TO THE PRESIDENT AND MEMBERS OF THE COURT OF JUSTICE OF THE EUROPEAN UNION

WRITTEN OBSERVATIONS

submitted pursuant to Article 23 of the Statute of the Court of Justice by the European Commission represented by Mr Friedrich Wenzel Bulst and Ms Julie Samnadda, members of its Legal Service, acting as agents with an address for service in Luxembourg at the office of Ms Merete Clausen also a member of the Commission's Legal Service, Bureau F3/907, Bâtiment BECH, 5 Rue A Weicker, L-2721 Luxembourg, who consent to service by e-Curia

in Case C-493/12

a request for a preliminary ruling by the High Court of Justice, Chancery Division (Patents Court) (United Kingdom) pursuant to Article 267 of the TFEU in proceedings between

Eli Lilly and Company

Claimant

and

Human Genome Sciences, Inc.

Defendant

1. THE LEGAL CONTEXT


2. The second to tenth recitals of the Regulation provide:

"[...]

(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.

(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.

(6) There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection.

(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 functioning of the internal market.

(8) Therefore, the provision 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.

[...].

3. Article 1 of the Regulation provides:

"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 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;

(d) 'certificate' means the supplementary protection certificate;

[...]."

4. Article 2 of the Regulation provides:

"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."
5. Article 3 of the Regulation provides:

"Conditions for obtaining a certificate

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

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

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

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

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

1.1. European Patent Convention

6. Under the heading 'Extent of Protection', Article 69 of the Convention on the Grant of European Patents, signed on 5 October 1973, in the amended version applicable at the time of the facts in the main proceedings ("the European Patent Convention"), provides as follows:

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

(2) For the period up to grant of the European patent, the extent of the protection conferred by the European patent application shall be determined by the claims contained in the application as published. However, the European patent as granted or as amended in opposition, limitation or revocation proceedings shall determine retroactively the protection conferred by the application, in so far as such protection is not thereby extended."

7. Article 1 of the Protocol on the Interpretation of Article 69 of the European Patent Convention, which forms an integral part of the convention in accordance with Article 164(1) thereof, provides as follows:

"Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the
description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties."

8. Article 123 of the European Patent Convention provides, in relevant part:

"[...]"

(2) The European patent application or European patent may not be amended in such a way that it contains subject matter which extends beyond the content of the application as filed.

(3) The European patent may not be amended in such a way as to extend the protection it confers."

1.2. Law governing the patent

9. The patent in question is a European (UK) No 0 939 804 ("the Patent"). Accordingly, the law governing the patents would be both the European Patent Convention and in addition, where applicable, the UK Patent Acts 1977.

2. THE MAIN PROCEEDINGS AND THE REFERENCE FOR A PRELIMINARY RULING

10. This is an action between Eli Lilly and company, the applicant in the national proceedings ("Eli Lilly") and Human Genome Sciences Inc. ("the Respondent") in the High Court of Justice (Chancery Division) (Patents Court) ("the Referring Court"). Eli Lilly is seeking a declaration that any supplementary protection certificate ("SPC") granted in respect of the Patent (UK No. 0 939 804) belonging to the Respondent ("the Patent") based upon any marketing authorisation ("MA") obtained by Eli Lilly for its product LY 2127399 would be invalid, if granted.

11. The facts are more fully set out in the approved judgment of 3 August 2012 by Mr Justice Warren ("Approved Judgment") which accompanies the order for reference of 24 October 2012 ("Order for Reference"). The Approved Judgment sets out a fuller view of the application before the Referring Court and should be read together with the Order for Reference.

to a tumour necrosis factor. The Patent has been subject to proceedings in terms of its validity before the European Patent Office; and there has also been litigation in the English Courts. This litigation is summarised at paragraph 38 of the Order for Reference and is not relevant to the application before the Referring Court.

13. It should be pointed out that Eli Lilly has not yet obtained an MA for its own product LY2127399 ("the Lilly antibody"). The Lilly antibody is still in clinical trials for us for treatment of systemic lupus erythematosus. The Respondent has not yet applied for an SPC. The Respondent, on the other hand, has applied for the matter to be struck out on the basis that the declaration sought by Eli Lilly is premature. However, it is in the nature of the declaratory relief available in the jurisdiction of the English courts, that a remedy of a declaration might be available at the discretion of the court. The Referring Court has declined to strike out the application on the grounds that it is premature. The action by Eli Lilly of seeking declaratory relief is, therefore, pre-emptive in the sense that Eli Lilly wishes to preclude the Respondent from applying for an SPC on the basis of Eli Lilly's (yet to be obtained) MA and by invoking the Respondent's Patent.

14. In essence, the application for a declaration by Eli Lilly is a request to refer certain matters to this Court. In particular, clarity is sought as to whether an SPC could be granted to the Respondent in accordance with the Regulation. However, the Referring Court has only agreed to refer one of the issues requested by Eli Lilly (see paragraph 16 below).

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1 Declaratory relief in the form of a declaration is a remedy which provides clarification of the rights and obligations of parties in a dispute. It is a form of preventive determination or adjudication which provides legal certainty for the parties. It is increasingly used in patent litigation in the UK. English courts have jurisdiction and discretion to grant declarations, both positive and negative, even when no other claim had been made. The limit on the jurisdiction is that the courts will not answer hypothetical questions. It is assumed, for present purposes that the Referring Court does not consider the issue before it to be hypothetical.
3. THE QUESTIONS REFERRED

15. "On article 3(a)

1(a) What are the criteria for deciding whether 'the product is protected by a basic patent in force' in Article 3(a) of Regulation 469/2009/EC (the "Regulation")?

(b) Are the criteria different where the product is not a combination product, and if so, what are the criteria?

(c) In the case of a claim to an antibody or a class of antibodies, is it sufficient that the antibody or antibodies are defined in terms of their binding characteristics to a target protein, or is it necessary to provide a structural definition for the antibody or antibodies, and if so, how much?"

4. PRELIMINARY REMARKS

16. It may be useful to comment briefly on both matters that Eli Lilly requested be referred although the Referring Court ruled that only one should be referred to this Court.

17. First, Eli Lilly raised the issue of whether it is possible to apply for and obtain an SPC under the Regulation based upon an MA obtained by another person. In particular, where the holder of the patent is different from the holder of the MA and there is no connection between them. This is described by the Referring Court as the "third party SPC issue", i.e. whether the Respondent could obtain the SPC on the basis of an MA obtained by Eli Lilly for the Lilly antibody (provided the remaining conditions of Article 3 of the Regulation are met).

18. The Referring Court considers that the Respondent would be able to obtain an SPC on the basis of a marketing authorisation obtained by Eli Lilly (provided the conditions of Article 3(a) SPC Regulation are met). The Referring Court's assessment in this respect is based on its reading of this Court's judgment in Case C-181/95 Biogen Inc. v SmithKline Biological SA [1997] ECR I-357 ("Biogen"). The Referring Court concludes from that case law that the third party SPC issue does not need to be referred. The arguments of the parties and the Referring Court's reasons are set out at paragraphs 30-62 of the Approved Judgment.
19. The second issue, if it is indeed possible to rely upon a marketing authorisation obtained by another person as the Referring Court believes, pertains to the question what criteria should be applied to specify or identify the Lily antibody in the claims for the Patent so that a valid SPC could be obtained. This is described by the Referring Court as "the Specification issue" and it is this issue that has been referred to this Court. As noted by the Referring Court at paragraphs 27-29 of the Order for Reference, the Specification issue raises the same issues of law as pending Case C-443/12 Actavis. The Referring Court has distinguished this case from Case C-443/12 Actavis on the facts. The arguments of the parties are summarised at paragraphs 30-50 of the Order for Reference and at paragraphs 63-73 of the Approved Judgment.

20. The Commission is of the view that in the context of this application before the Referring Court, the Specification issue would only fall to be determined as a consequence of the Referring Court's ruling on the third party SPC issue. In the absence of more specific information on the facts of the case, the Commission is not in a position to express a view either on the Referring Court's assessment of the third party SPC issue or whether it does not need to be referred. The Commission would observe, however, that had the Referring Court ruled differently on the third party SPC issue, then there would have been no need for a reference as the subsequent questions which concern the Specification issue would not have arisen in the context of this application before the Referring Court.

21. As regards the Specification issue, the Commission observes that this case, along with Case C-443/12 Actavis and also Case C-483/12 Georgetown form part of the second wave of references following Case C-322/10 Medeva BV v Comptroller-General of Patents, Designs and Trade Marks [2011] ECR I-0000 ("Medeva"). The Referring Court indicates at paragraph 29 of the Order for Reference that it considers it appropriate for this reference to be heard together with Case C-443/12 Actavis. The Commission agrees that it would be appropriate to hear both cases together.

22. The Commission herewith appends its observations in Case C-443/12 Actavis and Medeva to the present observations.
5. ANALYSIS OF THE QUESTIONS REFERRED

**Question 1(a)**

23. The Court should note that Question 1(a) raises the same issues of law as Question 1 in Case C-443/12 Actavis. The Commission would refer to its observations in Case C-443/12 Actavis in relation to Question 1, so far as these are relevant to Question 1(a).

24. As the Commission stated in its observations in Case C-443/12 Actavis, the Commission would respectfully suggest that the Court may choose to continue with the approach to Article 3(a) which began with Case C-392/97 Farmitalia [1999] ECR I-5553 ("Farmitalia"), paragraph 26 which acknowledges that national patent law has not been harmonised. Alternatively, the Court might wish to consider an interpretation of Article 3(a) which builds on the approach that the Court began in Medeva, paragraphs 24, 25 and 26 and give greater precedence to Union law. As in Case C-443/12 Actavis, the Commission would advocate the latter approach in order to resolve the perceived lack of clarity following Medeva.

25. Therefore, in the light of this proposed test, the Commission suggests that the Court reply to Question 1(a) in the same manner as the Commission has proposed in Case C-483/12.

**Question 1(b)**

26. In relation to Question 1(b), the Referring Court is asking whether the criteria are different if the product is not a combination product. This question is, in essence, similar to question 2 in Medeva as well as Case C-630/10 University of Queensland v Comptroller-General of Patents, Designs and Trade Marks [2011] ECR I-0000 ("Queensland"). Although in those cases the referring courts wanted to verify whether the criteria would be different if the product covers a combination of active ingredients, while in the case at hand, the Referring Court is seeking to verify whether the criteria would be different in the case of a product which covers a single active ingredient.

27. In its observations in Medeva and Queensland, the Commission put forward the view that there are no further or additional criteria since the text of Article 3(a) of
the Regulation does not differentiate between those products which are a single active ingredient and those which are a combination of active ingredients. Moreover, there is nothing in the rest of the text of the Regulation that could imply that the legislator intended that medicinal products comprising more than one active ingredient should be treated any differently than those medicinal products comprising only one active ingredient.

28. Therefore, the Commission suggests that the answer to question 1(b) should be answered in the light of its analysis and proposed response by the Commission in its observations in relation to Question 2 in Medeva. The Commission repeated this position in Queensland.

**Question 1(c)**

29. In relation to Question 1(c), the Referring Court is essentially asking whether a functionally defined antibody could be considered to be specified in the wording of the claims of the basic patent.

30. It follows from the Medeva that in order to obtain a valid SPC, the basic patent must specify the active ingredient in the wording of the claim. This leads to the question whether a functionally defined antibody is sufficiently specified in a claim for the purpose of obtaining an SPC.

31. In case C-443/12 Actavis in relation to Question 1, the Commission suggested in its observations that a literal reference to the active ingredient in question would seem unduly restrictive and suggested that it should be immediately evident from the wording of the claims to a skilled person that the active ingredient is claimed by the patent.

32. The Commission sees no reason to deviate from this test in the context of question 1(c). It is therefore, in the view of the Commission, not necessary to provide the general answer to functional definitions in patent claims on antibodies which question 1(c) seeks.

33. The Commission will therefore, not propose a separate response for Question 1(c).

34. For the sake of completeness, the Commission would, however, point out that in practice, it would seem that the said test will usually be satisfied by European
patents. This is for the following reason: it follows from the Order of Reference (paragraph 49) that functionally defined antibodies are routinely granted by the European Patent Office and routinely used to support SPCs for antibody products. Under the European Patent Convention (EPC), a claim must define the matter for which the protection is sought in terms of technical features. The most precise way to define a technical feature is in structural terms. However, that is not always possible in which case the technical feature could be defined functionally, i.e. in terms of what it does instead of what it is. This could however lead to a very broad scope of protection. Therefore the examination guidelines of the EPO provide as follows:

"The area defined by the claims must be as precise as the invention allows. As a general rule, claims which attempt to define the invention by a result to be achieved should not be allowed, in particular if they only amount to claiming the underlying technical problem. However, they may be allowed if the invention either can only be defined in such terms or cannot otherwise be defined more precisely without unduly restricting the scope of the claims and if the result is one which can be directly and positively verified by tests or procedures adequately specified in the description or known to the person skilled in the art and which do not require undue experimentation."2

35. The Commission considers in the light of the answer provided by the Commission in its observations on the first question in Case C-443/12 Actavis, the criteria established regarding the admissibility of functional definitions in the EPO's examination guidelines would appear to ensure that a product specified by functional terms in accordance with these guidelines may be considered to be "specified" in the wording of the claims of the basic patent within the meaning of Medeva.

6. CONCLUSION

36. The Commission submits that the Court should answer the questions of the Referring Court as follows:

Question 1(a) [and (c)]: "Article 3(a) of Regulation (EC) No 469/2009 precludes the competent industrial property office of a Member State from granting an SPC

relating to any active ingredient which is not specified in the wording of the claims of the basic patent relied on in support of the SPC application. An active ingredient is specified for these purposes where it is immediately evident from the wording of the claims to a skilled person that the active ingredient is claimed by the patent.

Question 1(b): "This interpretation of Article 3(a) of Regulation No 469/2009 applies independently of whether the product is a combination product."

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