Neutral Citation Number: [2019] EWHC 689 (Admin)

Case No: CO/471/2018

**IN THE HIGH COURT OF JUSTICE**
**QUEEN'S BENCH DIVISION**
**ADMINISTRATIVE COURT**

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 21/03/2019

**Before** :

**THE HONOURABLE MR JUSTICE LEWIS**

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**Between :**

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| **ORION CORPORATION** | **Claimant** |
| **- and -** | |
| **THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE ACTING AS THE LICENSING AUTHORITY** | **Defendant** |

**And**

**EVER NEURO PHARMA GmBH**

**Interested Party**

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**Jemima Stratford Q.C. and Emily MacKenzie** (instructed by **Arnold & Porter Kaye Scholer LLP**) for the **Claimant.**
**George Peretz Q.C. and Ewan West** (instructed by **Government Legal Department** ) for the **Defendant**
**David Scannell** (instructed by **Bristows LLP**) for the **Interested Party.**

Hearing dates: 11, 12 and 13 March 2019

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# Approved Judgment

**The Honourable Mr Justice Lewis:**

INTRODUCTION

1. This is a claim for judicial review of a decision of the defendant to grant the interested party, Ever Neuro Pharma GMBH ("Ever"), a UK marketing authorisation for a medicinal product under the trade name of Dexmedetomidine Ever Pharma ("DexEP") on 19 October 2017. The active substance in that product is dexmedetomidine hydrochloride ("DH"). The competent authorities of the relevant Member States, including the United Kingdom, accepted that Ever's product, DexEP, was the generic form of an existing medicinal product, namely Dexdor, which had been granted a marketing authorisation by the European Commission in 2011. A product called Precedex, whose active substance was also DH, had been granted a marketing authorisation in the Czech Republic in 2002 and that authorisation was to be treated as a marketing authorisation for the purposes of EU law from 1 May 2004 when the Czech Republic became a Member State of the European Union. The competent authorities accepted that the marketing authorisations for Dexdor and Precedex formed part of a single global marketing authorisation. They considered that the eight-year period of protection recognised by EU law in respect of data supplied as part of the application process began to run from 1 May 2004 and had expired. The competent authorities concluded, therefore, that they were entitled to use the data on pre-clinical tests and clinical trials submitted in relation to Dexdor in assessing Ever's application for a marketing authorisation for its product.

2. The claimant, Orion Corporation ("Orion"), is the holder of the marketing authorisation for Dexdor. It contends that the data used by it in obtaining a marketing authorisation for Dexdor was entitled to a period of eight years protection under EU law during which time that data could not be used for assessing the safety and efficacy of a generic product. As the marketing authorisation for Dexdor was granted in 2011, it contended that the eight-year period had not expired when Ever applied for a marketing authorisation in 2016. The claimant further contends that the marketing authorisation granted to Precedex did not comply with the requirements of EU law and it was not a valid marketing authorisation for the purposes of EU law. It contends, therefore, that the marketing authorisations of Precedex and Dexdor could not be treated as a single, global marketing authorisation with the date for the protection of data running from 1 May 2004, the date when the Czech Republic became a Member State of the Union. It contends that the data relating to Dexdor should not have been used in assessing the application for a marketing authorisation for DexEP and that this court can, and should, quash or set aside the marketing authorisation granted by the defendant on 19 October 2017.

3. In that regard, the claimant contends that courts in the United Kingdom are entitled to determine whether the marketing authorisation granted by the Czech authorities for Precedex is compatible with EU law. It contends that there are a number of requirements which had to be satisfied by an application for a marketing authorisation and, if they were not satisfied, the marketing authorisation was not valid under EU law. The claimant contends that, on the facts, the application to the Czech authorities did not comply with those requirements. The claimant recognises that the claim that a court in England and Wales can review the marketing authorisation granted by the Czech authorities appears to be inconsistent with the ruling of the Court of Justice of the European Union in Case C-557/16 *Astellas Pharma v Helm AG, Firmae*

EU:C:2018:181. It contends, however, that its case is distinguishable from *Astellas* and invites this court to refer certain questions to the Court of Justice under Article 267 of the Treaty on the Functioning of the European Union ("TFEU") for a preliminary ruling.

4. The defendant and interested party contend that it is clear from the judgment in *Astellas* that this court cannot embark on the task of reviewing the compatibility of a marketing authorisation granted in another Member State with EU law. They contend that a reference to the Court of Justice is not necessary or appropriate.

## THE SYSTEM FOR REGULATING THE LICENSING OF MEDICINAL PRODUCTS

5. The material provisions currently in force governing the regulation of medicinal products for human use are primarily contained in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 ("the Directive"). The Directive has been amended from time to time. In brief summary, the present position so far as concerns the issues material to this case is as follows.

### *A Marketing Authorisation*

6. A medicinal product cannot be placed on the market of a Member State unless it has been granted a marketing authorisation in accordance with the requirements of the Directive. That follows from Article 6.1 of the Directive which provides that:

> "Article 6
>
> 1. No medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State in accordance with this Directive or an authorization has been granted in accordance with Regulation (EEC) No 726/2004, read in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 1394/2007".

7. Where a medicinal product has been granted an initial authorisation, any additional variations and extensions are to be treated as included within the initial marketing authorisation. The initial authorisation and the variations are treated as a single, or global, marketing authorisation. That is provided for by Article 6.1 of the Directive which provides, so far as material, that:

> "All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purposes of the application of Article 10(1)."

### *The Information Required*

8. There are procedures whereby an applicant may apply for a marketing authorisation. In essence, there are categories of data or information that need to be provided with an application in order to enable the body dealing with the application to determine whether to grant it. That information is described in Article 8.3 of, and Annex I to, the Directive. They include, for example, data relating to the product's manufacture such as qualitative and quantitative particulars of all its constituents, a description of the

manufacturing method, therapeutic indications, contra-indications and adverse reactions: see Article 8.3(c), (d) and (e) of the Directive. Article 8.3(i) also provides that an application is to be accompanied by the:

> "Results of:
>
> - pharmaceutical (phyisco-chemical biological or micro-biological) tests,
> - pre-clinical (toxicology tests),
> - clinical trials."

9. Such tests are a means of ensuring the safety and efficacy of the medicinal product. The safeguarding of public health is the essential aim of the rules governing the production, distribution and use of medicinal products: see recital 2 to the Directive and the observations of the Court of Justice of the European Union in Case C-104/13 *Olainfarm* EU:C:2014:2316.

10. There is an exception or derogation from the requirements of Article 8.3(i) of the Directive in the case of what are known as generic medicinal products. A generic medicinal product is a product which is composed of the same active substances and the same pharmaceutical form as an existing medicinal product (referred to as a reference medicinal product): see Article 10.2 of the Directive.

11. If the application is for a generic form of an existing medicinal product, the applicant is not required to provide the results of pre-clinical tests and clinical trials if the reference product has been authorised pursuant to Article 6 of the Directive for a period of eight years. In effect, the applicant for the generic product is entitled to rely upon the pre-clinical tests and clinical trials carried out in relation to the existing medicinal product (i.e., the reference product). Such a generic product cannot be placed on the market for a further two years. That provides a period of 10 years when the holder of the marketing authorisation for the reference, or existing, product is protected from its data being used to obtain authorisations for, or from the marketing of, rival generic products. That reflects the balance between the aim of not deterring or providing a disincentive to companies from undertaking the often costly exercise of carrying out the trials necessary to demonstrate the safety and efficacy of a new medicinal product but not requiring tests to be repeated unnecessarily on humans or animals (see, e.g. recitals 3, 9 and 10 of the Directive). The company which invests in developing the drug and demonstrating its safety and efficacy receives a period of protection (a total of 10 years, eight years before its data can be used and a further two before the rival, generic product can be marketed) but, after that time, a generic product can obtain a marketing authorisation without having to repeat the clinical trials originally carried out.

12. The material provisions are set out in Article 10.1 of the Directive which provides:

> "Article 10
>
> 1. By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product

> which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.
>
> A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed form initial authorisation of the reference product.
>
> …..
>
> The ten-year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies."

13. The Court of Justice has recognised that the holder of the marketing authorisation for a product has a right to ensure that its product is not used as a reference product, and its data used to grant marketing authorisations for generic applications, before the expiry of the relevant period of protection for its data. Further, to that end, the holder of a marketing authorisation has a right to seek a judicial remedy against a national competent authority which seeks to treat a product as a reference product and use the data supplied in relation to that product to grant a marketing authorisation for a generic product. See case C-104/13 *Olainfarm* EU:C:2014: 2316.

*The Process of Obtaining a Market Authorisation*

14. There are, broadly, four routes by which a marketing authorisation may be obtained. First, an applicant may apply to the national competent authority of a Member State for a marketing authorisation for that Member State only. That is, the marketing authorisation will only authorise the placing of the product on the market of that particular Member State. See Article 8.1 of the Directive.

15. Secondly, an applicant may wish to apply for a marketing authorisation in more than one Member State. The applicant can submit the application to the competent authorities of each Member State for which an authorisation is sought. One Member State will act as what is known as the reference Member State and the other Member States are known as concerned Member States. There is provision for the reference Member State to prepare a draft assessment report on the product. That is provided to the concerned Member States and there is provision for them to approve the assessment report (or a process for resolving disagreement if one or more Member State cannot approve it). That method, known as the decentralised procedure, is provided for by Article 28.1 and 28.3 (and Article 29) of the Directive. Article 28.5 of the Directive provides that:

> "5. Each Member State in which an application has been submitted in accordance with paragraph 1 shall adopt a decision in conformity with the approved assessment report, the summary of produce characteristics, and the labelling and package leaflet as approved, within 30 days after acknowledgement of the agreement".

16. Thirdly, where a medicinal product has been granted a marketing authorisation in one Member State, there is provision for the applicant to request one or more other

Member States to recognise the marketing authorisation already granted. Again there is a procedure, known as mutual recognition, whereby one Member State acts as the reference Member State, and prepares an assessment report for consideration and approval by the concerned Member States. See Article 28.2 of the Directive. Once approved, Article 28.5 applies and each Member State in which the application was submitted must grant a marketing authorisation. Each of these three methods of application under the Directive requires the application to be accompanied with the materials referred to in Article 8 and are subject to the derogations set out in Article 10 of the Directive.

17. Fourthly, there is provision for applying to the European Commission for a marketing authorisation enabling a product to be placed on the market within the European Union: see now Regulation (EC) No 726/2004 ("the Regulation") which replaced a similar regime contained in Council Regulation (EEC) No 2309/93 of 22 July 1993 ("the 1993 Regulation"). In brief summary, whilst in the case of products in the Annex to the Regulation that process is compulsory, that process may be used where a product contains a new active substance or represents a significant therapeutic, scientific or technical innovation. Applications are to be submitted to the European Medicines Agency ("the Agency") and must be accompanied by the information required by Article 8 of the Directive subject to the derogations in Article 10: see Articles 4 and 6 of the Regulation. The application is assessed by the Committee for Medicinal Products for Human Use (known as CHMP) which is part of the Agency. A marketing authorisation granted in accordance with the Regulation is valid throughout the European Union, initially for five years but this may be renewed, and confers the same rights and obligations as a marketing authorisation under Article 6 of the Directive granted by a Member State: see Articles 13 and 14 of the Regulation.

## THE FACTS

18. The essential facts for present purposes are these. The claimant, Orion, is a pharmaceutical company based in Finland which develops and markets, amongst other things, pharmaceutical products for human use. It developed DH, the active ingredient in various pharmaceutical products, in the 1990s.

### *The First Application*

19. On 18 December 1998, Abbott Laboratories, who were licensed by Orion to use the relevant rights relating to DH in certain countries, applied to the predecessor to the Agency for a marketing authorisation for DH under the trade name Primadex. That name was subsequently changed to Precedex. The application was made for a marketing authorisation for the whole of the European Union, pursuant to the provisions of the 1993 Regulation, that is, using the fourth route described in paragraph 17 above. The application described the indication, or use, for the product as a sedative with analgesic properties for use in an intensive care setting.

20. During the application process, various questions were raised by the Committee for Proprietary Medicinal Products (the predecessor to the CHMP). Abbott took various steps to address the concerns raised. Ultimately, Abbott was advised that the members of the Committee were not in favour of recommending the grant of a marketing authorisation. Rather than reject the application, the Committee invited Abbott to withdraw it. Abbott did withdraw the application in March 2000.

*The Second Application*

21. Later in 2000, Abbott applied to a number of countries which were not then members of the European Union (or European Community as it was then known) for the equivalent of a national marketing authorisation for Precedex for each of those countries.

22. In particular, on 29 August 2000, Abbott applied to the Czech authorities for the grant of the equivalent under Czech law to a marketing authorisation. The Czech Republic was not, at that stage, a member of the European Union. The claimant contends that the dossier submitted to the Czech authorities was the same dossier in relation to pre-clinical and clinical studies that had been submitted to the predecessor to the Agency when Abbott made its first application, that is for a marketing authorisation for the whole of the European Community. There is a factual dispute between the parties as to whether the application included confidential data provided by Fermion, the manufacturer of the active substance, either in the form in which that data had been submitted as part of the first application or in some different form.

23. On 23 October 2002, the Czech authorities granted a market authorisation for Precedex. The indication, or use, which was approved was sedation of adult intensive care unit patients. Abbott then marketed Precedex in the Czech Republic. On 1 May 2004, the Czech Republic became a member of the European Union. Also on 1 May 2004, Abbott assigned its rights to Precedex to a company called Hospira. That company continued to market Precedex in the Czech Republic. It appears that it may not have been actively marketing Precedex after some time in about 2006. The claimant, Orion, re-acquired the rights to Precedex in relation to the Czech Republic from Hospira in September 2008. In July 2010, the claimant surrendered the Czech marketing authorisation for Precedex.

*The Third Application*

24. At some time in about 2002, the claimant, Orion, embarked on a series of clinical trials of DH with a view to seeking a marketing authorisation for the EU under the provisions of the Regulation. The studies lasted several years and cost over 50 million Euros. In September 2010, the claimant submitted an application to the Agency under the Regulation for a marketing authorisation for the EU for DH under the trade name Dexdor. The Commission considered that Dexdor represented a significant therapeutic innovation over other products within the meaning of Article 3 of the Regulation and so was eligible for consideration under the Regulation. A marketing authorisation was granted on 16 September 2011. The indication was use for particular patients in intensive care units.

The Fourth Application

25. In about March 2016, the interested party, Ever, applied to a number of Member States for a marketing authorisation for a product whose active substance was DH, i.e. DexEP. It used the procedure in Article 28 of the Directive. The reference Member State was Denmark. The United Kingdom was a concerned Member State. One of the indications was for patients in intensive care. The other indication was for sedation of non-intubated adult patients prior to and/or during diagnostic or surgical procedures requiring sedation. The application was subject to what was called a hybrid procedure.

In relation to the intensive care unit indication, Ever said that its product was a generic of DH and relied on Dexdor as a reference product within the meaning of Article 10.1 of the Directive. Ever contended that the Czech marketing authorisation granted in 2002 for Predcedex and the marketing authorisation granted in 2011 for Dexdor constituted a single, global marketing authorisation for DH. As Precedex and Dexdor were part of one global marketing authorisation, Ever contended that the eight-year period of protection of data provided for by Article 10.1 of the Directive ran from the date when Precedex was treated as a marketing authorisation within a Member State, i.e. 1 May 2004. That period (and the further two year period before Ever could place DexEP on the market) had therefore expired. Consequently, Ever said that it was not required to provide the results of pre-clinical tests and clinical trials but could rely on the tests undertaken in relation to Dexdor.

26. The application was considered by the Member States to whom applications had been made. The assessment report prepared by Denmark, the reference Member State, dated 21 November 2017, did proceed on the basis that Ever was able to treat Precedex as a reference product. It said:

> "The original product which is or has been authorised in accordance with Union provision in force for not less than 6/10 years in the EEA is "Precedex, 100 micrograms/ml concentrate for solution for infusion", which was authorised in [the Czech Republic] on the basis of a full national application on 21st November 2002 (MAH:Abbott Lab.)
>
> On 9th November 2008, the MA was transferred to Hospira UK Ltd., and on 19th May 2010, the MA was transferred to Orion Corporation. The Czech authority has confirmed that the MA has become *acquis communitaire* (full accordance with EU legislation and requirements) with the date of accession of CZ to EU, i.e. from 1st May, 2004. The national MA was withdrawn in the CZ by the MAH 30th July 2010.
>
> Accordingly, with the accession of [the Czech Republic] to EU on May 1st 2004, the MA for "Precedex" became an EU compliant MA that can be referred to as European Reference Product as detailed in article 10 of directive 2001/83/EC, provided that the data exclusivity period, which also starts at the day of the EU accession of the MS with the national licence to the EU (1st May 2004) and therefore expired on 1st May 2010/1st May 2014 (6 or 10 years of data exclusivity).
>
> On September 9th 2011 the dexmedetomidine hydrochloride containing product "Dexdor" (MA number EU/1/11/718/001-007) received an approval via a centralised procedure… Marketing authorisation holder of this product is Orion Corporation…
>
> Dexdor and Precedex are considered identical products, solely authorised under different trade names …..., the company Abbott Laboratories is considered as licensee of the Orion Corporation. Thus the concept of global marketing authorisation (GMA) as detailed in article 6(1) second subparagraph of directive 2001/83/EC is applicable here. Based on this knowledge, Dexdor is chosen to be the reference product (CP brand leader)."

27. The public assessment report records that the concerned Member States agreed that Ever had demonstrated essential similarity for its product, DexEP, with the reference product (Dexdor) and had therefore granted a market authorisation in their states. The United Kingdom granted Ever a marketing authorisation on 19 October 2017. It is that decision that is challenged in these proceedings.

THE CLAIM AND THE ISSUES

28. Against that background, the claimant contends that the courts in England and Wales, carrying out a judicial review of the marketing authorisation granted by the United Kingdom authorities in October 2017, can determine the question of whether the Czech marketing authorisation granted to Precedex was a valid authorisation for the purposes of Article 6 of the Directive from the 1 May 2004, that is the date the Czech Republic acceded to membership of the European Union. The claimant contends that the marketing authorisation granted in 2002 could not, in fact, have satisfied the requirements imposed by EU law (if that law had applied at the time it was granted in 2002). Consequently, it could not be treated after accession as a marketing authorisation granted in accordance with EU law.

29. The claimant contends that that marketing authorisation would not have complied with the requirements of EU law for three principal reasons. First it submits that part of the information which would have been required by the relevant parts of Article 8 of, and the Annex to, the Directive, that is the manufacturer's data, was not supplied to the Czech authorities. That claim would involve consideration of whether, as a matter of law, a marketing authorisation would be invalid if such data had not been supplied and whether as a matter of fact it had not been supplied. Secondly, the claimant contends that the assessment reports prepared by the Czech authorities were manifestly inadequate. That again requires consideration of whether, as a matter of law, the grant of a marketing authorisation would be invalid if the assessment reports were inadequate and whether, as a matter of fact, the reports in this case were inadequate. Finally the claimant contends that it would have been contrary to Article 12 of the 1993 Regulation, or to relevant guidance, to apply for a marketing authorisation in a single state where an application for authorisation under the 1993 Regulation had been withdrawn. That depends upon whether the guidance relied upon applies to applications to a single state and, if so, whether the guidance gives rise to a legal prohibition on making such an application for a marketing authorisation in one state.

30. The claimant recognises that in the light of the decision of the Court of Justice in *Astellas*, it would appear that a domestic court, such as this one undertaking a judicial review of a marketing authorisation granted by the United Kingdom, is not required or entitled to determine whether a marketing authorisation granted in another Member State is compatible with EU law. The claimant contends that that decision is distinguishable and does not apply to this particular case. Ms Stratford Q.C., for the claimant, recognises that realistically the claimant is unlikely to succeed unless a request for a preliminary ruling is referred to the Court of Justice so that that Court can be asked if its decision in *Astellas* applies in this case to preclude this court from carrying out a judicial review of the Czech marketing authorisation granted to Precedex.

31. Mr Peretz Q.C., for the defendant, and Mr Scannell for the interested party, contend that this court is precluded by the ruling in *Astellas* from reviewing the compatibility of the Czech marketing authorisation for Precedex with EU law. They contend that the matter is clear and no reference is required.

32. Against that background, the principal issues that arise, in my judgment, can usefully be characterised as follows:

(1) Is this court able to undertake a judicial review of the Czech marketing authorisation because an exception applies to the ruling in *Astellas?*

(2) Does the answer to that question require the reference of questions to the Court of Justice for a preliminary ruling under Article 267 of the TFEU?

THE FIRST ISSUE – THE MEANING AND SCOPE OF THE RULING OF THE COURT OF JUSTICE IN *ASTELLAS*

35 The first issue concerns the role of this court and the scope of the decision in *Astellas.* It is necessary to consider that case in detail.

36 On 19 July 2005, the German Federal Institute granted Astellas a marketing authorisation for the medical product known as Ribomustin. The active substance of that product was bendamustine. The product was authorised for two indications, namely non-Hodgkin's lymphoma and multiple myeloma.

37 On 15 July 2010, France granted a marketing authorisation for a medical product known as Levact. The active ingredient was also bendamustine. Levact was authorised for the same two indications as Ribomustin and was also authorised for a third indication, namely the treatment of chronic lymphocytic leukaemia. This was granted following an application under the decentralised procedure in Article 28 of the Directive for a marketing authorisation in a number of Member States, including Germany and France, The reference Member State was Germany. France was a concerned Member State. France was the first Member State to grant a marketing authorisation following the conclusion of the Article 28 procedure.

38 On 7 November 2012, Helm applied to a number of Member States for marketing authorisation of a product known as Alkybend using the procedure set out in Article 28 of the Directive. Helm stated that Alkybend was a generic medicinal product, the active substance being bendamustine hydrochloride. The assessment report for that application stated that the reference product was Levact but, as that product was part of a global authorisation which included the 2005 marketing authorisation granted for Ribomustin, that latter product was the reference product for the purposes of Article 10 of the Directive. As the period for exclusive protection of data had expired, the assessment of the application for Alkybend could rely upon the data relating to Ribomustin. On 28 March 2014, the Finnish authorities ("Fimea") granted a marketing authorisation to Helm for Alkbyend.

39 Astellas contended that the data exclusivity period began on 15 July 2010, which was the date of the grant of the first marketing authorisation for Levact, not 19 July 2005 which was the date of the grant of a marketing authorisation for Riboumstin. Consequently, Astellas contended, the period for protection of the data used for the application for Levact had not expired and that data could not be used for assessing Helm's application for a marketing authorisation for Alkybend.

40 Astellas applied to the Finnish courts to quash that marketing authorisation. Astellas submitted, amongst other arguments, that the 2005 marketing authorisation granted by the German Federal Institute was not in accordance with the Directive. It also argued

that the grant of the marketing authorisation for Levact had involved extensive additional tests.

41 The Finnish court noted that Astellas was not a party to the decentralised procedure for the grant of the marketing authorisation for Alkybend and might not be able to ensure protection of its data during that procedure. It noted that one Member State could not call into question (other than on grounds of a risk to public health) the assessments carried out in another Member State for the purpose of evaluating the medicinal product. The Finnish court therefore asked two questions to address the situation of how effective judicial protection could be provided for the rights of Astellas over its data if the Finnish authorities could not address the time when the period of protection for data expired. The two questions were:

> '(1) Are Articles 28(5) and 29(1) of Directive 2001/83/ ... to be interpreted as meaning that the competent authorities of the concerned Member State in the decentralised procedure for [MAs] for generic medicinal products in accordance with Article 28(3) of that directive are not themselves competent when issuing a national marketing authorisation to determine the time from which the data exclusivity period for the reference medicinal product begins to run?
>
> (2) If the answer to the first question is that, when issuing a national marketing authorisation, the competent authorities of a Member State are not competent to determine the time from which the period of data exclusivity of the reference medicinal product starts to run:
>
> - is the court of that Member State when dealing with an appeal by the holder of the [MA] for the reference medicinal product required to determine the time from which the period of data exclusivity starts to run, or is it subject to the same limit as the national authorities of that Member State?
>
> - In those circumstances, how is the national court to give effect to the right of the holder of the [MA] of the reference medicinal product under Article 47 of the Charter of Fundamental Rights of the European Union and Article 10 of Directive 2001/83 to effective legal protection with regard to data exclusivity?
>
> - Does the claim for effective legal protection require the national court to examine whether the original marketing authorisation granted in another Member State was issued in accordance with the rules laid down by Directive 2001/83?'.

*The First Question*

42. The Court of Justice noted that the first question, in effect, asked whether, in the context of the decentralised procedure for applying for marketing authorisations set out in Article 28 of the Directive, the competent authorities of a Member State could themselves determine the date from which the period of protection for data ran when granting a marketing authorisation pursuant to its obligation in Article 28(5) of the Directive. The Court of Justice concluded that the Member States participated in a procedure which led to general agreement for approving the grant of marketing authorisations in Member States in which an application was made. That process would involve Member States verifying whether the period for protecting data related to a reference product set out in Article 10 of the Directive had expired. Otherwise, the data relating to the reference product would not be available when assessing the application for a marketing authorisation for a generic product. A Member State must

be able to refuse to approve the assessment report on the generic medicinal product if it considered that the time for protection of data had not expired. Once the Member States had approved the assessment report however, it was not open to a Member State to repeat the process of verifying that the data protection period had expired. In other words, the Member State could not unilaterally consider and determine the question of whether the data protection period had expired once the assessment report had been approved and the Member State was under a duty under Article 28(5) of the Directive to issue a marketing authorisation.

*The Second Question*

43 As it explained in paragraph 33 of its judgment, the Court of Justice understood the second question in the following way:

" "33 By its second question, the referring court asks, in essence, whether Article 10 of Directive 2001/83, read in conjunction with Article 47 of the Charter, must be interpreted as meaning that a court of a Member State concerned by the decentralised procedure for MAs, hearing an action brought by the holder of the MA for the reference medicinal product against the MA decision for a generic medicinal product in that Member State taken by that State's competent authority, has jurisdiction to review the determination of the point in time from which the data exclusivity period for the reference medicinal product starts to run and to ascertain whether the initial MA for the reference medicinal product, granted in another Member State, was granted in accordance with that directive."

44. In that regard, the Court referred to its ruling in *Olainfarm* to the effect that Article 10 of the Directive sets out the circumstances in which the holders of a marketing authorisation for one product (the reference product) are required to accept that the manufacturer of another product (the generic product) may refer to the pre-clinical tests and clinical trials carried out for the reference product. It noted that the holder of a marketing authorisation is entitled to effective judicial protection and a judicial remedy against the decision of the competent authority granting a marketing authorisation for a generic product to ensure that the provisions of Article 10 of the Directive are observed.

45 In the light of those considerations, the Court considered that the holder of the marketing authorisation for the reference product had to be able to challenge the determination of the point in time from which the data exclusivity period provided for in Article 10 of the Directive starts to run. It noted that the decentralised procedure provided for in Article 28 of the Directive provided for each Member State to adopt a decision granting a marketing authorisation and did not provide for the adoption of any other measure against which the holder of a marketing authorisation could bring proceedings to assert its rights. In that context, the Court of Justice said this at paragraphs 39 to 41 of its judgment:

"39 It follows that effective judicial protection of the rights held by the holder of a MA for the reference medicinal product as regards the data exclusivity of that medicinal product can be ensured only if that holder can rely on those rights before a court of the Member State in which the competent authority adopted a MA decision for the generic medicinal product and if it can, inter alia, plead before that court an error relating to the

> determination of the point in time from which the exclusivity period, affected by that decision, starts to run.
>
> 40 However, that requirement of effective judicial protection does not mean that the holder of the MA for the reference medicinal product may call into question before that court the compatibility with Directive 2001/83 of MA decisions for that medicinal product taken in other Member States. That holder of the MA has a right to a judicial remedy which it can exercise, or which it could have exercised within the time limits set, against those decisions before the courts having jurisdiction to review the legality of the decisions adopted by the competent national authorities in each Member State.
>
> 41 In the light of the foregoing considerations, the answer to the second question is that Article 10 of Directive 2001/83, read in conjunction with Article 47 of the Charter, must be interpreted as meaning that a court of a Member State involved in a decentralised procedure for MAs, hearing an action brought by the holder of the MA for the reference medicinal product against the MA decision for a generic medicinal product in that Member State taken by its competent authority, has jurisdiction to review the determination of the point in time from which the data exclusivity period for the reference medicinal product starts to run. By contrast, that court does not have jurisdiction to review whether the initial MA for the reference medicinal product granted in another Member State was granted in accordance with that directive."

46 In the formal disposition of the case, the Court of Justice repeated its essential ruling on the first and second questions in the following terms:

> "1. Article 28 and Article 29(1) of 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, as amended by Directive 2001/83/EC of the European Parliament and of the Council of 25 October 2012, must be interpreted as meaning that, in a decentralised marketing-authorisation procedure for a generic medicinal product, the competent authority of a Member State concerned by that procedure cannot itself determine the point in time from which the data exclusivity period for the reference medicinal product starts to run when adopting, under Article 28(5) of that directive, its decision on the placing on the market of that generic medicinal product in that Member State.
>
> 2. Article 10 of Directive 2001/83, as amended by Directive 2012/26, read in conjunction with Article 47 of the Charter of Fundamental Rights of the European Union, must be interpreted as meaning that a court of a Member State involved in a decentralised procedure for marketing authorisations, hearing an action brought by the holder of the marketing authorisation for the reference medicinal product against the marketing-authorisation decision for a generic medicinal product in that Member State taken by its competent authority, has jurisdiction to review the determination of the point in time from which the data exclusivity period for the reference medicinal product starts to run. By contrast, that court does not have jurisdiction to review whether the initial marketing authorisation for the reference medicinal product granted in another Member State was granted in accordance with that directive."

*Discussion*

47 The ruling of the Court of Justice establishes that the holder of a marketing authorisation may bring legal proceedings to protect the exclusivity of its data and, in particular, to challenge an error in the calculation of the period of protection conferred by Article 10 of the Directive. That, however, does not extend to enabling the holder

of the marketing authorisation to challenge in the courts of one Member State the compatibility with EU law of marketing authorisations granted by the competent authorities in another Member State. If those decisions are to be challenged, they must be challenged in the courts of that other Member State in accordance with the relevant rules of national procedure including any applicable time limits for bringing such a challenge.

48 Applying that ruling to the facts of this case, the claimant cannot bring a challenge before this court seeking to establish that a marketing authorisation granted by the competent authorities in another Member State (here the Czech marketing authorisation for Precedex) is not compatible with EU law because it does not satisfy the requirements of the Directive.

*The Alleged Exceptions*

Pre-Accession Marketing Authorisations

49 The claimant contends that there are a number of reasons why the ruling of the Court of Justice in *Astellas* does not apply in this case. First, it is said that the ruling only applies to decisions of the competent authority in another Member State. The decision here was taken in the Czech Republic in 2002 before the Czech Republic became a Member State of the European Union on 1 May 2004.

50 The answer to that is as follows. The essential question is whether, as at the date of accession, the marketing authorisation was valid under EU law. The Treaty of Accession between the Member States of the European Union and 10 other states, including the Czech Republic, was signed on 16 April 2003 and came into force on 1 May 2004. Article 1.2 of that Treaty provided that:

> "The conditions of admission and the adjustments to the Treaties on which the Union is founded, entailed by such admission, are set out in the Act annexed to this Treaty. The Act shall form an integral part of this Treaty".

51 Article 2 of the Act of Accession provides that the Treaties, and EU legislation (including, therefore, the Directive) are binding on the new Member States, including the Czech Republic, from the date of accession and apply to those States under the conditions laid down in the Treaties and the Act of Accession. Article 10 of the Act of Accession provides that the application of the Treaties and the acts adopted by the EU institutions are subject to derogations provided for in the Act as a transitional measure. The Act of Accession then makes transitional provisions for certain countries in respect of certain measures of EU law. Article 24 of the Act of Accession provides that measures listed in certain Annexes apply in respect of the new Member States. Annex 12 deals with Poland and, in respect of the Directive, provides specific provision for marketing authorisations granted by Poland in the following terms:

> "By way of derogation from the requirements of quality, safety and efficacy laid down in Directive 2001/83/EC, marketing authorisations for the pharmaceutical products on the list (in Appendix A to this Annex as provided by Poland in one language) issued under Polish law prior to the date of accession, shall remain valid until they are renewed in compliance with the acquis and in accordance with the timeframe set out in the abovementioned list, or until 31 December 2008, whichever is the earlier. Notwithstanding the provisions of Title III, Chapter 4, of the Directive, marketing

> authorisations covered by this derogation shall not benefit from mutual recognition in the Member States."

52 In other words, marketing authorisations granted by the Polish authorities before accession for certain products listed in an appendix would remain valid in Poland – but could not be relied upon to obtain a marketing authorisation in other Member States using the route of mutual recognition. The implication underlying that provision is clear. Marketing authorisations for those products did not comply with the requirements of EU law, and the Directive in particular, and could not therefore be used to obtain marketing authorisations in the remainder of the EU. By contrast, there was no such provision restricting the validity or use of marketing authorisations granted by the Czech authorities prior to accession. Those marketing authorisations were assumed to have been granted in circumstances which would satisfy the requirements of EU law and, from the date of accession, were to be treated as marketing authorisations for the purposes of Article 6 of the Directive. The ruling in *Astellas*, therefore applies to prevent challenges in this court to the compatibility with the Directive of the marketing authorisation granted to Precedex.

53 I note that the interpretation I place on the Treaty and Act of Accession accords with the interpretation given to them by the District Court of Central Netherlands sitting in Utrecht. See the judgment in *Orion Corporation v the Medicines Evaluation Board* case UTR/18/1103 at paragraph 15. That court considered for the same reasons that it could be concluded that the marketing authorisation granted for Precedex was compliant with the Directive at the time of accession of the Czech Republic to the European Union.

54 Nor does the decision in Case C-350/08 *Commission v Lithuania* EU:C:2010:642 alter that conclusion. Lithuania like Poland, but unlike the Czech Republic, was subject to transitional provisions governing marketing authorisations for medicinal products. In those circumstances, it cannot be presumed that all marketing authorisations in force in Lithuania at the time of accession were to be treated as compliant with EU law. Indeed, the reverse was the case and only those subject to transitional provisions were valid. The validity of marketing authorisations, as in the case of Poland, extended only to those products listed in an Appendix, and then only until 1 January 2007 or when they were renewed in compliance with EU law (whichever was the earlier). A product, Grasalva, was not listed in the Appendix as one of the products where the marketing authorisation was treated as valid for a transitional period. Consequently, Lithuania acted in breach of Article 6 of the Directive by seeking to maintain in force a marketing authorisation for Grasalva after accession. In Lithuania, as in Poland, there is no general acceptance that marketing authorisations in force as at the date of accession complied with EU law and no transitional arrangements were made for this product. Consequently, for that reason, the marketing authorisation in that case was not valid for the purposes of Article 6 of the Directive. The position is different in relation to marketing authorisations granted by the Czech authorities prior to accession. They were regarded as compliant with the Directive and were to be treated on accession as valid for the purpose of Article 6 of the Directive.

The Alleged Perverse Consequences

55 The claimant contends that the inability of a domestic court to review the Precedex marketing authorisation results in perverse consequences. It contends that, on the

facts, following the withdrawal of the first application for a marketing authorisation for the whole of the European Union in 2000, the claimant could not have exploited its rights to DH throughout the European Union without carrying out further extensive tests. It submits that the fact that the application for a marketing authorisation under the 1993 Regulation had been withdrawn, and the fact that the dossier filed in support of that application was considered inadequate, meant that other marketing authorisations (such as that granted by the Czech authorities to Precedex) could not have been used as part of the process of seeking mutual recognition by other Member States under Article 28(2) of the Directive. The claimant submits that it had to carry out the further tests to obtain marketing authorisation for DH in the rest of the European Union. Consequently, under the balance struck by the Directive, the claimant should, it submits, be given the full period of data protection from the date when it was granted a marketing authorisation for Dexdor. The claimant submits that this is an important difference between the *Astellas* case and the present.

56 The legal position is governed by the provisions of the Directive as interpreted by the Court of Justice. The Directive strikes a balance between providing a period of protection for data, including the results of pre-clinical tests and trials, and permitting generic products to be granted marketing authorisation without having to repeat those tests. That reflects the balance between encouraging, or at least not unduly deterring, innovation and avoiding unnecessary replication of tests on animals and humans as recognised in the recitals. Built into that structure is provision that an initial marketing authorisation and a later one may be part of a global marketing authorisation and, if so, the period of protection for data runs from the date of the initial marketing authorisation: see Article 6 of the Directive. Furthermore, the Court of Justice has held in *Astellas* that the courts of one Member State may not review the grant of the initial marketing authorisation granted by another Member State to assess if that authorisation complied with EU law. Those provisions, and rules of law, are binding on this court. They may mean that the claimant may not derive all the benefits it anticipated from the later tests that it carried out. That however is implicit in the regulatory framework.

57 Furthermore, although not the basis for my decision, it is appropriate to note that the situation in this case results in part from the decision of the claimant's licensee to apply for a marketing authorisation in the Czech Republic for Precedex. It obtained that authorisation and Precedex was marketed in the Czech Republic for a number of years. On one analysis, the situation arises from a combination of the structure of the rules and the actions of the company entitled to exploit the rights to DH in a particular country rather than any perversity in the scope or application of the ruling in *Astellas* understood in the way described above.

Previous Case Law

58 Next, Ms Stratford for the claimant contends that the decision in *Astellas* is inconsistent with the previous case law of the Court of Justice and, in particular, the decision in case C-527/07 *R on the application of Generics (UK) Ltd. v Licensing Authority* EU:C:2009:379. The claimant submits that it is implicit in the judgment in *Generics* that the competent authorities and the national courts of one Member State must be able to decide whether the documentation required by Article 8 of the Directive was supplied to the relevant national authorities of another Member State when the product

was first granted a marketing authorisation so that they can be satisfied that the authorisation was granted in accordance with EU law.

59 The essential facts in *Generics* are as follows. In 1963, the Austrian authorities granted a marketing authorisation under the Austrian law then in force for a medicinal product, galantamine, trading under the brand name "Nivalin", for the treatment of poliomyelitis. The authorisation was subsequently modified in 1995 but it was agreed that the original dossier, on the basis of which the 1963 authorisation was granted, was not updated in order to comply with the requirements of EU law which did then apply in Austria in 1995.

60 The defendant, the licensing authority in the United Kingdom, was asked to treat Nivalin as the reference product for a generic of galantamine. The licensing authority concluded that Nivalin could not be used as a reference product because it had not been authorised on the basis of a dossier providing the material required by the Directive and that dossier had not been subsequently updated to comply with the Directive. The Court of Justice recognised that what was important was that the particulars and documents relating to the reference product remained available to the competent national authorities concerned by the application (under Article 28 of the Directive) for authorisation. The key paragraphs of the judgment for present purposes come at paragraph 28 to 30 and 33 to 35 where the Court said:

> "28. In that regard, Generics claims, in essence, that a medicinal product placed on the market in a Member State for a number of years in accordance with an authorisation issued on the basis only of the national provisions of that Member State - which were applicable before the transposition in that State of the Community legislation in that area - may be considered to be a reference medicinal product within the meaning of Article 10(2)(a) of Directive 2001/83.
>
> 29. Such an interpretation of Community law is unfounded.
>
> 30. It is apparent both from the wording and from the broad logic of Directive 2001/83, in particular from Articles 6, 8 and 10, that only those medicinal products benefiting from a marketing authorisation issued in accordance with that directive can be considered to be reference medicinal products. Likewise, as regards medicinal products for which marketing authorisation was sought prior to the entry into force of that directive, it is clear from the case-law that, in order to benefit from the abridged procedure, the applicant must show that the reference medicinal product was authorised on the basis of the Community law in force at the time of the application for marketing authorisation for the reference medicinal product…"

and

> "33. It follows from the foregoing considerations that, in order that a medicinal product may be considered to be a reference medicinal product, it must have been authorised in accordance with Community law before being placed on the market.
>
> 34. In the present circumstances, it is apparent from the file submitted to the Court that Nivalin has never been the subject of an application for marketing authorisation containing the particulars and the documents referred to in Article 8 of Directive 2001/83 and that, therefore, authorisation for it to be placed on the market has never been given in accordance with the requirements of that directive.

> 35. Likewise, it is not in dispute that Nivalin has also not been the subject of an application for marketing authorisation in accordance with the Community legislation applicable prior to the entry into force of that directive.
>
> 36. In actual fact, the placing of Nivalin on the market in Austria was authorised only under the legislation in force in Austria at the time of the granting of the authorisation, namely in 1963, as that authorisation was never updated in accordance with Community law following the accession of the Republic of Austria to the EEA and then the European Union.

61 In other words, the key fact in the *Generics* case was that the product in question had never been authorised in accordance with the requirements of EU law. The authorisation was granted under Austrian law at a time when Austria was not a member of the European Union in 1963 and was not purporting to apply laws equivalent to EU law. In the present case, the Czech Republic was not a member of the EU at the time that the authorisation was granted in 2002. But it was purporting to apply requirements equivalent to EU law. From 1 May 2004, the arrangements for the accession of the Czech Republic to the EU treated the marketing authorisation as granted in accordance with EU law. The position in this case is therefore materially different. In Generics, the competent authorities or courts were not being asked to review the initial marketing authorisation to determine whether it had been granted in accordance with EU law: the Austrian authorities had never sought to determine whether the marketing authorisation satisfied requirements equivalent to those imposed by EU law. The product could not therefore be treated as a reference product for the purposes of Article 10 of the Directive. In the present case, the claimant is seeking to persuade this court to review the initial marketing authorisation to determine if the Czech marketing authorisation was compatible with the requirements of EU law. The decision in *Astellas* does not permit the national court to carry out that exercise. The decision in *Astellas* is not inconsistent with *Generics*. It is dealing with a different situation.

Right to Effective Judicial Protection

62 The claimant submits that to conclude that it cannot now raise the question of whether Precedex can be used as a reference product would be to fail to respect its right to effective judicial protection of its right to protect its data.

63 The answer is that the scope of the right to effective judicial protection of the right to protect data in this context has been determined by the Court of Justice in *Astellas*. The claimant has the right to challenge an error relating to the start date of the period of protection. But the right to effective judicial protection does not extend to enabling the claimant to have this court review the compatibility of the initial marketing authorisation granted by the Czech authorities with the Directive. Any challenge to the Czech marketing authorisation after 1 May 2004 on the grounds that it was not a valid marketing authorisation for the purposes of Article 6 of the Directive was one that had to be brought in the Czech Republic and would be subject to Czech law on standing and time limits.

Case law of the English Courts

64 The defendant submits that the decision in *Astellas* is consistent with earlier domestic case law. In *R v Licensing Authority ex p. Monsanto* [1997] 3 C.M.L.R. 402, the High Court considered that there was no reason why a domestic authority should be

required to obtain the data used 10 or more years before for an application for a marketing authorisation in another Member State to assess whether that data complied with present day standards. The claimant contends that that case is distinguishable and, in any event, the High Court did express the view that it had not been established before the domestic court that there was any deficiency in the original application. That, the claimant submits, is consistent with the domestic court undertaking a review of the compatibility of the original marketing authorisation with the requirements of EU law.

65 In truth, the issues in the present case are to be determined by the proper application of the decision of the Court of Justice in *Astellas* in accordance with section 3(1) the European Communities Act 1972 as enacted by the United Kingdom Parliament. The decision of the High Court twenty years before is not determinative. In any event, the decision of the High Court is consistent with the approach of the Court of Justice. Member States, and their courts, are entitled to rely upon the authorisations granted in other Member States or, I would add, granted by the competent authorities in a State which accedes to the European Union and whose authorisations were recognised, or treated, as being in accordance with EU law under the arrangements governing the accession of that State to the European Union.

*Conclusion*

66 In the circumstances, this domestic court may not undertake a review of the marketing authorisation granted by the Czech authorities for Precedex in order to determine whether that marketing authorisation is compatible with the requirements of the Directive. That is established by the decision of the Court of Justice in *Astellas*.

67 I have reached that conclusion having regard to the relevant principles of EU law and the decision of the Court in *Astellas*. I note, however, that the Administrative Court in Uppsala, Sweden, and the District Court of Central Netherlands have reached the same conclusion, for essentially the same reason, in proceedings brought by the claimant, Orion, in those two Member States seeking to challenge the compatibility of the marketing authorisation for Precedex with the Directive. In each case, the courts of Sweden and the Netherlands considered that the matter was settled by the Court of Justice ruling in *Astellas.*

## THE SECOND ISSUE – WHETHER TO REFER TO THE COURT OF JUSTICE

68 The claimant contends that the position is not clear and that one or more of the arguments it made in this court might, in effect, persuade the Court of Justice to qualify, or clarify, its decision in *Astellas*. The claimant relied upon the dictum of the Master of the Rolls in *R v International Stock Exchange of the United Kingdom and the Republic of Ireland Ltd. ex p. Else* [1993] Q.B. 534 at page 545D-E. The Master of Rolls observed, that where the facts had been found, and the issue of EU law was critical to the final decision, the correct approach in principle of a court (other than a final court of appeal) is to refer the question unless it can with complete confidence resolve the issue. Those remarks need to be understood in the context in which they were made. There, the first instance judge had exercised his discretion to refer certain questions to the Court of Justice. The Court of Appeal heard full argument on the meaning of the relevant EU provisions and decided, in the light of those arguments,

that it could resolve the issue of EU law with complete confidence and set aside the order of the lower court making a reference.

69 In the present case, it is possible to resolve the issues with complete confidence. The meaning of the decision of the Court of Justice in *Astellas* is clear. None of the arguments advanced by the claimant cast any doubt upon the ruling or its scope. The status of marketing authorisations granted in pre-accession States appears clearly from a consideration of the Treaty and Act of Accession. The meaning and scope of the pre-existing case law of the Court of Justice appear clearly from the terms of the relevant rulings. The other arguments advanced do not, on analysis provide any justifiable reason for questioning the decision in *Astellas*.

70 In the circumstances, any issue as to the meaning and scope of the decision in *Astellas* can be resolved with complete confidence and no reference to the Court of Justice for a preliminary ruling is appropriate. For completeness, I note that, at first instance, a court has a discretion to make a reference and even if the matter could not be resolved with complete confidence, there may be other factors to consider in deciding whether or not a reference was appropriate. As the issues can be resolved with complete confidence, it is not necessary to consider those factors in this judgment.

ANCILLARY MATTERS

71 In the light of the above conclusions, it is neither necessary nor appropriate for this court to consider the claim made by the claimant that the marketing authorisation for Precedex granted by the Czech authorities was not compatible with EU law. In submission, Ms Stratford also indicated that the claimant would wish to contend that the United Kingdom had not properly discharged its obligations during the Article 28(2) procedure which considered the application by Ever for marketing authorisations for its product and, in particular, that the United Kingdom had not considered Orion's complaint that Precedex could not be treated as a reference product for that application as that marketing authorisation was not compatible with EU law. Furthermore, Ms Stratford submitted that the scope of the obligations on Member States in the Article 28 procedure could themselves usefully be the subject of a reference to the Court of Justice for a preliminary ruling.

72 First, on a fair reading of the claim form, the claimant was not seeking to challenge any actions or failure of the United Kingdom in the context of the Article 28 procedure. The focus of this claim is the compatibility of the Precedex marketing authorisation with EU law. The remedy sought was to quash the UK marketing authorisation granted for Ever's generic product and remit the matter back to the defendant to reconsider. Reference is made in the claim form to the defendant being obliged to consider Orion's representations as to why the marketing authorisation for Precedex was not compatible with EU law and that the defendant should have decided not to grant the marketing authorisation for Ever's product. On a fair reading of the claim form as a whole, those references concern the ability of the defendant unilaterally to decline to grant the marketing authorisation (not on any alleged failure during the Article 28(2) process). As a matter of law, the Court of Justice mades it clear in the answer to the first question in *Astellas* that the competent national authorities cannot unilaterally review the period of protection for data after the Member States have approved the report dealing with the application: the Member

State's obligation then is to grant the marketing authorisation as required by Article 28(5) of the Directive.

73 The conclusion that the claim is not concerned with the role of a Member State during the Article 28 procedure is reinforced by, but not dependent upon, the fact that the draft questions for a reference provided with the claimant's skeleton argument do not raise any questions concerning the Article 28 procedure. The role of the defendant during the Article 28 process is not therefore, on a fair reading, raised in these proceedings, and its role after the conclusion of the Article 28 procedure is clear. In those circumstances, it would not be appropriate for this court, and it would not be fair to the defendant or the interested party, to seek to resolve any issues concerning the operation of the Article 28 procedure.

74 Secondly, and separately, the only evidential material before this court dealing specifically with the role played by the United Kingdom in the Article 28 procedure is contained in the defendant's summary grounds, and later detailed grounds. Both those documents are accompanied by statements that the defendant believes that the facts stated are true. The summary grounds state that the defendant did consider the complaints made by Orion to the effect that the Czech authorisation was invalid but concluded that those complaints were not sufficiently made out. The detailed grounds make a similar point. In the circumstances, there could not realistically be any criticism that the defendant failed to consider the complaint. The only real complaint made by the claimant is that Precedex could not be used as a reference product as the Precedex marketing authorisation was not compatible with EU law. For the reasons given, that claim may not be determined by this court.

75 The claimant, the defendant and the interested party have relied upon a number of documents and a number of legal points were made by counsel for all parties in their skeleton arguments, oral submissions and closing submissions. I am grateful for all the submissions made. I have sought in this judgment, however, to deal with what I consider to be the principal points raised and the principal documents relating to those matters. All parties can be assured however, that I have carefully considered all the points made and all the documents relied upon.

## CONCLUSION

76 In the light of the ruling of the Court of Justice in *Astellas*, it is not open to this court to review the marketing authorisation for Precedex granted by the Czech authorities to determine whether that marketing authorisation is compatible with the requirements of the Directive. The claimant may bring legal proceedings to protect the exclusivity of its data and, in particular, to challenge an error in the calculation of the period of protection conferred by Article 10 of the Directive in respect of that data but that does not entitle the claimant to challenge in this court the compatibility with EU law of a marketing authorisation granted by the Czech authorities. Such a challenge must be brought in the courts of that Member State that granted the marketing authorisation in accordance with the relevant rules of national procedure including any applicable time limits for bringing such a challenge. Consequently, this claim for judicial review is dismissed.