Neutral Citation Number: [2019] EWHC 388 (Pat)

Case No: HP-2017-000044

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS
INTELLECTUAL PROPERTY LIST (CHANCERY DIVISION)
PATENTS COURT

Rolls Building
Fetter Lane, London, EC4A 1NL

Date: 1 March 2019

Before :

MR JUSTICE ARNOLD

- -

Between :

ELI LILLY AND COMPANY	**Claimant**
- and -	
GENENTECH, INC	**Defendant**

- -
- -

Andrew Waugh QC, **Thomas Mitcheson QC** and **Stuart Baran** (instructed by **Allen & Overy LLP**) for the **Claimant**
Michael Tappin QC, **Justin Turner QC, Mark Chacksfield** and **William Duncan** (instructed by **Marks & Clerk Solicitors LLP**) for the **Defendant**

Hearing dates: 16-19, 21-25, 30-31 January, 1 February 2019

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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MR JUSTICE ARNOLD

MR JUSTICE ARNOLD :

Introduction

1. The Defendant ("Genentech") is the proprietor of European Patent (UK) No. 1 641 822 entitled "IL-17A/F heterologous peptides and therapeutic uses thereof" ("the Patent"). The priority date of the Patent is 8 July 2003. Genentech does not itself have a product covered by the Patent at present. The Claimant ("Lilly") markets a formulation of an antibody called ixekizumab as a treatment for moderate to severe plaque psoriasis and psoriatic arthritis in adults under the trade mark Taltz by virtue of marketing authorisation EU/1/15/1085 ("the Taltz MA"). Ixekizumab is an antibody to interleukin-17A ("IL-17A") which also binds to interleukin-17A/F ("IL-17A/F"). Genentech contends that this falls within the scope of protection of the Patent.

2. Genentech has filed application SPC/GB16/056 ("the Application") for a supplementary protection certificate ("SPC") based on the Patent and the Taltz MA. Lilly seeks a declaration that an SPC granted pursuant to the Application would not be valid. There is no dispute that the Court has jurisdiction to grant such a declaration if it would serve a useful purpose. Nor is there any dispute that such a declaration would serve a useful purpose. Accordingly, the only issues are those raised by Lilly's grounds of invalidity.

3. Lilly contends that, even if it is assumed that the Patent is valid, there are two obstacles to the Application: first, it does not comply with Article 3(a) of European Parliament and Council Regulation 469/2009/EC of 6 May 2009 concerning the supplementary protection certificate for medicinal products (codified version) ("the SPC Regulation") because Taltz is not protected by the Patent; and secondly, it does not comply with Articles 2, 3(b) and/or 3(d) of the SPC Regulation because the Taltz MA is not a relevant authorisation since it is a third party marketing authorisation relied upon without that party's consent ("a third party MA").

4. This claim was tried together with claim number HP-2017-000041 ("the Patent Action"), in which Lilly attacks the validity of the Patent and seeks a declaration that dealings in ixekizumab do not infringe the Patent. I am giving separate judgments in the two claims at the same time.

Technical background

5. The general technical background to both claims is set out in my judgment in the Patent Action ("the Patent Judgment") at [39]-[133]. For the purposes of this judgment, the key point to explain is that the interleukin-17 (IL-17) family of cytokines was known before the priority date to consist of six members, IL-17A to IL-17F, which are homodimers (and hence they are also referred to as IL-17A/A to IL-17F/F).

The Patent

6. I have summarised the disclosure of the Patent in the Patent Judgment at [134]-[178]. The Patent is concerned with a heterodimer, IL-17A/F, which consists of an IL-17A monomer and an IL-17F monomer. The Patent provides evidence that IL-17A/F exists

in humans, being produced in activated T cells and having the effect of inducing the production of the cytokines IL-6 and IL-8 in *in vitro* tests.

7. I have set out the claims of the Patent as proposed to be amended by Genentech in the Patent Judgment at [179]-[181]. For the reasons given at [315]-[352], I have concluded that, subject to one very minor point, the amendments are allowable. For the purposes of this judgment, it is sufficient to set out new claims 1 and 12 in the form that I have concluded is allowable:

> "1. An isolated antibody which specifically binds to an isolated IL-17A/F heterodimeric complex and which inhibits the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6, wherein the isolated IL-17A/F heterodimeric complex consists of SEQ ID NO:3 and SEQ ID NO:4, without their associated signal peptides, and further comprises two interchain disulphide linkages between SEQ ID NO:3 and SEQ ID NO:4; and wherein the antibody is human or humanized.
>
> 12. Use of an antagonist anti-IL-17A/F antibody as defined in Claim 1 or 2 in the preparation of a medicament for the treatment of rheumatoid arthritis or psoriasis."

8. It can be seen that claim 1 is a claim to a human or humanised antibody defined in functional terms, namely binding to IL-17A/F and inhibition of production of the cytokines IL-8 and IL-6. (SEQ ID 3 and SEQ ID 4 are the sequences of the prior art IL-17A and IL-17F polypeptide monomers.) Claim 12 is a second medical use claim in Swiss form. I should explain that, for convenience, I have chosen to focus upon claim 12 for the purposes of this judgment, but the Patent also contains a second medical use claim in EPC2000 form (claim 22). I do not consider that anything turns upon the difference between these two types of claim for the purposes of this judgment.

The common general knowledge of the skilled team

9. As explained in the Patent Judgment at [182], as proposed to be amended, the Patent is addressed to two different, but overlapping, teams of persons skilled in the art, namely a psoriasis team and an RA team. For the purposes of this judgment, the relevant skilled team is the psoriasis team, which consists of (i) a dermatologist with both clinical experience of, and a research interest in, the treatment of psoriasis and (ii) one or more persons with expertise in antibody engineering. I have set out the common general knowledge of the dermatologist in the Patent Judgment at [210]-[292] and the common general knowledge of the antibody engineer at [209].

The development of ixekizumab

10. I have described the development of ixekizumab in the Patent Judgment at [582]-[593]. The key point for present purposes is that Lilly developed ixekizumab as an anti-IL-17A antibody for the treatment for psoriasis without knowing of the existence of IL-17A/F. It subsequently discovered that ixekizumab also bound to IL-17A/F, but only as result of tests carried out following the publication of scientific papers concerning IL-17A/F published in 2007 and 2008.

Ixekizumab

11. I have described ixekizumab and its properties in the Patent Judgment at [594]-[595]. The key points for present purposes are that it binds to IL-17A/F as well as IL-17A and that it inhibits the production of IL-6 and IL-8.

The SPC Regulation

12. The SPC Regulation enables the proprietor of a patent for a medicinal product to obtain an SPC which extends the duration of the patent with respect to that product so as to compensate the proprietor for the effective loss of patent term caused by the need to obtain a marketing authorisation before the product can be marketed.

13. The SPC Regulation includes the following recitals:

> "(3) 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.
>
> (4) At the moment, the period that elapses 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 under the patent insufficient to cover the investment put into the research.
>
> (5) This situation leads to a lack of protection which penalises pharmaceutical research.
>
> …
>
> (7) A uniform solution at Community level should be provided for, thereby 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 establishment and the functioning of the internal market.
>
> (8) Therefore, the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted is necessary. A Regulation is therefore the most appropriate legal instrument.
>
> (9) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity

from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community.

(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product"

14. Articles 1, 2, 3 and 4 of the SPC Regulation provide, so far as relevant:

"*Article 1*

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(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 2

Scope

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products may, under the terms and conditions provided for in this Regulation, be the subject 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;
>
> …
>
> (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.
>
> *Article 4*
>
> **Subject matter of protection**
>
> Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate."

Interpretation of the SPC Regulation

15. As is common ground, it is well established that the correct approach to the interpretation of the SPC Regulation is that stated by the Court of Justice of the European Union in Case C-482/07 *AHP Manufacturing v Bureau voor de Industriele Eigendom* [2009] ECR I-7295 at [27]:

> "Next, the Court observes that the second sentence of Article 3(2) of Regulation No 1610/96 must be interpreted not solely on the basis of its wording, but also in the light of the overall scheme and objectives of the system of which it is a part (see, by analogy, Case C-292/00 *Davidoff* [2003] ECR I-389, paragraph 24)."

16. As is also common ground, the SPC Regulation pursues a number of different objectives and aims to strike a balance between them. This was well described by Advocate General Trstenjak in her opinion in Case C-130/11 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents* [EU:C:2012:268], [2013] RPC 23:

> "41. Those rules are intended to achieve a balance between the various interests at stake in the pharmaceutical sector. Those

> interests include, on the one hand, the interests of the undertakings and institutions, some of which pursue very cost-intensive research in the pharmaceutical sector and therefore favour an extension of the term of protection for their inventions in order to be able to balance out the investment costs. On the other hand, there are the interests of the producers of generic medicines who, as a consequence of the extension of the term of protection of the active ingredients under patent protection, are precluded from producing and marketing generic medicines. It is also relevant in this connection that, in general, the marketing of generic medicinal products has the effect of lowering the prices of the relevant medicinal products. Against that background, the interests of patients lie between the interests of the undertakings and institutions conducting research and those of the producers of generic medicines. That is because patients have an interest, on the one hand, in the development of new active ingredients for medicinal products, but, on the other, they also have an interest in those products then being offered for sale as cheaply as possible. The same applies to State health systems in general which, in addition, have a particular interest in preventing old active ingredients from being brought onto the market in slightly modified form under the protection of certificates but without genuine innovation and thereby artificially driving up expenditure in the health section.
>
> 42. Against the background of that complex situation as regards interests, Regulation 1768/92 sought to achieve a balanced solution taking due account of the interests of all parties. In view of the complexity of that balance of interests, it is necessary to proceed with great caution when making a teleological interpretation of the individual provisions of the regulation."

Article 3(a)

The law

17. I reviewed the case law of the CJEU interpreting Article 3(a) in my judgment in *Teva UK Ltd v Gilead Sciences Inc* [2017] EWHC 13 (Pat) ("*Teva I*"). As a result, I referred a question to the CJEU asking "What are the criteria for deciding whether 'the product is protected by a basic patent in force' in Article 3(a)?".

18. The Grand Chamber of the CJEU gave its answer to that question in Case C-121/17 *Teva UK Ltd v Gilead Sciences Inc* [EU:C:2018:585] ("*Teva CJEU*"). The CJEU ruled that Article 3(a) was to be interpreted as meaning that:

> "a product composed of several active ingredients with a combined effect is 'protected by a basic patent in force' within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not

> expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:
>
> – the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and
>
> – each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent."

19. I considered and applied that guidance in *Teva UK Ltd v Gilead Sciences Inc (No 2)* [2018] EWHC 2416 (Pat) ("*Teva II*").

20. Two other references concerning the interpretation of Article 3(a) are currently still pending before the CJEU: Case C-650/17 *Royalty Pharma Collection Trust* and Case C-114/18 *Sandoz Ltd v GD Searle LLC*. The judgments of the CJEU on these references may provide further elucidation of the criteria to be applied under Article 3(a) in the future, but at present *Teva CJEU* represents the current state of the law.

21. The guidance given in *Teva CJEU* is specifically addressed to products which are combinations of active ingredients. As I noted in *Teva II* at [34], however, it represents an elaboration and elucidation of the test which the CJEU propounded in Case C-493/12 *Eli Lilly & Co Ltd v Human Genome Sciences Inc* [EU:C:2013:835], [2014] RPC 21. That case was concerned with a single active ingredient. Moreover, as explained in *Teva I* at [72]-[75], it was a case concerned with a claim to an antibody defined in functional terms.

Assessment

22. As discussed in the Patent Judgment, Lilly contends that ixekizumab does not fall within the scope of protection of the Patent. For the reasons given in the Patent Judgment at [293]-[314], [595] and [600]-[606], however, I concluded that ixekizumab does fall within the scope of protection of the Patent, and in particular new claims 1 and 12.

23. Even if ixekizumab does fall within the scope of protection of the Patent, however, Lilly contends that it is not "protected by" the Patent within the meaning of Article 3(a) since neither of the tests laid down in *Teva CJEU* is satisfied. In my judgment the resolution of this issue depends on which claim is under consideration.

24. *Claim 1*. So far as the first test is concerned, Lilly contends that this is not satisfied because the skilled team considering the matter as at the priority date of the Patent in the light of their common general knowledge would not understand ixekizumab to embody the technical contribution made by the Patent.

25. I have interpreted the claims of the Patent as covering antibodies which bind to IL-17A as well as IL-17A/F on a normal interpretation. It follows that ixekizumab is an antibody as claimed in claim 1. In my judgment the skilled team would understand that it embodies the technical contribution of that claim. Contrary to Lilly's argument, it is irrelevant for this purpose that ixekizumab was not created until after the priority date of the Patent, just as it is irrelevant to the question of whether ixekizumab falls within the scope of protection of claim 1. Accordingly, I conclude that ixekizumab does "necessarily fall under the invention covered by" the Patent.

26. As for the second test, Lilly contends that ixekizumab would not be specifically identifiable by the skilled team reading the Patent as at the priority date in the light of their common general knowledge. The CJEU made it clear in *Eli Lilly*, however, that a product may be specified in the claims of a basic patent in functional terms, and in particular an antibody may be specified in functional terms. In my judgment ixekizumab would be specifically identifiable by the skilled team because it is identifiable by reference to the functions specified in claim 1. Again, contrary to Lilly's argument, it is irrelevant for this purpose that ixekizumab was not created until after the priority date of the Patent. Accordingly, I conclude that ixekizumab is specifically identifiable as being covered by claim 1.

27. *Claim 12*. As explained in the Patent Judgment, Genentech accepts that (i) claim 12 requires the antibody to have a discernible therapeutic effect on psoriasis and (ii) inhibition of IL-17A/F by the antibody in question must make a contribution to that therapeutic effect. For the reasons given in the Patent Judgment at [522]-[577], I have concluded that the skilled team reading the Patent in the light of their common general knowledge as at the priority date would not have considered it plausible that an anti-IL-17A/F would have a discernible therapeutic effect on psoriasis. There is no dispute that ixekizumab is now known to be efficacious for the treatment of psoriasis, but that is only known due to the clinical trials carried by Lilly since July 2003. Furthermore, although I have concluded on the balance of probabilities for the reasons given in the Patent Judgment at [600]-[606] that ixekizumab's inhibition of IL-17A/F (as opposed to IL-17A) contributes to that therapeutic effect, that conclusion is primarily based on research reported in a scientific paper published in 2007 by authors from Wyeth.

28. In those circumstances, I conclude that, considered from the point of view of the skilled team as at the priority date, ixekizumab does not "necessarily fall under the invention covered by" claim 12, nor would it be specifically identifiable as being covered by claim 12. The reason why claim 12 stands in a different position to claim 1 is that the CJEU made it clear in *Teva CJEU* at [50] that it is not permissible to take into account the results of research carried out after the priority or filing date of the Patent for these purposes. In the present case, it is Lilly's research after the priority date which establishes the therapeutic efficacy of ixekizumab against psoriasis, not anything in the Patent. Moreover, it is third party research after the priority date which I have concluded makes it probable that inhibition of IL-17A/F makes a contribution to that efficacy.

29. *Conclusion*. I conclude that an SPC based on claim 1 of the Patent would comply with Article 3(a), but not one based on claim 12 of the Patent. The latter conclusion would not matter if claim 1 were held to be valid; but it would matter if claim 12 were held to be valid, but not claim 1.

Third party MA

Previous case law

30. In Case C-181/95 *Biogen Inc v SmithKline Beecham Biologicals SA* [1997] ECR I-386 Biogen was the proprietor of two European patents for DNA sequences and intermediaries used in the production of antigens to the hepatitis-B virus. Two French Institutes owned a number of Belgian and European patents in the same field. SKB marketed a vaccine against hepatitis-B called Engerix-B the active ingredient of which was HBsAG. SKB was licensed by Biogen and the French Institutes under their respective patents. SKB held four Belgian marketing authorisations for Engerix-B. Biogen and the French institutes applied for SPCs. SKB refused to supply a copy of the marketing authorisation to Biogen, but did supply copies to the French institutes. The Belgian Ministry of Public Health refused to supply copies to Biogen without SKB's consent. Biogen brought proceedings against SKB before the Tribunal de Commerce (Commercial Court), Nivelles, contending that SKB had discriminated against it. The Commercial Court referred four questions to the Court of Justice concerning the interpretation of Regulation 1768/92/EEC, the predecessor to the SPC Regulation. The first, third and fourth questions concerned the obligations, if any, of the holder of a marketing authorisation and of the relevant administrative authority to supply a copy of the marketing authorisation to the proprietor of a basic patent. The second question was whether the Regulation precluded the grant of an SPC to each holder of a basic patent where the same product was covered by several basic patents owned by different parties.

31. Advocate General Fennelly observed in his Opinion at [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."

32. He also said at [50]:

> "… 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."

33. The Court of Justice ruled that, where a medicinal product was covered by several basic patents, the Regulation did not preclude the grant of an SPC to each patent holder; that the Regulation did not require the holder of a marketing authorisation to provide the proprietor of a basic patent with a copy of the marketing authorisation; and that, where the basic patent and the marketing authorisation were held by different persons, an application for an SPC by the patent proprietor could not be refused solely on the ground that the patentee was unable to provide a copy of the marketing authorisation.

34. In *Novartis Pharmaceuticals UK Ltd v MedImmune Ltd* [2012] EWHC 181 (Pat), [2012] FSR 23 I said 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. Nevertheless, counsel for Novartis made it clear that Novartis was not taking this point."

35. *Eli Lilly* was a similar case to this one, in that HGS owned a patent which covered an antibody that bound to neutrokine-α now known as tabalumab which Lilly intended to market and for which Lilly was applying for a marketing authorisation. Lilly sought a declaration that any SPC granted to HGS would be invalid on essentially the same grounds as those raised in the present case, but did not pursue the third party MA issue. Warren J referred questions to the CJEU concerning Article 3(a).

36. In its judgment the CJEU stated:

> "41. Moreover, it should be recalled that the SPC is designed simply to re-establish a sufficient period of effective protection of the basic patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of that patent, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention by reason of the time which has elapsed between the date on which the application for the patent was filed and the date on which the first MA in the European Union was granted …"
>
> 43. As stated in recital 4 in the preamble to Regulation No 469/2009, the purpose of that additional period of exclusivity is to encourage research and, to that end, it is designed to ensure that the investments put into such research are covered.

> 43. In the light of the objective of Regulation No 469/2009, the refusal of an SPC application for an active ingredient which is not specifically referred to by a patent issued by the EPO relied on in support of such an application may be justified – in circumstances such as those in the main proceedings and as observed by Eli Lilly – where the holder of the patent in question has failed to take any steps to carry out more in-depth research and identify his invention specifically, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients. In such a situation, if an SPC were granted to the patent holder, even though – since he was not the holder of the MA granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention, that would undermine the objective of Regulation No 469/2009, as referred to in recital 4 in the preamble thereto. ”

37. In *Teva CJEU* the Court of Justice stated:

> “49. In the second place, having regard to the objective of Regulation No 469/2009, recalled in paragraph 39 above, for the purposes of assessing whether a product falls under the invention covered by a basic patent, account must be taken exclusively of the prior art at the filing date or priority date of that patent, such that the product must be specifically identifiable by a person skilled in the art in the light of all the information disclosed by that patent.
>
> 50. Were it to be accepted that such an assessment could be made taking into account results from research which took place after the filing date or priority date of the basic patent, an SPC could enable its holder unduly to enjoy protection for those results even though they were not yet known at the priority date or filing date of that patent, what is more outside any procedure for the grant of a new patent. That would, as pointed out in paragraphs 40 and 41 above, run counter to the objective of Regulation No 469/2009.
>
> 51. Therefore, for the purposes of determining whether a product which is the subject of an SPC is protected by a basic patent, within the meaning of Article 3(a) of that regulation, that product must be identifiable specifically by a person skilled in the art in the light of all the information disclosed by the basic patent and of the prior art at the filing date or priority date of that patent.

38. In *Sandoz Ltd v GD Searle LLC* [2018] EWCA Civ 49 Floyd LJ (with whom Kitchin LJ and Lewison LJ agreed) said at [105]:

> "Such help as the judgment in *Eli Lilly* gives as to what underlies the specificity requirement is to be found, not in its core reasoning, but in paragraph [43] of the judgment. That paragraph appears to be one designed to give the national court assistance in arriving at its judgment in the main proceedings. It is true that that paragraph is in the context, additionally, of an application for a SPC based on a third party's marketing authorisation. But the first part of the paragraph seems to me to indicate, albeit without great clarity, that the court considers that at least one way of preventing or hindering the marketing authorisations of third parties from being used as the basis for SPCs is to insist on a high degree of specificity in the basic patent. That might help to prevent a patentee spreading the net in his patent claims widely and unspecifically, and subsequently fastening on a competitor's successfully marketed drug to obtain an extended term which he has not earned. That is a consideration which does not only arise in the context of functional claims …"

Summary of Lilly's contentions

39. Lilly contends that it is the object of the SPC Regulation to compensate research organisations for the delay caused by going through the regulatory process to obtain a marketing authorisation, and the consonant loss of monopoly time in which to market their product. An undertaking which is not one that has suffered that lost time, because it is not the one that obtained the marketing authorisation, needs and deserves no such compensation. Accordingly, Lilly contends that an SPC cannot validly be granted on the basis of a third party MA. Lilly argues that these contentions are supported by the statements of the CJEU in *Lilly v HGS* and *Teva CJEU* and by the statements of the national courts in *Novartis v MedImmune* and *Sandoz v Searle* quoted above. Lilly accepts, however, that the point is not *acte clair*, and therefore a reference to the CJEU is necessary to determine it.

Summary of Genentech's contentions

40. Genentech points out that it appears from section 13.3.1.1 of the *Study on the Legal Aspects of Supplementary Protection Certificates in the EU* commissioned by the European Commission from the Max Planck Institute for Innovation and Competition and published in 2018 that it is the consistent practice of the national offices to grant SPCs on the basis of third party MAs, although some national offices require the applicant to provide a copy of the marketing authorisation relied on. In sections 13.2 and 13.9, however, the Max Planck Institute concludes that the question has not been clearly answered by the case law of the CJEU.

41. Genentech contends that it is implicit in *Biogen v SKB* that the basic patent and the marketing authorisation may be held by different and unconnected parties; that Lilly's contention requires the Court to read into the SPC Regulation words which are simply not present; and that, in accordance with recital (17) to European Parliament and Council Regulation 1610/96/EC of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products, the SPC Regulation should be interpreted in accordance with Article 3(2) of Regulation 1610/96/EC

which, so Genentech argues, makes it clear that SPCs can be based on third party marketing authorisations. Article 3(2) of Regulation 1610/96/EC provides:

> "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."

42. Genentech contends that the law is *acte clair* in its favour, but in the alternative argues that a question should be referred to the CJEU.

Conclusion

43. In my judgment the law on this issue is not clear. In my opinion the policy arguments recognised by the CJEU in *Eli Lilly* and *Teva CJEU* and by the national courts in *Novartis v MedImmune* and *Sandoz v Searle* support Lilly's interpretation. This interpretation is also supported by Jens Schovsbo, Ulla Callesen Klinge and Timo Minssen, "Reap what you sow! But what about SPC squatting?" [2018] JIPLP 569, although the authors opine that reliance upon a third party MA should be permissible in some circumstances. The arguments advanced by Genentech cannot lightly be dismissed, however.

44. Accordingly, I consider that a question should be referred to the Court of Justice along the following lines:

> "Does the SPC Regulation preclude the grant of an SPC to the proprietor of a basic patent in respect of a product which is the subject of a marketing authorisation held by a third party without that party's consent?"

<u>The need for a reference</u>

45. It can be seen from the Patent Judgment that I have concluded that all the claims of the Patent defended by Genentech are invalid. If that conclusion is correct, then it necessarily follows that the Application must fail. In those circumstances, it would at first blush appear that there is no need to refer the question identified above to the CJEU because the answer to the question would be academic.

46. Anticipating that outcome, counsel for Lilly submitted that a reference would nevertheless be necessary for the following reasons.

47. First, he pointed out that it was likely that Genentech would attempt to appeal against any such conclusion. If Genentech were granted permission to appeal and were successful in that appeal, then the answer to the question would cease to be academic. As he pointed out, however, as matters currently stand, there is a very real possibility that the courts of the UK will lose their jurisdiction to make references to the CJEU on 29 March 2019. Since any judgment of the Court of Appeal would necessarily be given some time after that, it could well be the case that, whereas this Court currently has jurisdiction to make a reference, the Court of Appeal would not have jurisdiction

to do so. In those exceptional circumstances, this Court should make a reference now. As he pointed out, it would be possible for the reference to be withdrawn later if circumstances changed.

48. Secondly, he submitted that, in any event, it would not be correct to say that a judgment that the Patent was invalid rendered the third party MA question academic. He pointed out that what Lilly sought in the present action was a declaration that an SPC based on the Application would not be valid. He argued that a declaration that an SPC based on the Application would not be valid because of the third party MA point would still serve a useful purpose even if the Patent was invalid. The reason for this was that the dispute between Lilly and Genentech was not confined to the UK. Genentech had filed parallel applications for SPCs based on the Patent and the Taltz MA in other EU Member States. Accordingly, an EU-wide answer to the question was required, which only the CJEU could provide.

49. Thirdly, he pointed out that this issue had arisen in previous cases, as discussed above, but for varying reasons no question had been referred to the CJEU. Moreover, it was one which had been discussed by commentators. Accordingly, he submitted that it was an issue for the pharmaceutical industry generally which should be resolved sooner rather than later. Only the CJEU could provide a definitive resolution.

50. I accept these arguments, and in particular the first one. Accordingly, I conclude that, in the current exceptional circumstances, it is necessary to refer the question to the Court of Justice even though I have concluded that the Patent is invalid.

Conclusion

51. For the reasons given above, I shall refer a question to the CJEU along the lines set out in paragraph 44 above. I will hear counsel as to the precise wording of the question.