neuropathic pain. These are essentially case management points, and all of them were deployed before the judge and the Court of Appeal. Both courts reached the same conclusion in rejecting them. Both courts consisted of judges experienced in the trial of patent cases, three of whom had, in turn, been the judge in charge of the

specialist Patents Court. In those circumstances this court would interfere only if the courts below had erred in law, left significant matters out of account, taken into account irrelevant matters, or gone clearly wrong. The submissions made to this court came nowhere near surmounting those steep hurdles. It is plain, as the judge held, that the occasion to consider whether to make an amendment to Claim 3 (which could have been conditional on that claim being found otherwise invalid) occurred at the very latest when Actavis and Mylan raised their plausibility case about central neuropathic pain shortly before trial. Instead Warner-Lambert chose to run a case for a narrow construction of Claim 3, to meet exactly the same potential problem. There was ample material upon which the judge and the Court of Appeal could properly have concluded that the attempt to make a post-trial amendment was an abuse of process, and no basis upon which this court could properly interfere, harsh though the consequences might have been if the cross-appeal had failed.

## *Liqwd Inc v L'Oreal – new point raised in cross-examination?*

## *Birss J – 11 June 2018*

210 In closing Olaplex made two submissions. The first was that this was an entirely new case, a deliberate ambush and should not be entertained. The court should exercise the power in CPR Part 3rule 3.1(2)(k) and exclude the issue from consideration. The second submission was that in any event the argument fails on the facts.

213 No authorities were cited on the extent of the court's powers under CPR Part 3rule 3.1(2)(k) . Although no doubt the power in rule 3.1(2)(k) would normally be exercised before trial, there is nothing stated in the rule which limits the occasions on which it could be exercised and in my judgment it could be exercised at any time prior to judgment being given. The fact that no objection had been taken to the line of questioning in cross-examination or that the point was only raised after the evidence had closed are relevant matters to take into account but they do not preclude the exercise of the power in circumstances which would otherwise be a furtherance of the overriding objective.

214 Olaplex made submissions about the principles by which the Patents Court operates. I agree with them. Some are elementary but are worth restating anyway. I set them out here with minor modifications:

(a) The critical points which are sought to be proven on each of the issues in the case need to be laid out in advance so that they can be properly addressed in evidence. Either in a Statement of Case, or (if the Statement of Case is broadly pleaded) in an expert's report served well in advance of trial.

(b) It is not acceptable to keep a new critical point going to a central issue in the case for ambush in cross-examination. Such points are commonly thought of late in the day, but they should be disclosed as soon as the decision is taken to run them so the judge can decide how to deal with them having heard the submissions of the other side.

(c) Where a new point of substance requiring investigation and technical analysis is thought of and intended to be run at trial, it is incumbent on the party who wishes to run it to give proper notice to the other party and not to seek to ambush an expert witness with the point at trial.

(d) If a new point of this nature requires expert evidence to prove it (as this one), it is incumbent on the party running it to serve his own expert evidence in advance setting out what the point is and the technical reasons why it is considered to be correct, to give the other side an opportunity to consider it and file their own counter-evidence. It may even be incumbent to file a new Statement of Case.

(e) A fortiori where (as here) the point may well have required research, experiment and historical evidence to deal with.

215 A further principle submitted by Olaplex was that the Patents Court procedure encourages counsel not to interrupt cross-examination to make objections as to lines of questioning. If there is a proper objection to a question then it ought to be taken, but I entirely agree that cross-examination should not be interrupted unless it is strictly necessary. That has the great advantage of avoiding a disruptive style of trial process. It is particularly advantageous when the questions involve highly technical subject matter whose significance can be quite unclear at the time. However a consequence of encouraging counsel not to interrupt cross-examination unless they really have to, is that the court must be prepared to exercise its power, in a proper case, to exclude an issue from consideration even after some testimony going to that issue has been given. Otherwise it would be too late once the witness has spoken. That is not a sensible way of proceeding.

216 I accept what I have been told on behalf of L'Oréal that the point only became apparent during the first week of trial. Nevertheless it obviously was not thought of during the time Prof Haddleton was under oath and therefore it could, and so should, have been raised with the other side before the professor was called as a witness. He was clearly the only relevant witness then being called by Olaplex to whom the point could be put. The fact it was not raised in advance is a relevant factor in the exercise of the power under r3.1(2)(k) .

[…]

221 This action is an important case between substantial commercial organisations in a high value market. Both sides have sophisticated legal teams well able to handle issues of this kind if they are raised at short notice. Even with that in mind however and even though the objection was taken in closing rather than during the cross-examination, in my judgment the issue of what is to be inferred from the NMR spectrum which forms figure 1 of US 239 should be excluded from consideration. To decide it now would not be to deal with this case justly and at proportionate cost.

***Edwards Lifesciences v Boston Scientific – point not challenged?***

***Floyd LJ – 28 March 2018***

58 Mr Meade's primary submission as to the consequences of the failure to cross-examine Prof. Lutter, was that the court was bound to accept his evidence and reject the allegation of obviousness. Alternatively, and perhaps more realistically, he submitted that this court would have to look at the issue again, and if persuaded that cross-examination could have made a difference to the outcome on this issue, set aside the judge's conclusion.

59 Mr Purvis submitted that the rules about what must be put in cross-examination were not to be rigidly applied in relation to expert evidence. Where the issue for the judge was obviousness, it was the expert's reasons which were important, and these had already been laid out in their reports for the judge to evaluate. It did not matter that the expert had not been challenged head-on in relation to each reason, particularly when each of the reasons had been advanced independently by both experts. Moreover, in the present case, two fundamental planks of Prof. Lutter's reasoning had been undermined by cross-examination. First, Prof. Lutter had said that he would not have been interested in transferring technology from the field of endografts to that of replacement heart valves. Secondly, he had argued that the skilled team would not have been aware of the problem of PVL. That was enough to reduce the effect of his overall opinion of non-obviousness.

[*quotation from Phipson on Evidence on the obligation to challenge evidence of the opposing party]*

63 As made clear by cases from *Browne v Dunn (1893) 6 R. 67* to *Markem Corp v Zipher Ltd [2005] EWCA Civ 267; [2005] R.P.C. 31* , the rule is an important one. However, it is not an inflexible one. Procedural rules such as this are the servants of justice and not the other way round.

64 I would start by accepting two of the points on which Mr Meade relies. In a case where it is proposed to save time by not cross-examining two witnesses in relation to the same or similar subject matter, it is good practice for the matter to be raised with the judge beforehand so that he can give directions in the light of the parties' submissions. The judge should in general give directions so as to ensure fairness to the parties without incurring unnecessary costs by extending the length of the trial. However, the fact that such a direction is not sought or given does not automatically require the judge to accept an unchallenged reason given by one expert.

65 Secondly I would agree, as a general matter, that the rule requiring important positive evidence to be challenged is a rule which is not simply for the benefit of the witness (whose honesty or professional reliability is challenged) but is also designed to ensure the overall fairness of the proceedings for the parties. […]

66 The rule applies with particular force where a witness gives direct evidence of a fact of which he has knowledge and which it is proposed to invite the court to disbelieve. Fairness to the witness and to the parties demands that the witness should be challenged on his factual evidence so as to give him the opportunity of affirming or commenting on the challenge, or on a positive matter which it is proposed to set against his evidence.

67 Not every situation however calls for a rigid application of the rule. At least part of the unfairness which the rule is intended to address is the lack of any opportunity for a witness to respond to a challenge to his evidence. In the present case there was more than one round of expert evidence. Boston put in three rounds, so each expert had more than ample opportunity to comment on the views of the other. The battle lines between the experts were clearly drawn in the pre-trial exchange of reports. The potential for unfairness to the witness in such circumstances is much reduced.

68 Even in the case of evidence of fact, it is no longer the law that every aspect of a witness' evidence needs to be challenged head-on. [….]

69 On an appeal to this court the question must be whether the decision not to cross-examine has led to unfairness to the extent that the judge's decision on the relevant issue is thereby undermined.

70 I am wholly unpersuaded that the judge's decision in the present case is rendered in any way unsafe by the fact that Prof. Lutter was not individually challenged in cross-examination on the points to which Mr Meade has drawn attention. My reasons in summary are the following [*reasons given]*

***Regeneron v Kymab – new sufficiency point not raised***
***Kitchin LJ – 28 March 2018***

152 These rival submissions therefore give rise to a number of issues: first, whether it is open to Regeneron to rely upon its arguments before this court or whether it is foreclosed from doing so by the position it took before the judge; secondly and on the assumption it is open to Regeneron to rely upon these arguments, whether they have any factual foundation; and thirdly, whether these arguments and any findings we consider it appropriate to make provide a basis for reversing the judge's findings of insufficiency.

[…]

169 As we have explained, the judge did not address the issue of minigenes in the draft of the judgment he supplied to the parties. […]

[...]

175 […]The one matter that has caused us considerable concern is that Regeneron did not raise the issue with the judge when it received the draft judgment. It is axiomatic that if an advocate believes that a judge has not dealt with a material issue then it should be drawn to the judge's attention pursuant to that advocate's duty to assist the court and to further the overriding objective. In *Re T (Contact: Alienation: Permission to Appeal) [2002] EWCA Civ 1736; [2003] 1 FLR 531* , Arden LJ said at [50]:

[….]

176 We think it highly unsatisfactory that this course was not followed by Regeneron in this case. Quite apart from the consequences to which Arden LJ referred, it means

that, if we allow Regeneron to develop its arguments before this court, we must either make an assessment of the evidence without the benefit of a reasoned decision of the trial judge, or remit it to him for his assessment with all the costs and delay that would entail.

177 In the end, however, we have come to the conclusion that the failure by Regeneron to raise the issue with the judge after receiving the draft judgment should not preclude it from relying upon it upon this appeal. As we shall explain, the relevant evidence is not extensive and was given primarily by Kymab's experts. Further, it is evidence which we can assess with the benefit of the full submissions we have had from both parties.

178 For all of these reasons, we decide the first issue in favour of Regeneron. It is not precluded from developing before this court its contention that the judge fell into error in failing to find that the skilled team could have implemented the teaching of the patents by using their common general knowledge and adopting simple and obvious adjustments to Example 3, including the use of minigenes.

***Illumina v Premaitha – new claim on a new patent?***

***Henry Carr J – 19 March 2018***

3 The application raises two issues: first, alleged abuse of process by each of the claimants. The defendants contend that the commencement of the actions in respect of EP '321, which I will call the '321 actions, constitute an abuse of the court's process and should be struck out, because they could and should have been brought in one or other of two earlier sets of proceedings which were brought by the claimants for patent infringement in relation to the IONA test, and in an earlier set of proceedings, brought against TDL and Ariosa in respect of the Harmony test.

**[…]**

16 Infringement of EP '321 is a different cause of action to those asserted in the first and second Premaitha actions and the first Ariosa action. This is not a case where the claimants have failed in their claims in previous proceedings, indeed they had a very considerable measure of success in those actions. It is not a case where the claimants ****522*** are seeking to relitigate claims which they lost based upon new information. In those circumstances, where there is an attempt to relitigate, reasonable diligence in finding evidence and in raising arguments is, of course, of very considerable importance. Raising late a different cause of action can be an abuse of process. The *Aldi* guidelines to which I shall refer make clear that such a case is possible. However, there is clearly an arguable cause of action for infringement of the '321 patent and, in the words of Kitchin L.J., it would take a rare or exceptional case to deny the claimants their art.6 rights in those circumstances.

17 The defendants relied on what has become known as the *Aldi* guidelines, as set out by Thomas L.J. in *Aldi Stores Ltd v WSP Group Plc [2017] EWCA Civ 260, [2008] 1 WLR 748* . Although the Court of Appeal allowed an appeal from a striking out on the basis of abuse of process by Jackson J., nonetheless it went on to consider the correct

approach that should be adopted in future by a party who, during the course of a first set of proceedings, became aware of a cause of action which could be brought as part of those proceedings.

[…]

21 The *Aldi* guidelines, as will be seen from the passages which I have cited, are concerned with cases where the claimant knows of a second cause of action, but in the words of Sir Anthony Clarke "keeps it secret", and in the words of Sedley L.J., "keeps the claim up his sleeve". They are not concerned with cases where the claimant does not know that he has a second cause of action, even if he should have known.

[…]

26 However, in order to appreciate that there was a cause of action for infringement of EP '321 against the defendants, an individual within the claimants would have needed to have considered the scope of its claims in the context of the Harmony and IONA tests, as marketed in the UK, and would have needed to conclude that there was sufficient evidence of infringement to bring proceedings in the English courts. In this regard, the facts, as between the Harmony and IONA tests, are somewhat different.

[…]

39 In any event, I do not accept that the allegation of commonality of issues could constitute a case of abuse of process. This is not a case where I made findings which are collaterally attacked by a second action. In so far as Premaitha has researched its own size separation step, or the common general knowledge on size separation in the first action, this may save them some work in the second action, but it does not make the second action oppressive.

[…]

49 Stepping back, I need to ask myself whether, in all the circumstances, commencement and continuance of the claim in respect of EP '321 against Premaitha constitutes an abuse of process, such that the claimants should be deprived of their Article 6 rights to a trial of an arguable case of infringement of the patent. The consequences of striking out the claim is that Premaitha will have effectively obtained a licence under EP '321 in respect of past and future acts of infringement which will not extend to any third parties. I have not found any conduct committed by the claimants which would justify this result.

## ***Relief – Arrow declarations***

### ***GSK v Vectura***
### ***Floyd LJ***

14 The *Arrow* declaration is, in effect, a declaration that a party has a *Gillette* defence as of a particular date against attacks by later patents. The *Gillette* defence can be traced to the speech by Lord Moulton in *Gillette Safety Razor Co v Anglo-American Trading*

*Co Ltd (1913) 30 RPC 465* . In a *Gillette* defence a defendant contends that the product he is selling was obvious at a particular date, and cannot accordingly fall within a valid claim of a later patent. Although such a defence is raised in circumstances where the defendant is sued on specific patents, there is no reason why a properly worded declaration that a product is obvious at a particular date cannot provide protection against any later patent. As pointed out in the *Arrow* case itself, however, in order to render the issues for the court properly justiciable, the characteristics of the product in respect of which the declaration is sought must be clearly defined (see per Kitchin J at [40], [59]).

24 In my judgment paragraphs 98(iv) and 98(v) of this court's judgment in *Fujifilm v AbbVie* need to be read together, taking into account what was said in paragraph 93. The statutory remedy of revocation (and I would add the declaration of non-infringement) are remedies which are available if a relevant patent exists. Thus "any person" may bring a revocation action by identifying a granted patent and without the need to show any particular commercial interest (see Patents Act 1977 section 72 and *Cairnstores Ltd v Aktiebolaget Hässle [2002] FSR 35* ). Similarly a person wishing to obtain a declaration of non-infringement needs to do no more than identify the patent and provide the statutory particulars of his proposed act (see section 71 of the Patents Act 1977 ). The person seeking revocation, or a declaration of non-infringement, does not need to justify the need for the relief any further. […]

25 The jurisdiction to grant an *Arrow* declaration is by contrast discretionary. Identification of a relevant application is a necessary but not sufficient condition for an application for such relief. It is necessary to go further and examine whether it would serve a useful purpose. The point being made by paragraphs 98(iv) and 98(v) in *Fujifilm* is the contrast between a remedy which depends only on the existence of a patent (or application) and one whose availability turns on a critical examination of the purpose which its grant would serve.

[…]

28 I do not accept that the judge was exercising a discretion when striking the claim for *Arrow* relief from the action. The task which he was required to undertake was to determine whether the pleaded facts and arguments gave rise to a realistic claim for *Arrow* relief which should go to trial. The discretion to grant *Arrow* relief is that of the trial judge, not that of the judge hearing the strike out application. In approaching this task at the interim stage one should have in mind that it is the facts and circumstances at the date of the trial which will ultimately be determinative of whether the discretion should be exercised: see per Lord Collins in *AK Investment CJSC v Kyrgyz Mobil Tel Ltd [2011] UKPC] 7* at [126]. For similar reasons I do not accept that it is sensible to ask, at this stage, whether the facts relied on are sufficiently "unusual" to justify *Arrow* relief. This would be a particularly difficult test to apply at this interim stage before any facts are found.

## ***Relief - delivery up, disclosure, publication of judgment***

### ***Regeneron v Kymab***

***Kitchin LJ – 23 May 2018***

1 […] The court has power to make an order for delivery up to render more effective the injunction preventing further infringement. Kymab has not suggested that these cells have any purpose other than making antibodies in accordance with claim 2 and we are satisfied it is both necessary and proportionate to make the order sought in support of the injunction to restrain further infringement.

[…]

15 Regeneron seeks orders requiring Kymab to make extensive disclosure of what it describes as relevant Products and Antibodies (each as defined above).

16 Regeneron says it needs all of this information in order to police its patent rights in the UK against those entities with infringing products in the jurisdiction at present and against those entities which may seek to import infringing products into the UK from abroad. It also seeks information to allow it to secure whatever relief it may be entitled to in foreign jurisdictions.

[…]

19 We are not persuaded it is appropriate to make these orders. As Kymab says, it is entitled to keep mice and mouse cells in any jurisdiction where Regeneron has no relevant patent rights and Regeneron no longer seeks an order for their delivery up. Nor are we persuaded that the disclosure of this kind is necessary to prevent Kymab from importing any of these materials into the UK in breach of an injunction restraining infringement. We therefore see no reason why Kymab should be required to disclose where such mice or cells are kept, still less where the progeny of such mice or cells are kept. The position in relation to antibodies and cells engineered to produce antibodies is just the same. Neither of the orders sought is necessary for the protection of Regeneron's rights in the UK, and we are not persuaded it is appropriate to grant relief in order to assist Regeneron to bring proceedings in any other jurisdiction.

20 We consider next the categories of disclosure summarised in paragraphs [15(iii) and (iv)] above. These correspond broadly to the first two categories of disclosure sought by Regeneron save that they now relate to materials which are not in Kymab's possession or control. We are not persuaded that it is appropriate to order such disclosure in order to allow Regeneron to bring proceedings against third parties in other jurisdictions. To the contrary, we think there is force in Kymab's concerns that Regeneron may seek to contact its collaborators even if they are operating in a territory where Regeneron has no relevant patent rights or their activities do not amount to an infringement in any territory where Regeneron does have such rights. In our judgment Regeneron has made out its case for disclosure here but only in so far as it concerns materials which it has disposed of in the UK. We consider that the form of order suggested by Kymab is appropriate. This limits disclosure to Products and Antibodies made or kept by Kymab in infringement of one or other of the patents in issue but which are no longer in its possession or control as a result of its disposal of them in the UK. Any wider order would not be just or proportionate.

[…]

24 We have come to the conclusion that it is not appropriate to make an order requiring Kymab to publicise our judgment. We are concerned here with a specialised and relatively small public. We think it highly unlikely that workers in this field have not become aware of our decision and its effect, at least in broad terms, and we are wholly unpersuaded that the order sought is necessary to act as a deterrent to future infringers or to contribute to the awareness of the public at large. To the contrary, we have come to the conclusion that the order sought would serve no proper purpose. It would merely cause Kymab embarrassment.

## ***Confidentiality clubs***

### ***TQ Delta v Zyxel Communications***
### ***Henry Carr J – 13 June 2018***

21 In my judgment, the authorities discussed above establish that it is exceptional to limit access to documents in the case to external eyes only, so that no representative from the party which is subject to the restriction can see and understand those documents. An external eyes tier does not require justification for the restriction by reference to individual documents. It enables one party to decide to exclude all representatives of the opposite party from access to *any* document that it chooses, and places the onus on the party seeking access to apply to court to obtain it. That approach, in my judgment, is wrong in principle.

23 However, it is important to emphasise that:

(i) parties may choose to agree an external eyes only tier, as in *Unwired Planet [2018] R.P.C. 8* ;

(ii) confidentiality club agreements are often essential in intellectual property cases, which cases require disclosure of confidential information. In such cases, a regime for disclosure which limits access to sensitive documents to specific individuals within one of the parties, in order to protect confidentiality, is now commonplace;

(iii) redactions to documents can be made to exclude material which is confidential and irrelevant to the dispute;

(iv) external eyes only access to individual documents of peripheral relevance, whose disclosure would be damaging, may be justified in specific cases; as in *IPCom [2013] EWHC 52 (Pat)* ;

(v) I do not exclude the possibility that in certain exceptional cases, external eyes only access to specific documents of greater relevance might be justified, at least at an interim stage;

(vi) however, in the absence of exceptional circumstances, each party must be able to see and discuss with its lawyers the relevant parts of the key documents in the case.

24 An external eyes only tier enables a blanket exclusion of access by one of the parties to the relevant parts of key documents. This is incompatible with the right to a fair hearing under art.6 of European Convention on Human Rights , and with the principles of natural justice. It is incompatible with the obligations of lawyers to their clients. The principles on which solicitors are obliged to act on behalf of clients instructing them require the sharing of all relevant information of which they are aware.