AIPPI MEET

DECEMBER 2017

PATENT ROUND UP

2017

ANDREW LYKIARDOPOULOS QC

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Unwired Planet v Huawei	Approach to meaning and enforcement of FRAND.	Global licence including rates settled and declared to be FRAND. "FRAND" injunction granted until global licence entered into (stayed pending appeal).
Varian Medical v Elekta	Patent concerning radiotherapy and radiosurgery equipment. *Construction, infringement, insufficiency, obviousness, added matter.*	Patent invalid for obviousness and added matter.
Sandoz & Hexal v GD Searle	SPC for Darunavir ("Prezista") for treatment of HIV. *Meaning of Art. 3(a) SPC Regulation when applied to a Markush claim.*	SPC complies with Art. 3(a) SPC Regulation.
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Illumina v Premaitha & TDL	Case concerning 5 patents concerning non-invasive prenatal diagnosis (genetic testing on foetus). *Priority, Obviousness, added matter, excluded matter, claim interpretation, whether exclusive licensee*	Claim 8 of one patent valid and infringed when used for sex determination. Two patents valid and infringed as amended. Two patents valid and infringed.

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COURT OF APPEAL	**About?**	**Result**
Fujifilm v Abbvie	Whether Court can grant "Arrow" type relief.	Appeal from Orders of Arnold J and Henry Car J dismissed.
Ian Shanks v Unilever	Approach to "outstanding benefit" under s.40(1) Patents Act	Appeal from the Order of Arnold J dismissed.
Wobben v Siemens	Appeal against obviousness and no infringement.	Appeal from Order of Birss J dismissed.
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Synthon v Teva	Appeal on finding of obviousness Cross-appeal on finding of added matter.	Both appeals from Order of Birss J dismissed.
Unwired Planet v Huawei	Appeal on obviousness, priority and approach to	Appeal from Order of Birss J dismissed.

	novelty.	
K. Philips v Asustek	Appeal on construction of a patent cross-licensing agreement.	Appeal from Order of Arnold J dismissed.
Actavis, Teva & Generics v Icos	Appeal on finding of obviousness and infringement.	Appeal from Order of Birss J allowed.
Actavis v Eli Lilly	Appeal on finding of infringement of UK patent and designations in France, Italy and Spain.	Appeal from the Court of Appeal allowed.

PART 1: THE 2017 SPC CASES

Article 1
Definitions

For the purpose of this Regulation:

(a) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product;

(c) 'basic patent' means a patent which protects a product as defined in (b) as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;

Article 3
Conditions for obtaining a certificate

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application -

...

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

(c) the product has not already been the subject of a certificate

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

Abraxis Bioscience LLC v Comptroller-General of Patents

Arnold J

This was an appeal against the decision of the CG of Patents to refuse Abraxis' SPC Application for "paclitaxel formulated as albumin bound nanoparticles" on the ground that it did not comply with Articles 1(b) and 3(d) SPC Regulation.

The contention:

5. Abraxis' contentions raise questions to the proper interpretation of Articles 1(b) and 3(d) of the SPC Regulation. Abraxis submits that the answers to the questions are not clear, and therefore the questions should be referred to the Court of Justice of the European Union. In support of this submission, Abraxis relies on the fact that SPCs have been granted for nab-paclitaxel in nine EU Member States (Austria, Denmark, Finland, France, Greece, Italy, Luxembourg, Portugal and Spain), refused in two Member States (Sweden and the UK) and are the subject of pending applications in a further three Member States (Germany, the Netherlands and Ireland) and also in Switzerland. The Respondent ("the Comptroller") submits that the answers to the questions are clear, and accordingly no reference is necessary.

The problems:

18. The first problem is that the SPC Regulation contains no definition of the expression "active ingredient". How, therefore, does one decide what constitutes an "active ingredient" within the meaning of Article 1(b)? In particular, what is the position regarding (i) substances which, in one way or another, assist an active ingredient to achieve a particular therapeutic effect and (ii) combinations of such substances and that active ingredient? Some light is shed on this question by paragraphs 11 and 12 of the Commission's Explanatory Memorandum proposing what became Council Regulation 1768/92/EEC, which state (emphases added):

> "11. The proposal for a Regulation therefore concerns only new medicinal products. It does not involve granting a certificate for all medicinal products that are authorized to be placed on the market. Only one certificate may be granted for any one product, a product being understood to mean an active substance *in the strict sense*. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester *or a different pharmaceutical form* will not lead to the issue of a new certificate.
>
> 12. However, the proposal is not confined to new products only. A new process for obtaining the product or *a new application of the product* may also be protected by a certificate. All research, whatever the strategy or final result, must be given sufficient protection."

19. The second problem is that Article 3(d) requires that the marketing authorisation relied upon be the first authorisation "to place the product on the market as a medicinal product". How is this requirement to be interpreted in circumstances where the same active ingredient or combination of active ingredients (depending, of course, on what is meant by "active ingredient") has previously been the subject of a marketing authorisation, but the new marketing authorisation is for a different formulation or a different therapeutic use of that active ingredient or combination of active ingredients?

The Conclusion:

Article 1(b)

55. In my judgment, it is clear that nab-paclitaxel is not the active ingredient of Abraxane within the meaning of Article 1(b) of the SPC Regulation: paclitaxel is the active ingredient and albumin is a carrier. It is not necessary to seek further guidance from the CJEU as to the interpretation of Article 1(b) since the interpretation of that provision is *acte éclairé*. My reasons are as follows.

56. First, it is clear from the judgments of the CJEU in *MIT*, *GSK* and *Forsgren* that Article 1(b) is to be interpreted narrowly and cannot cover a substance which does not itself correspond to an "active ingredient" or a "combination of active ingredients".

57. Secondly, it is clear from *Forsgren* that an active ingredient is a substance which produces a pharmacological, immunological or metabolic effect of its own.

58. Thirdly, the hearing officer found as facts that (i) nab-paclitaxel is not a single active ingredient, (ii) the active ingredient in nab-paclitaxel is paclitaxel and (iii) the albumin functions as a carrier which is not covalently bonded to the paclitaxel. As counsel for Abraxis expressly confirmed, Abraxis does not challenge the hearing officer's findings of fact. Abraxis argues that the hearing officer incorrectly interpreted Article 1(b), but his application of the law was based on his findings of fact.

59. Fourthly, it is clear from *Forsgren* that, consistently with Article 8(1)(b) of the SPC Regulation, when considering whether a substance produces a pharmacological, immunological or metabolic effect of its own so as to constitute an active ingredient, it is proper to refer to both the SmPC forming part of, and the EPAR which led to, the marketing authorisation which covers that substance. (In this respect, the position adopted by the CJEU with respect to the SPC Regulation differs from that adopted by it with respect of European Parliament and Council Regulation 1610/96/EC of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products in Case C-258/99 *BASF AG v Bureau voor de Industriële Eigendom* [2001] ECR I-3643 at [31].) As the Comptroller contends, in the present case, the SmPC and EPAR for Abraxane both make it plain that the active ingredient of Abraxane is paclitaxel and that what Abraxis calls nab-paclitaxel is a *formulation* of paclitaxel. This supports the hearing officer's findings of fact. I should make it clear that, in saying this, I am not ruling upon the Comptroller's contention advanced by way of respondent's notice that the hearing officer should have confined himself solely to what was stated in the marketing authorisation (and possibly the EPAR), since it is not necessary for me to do so.

Article 3(d)

62. In my judgment it is not clear how far the reasoning of the Court of Justice in *Neurim* extends. As Abraxis acknowledges, on its face, the reasoning is limited to new therapeutic uses of old active ingredients. As Abraxis contends, however, it is arguable that the same policy considerations support Article 3(d) being interpreted in the same way in the case of new formulations of old active ingredients even if the therapeutic use is the same. This was certainly the view of Jacob LJ in the cases mentioned above. On the other hand, as the Comptroller argues, it appears from *MIT*, *GSK* and *Forsgren* that SPCs cannot be granted merely for new formulations. But since none of those decisions squarely addresses this issue, the position is not clear. Accordingly, I shall refer a question to the CJEU the substance of which is as follows:

> "Is Article 3(d) of the SPC Regulation to be interpreted as permitting the grant of an SPC where the marketing authorisation referred to in Article 3(b) is the first authorisation within the scope of the basic patent to place the product on the market as a medicinal product and where the product is a new formulation of an old active ingredient?"

63. In case it assists the Court of Justice, I will offer my own answer to this question. While I fully acknowledge the force of counsel for Abraxis' argument that the primary purpose of the SPC Regulation is to reward innovative research of the kind that led to the development of nab-paclitaxel and to compensate patentees for delays in obtaining marketing authorisations of the kind that Abraxis experienced with Abraxane, it must be recalled that the SPC Regulation was intended to provide a simple and predictable system that could be operated by the competent authorities of the Member States, and in particular the national patent offices, in a uniform manner. Moreover, as discussed, the SPC Regulation aims to balance the interests of patentees with those of other stakeholders. To achieve those objectives, it is necessary to have bright-line rules even if they sometimes deprive meritorious inventions of extended protection. Article 1(b) is such a rule, and the Court of Justice has held that it should be strictly interpreted. In my view it would be inconsistent with a strict interpretation of Article 1(b) to interpret Article 3(d) as permitting SPCs to be obtained for new formulations of old active ingredients. If Article 3(d) were to be interpreted in that way, it would be likely to lead to uncertainty and inconsistency as to the circumstances in which SPCs for new formulations could be obtained, as the existing case law illustrates. For example, could an SPC be obtained where the basic patent protected a key ingredient in the new formulation other than the active ingredient (as in *MIT*, the first application in *GSK* and *Forsgren*), rather than the new formulation containing the active ingredient (as in the second application in *GSK* and the present case)? Moreover, I agree with the Comptroller that paragraphs 11 and 12 of the Explanatory Memorandum appear to indicate that SPCs should be available for new applications (i.e. new therapeutic uses) of old active ingredients, but not for new formulations. Accordingly, I would answer the question no.

Conclusion

64. For the reasons given above, I shall refer a question as to the interpretation of Article 3(d) of the SPC Regulation along the lines set out in paragraph 62 above. I shall hear counsel as to the precise wording of the question.

Teva v Accord & Gilead

Arnold J

SPC for a "composition containing both Tenofovir disoproxil...together with emtricitabine" covering the HIV medication "Truvada".

Claim interpretation:

18. Claim 27 is in the following terms:

> "A pharmaceutical composition comprising a compound according to any one of claims 1-25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients."

22. Claim 27 requires the presence in the pharmaceutical composition of a compound falling within any of claims 1-25 together with a pharmaceutically acceptable carrier. The significance of the words "comprising" and "optionally" is that claim 27 permits, but does not require, the presence of other ingredients, both therapeutic and non-therapeutic. Thus the scope of protection of claim 27 is not limited to a pharmaceutical composition containing two (or more) therapeutic ingredients, but extends to a pharmaceutical composition containing a single therapeutic ingredient consisting of a compound falling within claims 1-25. It follows that the presence or absence of another therapeutic ingredient is irrelevant to any assessment of whether a pharmaceutical composition falls within claim 27, and thus to whether dealings in such a pharmaceutical composition infringe that claim of the Patent.

Technical advance or technical contribution of the Patent:

23. In my judgment it is clear that the inventive advance (or the technical contribution, to use the language used in the jurisprudence of the Boards of Appeal of the European Patent Office) of the Patent lies in the disclosure of the new compounds of formulae (1a) and (1), including TD, as claimed in claims 1-25. It is also clear that, given that invention, claim 27 does not reflect any further inventive advance (or technical contribution). In the jargon of patent lawyers, claim 27 is not independently valid over claims 1-25.

The Problem:

32. The interpretation of Article 3(a) of the SPC Regulation (and its predecessor, Council Regulation 1768/92/EEC) has caused great difficulty over the years, as is illustrated by the successive judgments of the CJEU discussed below. It may be helpful if I attempt to explain the problem before turning to consider the case law. Article 3(a) requires that "the product is protected by a basic patent in force". The term "product" is defined in Article 1(b) and the term "basic patent" is defined in Article 1(c). The question is what is meant by the term "protected" in this context.

33. There is very little in the SPC Regulation which sheds any light on this issue. The most one can say is that the SPC Regulation appears to draw a distinction between the *protection* conferred by a basic patent (and a certificate) and the *rights* conferred (subject to limitations and obligations) by the basic patent (and the certificate): see Articles 4 and 5.

34. Approaching the issue from first principles, however, I would suggest that what is tolerably clear is that the product must at least be "protected" by the basic patent applying the applicable rules of patent law in the country where the SPC has been applied for. But less clear are the answers to the following questions: first, what the applicable rules of patent law are for this purpose; and secondly, whether satisfaction of that test is sufficient to establish that a product is protected by a basic patent for the purposes of the SPC Regulation or whether something more is required, and if so what. As I will explain, it is the second of these questions which is particularly difficult to answer.

35. So far as the first question is concerned, there are two sets of rules which might be relevant in a case such as the present, which concerns a European patent. The first set, which I shall call the "**Extent of Protection Rules**", consists of national laws which implement Article 69 EPC, of which all Member States of the European Union are Contracting States. Article 69 concerns the extent of protection of a European patent. Article 69(1) provides that:

> "The extent of the protection conferred by a European patent ... shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims."

Article 69 is supplemented by the Protocol on the Interpretation of Article 69, which concerns the manner in which the claims are to be interpreted. Article 69 and the Protocol are given effect to in the UK by section 125(1) and (3) of the Patents Act 1977 and by the case law referred to above.

36. The second set of rules, which I shall call the **"Infringing Act Rules"**, consists of national laws which define what acts amount to an infringement of a patent. In many, but not all, Member States of the EU, including the United Kingdom, the relevant laws were intended to implement Articles 25 and 26 of the Community Patent Convention (as revised in 1989), which never came into force. These provide for a patent to "confer on its proprietor the right to prevent all third parties not having his consent" from committing certain acts. Some acts amount to direct use of the invention (and hence direct infringement of the patent) and other acts amount to indirect use of the invention (and hence indirect infringement of the patent). In the UK, Articles 25 and 26 CPC are implemented by sections 60(1) and (2) of the 1977 Act respectively. There are similar kinds of laws in countries which did not implement the CPC.

37. Bearing in mind (i) the apparent distinction drawn by the SPC Regulation between the protection conferred by a basic patent and the rights conferred by that patent, (ii) the fact that the extent of protection conferred by a European patent is governed by the Extent of Protection Rules while the rights conferred by a patent are governed by the Infringing Act Rules, and (iii) the fact it is not a product which infringes a patent, but an act performed by a person in relation to a product which infringes a patent, then one might conclude that the answer to the first question posed in paragraph 34 above

was that the applicable rules are the Extent of Protection Rules, and not the Infringing Act Rules.

43. [*following a consideration of Jacob J in Takdeda]* These considerations suggest that it is not sufficient for the product in question to fall within the scope of protection of the basic patent applying the Extent of Protection Rules. Something more is required. But what? I shall return to this question after considering the case law.

Conclusion:

91. In my judgment the test to be applied in order to determine whether a product is "protected" by a basic patent within the meaning of Article 3(a) remains unclear. It is clear that it is not sufficient that dealings in the product would infringe a claim applying the Infringing Act Rules. It is also clear that it is necessary that the product falls within at least one claim of the basic patent applying the Extent of Protection Rules. But it is not clear whether that is sufficient. It appears from the case law of the CJEU that it is not sufficient, and that more is required; but it is not clear what more is required.

95. I shall therefore ask question 1 in *Actavis v Sanofi* again:

> "What are the criteria for deciding whether 'the product is protected by a basic patent in force' in Article 3(a) of the SPC Regulation?"

96. In the hope that it will assist the Court of Justice to provide a clear answer this time, I will again offer my own suggested answer to this question. As discussed above, it is now clear that it is not sufficient that dealings in the product would infringe a claim applying the Infringing Act Rules. It is also clear that it is necessary that the product falls within at least one claim of the basic patent applying the Extent of Protection Rules. In my view, however, it is not sufficient that the product falls within at least one claim of the basic patent applying the Extent of Protection Rules. As explained in paragraphs 39-43 above, and as the facts of the present case illustrate, the scope of protection test proves too much in this context. Accordingly, more is required.

97. What more is required? In my view, the answer is that the product must infringe because it contains an active ingredient, or a combination of active ingredients, which embodies the inventive advance (or technical contribution) of the basic patent. Where the product is a combination of active ingredients, the combination, as distinct from one of them, must embody the inventive advance of the basic patent. Thus in a case such as the present, where the inventive advance of the Patent consists generally of the compounds of formulae (1) and (1a), including specifically TD, a medicinal product whose active ingredient is TD is protected by the Patent within the meaning of Article 3(a) because it embodies the inventive advance of the Patent. A medicinal product whose active ingredients are TD and another therapeutic agent such as emtricitabine in combination is not protected by the Patent within the meaning of Article 3(a) because the combination, as distinct from TD, does not embody the inventive advance of the Patent. This is not a question of the wording of the claims of the basic patent, which as discussed above can be manipulated by the patent attorney who drafts it, but of its substance. By contrast, if Gilead (or another inventor) were to obtain a patent for an invention consisting of a combination of TD and substance X which surprisingly

had a synergistic effect in treating HIV, then a medicinal product whose active ingredients were TD and X would be protected by that patent since it would embody the inventive advance of that patent. In my view, this interpretation of Article 3(a) would accord with the object of the SPC Regulation, which is to encourage invention in the field of medicinal products by compensating inventors for the delay in exploiting their inventions due to the need to obtain regulatory approval, and not to confer unjustified monopolies.

98. For the avoidance of doubt, this interpretation of Article 3(a) would not prevent a patentee from obtaining an SPC in circumstances where the patent protected a single active ingredient A, but the patentee had only obtained a marketing authorisation for that active ingredient in combination with another active ingredient B. In those circumstances, as the Court of Justice held in *Medeva*, the patentee could obtain an SPC for product A.

Teva & Accord v Merck Sharpe & Dohme

Arnold J

Proceedings concerning SPC for a combination of efavirenz, emtricitabine and tenofovir, particularly tenofovir disoproxil, especially tenofovir disoprixil fumarate. SPC said not to comply with Arts. 3(a) or (c) of Regulation.

Interpretation of Article 3(c):

34. In my judgment it is clear from this case law that Article 3(c) precludes the grant of an SPC for a combination of active ingredients where one of those active ingredients embodies the "core inventive advance" or "sole subject-matter of the invention" of the basic patent and has already been the subject of an SPC based on that patent even if the patent contains one or more claims which protect the combination. On the other hand, it does not preclude the grant of an SPC for a combination of active ingredients, even if one of those active ingredients is protected by the basic patent and has already been the subject of an SPC, if the combination represents a distinct invention protected by the patent. If the combination is a distinct invention, it should not matter whether it is protected by the same patent or by a different patent.

Conclusion on Article 3(a)

166. For the reasons given above, I have concluded that the scope of protection of claim 16 of the Patent extends to a combination of efavirenz and tenofovir or to a combination of efavirenz and emtricitabine, but not to a combination of all three.

167. Since the minimum requirement for a product to be "protected" by a basic patent within the meaning of Article 3(a) of the SPC Regulation is that the product falls within the extent of protection of at least one claim, it follows that the Product is not

protected" by the Patent. Accordingly, the SPC is invalid because it does not comply with Article 3(a).

Conclusion on Article 3(c)

170. Counsel for the Claimants submitted that it should be assumed for this purpose that the skilled person had efavirenz and its activity against HIV reverse transcriptase disclosed to them at the priority date. Although counsel for MSD took issue with this, I consider that it is correct. The question to be considered is not the conventional one of whether a claim is invalid over a particular item of prior art read in the light of the common general knowledge, but whether, given the invention of efavirenz, claim 16 represents a distinct invention such that it could in principle form the subject-matter of a separate patent.

171. Considered in that way, I consider that claim 16 is not independently valid over the claims which protect efavirenz and does not represent a distinct invention. There is nothing in the Patent to suggest that claim 16 represents a distinct invention. Given the need for a simple and transparent system for the grant of SPCs, it seems to me that that should ordinarily be the end of the matter and that it should not be necessary to adduce expert evidence on this question.

Sandoz & Hexal v GD Searle

Arnold J

SPC for Darunavir, marketed in the EU as Prezista for treatment of HIV. The case concerned a claim to a Markush formulae.

The Problem:

58. The Claimants contend in summary that darunavir is not specified or identified in any of the claims of the Patent: although darunavir falls within the claims due to their immense breadth, it is not specifically identified by name or structure in the claims or anywhere in the specification, nor is there any teaching in the Patent which points to darunavir, and in particular its novel and unusual P^1 group. The Claimants say that a Markush claim does not specify or identity a product unless the skilled person would consider the product to be part of the subject-matter of the patent based on their reading of the specification and their common general knowledge as at the priority date without undue burden or further invention, and that this test is not satisfied in the present case. Accordingly, the Claimants contend that darunavir is not "protected" by the Patent within the meaning of Article 3(a). The Claimants accept, however, that it is not *acte clair* that this is how Article 3(a) should be interpreted. Accordingly, they contend that a question should be referred to the CJEU for a preliminary ruling.

59. The Defendants contend in summary that, although the correct interpretation of Article 3(a) remains unclear in certain respects, that does not matter for the purposes of the present case. The Defendants say that, upon any tenable

interpretation of Article 3(a), darunavir is a product which is "protected" by (at least) claims 1, 2, 5, 10 and 11 of the Patent. In particular, the Defendants say that, although the claims of the Patent must be interpreted as at the priority date of the Patent, the question whether a product is "protected" by those claims falls to be judged once the product is known (in practice, once it has been authorised to be placed on the market as a medicinal product): see Teva v MSD at [108]-[110] and [142]. Accordingly, the Defendants contend that it is not necessary to refer any question to the CJEU for a preliminary ruling.

60. In my judgment the Defendants are correct. My reasons are as follows.

61. The broadest tenable interpretation of Article 3(a) is that it is sufficient that the product falls within at least one claim of the patent applying the Extent of Protection Rules. At present, it does not appear that this interpretation is correct, because the CJEU has so far held that more is required. But if this interpretation is correct, there can be no doubt that darunavir is "protected" by the Patent.

62. As noted above, the CJEU held in *Medeva* and its progeny that it was necessary for the product to be "specified" or "identified" in the wording of the claims. Counsel for the Claimants reminded me that I said in *Novartis Pharmaceuticals UK Ltd v MedImmune Ltd* [2012] EWHC 181 (Pat), [2012] FSR 23 at [53] that the test laid down in those cases "was unclear save in its rejection of the infringement test in combination cases" and that it was unclear whether it was "sufficient, say, for the claim to incorporate a Markush formula which covers a large number of compounds one of which is the product in respect of which an SPC is sought".

63. Subsequently, however, the CJEU held in *Lilly* that it is not necessary for the active ingredient to be identified in the claim by means of a structural formula: it is sufficient for the active ingredient to be covered by a functional description provided that the claims "relate, implicitly but necessarily and specifically, to the active ingredient". It is clear from this that the identification of the active ingredient in the claim by means of a structural formula is permissible, but not essential; that it is not necessary for the claim individually to name or depict the active ingredient; and that it is not necessarily an objection that the claim in question covers a large number of other compounds in addition to the active ingredient in question (since, if that was so, it would have provided a simple answer to the *Lilly* case).

64. I remain of the view which I expressed in *Teva v Gilead* at [81] that the test laid down with respect to functional descriptions in *Lilly* is an unclear test which is difficult to apply. This does not matter for the purposes of the present case, however. What matters is the light which *Lilly* sheds on the test laid down in *Medeva*. For the reasons given in the preceding paragraph, this suggests that it is sufficient for the claim to specify the product by means of a Markush formula which covers it (at least without resort to equivalents). If so, then darunavir is "protected" by the Patent.

65. I also remain of the view that a better test would be the one stated in paragraph 11 above, which in a case such as the present requires that the product falls within the claim and that it embodies the inventive advance (or technical contribution) of the claim. If that test is applied to the facts of the present case, the answer is clear. The

inventive advance (or technical contribution) of claim 1 of the Patent lies in the identification of the compounds covered by claim 1 as having utility as HIV protease inhibitors. Darunavir embodies that inventive advance. It is not necessary on this approach to consider claims 2, 5, 10 and 11, but if it were necessary the answer would be the same.

66. In reality, the Claimants' objection is that claim 1 is of excessive breadth because it encompasses a vast number of compounds which the skilled person could not make even a tiny fraction of and which it is not plausible would all be efficacious as protease inhibitors (and the same goes for claims 2, 5, 10 and 11). If well founded, however, that is an objection to the validity of the Patent. It amounts to saying that the claims are obvious on *AgrEvo* grounds or insufficient. But as I have already pointed out, the Patent is presumed to be valid unless and until the Claimants put its validity in issue, which they have not done.

67. I cannot see that there is any tenable interpretation of Article 3(a) which leads to the conclusion that darunavir is not "protected" by the Patent. The Claimants' difficulty in this respect is illustrated by five points. First, counsel for the Claimants reminded me that a Markush formula was not a novelty-destroying disclosure of an individual compound covered by the formula (see *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd* [2009] EWCA Civ 1362, [2010] RPC 9), but then she expressly disavowed the adoption of a disclosure test under Article 3(a). Secondly, it was only in counsel for the Claimants' oral submissions that the test set out in paragraph 58 above was formulated, other tests having been proposed in her skeleton argument. Thirdly, counsel was unwilling definitely to commit to that test. Although I understood from her oral submissions that it represented her preferred test, she indicated that other tests might be possible. Fourthly, if one concentrates just upon that test, it is really a breadth of claim test. In my view it is not the function of patent offices when assessing applications for the grant of SPCs to have to consider whether the breadth of the claims of the basic patents relied on is justified. That would not make for a simple and transparent system, as envisaged in paragraph 16 of the European Commission's Explanatory Memorandum proposing the predecessor to the SPC Regulation. By contrast, paragraph 39 of the Memorandum did envisage SPCs being granted where "a patent protects a series of products based on the same formula". Fifthly, as counsel for the Defendants pointed out, it is implicit in the Claimants' case that some compounds covered by claim 1 of the Patent are "protected" by the Patent, while others are not; but it is wholly unclear where and how the line between the two groups of compounds is to be drawn.

68. Finally, I would add that counsel for the Claimants prayed in aid of her submissions two considerations which in my judgment are irrelevant to the question of whether the SPC complies with Article 3(a). First, she relied on the fact that darunavir was first reported six years after the priority date of the Patent. This does not mean that it cannot be "protected" by the Patent, however. It is commonplace for preferred embodiments of an invention to be developed some time after the patent is filed. Secondly, she relied on the allegation that darunavir was independently developed by Prof Ghosh. Counsel for the Defendants disputed that darunavir was independently developed, and I do not consider that the evidence enables me to make a finding one way or the other. Even if it was

independently developed, however, that has no bearing on whether it is "protected" by the Patent. The irrelevance of both these considerations to Article 3(a) is confirmed, if confirmation is necessary, by the CJEU's decision in *Lilly*. As counsel for the Defendants pointed out, the Claimants do not allege that the SPC is invalid for non-compliance with Article 3(b) or (d) of the SPC Regulation (cf. the observations of the CJEU in *Lilly* at [43] and my observations in *Novartis* at [61] and in *Teva v Gilead* at [82]).

PART 2: CLAIM INTERPRETATION

ACVAVIS V ELI LILLY

The Claim was brought by Actavis. Actavis' proposed products used pemetrexed compounds together with vitamin B12 for cancer treatment. The relevant active ingredient was pemetrexed *dipotassium*. Eli Lilly's patent claimed the use of pemetrexed *disodium* in the manufacture of a medicament for use in combination with vitamin B12 for the treatment of cancer. Actavis sought declarations of non-infringement for the UK, France, Italy and Spain.

Arnold J held that the Actavis products would not infringe either directly or indirectly. The Court of Appeal allowed Lilly's appeal on indirect infringement on the basis that ultimate users will dilute in saline and the solution which is administered will contain pemetrexed disodium.

Although the claims recited the use of pemetrexed disodium, Eli Lilly argued that the essence of the invention was the use of a pemetrexed salt with vitamin B12 and not any specific pemetrexed salt.

The ordinary language of the claims:

30. As a matter of ordinary language, it is quite clear that the only type of pemetrexed compound to which the Patent's claims expressly extend is pemetrexed disodium. One only needs to read claim 1 and claim 12 to justify that: as a matter of ordinary language, "pemetrexed disodium" means that particular salt, and no other salt, let alone the free acid.

31. In these circumstances, The Protocol on the Interpretation of article 69 as amended in 2000 ("the Protocol") is crucial to Lilly's contention that the scope of protection afforded by the Patent extends to the Actavis products.

The proper approach to infringement claims

54. In my view, notwithstanding what Lord Diplock said in *Catnic* [1982] RPC 183, 242, a problem of infringement is best approached by addressing two issues, each of which is to be considered through the eyes of the notional addressee of the patent in suit, ie the person skilled in the relevant art. Those issues are: (i) does the variant infringe any of the claims as a matter of normal interpretation; and, if not, (ii) does the variant nonetheless infringe because it varies from the invention in a

way or ways which is or are immaterial? If the answer to either issue is "yes", there is an infringement; otherwise, there is not. Such an approach complies with article 2 of the Protocol, as issue (ii) squarely raises the principle of equivalents, but limits its ambit to those variants which contain immaterial variations from the invention.

55. In *Kirin-Amgen* [2005] RPC 9, Lord Hoffmann, following his approach in *Improver* [1990] FSR 181 (which itself had followed Lord Diplock's analysis in *Catnic* [1982] RPC 183) effectively conflated the two issues, and indicated that the conflated issue involved a question of interpretation. I have considerable difficulties with the notion that there is a single conflated, or compound, issue, and, even if that notion is correct, that that issue raises a question of interpretation. Indeed, in my view, to characterise the issue as a single question of interpretation is wrong in principle, and unsurprisingly, therefore, can lead to error.

56. [....] In my opinion, issue (ii) involves not merely identifying what the words of a claim would mean in their context to the notional addressee, but also considering the extent if any to which the scope of protection afforded by the claim should extend beyond that meaning.

58. Turning to the two issues identified in para 54 above, issue (i), as already mentioned, involves solving a problem of interpretation, which is familiar to all lawyers concerned with construing documents. While the answer in a particular case is by no means always easy to work out, the applicable principles are tolerably clear, and were recently affirmed by Lord Hodge in *Wood v Capita Insurance Services Ltd* [2017] 2 WLR 1095, paras 8 to 15. In the present case, there is no doubt that, according to normal principles of interpreting documents, the Actavis products do not infringe the Patent, as in no sensible way can pemetrexed free acid, pemetrexed ditromethamine, or pemetrexed dipotassium mean, ie be said to fall within the expression, "pemetrexed disodium" in claim 1 of the Patent, any more than a slotted rubber rod can be said to be within the expression "a helical metal spring" in the claim in the *Improver* patent. According to normal principles of interpreting documents, then, this would be the end of the matter.

59. However, the second issue poses more difficulties of principle: what is it that makes a variation "immaterial"? In that connection, I consider that Hoffmann J's three questions in *Improver* [1990] FSR 181 provide helpful assistance, a view supported by the fact explained in paras 44 to 52 above that similar but not identical tests have been adopted in other EPC jurisdictions. However, each of the three questions requires some exegesis, and, particularly the second question, some reformulation.

62. In my opinion, the second question is 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. In other words, it seems to me that the second *Improver* question should be asked on the assumption that the notional addressee knows that the variant works to the extent that it actually does work. That, I think, would be a fair basis on which to proceed in terms of balancing the factors identified in article 1 of the Protocol, and it is, I think, consistent with the approach of the German, Italian and Dutch courts. It is also consistent with the fact that the notional addressee is told (in the patent itself) what the invention does.

63. This reformulated second question should also apply to variants which rely on, or are based on, developments which have occurred since the priority date, even though the notional addressee is treated as considering the second question as at the priority date. Such an approach is supported by the desirability of both consistency of approach and pragmatic justice. It seems right in principle to have the same question, including the same assumption (ie that the variant works) for all cases. As to pragmatism, the point is touched on by Judge Kalden in the passage quoted at the end of para 51 above: while the notional addressee may answer the reformulated second question affirmatively even where the variant was unforeseeable at the priority date, he is less likely to do so than in relation to a variant which was unforeseeable as at that date.

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".

Lord Hodge in Wood v Capita Insurance Services Ltd [2017] 2 WLR 1095:

10. The court's task is to ascertain the objective meaning of the language which the parties have chosen to express their agreement. It has long been accepted that this is not a literalist exercise focused solely on a parsing of the wording of the particular clause but that the court must consider the contract as a whole and, depending on the nature, formality and quality of drafting of the contract, give more or less weight to elements of the wider context in reaching its view as to that objective meaning. In *Prenn v Simmonds* [1971] 1 WLR 1381 (1383H-1385D) and in *Reardon Smith Line Ltd v Yngvar Hansen-Tangen* [1976] 1 WLR 989 (997), Lord Wilberforce affirmed the potential relevance to the task of interpreting the parties' contract of the factual background known to the parties at or before the date of the contract, excluding evidence of the prior negotiations. When in his celebrated judgment in *Investors*

Compensation Scheme Ltd v West Bromwich Building Society [1998] 1 WLR 896 Lord Hoffmann (pp 912-913) reformulated the principles of contractual interpretation, some saw his second principle, which allowed consideration of the whole relevant factual background available to the parties at the time of the contract, as signalling a break with the past. But Lord Bingham in an extra-judicial writing, *A new thing under the sun? The interpretation of contracts and the ICS decision* Edin LR Vol 12, 374-390, persuasively demonstrated that the idea of the court putting itself in the shoes of the contracting parties had a long pedigree.

11. Lord Clarke elegantly summarised the approach to construction in *Rainy Sky* at para 21f. In *Arnold* all of the judgments confirmed the approach in *Rainy Sky* (Lord Neuberger paras 13-14; Lord Hodge para 76; and Lord Carnwath para 108). Interpretation is, as Lord Clarke stated in *Rainy Sky* (para 21), a unitary exercise; where there are rival meanings, the court can give weight to the implications of rival constructions by reaching a view as to which construction is more consistent with business common sense. But, in striking a balance between the indications given by the language and the implications of the competing constructions the court must consider the quality of drafting of the clause (*Rainy Sky* para 26, citing Mance LJ in *Gan Insurance Co Ltd v Tai Ping Insurance Co Ltd (No 2)* [2001] 2 All ER (Comm) 299 paras 13 and 16); and it must also be alive to the possibility that one side may have agreed to something which with hindsight did not serve his interest: *Arnold* (paras 20 and 77). Similarly, the court must not lose sight of the possibility that a provision may be a negotiated compromise or that the negotiators were not able to agree more precise terms.

12. This unitary exercise involves an iterative process by which each suggested interpretation is checked against the provisions of the contract and its commercial consequences are investigated: *Arnold* para 77 citing *In re Sigma Finance Corpn* [2010] 1 All ER 571, para 10 per Lord Mance. To my mind once one has read the language in dispute and the relevant parts of the contract that provide its context, it does not matter whether the more detailed analysis commences with the factual background and the implications of rival constructions or a close examination of the relevant language in the contract, so long as the court balances the indications given by each.

13. Textualism and contextualism are not conflicting paradigms in a battle for exclusive occupation of the field of contractual interpretation. Rather, the lawyer and the judge, when interpreting any contract, can use them as tools to ascertain the objective meaning of the language which the parties have chosen to express their agreement. The extent to which each tool will assist the court in its task will vary according to the circumstances of the particular agreement or agreements. Some agreements may be successfully interpreted principally by textual analysis for example because of their sophistication and complexity and because they have been negotiated and prepared with the assistance of skilled professionals. The correct interpretation of other contracts may be achieved by a greater emphasis on the factual matrix, for example because of their informality, brevity or the absence of skilled professional assistance. But negotiators of complex formal contracts may often not achieve a logical and coherent text because of, for example, the conflicting aims of the parties, failures of communication, differing drafting practices, or deadlines which require the parties to compromise in order to reach

agreement. There may often therefore be provisions in a detailed professionally drawn contract which lack clarity and the lawyer or judge in interpreting such provisions may be particularly helped by considering the factual matrix and the purpose of similar provisions in contracts of the same type. The iterative process, of which Lord Mance spoke in *Sigma Finance Corpn* (above), assists the lawyer or judge to ascertain the objective meaning of disputed provisions.

And see Lord Clarke in *Rainy Sky v Kookmin Bank [2011] UKSC 50:*

21. The language used by the parties will often have more than one potential meaning. I would accept the submission made on behalf of the appellants that the exercise of construction is essentially one unitary exercise in which the court must consider the language used and ascertain what a reasonable person, that is a person who has all the background knowledge which would reasonably have been available to the parties in the situation in which they were at the time of the contract, would have understood the parties to have meant. In doing so, the court must have regard to all the relevant surrounding circumstances. If there are two possible constructions, the court is entitled to prefer the construction which is consistent with business common sense and to reject the other.

22. [...]

23. Where the parties have used unambiguous language, the court must apply it. This can be seen from the decision of the Court of Appeal in *Co-operative Wholesale Society Ltd v. National Westminster Bank plc* [1995] 1 EGLR 97. The court was considering the true construction of rent review clauses in a number of different cases. The underlying result which the landlords sought in each case was the same. The court regarded it as a most improbable commercial result. Where the result, though improbable, flowed from the unambiguous language of the clause, the landlords succeeded, whereas where it did not, they failed. The court held that ordinary principles of construction applied to rent review clauses and applied the principles in *The Antaios (Antaios Compania Naviera SA v Salen Rederierna AB)* [1985] AC 191. After quoting the passage from the speech of Lord Diplock cited above, Hoffmann LJ said, at p 98:

> "This robust declaration does not, however, mean that one can rewrite the language which the parties have used in order to make the contract conform to business common sense. But language is a very flexible instrument and, if it is capable of more than one construction, one chooses that which seems most likely to give effect to the commercial purpose of the agreement."

The effect of prosecution history

87. In my judgment, it is appropriate for the UK courts to adopt a sceptical, but not absolutist, attitude to a suggestion that the contents of the prosecution file of a patent should be referred to when considering a question of interpretation or infringement, along substantially the same lines as the German and Dutch courts. It is tempting to exclude the file on the basis that anyone concerned about, or affected by, a patent should be entitled to rely on its contents without searching

other records such as the prosecution file, as a matter of both principle and practicality. However, given that the contents of the file are publicly available (by virtue of article 128 EPC 2000) and (at least according to what we were told) are unlikely to be extensive, there will be occasions when justice may fairly be said to require reference to be made to the contents of the file. However, not least in the light of the wording of article 69 EPC 2000, which is discussed above, the circumstances in which a court can rely on the prosecution history to determine the extent of protection or scope of a patent must be limited.

88. While it would be arrogant to exclude the existence of any other circumstances, my current view is that reference to the file would only be appropriate where (i) the point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point, or (ii) it would be contrary to the public interest for the contents of the file to be ignored. The first type of circumstance is, I hope, self-explanatory; the second would be exemplified by a case where the patentee had made it clear to the EPO that he was not seeking to contend that his patent, if granted, would extend its scope to the sort of variant which he now claims infringes.

The Subsequent cases applying Actavis

Claim interpretation:

Generics, Synthon & Yeda v Teva
Arnold J.
26 October 2017

135. [...] One of the questions which arises in the light of the Supreme Court's decision is whether, before one comes to any question of equivalents, it remains the law that patent claims should be given a purposive construction.

136. Counsel for the Defendants submitted that this was no longer the law, and that instead a patent claim should be interpreted literally – by which counsel explained that he meant in the same manner as a clause in a commercial contract – and without regard to the patentee's purpose. In support of this submission, he relied upon the following paragraphs of the judgment of Lord Neuberger (with whom the other members of the panel agreed): [54], where Lord Neuberger referred to "normal interpretation" of claims; [58], where he said that "the applicable principles" for "interpreting documents" were those summarised by Lord Hodge in *Wood v Capita Insurance Services Ltd* [2017] UKSC 24, [2017] 2 WLR 109 at [8]-[15]; and [66(i)], where he referred to "the literal meaning of the relevant claim(s)".

137. Counsel for the Claimants submitted that it remained the law that a patent claim should be given a purposive construction. In support of this submission, he

relied upon the following paragraphs of Lord Neuberger's judgment: [22], where he said that "a patent is to be interpreted on the basis that it is addressed to a person or group of persons who is or are likely to have a practical interest in the claimed invention"; [54], where he said that both the issues of (i) "normal interpretation" and (ii) infringement by immaterial variants should be "considered through the eyes of a notional addressee" of the patent; and [56], where he referred to issue (ii) involving "not merely identifying what the words of a claim would mean in their context to the notional addressee".

138. In my judgment counsel for the Claimants is correct. As has often been pointed out, patents differ from commercial contracts in two key ways. First, a contract is (at least in principle) a bilateral statement agreed between the contracting parties, whereas a patent is a unilateral statement made by the patentee and addressed to the class of persons represented by the person skilled in the art. Secondly, whereas a contract is a document containing promises by the contracting parties to each other (in some cases for the benefit also of third parties), a patent is a document which describes and claims an invention for the purposes of establishing a legal monopoly with regard to that invention. One cannot rationally interpret a patent claim without taking these matters into account. Moreover, I do not consider that Lord Neuberger can have meant anything different, even though he appears to have eschewed the expression "purposive construction" when describing the correct approach. On the contrary, in the passages relied upon by counsel for the Claimants, he expressly stated that a patent was to be interpreted through the eyes of the person skilled in the art and that the exercise involved interpreting the words of the claim in context. The context must include the very purpose for which the document exists, namely to describe and claim an invention.

Illumina v Premaitha Health & TDL Generics
Henry Carr J
21 November 2017

201. The use of the word 'literal' may be confusing. In *Generics (UK) Ltd (t/a Mylan) & Anor v Yeda Research and Development Company Ltd* [2017] EWHC 2629 at [134] – [139] Arnold J rejected a submission that a patent claim should be interpreted in the same way as a commercial contract. He referred to (amongst others) the following paragraphs in the judgment of Lord Neuberger: [22], where he said that "*a patent is to be interpreted on the basis that it is addressed to a person or group of persons who is or are likely to have a practical interest in the claimed invention*"; [54], where he said that both the issues of (i) "*normal interpretation*" and (ii) infringement by immaterial variants should be "*considered through the eyes of a notional addressee*" of the patent; and [56], where he referred to issue (ii) involving "*not merely identifying what the words of a claim would mean in their context to the notional addressee*". Arnold J held that normal interpretation involves interpreting the words in context and the context must include "*the very purpose for which the document exists, namely to describe and claim an invention.*"

202. I agree with Arnold J. The Protocol on the Interpretation of Article 69 precludes a strict, literal interpretation, where the description and drawings are used only to resolve an ambiguity in the claims. This applies generally to interpretation of claims and is not confined to consideration of equivalents. Normal interpretation means purposive interpretation.

Impact on Validity?

Generics, Synthon & Yeda v Teva
Arnold J.
6th October 2017

159. Prior to 12 July 2017 it was settled law that the claim should be interpreted in the same manner, and had the same scope, for the purposes of considering both novelty and infringement: see *Terrell on the Law of Patents* (18th ed, 2016) at §§9-12 to 9-19 and the authorities cited, many of which emphasise the importance of ensuring that the patentee cannot maintain a broad scope of claim for the purposes of infringement, but a narrow one for the purposes of validity.

[...]

161. Another question which arises in the light of the Supreme Court's decision is what effect, if any, this has on the law of novelty. This issue is not addressed in the judgment of Lord Neuberger, and he makes no reference to *Synthon v SKB*. It will require another decision of the Supreme Court to supply a definitive answer to the question. Given the conclusion I have come to with respect to obviousness, however, I do not propose to consider the matter at length.

162. Counsel for the Claimants submitted that it remained the law that a claim lacked novelty if the prior publication disclosed subject-matter which, if performed, would necessarily infringe the claim. Even if the subject-matter would not fall within the claim on its proper interpretation, it was sufficient that the subject-matter would infringe the claim applying the doctrine of equivalents. Otherwise, a claim could be infringed by a person who did exactly what the prior publication taught, yet the claim would be novel over that prior publication. This would be a radical departure from English patent law as it had previously been understood for many decades.

163. Counsel for the Defendants submitted that it was no longer the law that a claim lacked novelty if the prior publication disclosed subject-matter which, if performed, would necessarily infringe the claim. Rather, the claim would only lack novelty if the prior publication disclosed subject-matter which fell within the claim on its proper interpretation. It was not sufficient that the subject-matter would infringe the claim applying the doctrine of equivalents.

164. In support of this submission, counsel for the Defendants made three main points. The first is that in *Synthon v SKB* the House of Lords had not been considering the question of anticipation by equivalents, because at that time it was not possible to infringe by virtue of a doctrine of equivalents if the alleged infringement fell outside the claim on its proper interpretation.

165. The second point is that it is established in the jurisprudence of the Boards of Appeal of the EPO that a claim is not deprived of novelty by an obvious equivalent of a feature in a prior publication. Thus the *Case Law of the Boards of Appeal of the European Patent Office* (8th ed, 2016) states at pages 108-109:

[*sets out extract from Case Law of the EPO]*

166. The third point is that the decision of the Supreme Court was based on Article 2 of the Protocol on the Interpretation of Article 69 of the European Patent Convention, which is concerned with the extent of protection conferred by a European patent or patent application, that is to say, with infringement and not with validity.

167. The conclusion I reach is that counsel for the Defendants is correct. Nevertheless, in case this case goes further, I shall consider what the position would be if counsel for the Claimants were correct.

Novelty over Pinchasi

[...]

172. Accordingly, I conclude that, if it is legally possible for a claim to be deprived of novelty by virtue of the doctrine of equivalents, then claim 1 lacks novelty over Pinchasi.

PART III: FUFJIFILM V ABBVIE

PRODUCT OR PROCESS FOCUSSED DECLARATIONS

The Judgment of Floyd LJ

The Issue:

2. The appeals raise the question of whether, in proceedings such as the present, the court can properly grant declarations that a product was old or obvious in patent law terms at a particular date. An action for such a declaration was held to be arguable by Kitchin LJ (as Kitchin J) in *Arrow Generics Limited v Merck & Co. Inc.* [2007] EWHC 1900 (Pat), [2007] FSR 39 ("the *Arrow* case"). A declaration in these terms has been referred to in argument, for brevity, as an "*Arrow* declaration", and we will continue to do so.

The Reasoning:

86. In our judgement there is nothing in the scheme of the EPC and the Act to prevent such declarations in cases where there is a real justification for their grant. It is necessary to examine quite carefully the ways in which it is suggested that the grant of such a declaration would conflict with that scheme.

87. So far as the EPO is concerned, the following considerations are relevant. Firstly, the declaration has no direct impact on what the EPO can or cannot do in relation to any given application. The EPO will apply its own internal legal order and procedures irrespective of any decision of the national court. Secondly, the court is not being asked to review or adjudicate on past action within the EPO, as it was in *Lenzing* or *Virgin*. It is, however, correct to say that the court is being asked to adjudicate on an issue which *may* arise in proceedings in relation to one or more applications proceeding in the EPO.

88. We do not think that this latter consideration means that the declaration is a collateral attack on the proceedings in the EPO. On the contrary it is an inevitable feature of the scheme set up under the EPC that national courts will have to decide whether combinations of features are old or obvious, and that they will have to do so while possible divisional applications are still pending in the EPO (or indeed in the national patent office). Whenever a national court decides that a claim with features A, B and C is old or obvious in the course of revocation proceedings against a granted patent, it is deciding an issue which *may* arise in relation to a

pending application. That is exactly what happened in the *Arrow* case itself, when divisionals were prosecuted in relation to essentially the same idea as had been held obvious (albeit in normal revocation proceedings) by Jacob J and the Court of Appeal. Because of the structure of the EPC, the EPO cannot be insulated from findings by national courts which may run contrary to applications which it is in the process of examining. The EPO is considered by the scheme to be capable of deciding its cases in accordance with its own legal order.

89. For similar reasons, the grant of an *Arrow* declaration is not inconsistent with the abolition of the right to oppose a patent in pre-grant opposition proceedings. The declaration will not prevent the EPO from granting any patent.

90. Is the grant of *Arrow* declarations incompatible with the Act (albeit not expressly prohibited by it)? This is the main argument based on the *Barraclough* principle. At its most straightforward, the argument is that it is the Act which grants the patent rights enjoyed by the patentee, and which provides for the manner in which their validity is to be examined. It is not for the courts in those circumstances to find other ways of making findings of invalidity which are not contemplated in the statute. The statute provides the exclusive remedy.

91. Despite the attractive force of Mr Hobbs' submissions on this point, we have in the end not been able to accept them for essentially the following reasons. Firstly, although we agree with Mr Hobbs that the Act is a complete statutory code for challenging the validity of a granted patent, the *Arrow* declarations sought do not declare any patent invalid. In the present case, it is to be noted that there are now no longer any granted patents in the background in relation to which they could (even possibly) have that effect.

92. Secondly, the remedy which the statute provides exists only in relation to granted patents. We have already said that the *Barraclough* principle operates to prevent a disguised challenge to validity of a granted patent where such a patent exists. However, it is one thing to say that the statute should be understood to be providing an exclusive statutory remedy in relation to granted patents (which it does). It is going much further to say that it is providing an exclusive remedy in relation to patents which have not and may never be granted. We do not think that it can have been the intention of Parliament to preclude the grant of declarations, however strongly justified, in circumstances where the statutory remedy is simply not available.

93. The eventual existence of the statutory remedy of revocation is, in our judgment, of relevance to the question of whether a declaration should be granted in the exercise of the court's discretion. A claimant cannot seek an *Arrow* declaration simply because it would like to know whether a patent application in the course of prosecution will result in a valid patent. The course envisaged by the statute is that he should wait and see what, if any, patent is granted. The statutory remedy does not constitute a bar in principle to the granting of declaratory relief in appropriate cases, however. Where, for example, it appears that the statutory remedy is being frustrated by shielding subject matter from scrutiny in the national court, it should be open to the court to intervene. Just as in *Nokia*, the statutory remedy does not provide, in practical terms, the relief which the claimant needs.

94. It follows that we do not accept Mr Hobbs' criticism of the reasoning in the *Arrow* case itself. In saying, in paragraph 36 of his judgment in that case, that the court would have no jurisdiction to declare invalid or revoke the 904 patent, Kitchin J was doing no more than reflecting the fact that there was and never had been a 904 patent. It therefore made no sense to speak of the invalidity of its (non-existent) grant or permit a claim for revocation of a non-existent patent. What was permissible, as the rest of the judgment shows, is to identify features of a product or process which the claimant is selling or intends to sell, and to ask the court to determine whether those features are obvious.

95. We are not persuaded that declarations in the *Arrow* form will open any floodgates. The *Arrow* decision is now of some age, and has not resulted in many such cases being brought. The circumstances in which such declarations will be justified, will, we would have thought, be uncommon. Mr Hobbs' example of a business problem in Romania would be unlikely to justify the grant of a declaration by the English court.

96. Likewise we do not think that the availability of such declarations will undermine the system of allocation of jurisdiction under the recast Brussels Regulation. Insofar as the declaration can be said to be "concerned with the registration or validity of patents", it can only be concerned with the registration or validity of EP (UK)s. When the declaration states that the product is obvious, it will so state as a matter of the law of the United Kingdom. The validity of other patents for other designated states is a matter for the law of those states. The grant of declarations in those terms is no more inconsistent with the Brussels system for allocation of jurisdiction than is the revocation of an EP (UK).

97. For similar reasons, the priority date which the declaration puts in issue will be decided only as a matter of English law and in relation to a granted EP (UK) (now revoked). It does not offend against the recast Brussels Regulation.

98. We have said enough to explain why we do not consider that there is any issue of principle which prevents the granting of *Arrow* declarations in appropriate cases. Drawing the threads together:

i) A declaration that a product, process or use was old or obvious at a particular date does not necessarily offend against section 74 of the Act.

ii) Such a declaration may offend against the Act where it is a disguised attack on the validity of a granted patent.

iii) Such declarations do not offend against the scheme of the EPC or the Act simply because the declaration is sought against the background of pending divisional applications by the counter-party.

iv) On the other hand the existence of pending applications cannot itself be a sufficient justification for granting a declaration.

v) Whether such a declaration is justified depends on whether a sufficient case can be made for the exercise of the court's discretion in accordance with established principles.

99. Given that a discretionary power exists, it is for the Patents Court to develop the principles for its exercise in more detail. It will be apparent from the above, however, that we consider an important factor to be borne in mind in the exercise of the discretion is the existence of the statutory proceedings for revocation, which should be regarded as the normal vehicle for obtaining any desired findings of invalidity.

Fujifilm v Abbvie

Henry Carr J

3rd March 2017

370. In the FKB Appeal Judgment, the Court of Appeal rejected the submission that *Arrow* was wrongly decided, and made clear that there was jurisdiction to grant such declarations. The issue is whether a sufficient case can be made out for the exercise of the court's discretion, in accordance with established principles, and having regard to the existence of the statutory remedy of revocation provided for by section 74 of the Patents Act 1977.

[...]

372. The Claimants emphasise the assistance that judgments of the Patents Court can provide to other courts in EPC contracting states who are required to consider the same issues.

[...]

374. I accept that the spin-off value of a judgment in a contracting state can be very valuable, and it is legitimate for parties to rely upon such judgments in other contracting states. However, it is important not to extend this principle too far. Statements as to the spin-off value of UK judgments have been made in the context of applications to stay pending resolution of EPO oppositions, or of applications to expedite trials. Those cases are very different from the present. It is also important to guard against forum shopping, where a declaration from the UK Court is sought in cases which have no connection with this jurisdiction.

[...]

386. I do not accept AbbVie's submissions, and I accept the Claimants' case on this issue, to the extent set out below. If, as AbbVie submits, the declarations have no useful purpose, and the steps that they have taken have the same effect in achieving commercial certainty, there is no coherent explanation as to why it refuses to submit to judgment, or alternatively to give an acknowledgement in the same form as the declarations. The suggestion that AbbVie resists the declarations because it does not accept that the relevant dosing regimens were anticipated or obvious does

not withstand examination, and has not been put forward in evidence. If that were the case, AbbVie would not have abandoned its UK patent protection. Had it maintained that protection, and won the trial, it would have been able to stop the launch of the Claimants' biosimilars.

[...]

389. I do not accept that AbbVie was unable to advance an explanation for its conduct in evidence, without waiving privilege.

[...]

392. I do not accept that the history of these proceedings is irrelevant. The Claimants have, on a number of occasions, tried to exercise their statutory right to seek revocation of AbbVie's UK patents. AbbVie has abandoned its UK patent protection shortly before trial, and has a long record of similar conduct. This is quite different from a case which has never had any connection with the United Kingdom, and is brought purely to influence foreign courts.

[...]

394. I consider that the grant of a declaration would serve a useful purpose, for the following reasons. First, commercial certainty. Mr Inman and Dr Gilbert suggested in their evidence that the reason why AbbVie had abandoned its UK patents was to shield them from the scrutiny of the UK Courts. They claimed that AbbVie continued to resist the declarations precisely because they would serve a useful purpose, namely to provide the Claimants with adequate certainty as regards the intended launch of their biosimilar adalimumab products; see for example Gilbert (3) [33].

[...]

396. In my judgment, AbbVie has consistently adopted a policy of publicly expressing its confidence in its Humira patent portfolio, and its intention to enforce it against competition from biosimilars, whilst at the same time shielding patents within the portfolio from scrutiny by the court. When patent protection has been abandoned by AbbVie, another sub-divisional has been applied for, thereby perpetuating commercial uncertainty.

[...]

400. Furthermore, I need to consider the consequences if I were to refuse to grant the declarations, having decided that the Claimants should succeed in their technical case. In those circumstances the Claimants will have failed to obtain the relief which they sought, in spite of winning the trial. That, in my judgment, would be a recipe for uncertainty, which the undertakings would be unlikely to remedy.

401. I also consider that the declaration would serve a useful purpose in protecting the Claimants' supply chain for the UK market. At [2.8(a) – (b)] of his eleventh Statement, Mr Inman expressed concern as to the "chilling effect" in the market, in

the absence of a declaration, in that manufacturers of products are likely to find it more difficult to enter into an agreement with a prospective EU marketing partner, when despite the UK being patent free, the rest of the EU remained subject to the threat of potential patent litigation. He explained that, as a practical matter, due to the international nature of the industry, most biosimilar manufacturers will be unable to confine their manufacture and supply chain to within the UK, so the UK market may not be able to be exploited without being at risk of AbbVie's patents in other jurisdictions.

[...]

405. This evidence goes beyond spin-off value to assist the Claimants' products to be launched in other jurisdictions. It explains how the grant of a declaration will make injunctive relief in other jurisdictions less likely, and why this will be of direct benefit to the UK market. [...]

[...]

407. I also consider that the promotion of settlement is relevant. At [2.6] of his eleventh statement, Mr Inman stated that a useful purpose of the declaration would be that it was likely to promote settlement. The Claimants submit that a declaration that a material part of AbbVie's portfolio cannot be enforced in the UK would change the parties' negotiation leverage and promote settlement on fairer terms. This, it is said, is of direct benefit in the UK (as well as the rest of the world) as AbbVie may seek to enforce other patents in the UK (for example formulation patents).

[...]

410. The circumstances of this case are most unusual, given AbbVie's strategy which I have outlined above. I consider that the promotion of settlement, in combination with the other factors relied on by the Claimants, provides a useful purpose for granting the declarations.

411. I now turn to the question of spin-off value. The Claimants submit that the declarations will be influential in other European Courts and tribunals, and will make it more difficult for AbbVie to obtain preliminary injunctions, particularly in jurisdictions where validity cannot be challenged whilst patents are under opposition in the EPO.

412. I accept that the spin-off value of a judgment in a contracting state can be very valuable, and it is legitimate for parties to rely upon such judgments in other contracting states. However, on reflection and having regard to the legal principles which I have set out above, I have not taken this into account other than to the extent that this issue may have an impact on the UK market (see Gilbert (4) [7] - [9]).

204. The principles upon which the Court will grant discretionary relief were considered by Henry Carr J at [365]-[371]. In summary, the Court must consider:

i) justice to the claimant;

ii) justice to the defendant;

iii) whether the declaration will serve a useful purpose. The attainment of commercial certainty in patent cases can constitute a useful purpose. The spin-off value of a judgment in other states may be such a factor, but a declaration sought solely for the benefit of foreign courts will rarely be justified; and

iv) whether or not there are any other special reasons why the court should or should not grant the declaration.

Assessment

[...]

206. In the light of my conclusions above, I consider that the use of the Claimants' Product in a 40 mg TIW regimen would have been novel, but obvious, as at 20 August 2009. That is a necessary, but not a sufficient, foundation for the relief sought by the Claimants. I turn, therefore, to consider the factors relied upon by the Claimants as justifying the grant of an *Arrow* declaration.

207. First, the Claimants rely upon the pendency of 962A and 172A. It is clear from the judgment of the Court of Appeal in *AbbVie*, however, that the existence of pending divisional applications is not sufficient to justify the making of an *Arrow* declaration. More is required.

208. Secondly, the Claimants contend that the Defendants have sought to shield the subject-matter of the Patent from scrutiny by the courts of this country and the Netherlands and the Boards of Appeal. I do not accept this. Whatever may have happened elsewhere in other cases, the Defendants have vigorously defended the validity of the Patent at trial before this Court, resulting in the giving of this judgment.

209. Thirdly, the Claimants rely upon the spin-off value of a declaration even if the declaration is confined to the UK. When I asked counsel for the Claimants why an *Arrow* declaration should have any greater persuasive value than a reasoned judgment of this Court on the validity of the Patent, however, he had no real answer.

210. Fourthly, the Claimants rely upon Teva's public statements to the effect that it intends to enforce its patent portfolio, including the Patent. In itself, however, there is nothing wrong with this. Moreover, in future, Teva will have to acknowledge the judgment of this Court (subject, of course, to any appeal).

211. Fifthly, the Claimants rely upon their need for commercial certainty. I am unclear, however, how an *Arrow* declaration would provide the Claimants will greater certainty than this judgment. If this judgment stands, but 962A and/or 172A proceed to grant, then any claim for infringement by the Defendants against the Claimant in respect of the 40 mg TIW regimen can be met by an application for summary judgment seeking revocation of the patent(s) relying upon issue estoppels arising out of this judgment. An *Arrow* declaration would not preclude the need for an application for summary judgment, albeit based on the declaration, in such circumstances.

212. Accordingly, I decline to grant the Claimants an *Arrow* declaration.

PART IV: UNWIRED PLANET v. HUAWEI

FRAND

Enforceability of the FRAND undertaking

139. I accept Prof Fauvarque-Cosson's analysis and find that the doctrine of "*stipulation pour autrui*" applies to the FRAND undertaking and renders it enforceable by third parties.

146. Standing back I recognise that the enforceability of the FRAND undertaking in French law is not a clear cut question. Prof Libchaber stated that there remains widespread uncertainty about the issue of whether the doctrine of "*stipulation pour autrui*" can be applied to ETSI. In my judgment it can be applied in that way and should be. The reason it should be applied is because the FRAND undertaking is an important aspect of technology standardisation. Holders of essential IPR are not compelled to give a FRAND undertaking but it serves the public interest that they make it clear whether or not they are doing so, and it serves the public interest that if they do, the undertaking is public, irrevocable and enforceable. To avoid hold up, implementers need to know that they can hold SEP owners to a FRAND obligation.

A single set of FRAND terms

156. Accordingly the concept that there exists only a single set of FRAND terms for a given situation is workable. It will promote certainty and will enhance the normative aspect of FRAND. It would make the enforcement of the ETSI FRAND undertaking conceptually straightforward. If there is only one set of true FRAND terms for a given situation then a court will be able to hold parties to their obligations arising from the FRAND undertaking. Both parties would be entitled to insist on FRAND terms and neither would be entitled to insist on anything other than FRAND terms. By definition the FRAND terms are the terms which are fair, reasonable and non-discriminatory. They are the terms which a truly willing licensor and truly willing licensee would agree upon in the relevant negotiation in the relevant circumstances absent irrelevant factors such as hold up and hold out.

157. The fact that the evidence of putative comparable licences might show a range of rates and other terms as having been agreed between other parties does not falsify the idea that for a given situation there is only one set of true FRAND terms. Each real licence was arrived at between particular parties in particular circumstances which may or may not be good evidence about what would be FRAND in the case in issue. Furthermore the fact that the terms of a given comparable licence, objectively speaking, may not represent the true FRAND terms for the circumstances in which they were agreed does not mean those contracts would all be vulnerable to being unwound, for the reasons already addressed.

[...]

163. [...] Both patentees and implementers should take a FRAND approach to the negotiation of a licence under a SEP or SEP portfolio governed by a FRAND undertaking. The patentee is obliged by contract to take a FRAND approach to the negotiation and to grant a licence on FRAND terms. The implementer must take a FRAND approach to the negotiation and accept a licence on FRAND terms if it wishes to take advantage of the constraint on the patentee's rights imposed by the FRAND undertaking. A FRAND approach to negotiation does not mean that parties cannot negotiate in good faith and a FRAND approach will allow for starting offers which leave room for negotiation. The fact an opening offered rate is higher than the true FRAND rate does not mean of itself that a patentee has failed to take a FRAND approach any more than the converse could be said about an implementer. On the other hand, making extreme offers and taking an intransigent approach which prejudice fair, reasonable and non-discriminatory negotiation is not a FRAND approach.

[...]

165. Therefore the solution to the problem of parties presenting rival FRAND terms to the court is simple enough. The court has to decide what terms would be FRAND in the given circumstances and can grant a declaration to that effect. Only one set of terms will be compliant with the FRAND undertaking.

166. A patentee who refuses to accept those terms would be in breach of its FRAND undertaking. Even if a court cannot go as far as directly enforcing the FRAND undertaking by compelling a patentee to make an offer in those terms (see the section on French law), I think an English court would at least refuse to grant a patentee an injunction if it refused to accept FRAND terms. That would be a proper exercise of the court's equitable jurisdiction to grant or refuse an injunction.

167. A defendant who had already been found to infringe a valid patent cannot be compelled to accept an offer of a licence but a defendant with no licence, who had refused to accept terms on offer which had been found to be FRAND, would not be entitled to the protection from injunctions provided for by the patentee's FRAND undertaking. An injunction would follow and to grant it would be a proper exercise of the court's equitable jurisdiction. The only coercion in that case would be to enter into a licence on FRAND terms. It would apply to both sides with equal force.

[..]

542. Before turning to the impact of the litigation, this is a convenient point to ask what sort of licence for Unwired Planet's portfolio would be FRAND in terms of its geographical scope when applied to a multinational licensee like Huawei? I will start by asking what a willing licensor and a willing licensee with more or less global sales would do. There is only one answer. Unwired Planet's portfolio today is (and in 2014 it was) sufficiently large and has sufficiently wide geographical scope that a licensor and licensee acting reasonably and on a willing basis would agree on a worldwide licence. They would regard country by country licensing as madness. A worldwide licence would be far more efficient. It might well have different rates for different regions and for different standards but that

is another matter. The employment of different rates would not lead the parties to abandon a worldwide licence and go for country by country licensing. Assuming the licensee was a Chinese multinational like Huawei, they might well agree on different rates for China as for the Rest of the World but again they would not go for country by country licensing. If the multinational had a significant manufacturing base in another country in which the portfolio was weak, again that could be taken into account.

[...]

572. I conclude that a worldwide licence would not be contrary to competition law. Willing and reasonable parties would agree on a worldwide licence. It is the FRAND licence for a portfolio like Unwired Planet's and an implementer like Huawei. Therefore, Unwired Planet are entitled to insist on it. It follows that an insistence by Huawei on a licence with a UK only scope is not FRAND.

Assessment of the correct rate

170. There was no real dispute of principle about how to work out what is and is not FRAND. The question is what would be fair, reasonable and non-discriminatory. Asking what a willing licensor and a willing licensee in the relevant circumstances acting without holding out or holding up would agree upon is likely to help decide that question. The evidence of the parties themselves will be relevant, including evidence of how negotiations work in practice in the industry. To the extent they are available other licences may be deployed as comparables. Just as comparables may be useful in a damages enquiry when considering a reasonable royalty and may be useful in determining the terms of a licence of right or in a Copyright Tribunal, so comparables may be useful in deciding what is FRAND. As always judgments will have to be made about how closely comparable any given licence is to the relevant circumstances in issue. The relevance of comparables is that they are evidence of what real parties in real negotiations have agreed upon. But like any real situation many factors may have been in play which make the licence less relevant. The negotiations may have involved a greater or lesser degree of hold up or hold out and it may be impossible to know that from the evidence available.

171. The decisions of other courts, assuming they are not binding authorities, may be useful as persuasive precedents. A point arises in this case about a licence which was the product of an arbitration. A licence agreement settled in an arbitration is more like terms set by a court than it is like a licence produced by negotiation and agreement. Huawei submitted that such a licence would be evidence of what a party was actually paying and as such was relevant. Aside from certain aspects of non-discrimination which I will address separately, I do not accept that evidence of what a party is paying as a result of a binding arbitration will carry much weight. If the licence is the product of an arbitration then the paying party has no choice. A further difficulty with the particular licence in question is that the arbitral award has not been produced. So although we know what the licence terms are, we do not know what the reasoning was which led to them. As a persuasive authority an arbitrated licence without the arbitral award is not much use. There were a few references in the evidence to the way the arbitrators

decided the case but without seeing the award itself I will not place weight on that.

The meaning of the non-discrimination limb of FRAND

503. Therefore I conclude that the true interpretation of the ETSI FRAND undertaking from the point of view of non-discrimination is that a benchmark FRAND rate should be derived which is applicable to all licensees seeking the same kind of licence. That is what I have called general non-discrimination. If, contrary to this view, the FRAND undertaking also includes a specific non-discrimination obligation whereby a licensee has the right to demand the very same rate as has been granted to another licensee which is lower than the benchmark rate, then that obligation only applies if the difference would distort competition between the two licensees.

Competition law issues:

Dominant position:

670. Standing back, the question I have to decide is whether Unwired Planet is in a dominant position in the relevant market. The relevant market is a market for licences under the SEPs. It is a market in which the SEP owner has 100% market share. The market is covered by the FRAND undertaking which does weaken the SEP owner's position. It is a market in which licensees can engage in holding out and there is some evidence that they do, particularly given the relative weakness of Unwired Planet. If a proper economic analysis had been done into this market then the issue might be more finely balanced but as it stands, and without that analysis, I am not satisfied either of these points alone or together is sufficient to justify not drawing the inference that the holder of a 100% market share is likely to be dominant. I hold that as the owner of SEPs, Unwired Planet is in a dominant position in the market for licences under those SEPs.

Premature litigation: the Interpretation of the CJEU in Huawei v ZTE:

744. The principles I derive from ***Huawei v ZTE*** are these:

a. In the judgment the CJEU has set out a scheme which both the patentee and implementer can be expected to follow in the context of a dispute about a patent declared essential to a standard and subject to a FRAND undertaking.

b. In stating that the implementer and patentee must express a willingness to conclude a licence on FRAND terms, the CJEU is referring to a willingness in general terms. The fact that concrete proposals are also required does not mean it is relevant to ask if those proposals are actually FRAND or not.

c. If the patentee complies with the scheme prior to starting a claim for infringement of that patent which includes a claim for an injunction, then bringing such a claim will not be abusive under Art 102. That is the *ratio* of the CJEU's decision.

d. In the circumstances contemplated by the CJEU, bringing a claim for infringement of a SEP which includes a claim for an injunction without prior notice of any kind will necessarily be an abuse of dominant position. Insofar as the decision identifies what is abusive rather than what is not, the decision does not go further than that.

e. Bringing a claim for infringement which includes a claim for an injunction even with sufficient notice is capable of being an abuse of dominant position. However the judgment does not hold that if the circumstances diverge from the scheme set out in any way then a patentee will necessarily abuse their dominant position by starting such a claim. In those circumstances the patentee's conduct may or may not be abusive. The scheme sets out standard of behaviour against which both parties behaviour can be measured to decide in all the circumstances if an abuse has taken place.

f. Nor does it follow that if the patentee complies with the scheme such that bringing the action is not *per se* abusive, the patentee can behave with impunity after issue. Again, the scheme sets out standards of behaviour against which both parties' behaviour can be measured to decide if an abuse has taken place.

g. If the patentee does abuse its dominant position in bringing the claim or in its conduct after issue, that affords a defence to the claim for an injunction. In other words the proper remedy is likely to be refusal of an injunction even though a patent has been found to be valid and infringed and the implementer has no licence.

h. The legal circumstances of this case differ from the circumstances assumed by the CJEU in a crucial respect. FRAND is justiciable and the undertaking can be effectively enforced at the suit of the defendant irrespective of Art 102. The defendant does not need Art 102 to have a defence to the injunction claim.

755. Huawei's stance before the court throughout this claim has been that because they were sued before FRAND terms were offered they have a defence to the injunction claim. That stance is founded on a narrow interpretation of ***Huawei v ZTE*** which I have rejected. I am satisfied that the commencement of this action, including the claim for an injunction, was not an abuse of Unwired Planet's dominant position. The same goes for Unwired Planet's conduct during the proceedings. I reject the "premature litigation" head of abuse.

Excessive pricing:

765. In the context of SEPs and FRAND, as long as the recipient of the offer can see it is made in that context, then it seems to me that only an offer which is so far

above FRAND as to act to disrupt or prejudice the negotiations themselves in the manner described by Prof Neven above will fall foul of Art 102(a). That is a high standard to reach but otherwise it would be too easy for the recipient of an offer to throw up their hands and refuse to negotiate at all. This does not contradict ***Huawei v ZTE*** because the abuse in that case is not the demand of a non-FRAND rate, the abuse is to bring injunctive patent infringement proceedings prematurely.

[...]

784. I reject the competition law case on unfair pricing. The finding is not that the imposition of a rate three, five or ten times the FRAND rate would be acceptable. Far from it. The flaw in Huawei's case is these offers were obviously made as a step in negotiation and did not prejudice or disrupt it.

Bundling/Tying SEPs and Non-SEPs:

787. Having heard the evidence in this case I am in no doubt that a patentee subject to a FRAND undertaking cannot insist on a licence which bundles SEPs and non-SEPs together. But it does not follow from this that it is contrary to competition law to make a first offer which puts SEPs and non-SEPs together. There is clear evidence that in some cases the parties agree to a licence which includes both SEPs and non-SEPs together. The mere fact a licence includes both does not take it out of FRAND nor does it indicate that a patentee has used the market power given by the SEPs to secure a licence under the non-SEPs. Everything will depend on the circumstances.

UP v Huawei Judgment on remedies [2017] EWHC 1304:

13. Like many aspects of this case, this dispute about relief raises some new problems. One suggestion was that the real problem was that the Settled Licence had no terms dealing with appeals. Huawei submitted that if it did then they might be able to enter into it now but still argue on appeal that a UK licence was the right outcome. I agree that it might be possible to craft terms in a licence which could allow for something like that and perhaps the next time a court is called upon to settle FRAND terms, that could be considered. [...]

14. Another point is the issue of what happens in 2020. This arises from the fact that the eight year term of the Settled Licence runs from 2013 until 2020. That term arose because the parties at trial were agreed that the UK licence should work that way. When I came to consider the worldwide licence I started from the UK terms, finding (paragraph 593) that the points the parties were able to agree upon as FRAND in the UK licence were just as applicable to a worldwide licence. That included recognising that it would be an eight year licence running from expiry of the 2009 Ericsson-Huawei licence until the end of 2020.

[...]

16. Huawei are right to raise this problem. It is inherent in settling licences in this field. It would have arisen just the same if Huawei had won on the UK/worldwide issue. It has to be sorted out whoever is correct about the final form of relief.

20. With this problem in mind and assuming an injunction should be granted at all I will consider, absent appeal, what the correct form of a final injunction in respect of patents the subject of a FRAND undertaking should be when the court has settled a FRAND licence but the defendant has not entered into it. I will call this a FRAND injunction. The answer is simple. A FRAND injunction should be in normal form to restrain infringement of the relevant patent(s) but ought to include a proviso that it will cease to have effect if the defendant enters into that FRAND licence. If as in this case, the FRAND licence is for a limited time, shorter than the lifetime of the relevant patents then the injunction should also be subject to an express liberty to either party to return to court in future to address the position at the end of the term of the FRAND licence. In any case the FRAND injunction should also be subject to an express liberty to apply in the event the FRAND licence ceases to have effect for any other reason.

21. Normally in English law when the court grants final relief a party is not entitled to come back to court in future even if circumstances change but these unusual terms arise from dealing with patents the subject of a FRAND undertaking. A FRAND injunction in this form reflects the finding that what the patentee is entitled to today, bearing in mind its FRAND undertaking, is a licence on FRAND terms but if the defendant has the ability to take the licence and does not do so, then an injunction is appropriate for as long as the defendant does not enter into that licence. If the defendant enters into the FRAND licence there should be no injunction at all. The fact the FRAND licence is limited in time does not justify an injunction continuing into the future. The court should not pre-judge at this stage what should happen if or when the FRAND licence ceases to have effect.

Part V: Other points of Interest

Time Zones for Art. 54

Unwired Planet v Huawei :

[2017] EWCA Civ 266

The issue arose as to the proper approach to Art. 54 EPC when considering time zones. The state of the art includes all matter made available to the public "before the filing date" (Article 54(2)). The issue arose because at any point in time the date in different parts of the world can be different.

The priority document in the case was filed at the USPTO with a date of 8 January 2008. The prior art was uploaded to a publicly accessible server on the 8th January 2008 (European time and EST in the USA) but on 7th January 2008 Pacific Time.

The Court held that the relevant controlling date for Art. 54(2) was the date of the patent office where the application (or priority document) is filed. Different policy considerations arise for Art. 54(3). For Art. 54(2) the priority date is the 24 hour period of the day the filing took place, in the time zone of the patent office where it was filed. The publication must occur before that day, on a time basis, by reference to the time zone of the patent office of filing [see [161]).

Inventor's remuneration

Ian Shanks v Unilever

[2017] EWCA Civ 2

Prof Shanks brought a claim under s.40 Patents Act 1977 for compensation in respect of patents resulting from his invention during employment. The Hearing Officer had concluded that the financial benefit to Unilever from the patents was £24.5 million. He had held that this did not amount to an "outstanding benefit" as required by the Act. Had he been wrong, he would have awarded 5% to Prof Shanks.

On first appeal, Arnold J discounted the receipts to Unilever by 30% to account for corporation tax thereby reducing the benefit to Unilever to £17 million. Had he needed to do so, he would have awarded Prof Shanks no more than 3%.

Patten LJ held that "outstanding benefit" should be given its ordinary meaning *"It may be useful for this purpose to consider whether the benefit to the employer exceeded what would normally be expected to result from the work for which the employee was paid"* [23].

It is not just a question of *"Too big to pay"*. Outstanding benefit *"cannot be determined simply by comparing the income generated by the patent with the overall turnover and profitability of the employer's undertaking* [28]. *"" Outstanding is a relative concept which requires to be measured against the relevant factors of the case. In relation to a large conglomerate like the Unilever group, turnover and profitability will be relevant factors"*. [29].

As regards the correct "undertaking" *"an assessment of what constitutes the undertaking based on the economic and business realties of the employer's organisation is the correct approach"* [33].

The Court held that Arnold J ought not to have deducted the tax and so the relevant sum was £24.5 million. The patents did not bring outstanding benefit when looked at the overall performance of the group. *"As I have already said, s.40(1) was designed, as I read it, to deal with exceptional cases. There must be an outstanding benefit to the employer company and not just generally"* [59].

US vs UK Common General Knowledge

Generics v Teva

[2017] EWHC 2629 at [95]

"The Claimants accept that this Court should proceed on the basis that it must be shown that information was common general knowledge in the UK and that it is not sufficient to show that it is common general knowledge elsewhere in the world, such as in the UK (see Generics (UK) Ltd v Warner Lambert Co LLC [2015] EWHC 2548 (Pat), [2016] RPC 3 at [123]-[124], but reserve the right to contend to the contrary in a higher court".

"Chain of Title" priority

Accord v Research Corp.

[2017] EWHC 2711 at [76]-[78].

"In my judgment Accord is right that following from those principles [as set out in Edwards v. Cook, KCI, HTC, Idenix and Fujifilm] *a person who at the relevant time and under the relevant applicable law, acquired only the bare legal title to an invention and not the equitable title, when the equitable title is held by another, does not then hold the substantive right and title to claim priority".*

"However, I cannot help but observe that if priority is lost this patent would be revoked over a publication by the inventor in the period between the priority date and the filing date which I infer was assumed to be a safe thing to do because it was assumed by everyone involved that

priority would be successfully claimed. There is be many cases like this. There is no obvious public interest in striking down patents on this ground, unlike all the other grounds of invalidity. The difficulty starts with the point that the title cannot be fixed retrospectively. If I may say so the reasons given by Kitchin J in Edwards v Cook are compelling reasons why that should be so. However, the legal/equitable analysis chips away at that principle since what is happening in those cases is that the equitable owner's imperfect title on the relevant date is only perfected after the event. No doubt that is why, in the Court of Appeal, Kitchin LJ declined to get into the issue any further since he did not have to.

I offer the following tentative suggestions. One approach could e that the effect and devolution of the priority right as to be purely governed by a sui generis law applicable priority rights in all signatory states to the Paris Convention equally and applicable in all those states regardless of whether those states recognise a legal/equitable distinction. Flaws in title cannot be fixed retrospectively. That is one way of interpreting Edwards v. Cook and there are good reasons for it. However, it does not sit happily with the equitable/legal distinctions made in the later cases. An alternative could be to apply the same approach and the same applicable law to the priority claim as applies to ownership of the invention and the right to the patent. In a case in which there is some doubt about the claimant's title to the pat3nt itself, that title has to be perfected by the judgment e.g. by assignment or the legal owner must be joined to the proceedings...the moment the title matters is judgment.

In ***Actavis v ICOS at [92]***, Kitchin LJ upheld the approach of Birss J to who has the burden of proving chain of title priority to the cited prior art. Although the Claimant seeking to revoke the patent had the legal burden to prove that the cited prior art was entitled to its priority date, the contents of the prior art supported an inference that title to priority was in order. Accordingly, the evidential burden to show otherwise fell on the Defendant who had not rebutted that inference.

Validity of US patents?

Chugai Pharmaceutical Co. Ltd & UCB v UCB Biopharma [2017] EWHC 1216

Henry Carr J

69. I do not consider that this court should decline jurisdiction in respect of the disputed paragraphs of Chugai's Statement of Case on the basis that its adjudication would be contrary to the doctrine of act of state, for the reasons set out above in relation to the rule in *Moçambique*. It is not a breach of the principle of comity to exercise jurisdiction where the parties have chosen, by agreement, to submit their dispute to the adjudication of the English courts. Furthermore, the act of state doctrine does not present an impediment to an action for infringement of a foreign patent, even if validity is in issue (although in this case, Chugai does not seek to invalidate the 771 Patent).

[...]

71. That leaves the wider question of whether, in the absence of agreement, direct challenges to the validity of foreign patents which are outside the scope of article 22(4) of the Brussels I Regulation (for example claims for revocation or declarations of invalidity) are justiciable here. Professor Briggs in *Civil Jurisdiction and Judgments (6th Ed, 2016)* states at [4.09]:

> "The grant of a patent is closer to an act of sovereign power than many; if a court considers that a patent should be held to be invalid and cancelled as a result, it is hard to see how this can be done and made effective by a court other than at the place where the patent was granted and must now be cancelled. Moreover, as the Brussels 1 Regulation reserves proceedings which have as their object the validity of a patent to the courts of the Member State under which it was granted, it would be difficult to attack a rule of the common law which was built on the same foundation".

72. Mr Raphael, who recognised that his case would be considerably more difficult if Chugai was mounting a direct challenge to validity in the English court, did not dissent from this reasoning, apart from the suggestion that the act of state doctrine might preclude challenges to validity. He suggested that such challenges might be precluded by the rule in *Moçambique* or by the use of the public policy exception which applies at common law; the latter possibility is referred to in *Dicey* at [34-027].

73. In my view, there are powerful arguments that such direct challenges, where validity is the principal issue, are not justiciable. In particular:

    i) There is basis for drawing a distinction between claims for infringement and invalidity of patents. A claim of infringement is an action *in personam*, which affects the parties to the action. A patent is a monopoly right *in rem,* which applies to the entire population of the territory in which it is granted.

    ii) This distinction is reflected in the allocation of jurisdiction in the Brussels I Regulation. Article 24(4) compulsorily allocates jurisdiction over a dispute concerning the validity of a patent to the courts of the Member State in which (or for which) that patent is registered; the article does not apply to claims for infringement.

    iii) The rule in *Moçambique* no longer applies to claims for damages for trespass. However, it continues to apply to actions for the determination of the title to, or the right to possession of, foreign land. Infringement of patent is analogous to trespass, whereas validity is analogous to a challenge to the title to or right to possession of land.

    iv) As well as comity, the *Moçambique* rule is founded on the principle of territoriality. Lord Neuberger stated in *Shergill v Khaira* [2014] UKSC 33; [2015] AC 359 at [41] that the rule

was "*probably best regarded as depending on the territorial limits of the competence of the English courts or of the competence which they will recognise in foreign states*".

v) Patents are local monopolies which involve local policies and local public interest. Their effect is territorially limited. Their validity should be matters for the local judges of the country in which the patent right was first created: see *Lucasfilm* [2009] EWCA Civ 1328; [2010] Ch. 503 at [175] *per* Jacob LJ.

74. So, whilst my provisional view is that direct challenges to the validity of foreign patents should not be justiciable in the English courts, it is not necessary for me to reach a conclusion on this important question, which should be decided in circumstances where it matters to the result.

Generics v Teva - Multiple expert witnesses

[2017] EWHC 2629 at [83]

Beware duplication of expert evidence:

Arnold J at [83]:

"Where parties adduce evidence from more than one expert, the evidence of the respective experts should be clearly delineated. Parties who flout the guidance which the courts have repeatedly given can expect to be heavily sanctioned in costs. This may extend to their legal advisors if the circumstances warrant such an order"