Case No: HC12C00361

Neutral Citation Number: [2012] EWHC 2290 (Pat)
IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 03/08/2012

Before :

MR JUSTICE WARREN

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Between :

ELI LILLY AND COMPANY	**Claimant**
- and -	
HUMAN GENOME SCIENCES INC.	**Defendant**

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- -

Tom Mitcheson (instructed by **Field Fisher Waterhouse LLP**) for the **Claimant**
Daniel Alexander QC and Mark Chacksfield (instructed by **Powell Gilbert LLP**) for the **Defendant**

Hearing date: 13th June 2012

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Judgment

Mr Justice Warren :

1. There are two applications before the Court. The first is an application by the Claimant, Eli Lilly and Company ("**Lilly**"), for the Court to make an immediate reference to the Court of Justice, formerly the European Court of Justice and now part of the Court of Justice of the European Union, to which I will refer as "the **ECJ**". The second is an application by the Defendant, Human Genome Sciences, Inc, ("**HGS**") to strike out the claim.

2. The action concerns the possibility of HGS applying for a supplementary protection certificate ("**SPC**"). Lilly seeks a declaration that any SPC which might be granted to HGS in respect of HGS's European Patent (UK) No 0 939 804 ("the **Patent**") based upon any marketing authorisation ("**MA**") obtained by Lilly for Lilly's own product LY2127399 ("**the Lilly antibody**") would be invalid.

3. Lilly has two bases on which it seeks a reference. The first is that it is impermissible for a person (HGS in the present case) to apply for an SPC based upon an MA obtained by another person (Lilly in the present case) when the two persons have no connection with each other. I will refer to this as "the **third party SPC issue**". The second is that the Patent does not specify or identify the Lilly antibody in its claims so that a valid SPC could not be obtained even where the Patent itself has been upheld as valid. I will refer to this as "the **Specification issue**". Although Lilly considers that it is correct on both bases, it accepts that the issues are ones of EU law which are not *acte clair*. It seeks an immediate reference for reasons which I will come to.

4. HGS opposes the application for an immediate reference. In addition, it seeks to strike out the action on the basis that it is "premature and incapable of resolution given the current factual uncertainties" to use the words of Dr Penny Gilbert, HGS's solicitor, in her evidence in support of the application.

Summary of conclusions

5. My conclusions, in summary, are as follows:

   i) The Court has jurisdiction to grant the declaratory relief sought. Given Lilly's commercial position, this is not a purely hypothetical question.

   ii) The Court should accept jurisdiction and allow the action to proceed.

   iii) HGS is correct on the third party SPC issue, although whether the matter should be referred to the ECJ is something I will come to later.

   iv) The answer to the Specification issue is a matter of EU law to which the answer is unclear in the light of the guidance so far given by the ECJ on the meaning of Council Regulation No 469/2009 ("the **SPC Regulation**"). A reference on this issue will be needed before the Patents Court is able to give an answer to the Specification issue.

   v) If a reference is made in relation to the Specification issue, it would be sensible also to raise the third party SPC issue in order to obtain a definitive answer to the issue.

vi) But a reference should only be made on the basis of established facts, if necessary on the basis of findings of fact after a trial. A reference should not be made at this stage.

6. After setting out some preliminary matters, I propose to deal with the third party SPC issue and the Specification issue before dealing with the procedural matters of strike out, stay and reference.

Background

The Patent

7. The Patent was filed by HGS on 25 October 1996. It was eventually granted by the Examination Division of the EPO, but not until 17 August 2005. It is due to expire on 25 October 2016. The relevant Claim of the Patent (as amended) is set out at paragraph 67 below.

Proceedings concerning the Patent

8. On 16 May 2006, Lilly filed an opposition to the Patent. On 5 July 2006 proceedings were commenced by Lilly in the Patents Court seeking revocation of the Patent ("the **Main Action**"). In November 2006, HGS sought to raise a counterclaim in the Main Action alleging infringement. That was successfully resisted by Lilly.

9. In July 2008, Kitchin J (following a hearing in December 2007) gave judgment holding that the claims of the Patent (as proposed to be amended) were novel and involved an inventive step over the pleaded prior art. He also found that the claims were not susceptible of industrial application, that they were insufficient and that they were obvious because of a lack of technical contributions.

10. At that point of time, the Patent had also been held invalid by the Opposition Division of the EPO for lack of technical contributions, written reasons being given in December 2008. An appeal was heard by the Technical Board of Appeal ("the **TBA**") in October 2009 which considered all of the issues raised in the opposition (including industrial application and sufficiency as well as inventive step). The Patent was held valid in October 2009 on the basis of the amended claims. Written reasons were given by the TBA on 1 December 2009 shortly before the Court of Appeal hearing in the Main Action commenced on 8 December 2009.

11. In February 2010, the Court of Appeal, contrary to the decision of the TBA, upheld the decision of Kitchin J in relation to industrial applicability and related matters, and decided that it did not need to resolve certain of the other issues before it. In November 2011, the Supreme Court reversed that decision and found in HGS's favour in respect of certain related matters of sufficiency. The case was remitted to the Court of Appeal to resolve the outstanding issues. Those issues concern the validity and scope of the antibody claims. Accordingly, the validity of the claims of the Patent which are the issue in the matter not before me, remain to be finally determined.

12. There is mutual blame cast by each side on the other for the delay in achieving a final result on validity. I do not consider it productive to go into why we are where we are.

The antibodies and clinical trials

13. In his first witness statement, Mark Stewart (a Senior Director and Assistant General Patent Counsel at Lilly) states that Lilly has developed a fully human IgG4 monoclonal antibody with in vitro neutralising activity against both membrane-bound and soluble TNFSF13b. That antibody has Lilly's designation LY2127399, that is to say, what I have called the Lilly antibody. He goes on to say that the exact nature and scope of the phase III clinical studies undertaken in relation to that antibody for the treatment of Systemic Lupus Erythematosus ("**SLE**") have been published. The clinical studies on the Lilly antibody have not been limited to its use for the treatment of SLE. There have, for instance, been phase III clinical trials for the use of the Lilly antibody for the treatment of Rheumatoid Arthritis ("**RA**"). Mr Stewart notes that whilst the Patent discloses a very wide range of diseases which TNFSF13b and antagonists to TNFSF13b could treat, in fact SLE is one of the few diseases that is not referred to at all in the Patent.

14. HGS, with its partner GlaxoSmithKline has invested considerable resources in developing an antibody to TNFSF13b, known as BENLYSTA® (belimumab). After the successful completion of two phase III trials investigating the safety and efficacy of belimumab in SLE patients, on 9 March 2011 the US FDA approved the use of belimumab for the treatment of patients with active, autoantibody-positive SLE. This is the first such treatment approved for SLE in 56 years. On 13 July 2011 the European Medicines Agency ("**EMA**") granted a marketing authorisation for belimumab as an add-on therapy in adult patients with active autoantibody-positive SLE, with a high degree of disease activity despite standard therapy.

15. HGS has also completed successful phase II trials using belimumab for the treatment of the autoimmune disease RA. In addition, HGS and its partners have begun phase II trials using belimumab for treating primary Sjögren's syndrome, chronic immune thrombocytopenia and myasthenia gravis (all autoimmune diseases), symptomatic Waldenström's macroglobulinaemia (an immune cancer), and for immune desensitizing (i.e. suppression of the immune response) of patients awaiting kidney transplant.

Time-lines for the future and the need for certainty

16. In relation to Lilly's own trials of the Lilly antibody, Lilly's original estimate, made in September 2011, was for completion of SLE clinical trials in February 2013. That estimate was reviewed in January 2012 with a revised estimate of August 2013. It was further reviewed for the purposes of the hearing before me, with a further delay to January to March 2014. One can only speculate about how reliable that estimate is. Lilly's current estimate for the start of patient visits in rheumatoid arthritis trials is April to June 2014. Lilly's present intended date for the submission of an application for an MA (assuming that it is right in saying that HGS cannot make a valid application for an SPC) is June 2014.

17. In relation to these proceedings (*ie* the claim for declaratory relief) HGS hopes for a trial date of up 5 days (but more likely 3 to 4 days) in April to June 2013. HGS's advisers consider that if a reference to the ECJ needed to be made and was made after trial, a decision would be obtained from the ECJ between July and October 2014, some 2 years before the expiry of the Patent.

18. If Lilly is correct in its contentions on either the third party SPC issue or the Specification issue, then it can safely obtain an MA well in advance of the expiry of the Patent without the risk that HGS will obtain an SPC thereby effectively obtaining an additional 5 years protection. But if it is wrong in its contentions on each of those issues, HGS may well obtain an SPC if Lilly applies for, and obtains, an MA prior to the expiry of the Patent (once it has expired, no claim for an SPC can be made).

19. Lilly's position is that the current uncertainty (as it would have it) surrounding the third party SPC issue and the Specification issue means that it may have to delay making an application for an MA in order to ensure that the MA is not granted until after the Patent has expired; this would in turn delay its entry into the market, cause delay in generating revenue and erosion of the life of its own patent amongst other matters.

20. It is not possible to predict with precision how long the EMA will take to grant an MA. The evidence is that once an application has been made, the applicant has very little control over its progress. This adds to the uncertainty and makes it difficult for Lilly to time its application so that the grant of the MA would take place shortly after the expiry of the Patent. It would have to take a cautious approach to avoid the grant of an MA before the expiry of the Patent, which will carry the risk that there would be a significant period between expiry of the Patent and the grant of the MA.

21. In order to address both HGS's application to strike out the claim and also Lilly's application for an immediate reference to the ECJ, it is helpful, I think, to consider in some detail the two underlying issues, the third party SPC issue and the Specification issue, albeit that, if HGS is right in its approach to striking-out, that detailed consideration might be seen as not strictly necessary. I now turn to those issues, starting first with the law relating to SPCs.

SPCs: the law

22. SPCs are a form of extended intellectual property protection created by Council Regulation No 469/2009 ("**the SPC Regulation**"). The purpose of the SPC Regulation can be detected from its Recitals:

    i) Recital (3) states that medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

    ii) Recital (4) states that the current period between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection too short to cover the investment put into the research. According to Recital (5) this situation leads to a lack of protection which penalises pharmaceutical research with a risk (see Recital (6)) of research centres situated in the Member States relocating to countries that offer greater protection. This leads to a requirement (see Recital (7)) for a uniform solution at Community level, thus preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of

medicinal products within the Community and thus directly affect the functioning of the internal market.

iii) Recital (10) notes that all interests should be taken into account and that an SPC should not be granted for more than 5 years and the protection afforded should be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.

23. Recitals (4) and (10) both appear to assume that the original patent application relates to a medicinal product and that the MA will relate to that same product. That is not quite what the operative parts of the SPC Regulation provide.

24. Article 1 of the SPC Regulation is a definitions provision. There is a definition of "medicinal product" (see Article 1(a)) the detail of which I do not need to set out but which basically means a substance or combination of substances presented for treating or preventing disease. There is a definition of "product" (see Article 1(b)) which means the active ingredient or combination of active ingredients in a medicinal product. Finally, so far as relevant for present purposes, there is a definition of "basic patent" (see Article 1(c)) which means a patent

> "which protects a product 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" (a certificate being an SPC).

25. Article 3 sets out the conditions for obtaining an SPC:

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

ii) a valid MA has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC;

iii) the product has not already been the subject of an SPC;

iv) the MA referred to above is the first authorisation to place the product on the market as a medical product.

26. Article 6 states that the SPC "shall be granted to the holder of the basic patent or his successor in title".

27. Article 7 requires the application for an SPC to be lodged by the later of (i) 6 months from the date of grant of the first MA and (ii) 6 months following the grant of the Patent.

28. Article 10(2) provides that an application for an SPC shall be rejected if the application or the product to which it relates does not meet the requirements of the SPC Regulation. And Article 15 provides that an SPC shall be invalid if, among other reasons, it was granted contrary to the provisions of Article 3 (see Article 15(1)(a)).

29. The effect of an SPC is not formally to extend the duration of a patent. Instead, protection is afforded under Article 4 only in relation to the product covered by the MA and for any use of the product as a medicinal product that has been authorised

before the expiry of the SPC. But subject to that, the SPC confers, in accordance with Article 5, the same rights as the basic patent.

The third party SPC issue

30. The answer to the third party SPC issue turns on the interpretation of Article 3. If Lilly obtains an MA before the expiry of the Patent, all of the conditions set out in Article 3 would appear, at first sight, to be satisfied:

    i) the Lilly antibody is protected by the Patent which will still be in force;

    ii) the MA obtained by Lilly will fall within Article 3(b);

    iii) the Lilly antibody will not already be the subject of an SPC;

    iv) the MA obtained by Lilly will be the first authorisation to place the Lilly antibody on the market as a medical product.

31. Mr Mitcheson argues, however, that for an applicant to be able to rely on an MA, it must be one which is granted to the patent owner or to a person having a relevant connection with the patent owner. Relying on the Recitals which I have referred to, he submits that the purpose of the SPC Regulation is clear: the extra protection afforded by an SPC is there to compensate research entities for the delay caused **to them** by the need to achieve regulatory authorisation for placing a medicinal product on the market. He argues that, since the principle of compensation underpins the entire SPC Regulation, it follows that the SPC Regulation cannot have been intended to reward a party who suffers no such delay. Thus if a patent owner is not a person who suffers any delay in getting an MA (because no application has been made by the patent owner for one) then there is no need to provide the patent owner with compensation for that delay and the occasion for the grant of an SPC does not arise.

32. Recognising that this argument might prove too much, he restricts its application to cases where the MA belongs to an unconnected person (as in the present case where Lilly and HGS are unconnected). That approach is not without its difficulties, to which I will come later.

33. So far as authority is concerned, Arnold J raised the problem in *Novartis Pharmaceuticals Ltd v MedImmune* [2012] EWHC 181 (Pat) ("***MedImmune***"). The point did not actually arise for decision since neither side took it but the Judge himself noted it, saying this at [61]:

> "As noted above, in the present case the SPC is based upon a product obtained by means of an allegedly infringing process and upon a marketing authorisation obtained by an alleged infringer of the Patent. It might be thought that it was not the purpose of the Regulation to enable a patent owner to obtain an SPC in such circumstances, since the owner has not been delayed in getting the product to market by the need to get a marketing authorisation, and therefore no extension to the term of the patent is needed to compensate him for that delay. Counsel for MedImmune accepted that it was not clear from the

judgment of the Court of Justice in Case C-181/95 *Biogen Inc. v SmithKline Biologicals SA [1997] ECR I-386* that this was permissible."

34. It may not have been clear, but it is very surprising that the Court in *Biogen* did not say something about the point if it thought that there was any doubt that an SPC could be applied for in such circumstances. After all, if there was no such right, then the answers to the questions asked were obvious and the Court need not have gone into the detail which it did in addressing the arguments actually put to it. I therefore need to say something about that case.

35. SmithKline Beecham Biologicals SA ("**SKB**") was a licensee of Biogen Inc paying royalties under a relevant basic patent. It refused to supply Biogen with copies of its MAs which Biogen needed in order to be able to comply with Article 8(b) when making an application for an SPC. The referring court asked four questions. The second question is not relevant for present purposes. I can summarise the first, third and fourth questions in this way:

    i) Question 1: If the holder of the basic patent is a different person from the holder of the MA, is the latter obliged to provide to the former a copy of the MA?

    ii) Question 3: Having regard to what can now be found in Article 6 of the SPC Regulation, may the holder of the MA refuse to give the holder of the basic patent a copy of that MA and thereby deprive him of the possibility of completing his application for an SPC?

    iii) Question 4: Can the national authority granting the MA refuse to supply a copy to the holder of the basic patent or may it supply a copy or may it decide, arbitrarily or subject to conditions, whether to supply a copy with a view to its being used in support of an application for an SPC?

36. The ECJ expressed its conclusions on the first and third questions together at [38] to the effect that there was no requirement on "the holder of the marketing authorization to provide the patent holder with a copy of that authorisation". And that was the answer given in paragraph 2 of the disposition at the end of the judgment. The reason given for that conclusion and answer, however, had nothing to do with the proposition now advanced by Mr Mitcheson that a patent owner cannot rely on an SPC granted to an unconnected third party.

37. I should add here that the section beginning at [31] and ending at [38] is headed "The third and fourth questions" and those are the questions referred to in the opening words of [31]. But this must be an error. It is apparent that the discussion in that section in fact relates to the first and third questions and, indeed, [38] actually refers to those questions. Further, the fourth question is in fact dealt with later: the heading above [39] is "The fourth question" and [39] itself refers to the fourth question.

38. The fourth question was reformulated by the Court at [39]. The question was to be understood as seeking in substance to ascertain whether, where the basic patent and the MA are held by different persons and the patent holder is unable to provide a copy of the MA, an application for an SPC must be refused on that ground alone. In

reformulating the question in that way, the ECJ made it clear that it was concerned only with the effect of the inability to provide a copy of the MA on the possibility of an SPC being granted nonetheless. But it also made it clear that it was answering that question in the context where the basic patent and the MA were held by different persons.

39. The ECJ expressed its conclusion on the fourth question at [47] to the effect that, where the basic patent and the MA are held by different persons and the patent holder is unable to provide a copy of the MA, the application for an SPC must not be refused on that ground alone. And that was the answer given in paragraph 3 of the disposition at the end of the judgment.

40. Mr Mitcheson relies on the presence of the words "on that ground alone" in the answer to the fourth question. That, of course, shows that the Court was not expressly deciding whether it was possible, in principle, for an SPC to be granted to a patent holder where the MA is held by another person.

41. But the Court would also have had in mind what Advocate General Fennelly had said at [43] of his Opinion:

> "43. The Regulation is silent on the relationship between the holder of a basic patent and the holder of a related marketing authorization for the Member State in question, due again, I imagine, to the implicit assumption on the part of the draughtsman that they would be concentrated in the hands of a single undertaking. It is, in effect, the legislative failure to advert to the possible divergent ownership of patents and marketing authorizations that creates the problem in the present case."

42. The AG made those observations in the context of addressing the argument that additional obligations were not to be imposed on private individuals or bodies "by mere implication from the functional needs of the legislation which has failed to provide for an unforeseen circumstance". He was clearly not saying anything about the point which Mr Mitcheson now raises. However, the legislative failure which he identified is as relevant to that point as it was to the issue on which he expressed his views. It is not easy to imagine that the point would not have occurred to the AG in the light of his analysis of the SPC Regulation; nor is it easy to conclude that he would have said nothing about it if it had occurred to him. Indeed, that passage lends some support to HGS's case. The failure of the legislation to address the possible divergent ownership of patents and MAs is seen by the AG as a failure leading to the problem in the case before him. That problem would not have arisen in the first place if the SPC Regulation did not apply because of the divergent ownerships.

43. It seems to me, therefore, that it must have been assumed by the ECJ in reformulating and then answering the question in the way in which it did that it was, in principle, possible to grant an SPC even where the patent is held by one person and the MA is held by another.

44. That assumption is entirely justified on a literal reading of the operative parts of the SPC Regulation. Mr Daniel Alexander QC, who appears with Mr Mark Chacksfield

for HGS, correctly observes that Lilly's approach requires the court to read into it an additional condition which is not reflected in the text. He puts the purpose of the SPC Regulation in a different way from Mr Mitcheson. The SPC regime is justified, he says, by the need to ensure that patents in the pharmaceutical field last sufficiently long to provide adequate protection given the length of time it takes for products to come to the market. It is not meant to measure the quantity or quality of the research underlying the patent, nor is it intended as some sort of reward for getting a product to the market. In that context, it is worth referring to another passage (see [50]) of the Opinion of Advocate General Fennelly in *Biogen*:

> "50. Fourthly there is nothing to support the defendant's contention that the Regulation was designed primarily to reward the expense and effort involved in developing marketable medicinal products, rather than pharmaceutical research in general, the results of much of which may require further development before marketing. While it is essential under the scheme of the Regulation that research ultimately results in a marketable medicinal product, the recitals in the preamble to the Regulation (such as the first, second and fourth) speak of pharmaceutical research in general, while Article 1(c) of the Regulation suggests that any patent, including one based on the most elementary research, may be designated as a basic patent for the purposes of applying for a certificate."

45. That passage lends support to the proposition that it is the research leading to the basic patent which the SPC Regulation is designed to recognise and that protection is to be given in relation to that basic patent albeit that a marketable product must be produced. But it is no part of the philosophy as articulated by the AG that the protection should be afforded only if the product is brought to the market by the holder of the patent.

46. It is, however, the purpose, or at least a primary purpose, of the SPC Regulation to "confer supplementary protection on the holders of [basic patents], without instituting any preferential treatment amongst them.": see [27] of the Judgment of the Court in *Biogen*. And see to similar effect [26] of the Opinion of the AG.

47. Proceeding on the basis that Biogen was entitled in principle to obtain an SPC based on an MA obtained by SKB, the ECJ found a practical solution to the requirement, found in Article 8(1)(b), that a copy of the MA had to be provided with the application for an SPC. The parties had fallen out, leading to the refusal by SKB to provide a copy of the MA in turn leading to the litigation. I would take a great deal of persuasion before concluding, for the purposes of the third party SPC issue, that there is any material difference between a case such as *Biogen* (where a licence had been granted) and a case such as the present case (where there is no licence) even if on Lilly's approach, there is no connection at all between the parties.

48. Mr Mitcheson suggests however, that the royalty licence in *Biogen* gave rise to a connection which may have been enough to justify a conclusion that, in principle, an SPC could be granted based on the basis of the MA held by SKB. Accordingly, it was necessary for the ECJ to rule on the questions which it was asked. But there is no

hint that the AG and the ECJ made the assumption that an SPC could, in principle, be obtained because of the presence of some connection. It would be very surprising if, having detected a difference in that regard between a case where a connection is to be found and one where there is not, that they would not have said something about it. If a connection was a consideration they had in mind, there would surely have been a debate about where the line was to be drawn, particularly since it is far from obvious that a royalty licence would bring the case within the "connected class" rather than the "unconnected" class.

49. Further, what the AG said in [63] of his Opinion in *Biogen* is of interest:

> "63. ... In these circumstances, I consider that it would be contrary to the objectives and scheme of the Regulation if patent holders were prevented from availing of their right to supplementary protection, where all substantive conditions are satisfied, simply because they are not part of a vertically integrated pharmaceutical undertaking which also markets medicinal products and because they are unable to produce published evidence of information already in possession of the authorities of the Member State in question. ..."

50. This was not, of course, said in the context of addressing the third party SPC issue but in the context of the possible obligation of the parties or public authorities to provide copies of the MA. It does, nonetheless, seem to me to be difficult to reconcile with Lilly's position. I find it difficult because the whole thrust of that passage is that there can be divergent ownerships of the patent and the MA; the only way in which to render that passage consistent with Lilly's position is to argue that what the AG said was applicable only where there is some sufficient connection between the holder of the patent and the holder of the MA, a connection the existence of which the AG did not even hint at.

51. Mr Alexander has shown me that the practice of the UKIPO, and indeed of other patent offices across the EU, (at least in Germany, France and Ireland) is to grant SPC's in respect of third party products brought to the market with appropriate MAs. I do not propose to go into any detail about this since the practice of authorities across the EU cannot affect the meaning of the SPC Regulation itself; it is no more than the interpretation of the SPC Regulation itself by those authorities in the light of relevant case-law, in particular *Biogen*.

52. Mr Alexander also submits that support is to be found for HGS's position in the Plant Protection Regulations (Council Regulation (EEC) No 1610/96). It operates in a way broadly similar to the SPC Regulation and its structure is based very much on that of the predecessor Medicinal Products Regulation (Council Regulation (EEC) No 1768/92) which, with amendments subsequently made, is consolidated in the SPC Regulation. Indeed, the Plant Protection Regulation actually refers to that Medicinal Products Regulation in Recital (17) providing that "the detailed rules in recitals 12, 13 and 14 and in Articles 3 (2), 4, 8 (1) (c) and 17 (2) of this Regulation are also valid, *mutatis mutandis*, for the interpretation in particular of recital 9 and Articles 3, 4, 8 (1) (c) and 17 of Council Regulation (EEC) No 1768/92". Article 3(1) is in almost identical terms to Article 3 of the SPC Regulation. But there is also an Article 3(2) in the following terms:

> "The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders"

53. That provision is widely drawn. It envisages the holders to two or more patents being able to obtain an SPC in relation to a single product subject to a single MA. There is nothing in the legislation to suggest that that Article 3(2) is limited only to the holder of the MA (that would be an impossible construction) or a group company or related entity or its licensee or an entity connected in some other unspecified way. It cannot be supposed – and I would firmly reject any suggestion – that the SPC Regulation and the Plant Protection Regulation should be interpreted in different ways so far as concerns the third party SPC issue. HGS's position on that issue is enormously strong in the context of the Plant Protection Regulation which therefore strongly supports its position in relation to the SPC Regulation.

54. Mr Alexander also makes this submission which has very considerable force. On Lilly's case, an application for an SPC would require the relevant national authority to investigate the relationship between the holder of the patent and the holder of the MA to ascertain whether the necessary element of connection existed. Apart from the difficulty in identifying the relevant criteria, the application in any particular case will be fact-sensitive. Nothing in the SPC Regulation suggests that the authority was to be burdened with such a task. Indeed, the original Explanatory Memorandum produced by the Commission (Com (90) 101 final – SYN 255 (dated 11 April 1990)) explained at paragraph 16 that "the proposal….provides for a simple, transparent system which can easily be applied by the parties concerned. It therefore does not lead to excessive bureaucracy". That is reflected in the commentary on the proposed Article 8: "… the system must be kept simple, while allowing for a certain degree of balance between all of the interests involved". The result of Lilly's approach would be the antithesis of the Commission's approach which one can properly take to be the approach of the legislature. That it may be obvious in many cases that there is, or is not, a relevant connection (*eg* on the one hand where there is no connection at all or, on the other hand, where the holder of the patent and the holder of the MA are the same), is no answer to the point.

55. Mr Alexander also asks why an SPC should be granted where litigation brought by a patentee has forced an MA holder to take a licence but should not be available where there is an ongoing dispute between the two. That would be an arbitrary and unprincipled result. And yet that, he says, is the result of Lilly's approach. This argument, it seems to me, is not as strong as it appears stated in that way. An application for an SPC must be made within the period of 6 months from the grant of the MA. In a case where the patent is under challenge, whether by way of a defence to an infringement action or by an action asserting invalidity, it may well be that more than 6 months will pass from the date of the MA to the date of resolution of the action. In that period, it is unlikely that a licence will come into being. If the owner of the patent succeeds, it may then force the holder of the MA to take a licence (assuming that the patent has not by this time expired) but it must follow on Mr Mitcheson's argument that an application for an SPC prior to the grant of that licence

would fail because of the lack of connection. He could, I suppose, argue that the litigation itself gives rise to a sufficient connection: but if he needs to rely on an argument such as that, it demonstrates, in my view, that his approach cannot be right.

56. Let me then take another example. Suppose that the owner of a patent, A, is developing a product which it wishes to bring to the market. A competitor, B, having no connection with A, obtains an MA for a product which would infringe A's patent. 9 months later, A obtains an MA for its own product. Can A obtain an SPC or not? On Lilly's case, A cannot rely on B's MA since there is no connection between A and B. It would, however, be entirely contrary to the purpose of the SPC Regulation if A could not obtain an SPC at all. Lilly must, therefore, accept that its argument leads to two results in the example. The first is that, when A comes to make its application for an SPC based on its own MA, the MA granted to B is not within Article 3(b), on the basis that it must be read as if the words "to the holder of the basic patent or a person connected with it" after the words "has been granted". The second, which is not part of Lilly's case, is that the MA granted to B is not within Article 3(d) either. This is because, if it did fall within Article 3(d), the MA granted to B and not the MA subsequently granted to A, would be the first authorisation to place the product on the market. A's application for an SPC would then fail because Article 3(d) would not be fulfilled.

57. To avoid that result it would be necessary to imply into Article 3(d) after the words "the first authorisation" words such as "granted to the holder of the basic patent or a person connected with it". I can see no justification for such an implication. It is one thing to imply into Article 3 a requirement that, in order to obtain an SPC, the holder of the basic patent (or a connected person) must itself obtain an MA. It is quite another to imply a term to the effect that the basic patent holder can obtain an SPC even where the application is more than 6 months after the date on which an MA had been obtained by an unconnected third party. There is nothing, in my view, either in the Recitals to the SPC Regulation or in its operative provisions which would justify such an implication. If that is correct, as I think it is, it seriously undermines Lilly's case on the third party SPC issue.

58. That is not an end of the difficulties facing Lilly's approach to the third party SPC issue. Mr Mitcheson says that if there is no connection at all between the two holders, then the SPC Regulation is not engaged. In the present case there is, he says, no connection on any view between Lilly and HGS. Accordingly, HGS would not be entitled to apply for an SPC on the basis of an MA granted to Lilly.

59. That is an unsatisfactory argument given that the rejection of the literal approach necessarily entails, if the argument is correct, that some criteria need to be established in order to decide what is, and what is not, a sufficient connection between the holder of a patent and the holder of an MA to bring the case within the SPC Regulation. It would no doubt be possible for the EU legislator to lay down such criteria. One might think that it would go beyond any interpretative function of the ECJ, still less of the national court, to lay down such criteria. But, if Mr Mitcheson's argument is to succeed, that is precisely what must be done. The ECJ would have to give guidance about how such criteria are to be identified and the national court would then have to apply that guidance in practice. I do not consider that this is what the legislation envisages or requires.

60. In any case, the Recitals to the SPC Regulation do not lead, in my view, to the conclusions which Mr Mitcheson wishes me to reach. I have already mentioned (see paragraph 31 above) what he says the purpose of the SPC Regulation is: it is the extra protection afforded by an SPC to compensate research entities for the delay caused **to them**. That, I consider, is no more than an assertion of the result for which he contends. That is not what the recitals to the SPC Regulation actually say. The significant recitals are (3) and (4) which I have already referred to. Recital (3) recognises the need for further protection. Recital (4), in similar vein, states that the period which can elapse between the filing of a patent application and the grant of an MA makes the period of effective protection under the patent insufficient. Additional protection could have been provided by having an extended duration for relevant patent. That was not the route which the Community legislator took. Instead, the protection was afforded in the way which is to be found in the operative parts of the SPC Regulation. But Recitals (3) and (4) are as consistent with a simple extension of the duration of the relevant patent as they are with the route which was actually adopted. In my judgment, they do not provide any assistance insofar as the third party SPC issue is concerned. Nor do the other recitals referred to by Mr Mitcheson point to the interpretation for which he contends.

61. Finally, I note that even if he was right to identify the purpose of the SPC Regulation in the way he does, it is a purpose which would be achieved by the literal interpretation of the SPC Regulation. It is true that the SPC Regulation would then go further than achieving only that purpose. But there would be nothing inconsistent with the purpose which he identifies.

62. I therefore conclude that the answer to the third party SPC issue is that the holder of a basic patent can make an application for an SPC in reliance on an MA granted to a third party having no connection of any sort with that holder. I do not consider that there is any real doubt about this such as would justify a reference to the ECJ if this were the only matter to be referred.

The Specification issue

63. The Specification issue goes to what express words need to be found in a patent in order to enable the grant of an SPC relating to an active ingredient within the scope of the patent. The story relating to a number of references to the ECJ in relation to the SPC Regulation, and in particular Article 3, is set out at some length in the judgment of Arnold J in *MedImmune* at [25] to [49]. I do not propose to rehearse the same history in this judgment and I adopt his masterly exegesis. Mr Mitcheson submits that the law remains unclear on the Specification issue and that a reference to the ECJ is necessary.

64. He is obviously right that the law remains unclear in many aspects. Whilst sharing Arnold J's puzzlement with the reasoning in Case C-322/10 *Medeva BV v Comptroller General of Patents, Designs and Trade Marks* 24 November 2011, [2011] ECR I-0000 ("***Medeva***") and Case C-630/10 *University of Queensland v Comptroller General of Patents, Designs and Trade Marks* [2011] ECR I-0000 ("***Queensland***") (see at [37] and [49] of his judgment), it is not possible to disagree with what he says at [53] to the effect that the test laid down in *Medeva* and its progeny is unclear save in its rejection of the infringement test in combination cases

or with his statement in [62] that it is inevitable that there will have to be further references to the ECJ.

65. Since Arnold J's decision in *MedImmune*, the Court of Appeal has given its decision in *Medeva BV v Comptroller General of Patents, Designs and Trade Marks* EWCA Civ 523, following the ECJ's answers in the preliminary reference in *Medeva*. In the only reasoned judgment of the Court, the Chancellor considered a number of the cases referred to by Arnold J in *MedImmune*. At [13] to [16] of his judgment, the Chancellor succinctly identified the rival contentions by reference to the various arguments advanced to the ECJ. The first approach, the infringement test, is straightforward and involves determining what is protected by the basic patent by reference to the national law of patent infringement. The second approach is rather more difficult to articulate but essentially involves identifying the active ingredients which are protected by the patent in question, the question being whether they are sufficiently specified or identified in the claims in the patent. He then went on to consider in some detail the Opinion of the AG and the Judgment of the Court. After re-iterating the conclusions of Arnold J in [53] of his judgment in *MedImmune*, his conclusions are set out in [33] and [34] as follows:

> 33. Thus the issue for the national court is to determine which active ingredients are specified in the wording of the claims. The ambit of "specified" may range from express naming, through description, necessary implication to reasonable interpretation. Where on that scale the dividing line is to be drawn will necessitate further references in due course in the light of the facts of the cases in which the issue arises. The problem for Medeva in this case is that wherever the dividing line is to be drawn the active ingredients relating to vaccines against diphtheria, tetanus, meningitis and polio are excluded.
>
> 34. The only ground for suggesting that they may be included is a rule or convention used in drafting patent specifications to the effect that the word "comprising" does not exclude other elements. But that is insufficient. The ruling of the Court of Justice requires that the other elements or active ingredients are specified in the wording of the claims. There must be some wording indicating that they are included in the claims. Were it otherwise the Court of Justice would be imposing the infringement test which the Advocate General expressly and the Court of Justice by necessary implication had excluded. There is no wording in the claims of the patent relevant to this case to indicate that the active ingredients of the vaccines against diphtheria, tetanus, meningitis and polio are included. That is sufficient to determine this appeal. It follows that there is no occasion to make any further reference."

66. In the present case, Mr Mitcheson submits that the judgment of the Chancellor makes it clear that he considered that further references will be necessary to determine what "specified in the wording" means. The decision in *Medeva* was confined to its facts and insufficient guidance has been provided in relation to other types of claim such as those relating to antibodies. Thus he submits that it remains unclear whether

"specified in the wording of the claim" requires a product to be named explicitly and individually within the claim wording, whether it includes implicit coverage within a generally-defined class, or whether some other test is intended.

67. In the present case, the relevant claim is Claim 13 of the Patent which reads as follows:

> "13. An isolated antibody or portion thereof that binds specifically to:
>
> (a) the full length Neutrokine-α polypeptide (amino acid sequence of residues 1 to 285 of SEQ ID NO:2); or
>
> (b) the extracellular domain of the Neutrokine-α polypeptide (amino acid sequence of residues 73 to 285 of SEQ ID NO:2)"

68. Lilly accepts, at least for the purposes of the applications now before the Court, that the Lilly antibody falls within the scope of Claim 13 but asserts that it is not specified within the wording of the claim. I have already set out at paragraph 13 above, what Mr Stewart has said about that. In a further witness statement, he explains Lilly's case that Claim 13 is simply too broadly drafted to "specify" any antibody that binds full length hTNFSF13b or the extracellular domain of the hTNFSF13b polypeptide according to the test set out in *Medeva*. In particular, Claim 13 (a) provides no specified primary antibody sequence and (b) fails to disclose any functional information besides the broad assertion that the antibody binds full length hTNFSF13b or its extracellular domain.

69. He goes on to illustrate this by reference to the claims of other HGS patents which do provide at least some structural definition for the antibodies claimed. As Mr Mitcheson helpfully puts it in his skeleton argument, these other claims give the amino acid sequences of the variable heavy chain and variable light chains, or specify the sequences for the CDR sections of the antibody. In contrast, the Patent gives no information whatsoever about the sequence of the antibody claimed. In the absence of such structural definition, Lilly submits that on a proper interpretation of the SPC Regulation, the Lilly antibody is not specified within the wording of the claim. At the very least, whether a structural definition is required for antibody claims is something on which the guidance of the ECJ is required.

70. Mr Alexander, for his part, submits that the grant of SPCs for antibody products based on broadly defined claims, including claims defined in functional terms, has been established at the UKIPO since at least 2002, basing himself on the evidence of Dr Gilbert. He says that this appears to have been the position of the ECJ in Case C-518/10 ("***Yeda***"). The importance of the decision lies in what the ECJ said about combination claims, rejecting the proposition that an SPC may be granted where the application relates to a product comprising a single active ingredient but the basic patent claims the active ingredient only in combination with another. Mr Alexander submits, however, that what the Court had to say about the monoclonal antibody component itself, supports HGS's case that the Patent contains a sufficient specification to enable an SPC to be granted. Claim 1 of the patent in suit in that case concerned a therapeutic composition comprising:

> "(a) a monoclonal antibody which inhibits the growth of human tumour cells by said antibody binding to the extra-cellular domain of the human EGF receptors of said tumour cells in an antigen-antibody complex, said tumour cells being characterised by their expression of human EGF receptors and mitogenic stimulation by human EGF; and
>
> (b) an anti-neoplastic agent …"

71. The ECJ reformulated the question in the reference:

> "By its question, the Court of Appeal asks, in essence, whether Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting a SPC where the active ingredient specified in the application, even though identified in the wording of the claims of the basic patent as an active ingredient forming part of a combination in conjunction with another active ingredient, is not the subject of any claim relating to that active ingredient alone."

72. Mr Alexander draws attention to the words "even though identified in the wording of the claims in the basic patent", the same phrase being found in the answer to that reformulated question, to show that the ECJ was of the view that the antibody was specified in the claims of the basic patent despite the functional wording of the claim, submitting that it was right to do so. He adds that if and insofar as there is uncertainty arising out of the decision of the ECJ in *Medeva*, that uncertainly relates to combinations and that the decision has no impact on the (hypothetical) SPC in the present case.

73. I am not sure whether he submits that the answer to the Specification issue is *acte clair*. I consider that if this court ever needs to provide an answer to the Specification issue, a reference will be necessary, but that will be a matter to be determined on another occasion.

The strike-out application

74. There are essentially two, albeit overlapping, broad reasons why Mr Alexander says the claim should be struck out. The first is that the claim raises purely hypothetical questions to which an answer may never be needed. The second is that the claim seeks to raise matters in relation to which there is in a place a statutory procedure under which the grant of and challenge to SPCs is to be made and that the Patents Court should not subvert that procedure by entertaining actions for declaratory relief.

75. CPR 40.20 provides that the Court (which includes the Patents Court) may make binding declarations whether or not any other remedy is claimed. The jurisdiction to make declarations does not, however, derive from that rule which is concerned only with the point whether a declaration can be made when no other relief is sought. As it is put in the White Book commentary at CPR 40.20.2

> "The power to make declarations is discretionary. As between the parties, the court can grant a declaration as to their rights, or

> as to the existence of facts, or as to a principle of law (*Financial Services Authority v Rourke* [2002] CP Reports 14 (Neuberger J)). When considering whether to grant a declaration or not, the court should take into account justice to the claimant, justice to the defendant, whether the declaration would serve a useful purpose, and whether there are any other special reasons why or why not the court should grant the declaration (*ibid.*)."

Reference is then made to a number of cases where the principles have been considered including *Nokia Corp v InterDigital Technology Corp* [2006] EWHC 802 (Pumfrey J) and [2006] EWCA Civ 1618 (CA dismissing the appeal) and *Arrow Generics Ltd v Merck & Co Inc* [2007] EWHC 1900 (Kitchin J) ("***Arrow***").

76. In *Arrow*, the defendants sought to strike-out the claimant's claim seeking declarations concerning a European patent and divisional applications arising out of that patent. Kitchin J struck out the claim insofar as it sought a declaration referring to the patent on the basis that the patent had never been granted: see [36] of his judgment. The patent never having been granted, it was inappropriate to entertain questions as to the validity or revocation of the (non-)patent.

77. So far as the claims for declaratory relief in relation to the divisional applications were concerned, Kitchin J considered that these were not outside the jurisdiction of the Patents Court. In particular, they were not barred by section 74 Patents Act 1977 which, he held, should not be construed any more widely than necessary to give effect to its purpose. Mr Alexander does not rely on section 74 and I need say no more about it.

78. What Arrow in effect sought was a determination that its own product was obvious at the priority date of the divisional applications. A declaration to that effect would, to use the judge's words:

> "give Arrow the security that dealing with its own alendronate product in this country will not give rise to any liability to Merck for infringement of any patent granted pursuant to the divisional applications or any further divisional applications arising under them. It says this court has jurisdiction to grant such a declaration and that it is appropriate so to do because Merck has shown every intention of (a) pursuing and (b) relying upon the divisional applications against Arrow *inter alia* in the UK. There is therefore an issue between the parties and a real commercial need for the clarification sought."

79. Before turning to the general principles concerning the power of the court to grant the relief, the Judge identified the particular circumstances on which Arrow relied which "collectively make this a very unusual case". He then set out in [40] to [46] seven important aspects of the case to show why it was not an ordinary case. I need to mention them briefly because it is only with an understanding of the nature of the points that one can see why the Judge reached the conclusion which he did.

i) Arrow was seeking a declaration of obviousness in respect of particular characteristics of its own product.

ii) It followed that Arrow was not seeking a declaration that no valid patent could be granted to Merck based upon the divisional applications.

iii) Arrow had sought to clear the way of the launch of its product by bringing proceedings to revoke the 292 patent both in the UK and before the EPO. It succeeded. As a result, it reasonably supposed that no objection could be raised to the manufacture of its product which it duly launched. But then it faced the prospect of EP(UK) patents being granted on the divisional applications that would cover the very same products.

iv) Arrow submitted that it had a very strong case. The Judge could not express any conclusion about the merits but was satisfied that Arrow had a real prospect of success in establishing that its product was obvious as of July 1997.

v) Arrow was currently incurring a liability (were it eventually to lose) in respect of two of the divisional applications.

vi) Merck had made it clear that it would seek to enforce its patent in respect of Arrow's product. Arrow had put forward proposals for Merck to give certain undertakings which invitation had been rebuffed. There was therefore an ongoing threat that Merck would seek to enforce any patent rights that it might obtain in the UK against Arrow's product.

vii) Arrow was unable to commence revocation proceedings in the UK until the divisional applications had proceeded to grant. On Merck's estimate, that could be any time between the last quarter of 2007 and the end of 2008. In the meantime, the scope of the claims of the divisional applications could change creating yet further delays. Arrow therefore faced a considerable period of commercial uncertainty.

80. The Judge then went on to consider the general principles applicable to the grant of declaratory relief. He referred to the discretionary nature of the remedy, citing as a passage from the judgment of Lord Woolf MR in *Messier-Dowty v Sabena* [2001] 1 All ER 275 to the effect that the use of negative declarations should be rejected where it would serve no useful purpose and that their use in relation to commercial disputes should not be constrained by artificial limits wrongly related to jurisdiction, rather the use should be kept within proper bounds by the exercise of the court's discretion.

81. He cited also from the decision of Neuberger J in *FSA v Rourke* which I have already mentioned. He also cited from Pumfrey J's decision in *Nokia* who had distilled these propositions from the cases:

i) The correct approach to the question of whether to grant negative declarations was one of discretion rather than jurisdiction.

ii) The use of negative declarations should be scrutinised and their use rejected where it would serve no useful purpose, but where such a declaration would

help ensure that the aims of justice were achieved, the court should not be reluctant to grant a negative declaration.

iii) Before a court can properly make a negative declaration, the underlying issue must be sufficiently clearly defined to render it properly justiciable.

82. That decision was, as Kitchin J recorded, upheld by the Court of Appeal. Jacob LJ explained that normally a court would decline to grant a declaration in favour of a party against whom no claim had been formulated for the obvious reason that there is no real point in doing so. However, in the context of *Nokia* there was, he considered, a real point, basing his conclusion on the real commercial reasons which there were for seeking the declaration sought.

83. Those, then, are the principles. Kitchin J, in applying those principles, made the point (with which I agree) that there is, as he put it, "a public interest in commercial certainty in patent matters as in any others. Business needs to know where it stands. I believe this court should assist in providing that certainty where it properly can".

84. Thus in the context of the unusual features of that case – the seven factors identified and which I have referred to – the Judge was not satisfied that the court had no jurisdiction to make a declaration nor was he satisfied that the court would necessarily refuse such declarations in the exercise of its discretion. There was a reasonable prospect of success and the matter was allowed to proceed to trial.

85. It is relevant to note, however, that the Judge (see [60] of his judgment) accepted Merck's argument that the Court should not make declarations about the validity of a patent application because they are the subject matter of examination by the EPO and the claims can change. For the court to start anticipating the examination process would be to usurp the function of the EPO and would be inconsistent with the framework of the EPC and the Act. He found it hard to conceive of any circumstance in which it would be appropriate for this court to grant a declaration that no valid patent could be granted on a divisional application which was being prosecuted before the EPO. But that was not what Arrow was seeking.

86. Mr Mitcheson refers to the Judge's observation that the purpose of section 74 is to ensure that invalid patents are not merely declared to be invalid but are revoked, with the register being altered to reflect the revocation. He submits that this "mirror" principle points in favour of the grant of a declaration at this stage in the present case.

87. Finally, referring to the "real commercial basis" described by Jacob LJ in the Court of Appeal he identifies the following parallels:

i) The present case is also one where it is a matter of the court's discretion rather than a technical matter of jurisdiction whether or not to grant the declarations sought.

ii) The declarations would serve a useful purpose.

iii) The underlying issue – which he identifies as the ability of the Patent to support an SPC in respect of Lilly's antibody – is well-defined and is exactly the sort of question which the court is well-placed to examine. He does not

make the same point in relation to the Specification issue, but it is implicit in what he has said.

iv) Lilly has a real commercial interest in obtaining the declaration sought, adding that so, too, do the potential patients of the Lilly antibody.

88. In contrast, Mr Alexander, relying on [60] of Kitchin J's judgment (which passage forms the basis of paragraph 85 above), says that it applies with even greater force to an application which has not been made. I am not sure that that is so. Where an application has been made, the scope of the patent applied for will be known and its claims identified. The right place to deal with the validity of what is applied for is not the court but the EPO or other relevant office. But where no application has been made, there is nothing to oppose: the EPO or other relevant office is simply not seized of the matter. If there is a commercial imperative that a clearly defined dispute should be adjudicated on, I do not see why the Court should not have jurisdiction to resolve that dispute by granting declaratory relief.

89. Whether it should entertain that jurisdiction is a different question from whether the jurisdiction exists. As Kitchin J puts it, it is hard to conceive of circumstances where it would be appropriate for this court to grant the sort of declaration which he referred to. Where it is necessary to investigate facts, it is hard not to agree with him. The court would not entertain the jurisdiction even if it exists. But where a pure point of law is concerned, and there are strong commercial reasons why a party to a dispute needs to have it resolved, the answer is not so clear.

90. The present case is not, however, one which concerns an application for a patent. It is one which relates to a potential application for an SPC. In relation to such claims, it is provided that the Comptroller is to determine whether an SPC should be granted with a right of appeal to the court. As Mr Alexander says, that is a structured approach for the determination of whether an SPC should be granted with a procedural code applicable to such applications. Just as Kitchin J found it hard to conceive of circumstances where the court would grant the sort of declaration which he was concerned with, so too would I find it hard to conceive of circumstances where, an application for an SPC having been made on the basis of an MA granted in respect of the Lilly antibody, the court would make a declaration to the effect that any SPC in fact granted would be invalid; the same would apply if the declaratory relief sought were slightly amended to seek a declaration that no valid SPC could be granted on the basis of such an application.

91. It seems to me however, that the decision in *Arrow* provides no real support for Lilly's case. The point which was of central importance to the actual decision was that Arrow was not seeking to prevent Merck from obtaining a patent: the declaratory relief sought went nowhere that far but was restricted to a declaration concerning the obviousness of Arrow's own product. In the present case, in contrast, Lilly seeks a declaration the practical effect of which would be to prevent HGS obtaining an SPC at all.

92. I must therefore approach the matter as one of principle. In my judgment, this court does have jurisdiction to entertain an action for the declaratory relief which Lilly seeks. As I have said, it is a different question, to which I come in a moment, whether the court should actually exercise that jurisdiction, the answer to which depends on

carrying out a balancing exercise. But I make the following suppositions: first, that the case concerned only the third party SPC issue; secondly, that it were absolutely clear that there was no connection between Lilly and HGS in the sense required, on Mr Mitcheson's submissions, by Article 3; the third party SPC issue would then be a pure question of law; and thirdly, that it were absolutely clear too that there were the strongest possible commercial reasons for Lilly to know the answer to the third party SPC issue well before the date of expiry of the Patent. Making those suppositions, I can see no reason why, in principle, this court should not have, and should not exercise, the jurisdiction to deal with a claim for appropriate declaratory relief. If this is to usurp the function of the Comptroller, it is the most technical of usurpations. Indeed, if this court did not accept jurisdiction, the point could, at least in theory, be decided by the ECJ on a reference from another court, perhaps in a different Member State, which would then be binding in the UK.

93. I conclude that this court has jurisdiction to entertain the present action. Should it actually do so? The first question is whether the declaration sought would serve a useful purpose. The only useful purpose which might exist is the provision of commercial certainty to Lilly. It would know whether or not HGS would be able to obtain an SPC on the basis of an MA obtained by Lilly for the Lilly antibody. If Lilly obtained the declarations it seeks, it would know that it could market its medicinal product for which the MA is obtained without fear of infringement of the Patent after its expiry in October 2016. But if it failed to obtain the declarations having lost on both the third party SPC issue and the Specification issue, it would know that the grant of an MA in respect of the Lilly antibody would expose it to the risk of HGS obtaining an SPC with the consequent further 5 year protection afforded to HGS and a corresponding delay in the launch of its own product. It wishes to clear the way. Whilst Lilly is no doubt primarily concerned with its own commercial position, there is also the point it makes that many patients may benefit if it is able to bring its own medicinal product to the market.

94. Although presented as a case of clearing the way, it is at best, however, only a partial clearing. Indeed, Mr Alexander suggests that Lilly's actions have not been entirely consistent with that presentation.

i) First of all, the Patent in its amended form was held by the TBA in October 2009 to be valid. The only continuing challenge to that is in the UK. In particular, there is no challenge in the Republic of Ireland where at least some of the manufacturing of the medicinal product which Lilly intends to market will take place.

ii) Secondly, there has been no attempt to obtain a declaration of non-infringement in relation to the proposed marketing of the product in question. Lilly has certainly in the past said that there would be no infringement and, so far as I am aware, it has not retreated from that position. HGS says that it has no idea of the basis of the denial of infringement.

iii) Thirdly, there may be other obstacles facing Lilly in the shape of a patent held by Biogen which expires in 2020. Although there was some discussion of this at the hearing, there is not sufficient certainty about the disputes between Lilly and Biogen for me to place any reliance on those possible obstacles as a factor in the exercise of my discretion.

95. Mr Alexander also identifies the following factors as pointing against the court allowing the action to go forward:

i) The outcome of Lilly's clinical trial is not yet known. If they fail, or are further delayed, or require additional studies, no MA could be applied for and obtained in time to attract an SPC application. In other words, it may turn out that Lilly is simply unable to obtain an MA before the Patent expires in which case the declaratory relief sought would not be needed.

ii) The Court of Appeal may hold the Patent to be invalid. Subject to any further appeal to the Supreme Court, declaratory relief would again not be needed.

iii) It may be that HGS will not apply for an MA even if Lilly obtains one before the expiry of the Patent. That is of course true, but it is equally true that it may do so. If Lilly is reasonably entitled to certainty, HGS could provide it by making clear that it would not apply for an SPC on the basis of an MA granted to Lilly. I do not think that HGS can derive any support for its position from this consideration.

iv) Lilly's attitude to whether or not it accepts that its proposed medicinal product will infringe the Patent is said to be a relevant factor. If it does not accept that there will be infringement, a substantial trial will be required to determine that issue. It is said that the SPC point would be a secondary consideration. But that argument, it seems to me, misses the point. If Lilly were to obtain the declaratory relief it seeks, it could safely obtain an MA prior to the expiry of the Patent and put itself into a position to launch its medicinal product reasonably soon after the expiry of the Patent. There may be no need for a long and costly infringement action at all.

96. There are also these considerations. It is one thing to allow an action for a declaration to proceed where a point of law is raised on agreed facts, or in the case of disputed facts, when the determination of those facts does not usurp the role of the Comptroller.

97. But that is not the case in the present case. In relation to the third party SPC issue, the court, if it were to make the declaration sought, would have to conclude that, before an application for an SPC could be made, there must be some relevant connection between the holder of the patent and the holder of the MA. It could not do that, in my view, unless it identified the criteria by which that connection is to be judged. At a general level, the court could conclude that some connection was necessary only if it was able to explain why that should be so. And in order to do that, it would need to understand and articulate the criteria by reference to which the line is to be drawn between what is and what is not a sufficient connection. Further, at the specific level of the present case, it would need to decide whether on the facts, the necessary connection is to be found. As already explained, HGS may argue that there is a relevant connection because of the relationship between Lilly's research and that of HGS. That, it seems to me, will involve a factual enquiry which it is more appropriate to be conducted in the course of an actual application for an SPC.

98. Test the matter this way. Suppose that the ECJ had ruled that there had to be some sort of connection and had given guidance about what is necessary. The national

authorities (be it the Comptroller or the court in the UK) would have to apply that guidance on the facts of any particular case. It would need to resolve any factual dispute and then it would need to apply the guidance to the facts as found. That is an exercise that ought normally to be undertaken by the Comptroller and not by the court.

99. I do not say that these considerations lead conclusively to a refusal by the court to exercise its jurisdiction, but they do point to that result.

100. As to the Specification issue, Mr Alexander suggests that the terms of any granted MA or product definition in an SPC application will be relevant. That may well be the case when it comes to testing the validity of an SPC application if one can be made. But Lilly's point is different. It is that HGS will not be able to make an application in the first place because the Patent does not sufficiently specify or identify the Lilly antibody. That point does not turn on the actual MA granted or the product definition in any SPC application. The court hearing the claim for a declaration, if it is allowed to proceed, will no doubt need to know far more about the technical aspect of the Patent and how and why the Lilly antibody falls within the scope of Claim 13 than I have been told; and it will need to know far more about the Lilly product itself than I have been told. But that is not of itself a sufficient reason for the court to refuse to allow the action to proceed, although it is a factor.

101. The arguments are, I consider, finely balanced. In my judgment, the action for a declaration should not be struck out. There are powerful commercial reasons why Lilly should be allowed to proceed with this action and I do not consider that the countervailing factors which I have identified are sufficient to tip the balance. Lilly is unable to invoke the procedures for challenging the grant of an SPC because no MA has yet been obtained and no application for an SPC can be made; indeed, it is the very uncertainty of the meaning of the SPC Regulation which creates the commercial uncertainty facing Lilly. The court should assist in providing the certainty which Lilly reasonably requires.

102. This conclusion is not to be seen, however, as opening the gates to actions for declarations concerning SPCs. The main uncertainties in the present case result from a lack of clarity in the law, namely the correct answers to the third party SPC issue (although for my part I think the answer is reasonably clear) and the Specification issue (where the answer is not clear). Once the answers to those issues of principle are clear and guidance has been given by the ECJ, the application of the law and that guidance to the facts of any particular case should not, save in exceptional circumstances which it is not easy to envisage, be brought before the court rather than being dealt with by the Comptroller.

103. The action should not, however, be allowed to proceed until the Court of Appeal has given its decision about the validity of the Patent and any application for permission to appeal (if any is made) has been finally dealt with. If the Patent is invalid and no appeal to the Supreme Court is made, that will be an end of the matter and this action serves no purpose. If the Patent is valid, then this action should be allowed to proceed and the stay should come to an end.

104. So far as a reference to the ECJ is concerned, it is not appropriate to make one so long as the stay is in place. However, if the stay is lifted and the action proceeds, the

question of a reference becomes live. It is appropriate that I should say something about that now.

Should there be a reference once the stay is lifted?

105. Dealing with the third party SPC issue first, I doubt very much that it would be appropriate at any stage for this court to make a reference if that issue stood alone. I regard the answer to that issue as sufficiently clear to be decided at this level without a reference. However, it does not stand alone, but stands with the Specification issue. The answer to that can only be provided after a preliminary ruling from the ECJ. If this court is to make, or were ever to make, a reference in these proceedings on the Specification issue, it would be entirely appropriate and sensible for the third party SPC issue to be referred at the same time in order to obtain a definitive ruling which will be of importance, not only in the present case, but generally. Not only would it be appropriate and sensible, but it would also be neither appropriate nor sensible to refer the Specification issue without at the same time referring the third party SPC issue, at least so long as Lilly continues to maintain that it is entitled to succeed on the third party SPC issue.

106. There are three arguments that a reference should not be made until after this action has been heard. The first is that the facts should be determined before any reference is made. The second is that the dispute between Lilly and HGS may be decided on grounds which do not require a reference. The third is that, even if HGS is successful in the Main Action, it may never be necessary to resolve either the third party SPC issue or the Specification issues because either (i) Lilly does not obtain an MA before the Patent expires or (ii) even if Lilly does so, HGS may not apply for an SPC. I take those arguments in turn.

107. In principle, a reference should only be made in the context of facts agreed or determined by the national court. That is, perhaps, not an entirely rigid rule in the sense the ECJ will give answers to questions on the basis of facts contained in the reference even if those facts have not yet been found. But that is an inherently undesirable procedure. In the present case, therefore, a reference ought only to be made if the facts relevant to each of the third party SPC issue and the Specification issue have been established.

108. This is particularly so in relation to the third party SPC issue where one of the central issues will be where the line is to be drawn, if one is to be drawn at all, between what is and is not a sufficient connection between the holder of the patent and the holder of the MA. Although Mr Mitcheson has based his submission on the third party SPC issue on the proposition that there is no connection between Lilly and HGS, that may not be so; it all depends on the criteria for judging the connection. Mr Alexander has referred to the brief summary of the work carried out by Lilly in the process leading up to the Lilly antibody set out in the judgment of Kitchin J at [1158] to [1168]. He says that the Judge did not obtain a complete picture of the detail of the whole process. A further summary is to be found in the witness statement of Dr Gilbert. Mr Alexander refers to some of the problems encountered by Lilly in its research and submits (with some force) that Lilly was given a substantial boost by its reading of an HGS paper by *Moore* which included, among other matters, information in the Patent. If a connection between the holder of the patent and the holder of the MA is, as a matter of EU law, a necessary condition for the granting of an SPC, the nature of that

connection is, in the present state of the law, entirely uncertain and at large. It may be that some sort of relationship between the patent and the product to which the MA relates is relevant, for instance, to take Mr Alexander's example, where the product is derived from (or enabled by) research undertaken by the patentee. An issue of that sort could only be framed in the context of fairly detailed factual findings.

109. Similarly, in relation to the Specification issue, the ECJ could only properly be asked to answer questions raised in a preliminary reference against an established factual background. Mr Mitcheson has produced a draft reference to the ECJ, setting out the issues and the arguments. There is, however, insufficient factual material in that draft reference to enable the ECJ, without a far greater explanation of the science involved, to give meaningful guidance. Of course, the submissions made by the parties to the ECJ will be able to fill the gaps to a large extent. But I would be unwilling to make a reference solely on the basis of the factual material in relation to the Specification issue contained in the draft reference. Possibly the parties would be able to agree further factual (including scientific) material to provide enough, although for my part I think it would be preferable for that to be done following the hearing of the action. It is not, however, necessary to reach a conclusion on that since it does not address the corresponding need for factual findings of the third party SPC issue.

110. The conclusion on the first argument must be that it points quite strongly against the making of an immediate reference.

111. Turning to the second argument, the point is that Lilly contends that the Lilly antibody would not infringe the Patent. If that is correct, there would be nothing which needed to be the subject of a reference. In relation to the dispute in the Main Action, that is of course correct. But once it has been decided, as I have decided, that Lilly should be able to bring proceedings seeking declaratory relief, the question is whether a reference will be required to resolve the issues in the present action. Clearly a reference will be necessary in order to resolve the Specification issue.

112. The conclusion must be that the second argument does not assist HGS.

113. The first limb of the third argument is that it may never be necessary to resolve either the third party SPC issue or the Specification issues because Lilly does not obtain an MA before the Patent expires. That is an unattractive argument. It is precisely because of the uncertainty on the third party SPC issue and the Specification issue that Lilly now seeks to clear the way by obtaining certainty on those issues one way or the other. As to the second limb, this is also unattractive. So long as HGS wishes to keep open the option of applying for an SPC if Lilly obtains an MA before the Patent expires, it is no answer to Lilly's justifiable commercial need for clarity for HGS to assert that the matter may never need to be resolved because it may not apply for an MA. It is open to HGS to resolve that particularly uncertainty by stating that it will not apply for an SPC. If it is not willing to do so, for perfectly understandable reasons, it cannot at the same time say that the matter is entirely academic.

114. The conclusion must be that the third argument does not assist HGS either.

115. Why does Lilly want a reference to be made immediately? It is to be sure of obtaining a ruling from the ECJ in time for the making of its application for an MA. I have set out at paragraphs 16 to 21 above the relevant time-lines.

116. Lilly's present intended date for the submission of an application for an MA (assuming that it is right in saying that HGS cannot make a valid application for an SPC) is June 2014. I would not be in the least surprised to find some slippage in that. HGS hopes for a trial date of up 5 days (but more likely 3 to 4 days) in April to June 2013. I consider that to be optimistic unless an order for an expedited trial is made. HGS's advisers consider that if a reference to the ECJ is needed to be made and was made after trial, a decision would be obtained from the ECJ some time between July and October 2014, some 2 years before the expiry of the Patent. Again, I think that is likely to be over-optimistic and there must be a real possibility that an answer would not be obtained until perhaps the middle of 2015, although still well over 1 year before the Patent expires. By that time, and one hopes well before, the validity or otherwise of the Patent will have been finally established and, if invalid, the need for a reference falls away.

117. But if the Patent is held to be valid, Lilly could not, safely at least, market its proposed medicinal product until after the Patent had expired, even if it is right that HGS cannot apply for an SPC on the basis of its (Lilly's) MA. Assuming that Lilly is successful in the ECJ, the period between mid-2015 and the expiry of the Patent may not be as much as it would like in order to apply for an MA and, following its grant, starting negotiations with health authorities and obtaining NHS approval for the use of its medicinal product, but it will at least have achieved certainty before the time when it could safely apply for an MA anyway.

118. My decision, taking into account all of the matters which I have mentioned, is that it is not appropriate to make a reference to the ECJ at this time – or to be more precise, even, once the Court of Appeal has given its decision on the validity of the Patent later this year.

119. However, this should not be seen as shutting Lilly out altogether from making a further application for a reference before the hearing of this action. The issues between the parties are, as a result of the applications before me, more fully identified than when the Particulars of Claim and the Defence were served. In particular, there is now clearly an issue about whether any connection at all is necessary and where, if it is necessary, the line is to be drawn. The evidence will need to address the way in which HGS's research and the Patent was actually utilised by Lilly. That may be a matter which, after exchange of evidence, is not a matter of contention. There would then be a sufficient factual context in which to refer the third party SPC issue to the ECJ. Similarly, the evidence relevant to the Specification issue may be agreed although not, of course, the conclusions to be drawn from it. I see no reason why directions should not be made (I hope by agreement) under which all the evidence on which the parties would seek to rely at the trial of this action is produced with proper expedition once the decision of the Court of Appeal is known. The question of a reference can then be reviewed.

Conclusions

120. This action, in which Lilly seeks declaratory relief, is not to be struck out but should be allowed to proceed. The action is to be stayed pending the decision of the Court of Appeal in the Main Action. The application for an immediate reference is refused; but it may be renewed as indicated above.