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

In

Case C-557/16

between

Astellas Pharma GmbH

and

Helm AG

WRITTEN OBSERVATIONS OF IRELAND

Pursuant to the second paragraph of Article 23 of the Statute of the Court of Justice of the European Union, Ireland, represented by Eileen Creedon, Chief State Solicitor, Osmond House, Little Ship Street, Dublin 8 acting as Agent and accepting service by e-Curia, with an address at the Embassy of Ireland, 28 Route d'Arlon, Luxembourg, assisted by Suzanne Kingston B.L. of the Bar of Ireland, submits the following written observations to the Court of Justice on the questions referred for preliminary ruling pursuant to Article 267 of the Treaty on the Functioning of the European Union by the *Korkein hallinto-oikeus*, lodged at the Registry of the Court of Justice on 4th November 2016.

Dated 22 February 2017

I — Introduction and summary

1. The present preliminary reference concerns the extent to which the competent national authority, and national courts, of the concerned Member State in the decentralised procedure laid down in Article 28(3) of Directive 2001/38[1] may re-examine the decision to grant a marketing authorisation ("*MA*") for the reference product. Specifically, it concerns the extent to which such national authority and/or national courts may determine the time from which the data exclusivity period for the reference medicinal product begins to run.

2. By way of summary, Ireland submits that neither the competent national authority nor national court of the concerned Member State in such circumstances has any power to determine the time from which the data exclusivity period for the reference medicinal product begins to run. Rather, the national authority of a concerned Member State is bound to adopt a decision in conformity with the assessment report and product information, as approved by the national authority of the reference Member State unless the procedure envisaged by Article 29 of Directive 2001/38 has been invoked. Nor are the national courts of a concerned Member State competent to determine the time from which the period of data exclusivity starts to run, or whether the original marketing authorisation granted in another Member State was issued in accordance with the rules laid down by Directive 2001/83.

I — Legal framework

3. Title III of Directive 2001/83 governs the placing on the market of medicinal products.

4. By Article 6(1) of Directive 2001/83, in order to place a medicinal product on the market within a Member State, it is an essential precondition that a MA must have

[1] OJ 2001 L 311/67.

been issued by the competent authority of that State or granted in accordance with Regulation 726/2004.[2]

5. Article 6(1), as amended by Directive 2004/27/EC,[3] specifically deals with situations where a further MA has been granted to a form (e.g., variation, extension) of the same medicinal product that differs in some way from the original product, by providing that such MAs must be considered as forming part of the same "*global marketing authorisation*" for the purposes of Article 10(1) of Directive 2001/83.[4]

6. Article 8(1) of Directive 2001/83 obliges applicants for a MA for a medicinal product to apply to the competent authority of the Member State concerned. Article 8(3) contains an extensive list of particulars and documents that must accompany such applications, including proof of the results of pre-clinical tests and of clinical trials, and copies of any MA obtained in another Member State or third country.

7. The first paragraph of Article 10(1) of Directive 2001/83 in its current form (as amended by Directive 2004/27/EC) provides, insofar as relevant,

> "*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*

[2] OJ 2004 L 136/1.
[3] OJ 2004 L 136/34.
[4] Article 6(1) of Directive 2001/83, as amended, provides, "*When a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted an authorisation in accordance with the first subparagraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10(1)*."

> *authorised under Article 6 for not less than eight years in a Member State or in the Community*."[5]

8. This period is known as the period of data exclusivity.[6] At the relevant time for the purposes of the present case, Directive 2001/83 permitted Member States to elect to have a period of data exclusivity of either six years or ten years. Finland elected to have a period of six years.

9. The third paragraph of Article 10(1) of Directive 2001/83 provides,

> "*The first subparagraph shall also apply if the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month, a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation*."

10. Article 17(1) of Directive 2001/38 provides, insofar as relevant, that applications for MAs in two or more Member States in respect of the same medicinal product shall be submitted in accordance with Articles 28 to 39. Article 17(2) provides that, where a Member State notes that another MA application for the same medicinal product is being examined in another Member State, the Member State concerned shall decline to assess the application and shall advise the applicant that Articles 28 to 39 apply.

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[5] "*Reference medicinal product*" is defined by Article 10(2)(a) as "*a medicinal product authorised under Article 6, in accordance with the provisions of Article 8*."

[6] To be distinguished from the period of marketing exclusivity, which is dealt with in the second paragraph of Article 10(1) and which is not at issue in the present case.

11. By Article 18, where a Member State is informed in accordance with Article 8(3)(1) that another Member State has authorised a medicinal product which is the subject of a MA application in the Member State concerned, it shall reject the application unless it was submitted in compliance with Articles 28 to 39.

12. Article 19(1) of Directive 2001/38 provides,

> "*In order to examine the application submitted in accordance with Articles 8, 10, 10a, 10b and 10c, the competent authority of the Member State:*
>
> *1. must verify whether the particulars submitted in support of the application comply with the said Articles 8, 10, 10a, 10b and 10c and examine whether the conditions for issuing an authorization to place medicinal products on the market (marketing authorization) are complied with*."

13. Articles 28 to 39 of Directive 2001/38 are located within Chapter 4 of Title III of Directive 2001/38, entitled "*Mutual recognition and decentralised procedure*".

14. Article 28(1) provides,

> "1. *With a view to the granting of a marketing authorisation for a medicinal product in more than one Member State, an applicant shall submit an application based on an identical dossier in these Member States. The dossier shall contain the information and documents referred to in Articles 8, 10, 10a, 10b, 10c and 11. The documents submitted shall include a list of Member States concerned by the application.*
>
> *The applicant shall request one Member State to act as 'reference Member State' and to prepare an assessment report on the medicinal product in accordance with paragraphs 2 or 3."*

15. Article 28(2) sets out the mutual recognition procedure, and provides,

> *"2. Where the medicinal product has already received a marketing authorisation at the time of application, the concerned Member States shall recognise the marketing authorisation granted by the reference Member State. To this end, the marketing authorisation holder shall request the reference Member State either to prepare an assessment report on the medicinal product or, if necessary, to update any existing assessment report. The reference Member State shall prepare or update the assessment report within 90 days of receipt of a valid application. The assessment report together with the approved summary of product characteristics, labelling and package leaflet shall be sent to the concerned Member States and to the applicant."*

16. Article 28(3) sets out the decentralised procedure, and provides,

> *3. In cases where the medicinal product has not received a marketing authorisation at the time of application, the applicant shall request the reference Member State to prepare a draft assessment report, a draft summary of product characteristics and a draft of the labelling and package leaflet. The reference Member State shall prepare these draft documents within 120 days after receipt of a valid application and shall send them to the concerned Member States and to the applicant.*

17. Article 28(4) and (5) provide for further detail on timelines for the mutual recognition and decentralised procedures:

> *"4. Within 90 days of receipt of the documents referred to in paragraphs 2 and 3, the Member States concerned shall approve the assessment report, the summary of product characteristics and the labelling and package leaflet and shall inform the reference Member State accordingly. The reference Member State shall record the agreement of all parties, close the procedure and inform the applicant accordingly.*

> *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 product characteristics and the labelling and package leaflet as approved, within 30 days after acknowledgement of the agreement*."

18. Article 29(1) of Directive 2001/38 provides,

> "1. *If, within the period laid down in Article 28(4), a Member State cannot approve the assessment report, the summary of product characteristics, the labelling and the package leaflet on the grounds of potential serious risk to public health, it shall give a detailed exposition of the reasons for its position to the reference Member State, to the other Member States concerned and to the applicant. The points of disagreement shall be forthwith referred to the coordination group*."

19. Article 30(1) provides for a procedure whereby, if two or more MA applications have been made for a particular medicinal product and if Member States have adopted divergent decisions concerning the authorisation of the product or its suspension or revocation, the matter may be referred to the Committee for Medicinal Products for Human Use.

20. Article 125 of Directive 2001/38 provides, insofar as relevant,

> "*Every decision referred to in this Directive which is taken by the competent authority of a Member State shall state in detail the reasons on which it is based.*
>
> *Such decision shall be notified to the party concerned, together with information as to the redress available to him under the laws in force and of the time-limit allowed for access to such redress*."

21. Article 126 provides, insofar as relevant,

"*An authorization to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in this Directive*."

II — Factual background

22. On 19 July 2005, the competent German authority (*Bundesinstitut für Arzneimittel und Medizinprodukte* or "*BfArM*") granted the plaintiff in the main proceedings, Astellas Pharma GmbH ("*Astellas Pharma*"), a MA for the medicinal product Ribomustin, pursuant to the German Law on Medicinal Products. The active substance in Ribomustin is bendamustine.

23. Astellas Pharma was subsequently issued with a first MA for the medicinal product Levact® from the competent French authority (*Agence nationale de sécurité du médicament et des produits de santé*[7] or "*ANSM*") on 15 July 2010 under the decentralised procedure pursuant to Article 28(3) of Directive 2001/83. While the active substance in Levact® is also bendamustine, the therapeutic indications differ in part from those of Ribomustin.

24. The defendant in the main proceedings, Helm AG ("*Helm*") applied for a MA for the medicinal product Alkybend on 7 November 2012 under the decentralised procedure pursuant to Article 28(3). The reference Member State in this application was Denmark, and the concerned Member States were Finland and Norway. According to this application, Alkybend is a generic medicinal product within the meaning of Article 10(1) of Directive 2001/83, the active substance of which is bendamustine hydrochloride. The application states that the reference medicinal product is Levact®.

25. On 17 January 2014, the competent Danish authorities issued an evaluation report at the end of the decentralised procedure for Helm's application, stating that Ribomustin was to be treated as the reference medicinal product for the purpose of calculating the end of the data exclusivity period. As a MA for Ribomustin had been issued on 19 July 2005, the data exclusivity period had therefore expired in

[7] At the relevant time known as the *Agence française de sécurité sanitaire des produits de santé.*

those States which have a six-year data exclusivity period. While all of the States participating in the decentralised procedure had used Levact® as the reference product, according to the Danish evaluation report, the MA issued for Levact® must be regarded as being included within the global MA issued for Ribomustin.

26. The evaluation report also states that the reference Member State and the concerned States have approved Helm's application. During the application procedure, the concerned Member States did not mention any risks to human health linked to Alkybend.

27. The competent Finnish authority, *Lääkealan turvallisuus- ja kehittämiskeskus Fimea* ("*Fimea*") issued a national MA for Alkybend pursuant to the decentralised procedure on 28 March 2014. Astellas Pharma appealed against Fimea's decision to the Helsinki Administrative Court, which dismissed the appeal on the ground *inter alia* that Astellas Pharma was issued with the first MA for that medicinal product on 19 July 2005, and the data exclusivity period for that product is six years, meaning that a MA could be issued for the generic product Alkybend on 28 March 2014.

28. Astellas Pharma made a subsequent appeal to the *Korkein hallinto-oikeus* (Supreme Administrative Court), which is asked to decide whether Fimea was, by its decision of 28 March 2014, entitled to issue a MA to Helm for Alkybend, or whether it should have rejected the application on the basis that it infringes Astella Pharma's data exclusivity period with respect to Levact®. In these circumstances the *Korkein hallinto-oikeus* has referred the following questions to the Court:

"*1. Are Articles 28(5) and 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 to be as interpreted as meaning that the competent authorities of the concerned Member State in the decentralised procedure for marketing authorisations 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 marketing authorisation 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 marketing authorisation 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?*

III — Analysis

The first question referred

29. By its first question, the referring court essentially asks whether the competent authorities of the concerned Member State in the decentralised procedure for MAs for generic medicinal products provided in Article 28(3) of Directive 2001/83 may themselves, when issuing a national MA, determine the time from which the data exclusivity period for the reference medicinal product begins to run.

30. In Ireland's submission, this question should be answered in the negative, based on the wording, scheme and purpose of the decentralised procedure.

31. First, it is clear from the express wording of the Directive, as interpreted by the Court of Justice, that it is the reference Member State, and not the concerned Member State, which has competence for assessing the substantive merits of an application for a MA.

32. In the case of the mutual recognition procedure, i.e., where the medicinal product has already received a MA at the time of application, this is provided by Article 28(2) of Directive 2001/93 ("…*the concerned Member States shall recognise the marketing authorisation granted by the reference Member State*…). In the case of the decentralised procedure, i.e., where the medicinal product has not received a MA at the time of application, this is provided by Article 28(3)-(5) of the Directive. Specifically, the applicant "*shall request the reference Member State to prepare a draft assessment report, a draft summary of product characteristics and a draft of the labelling and package leaflet*" (Article 28(3)). This report "*shall*" be sent to the concerned Member States, which "*shall approve*" the report and other documents (Article 28(4)), and "*shall adopt a decision*" in conformity with the approved assessment report (Article 28(5)).

33. The sole exception to the above arises in the circumstances envisaged by Article 29(1), i.e., if the concerned Member State has concerns of a "*potential serious risk to public health*". If this is the case, the procedure set out in Article 29 (which requires referral to the coordination group) must be followed.

34. The Court of Justice has confirmed that the obligation of mutual recognition of a MA granted by another Member State is, where the requirements of Article 28(2) are satisfied, in principle absolute - subject only to the Article 29(1) derogation. Thus in Case C-452/06 *Synthon* ECLI:EU:C:2008:565, the Court held (at §§25 – 28):

"*In accordance with the objective of abolishing all barriers to the free movement of medicinal products in the Community referred to in recitals 12 and 14 in the preamble to the directive, it is apparent from Article 28(4) that a marketing authorisation granted by a Member State must, in principle, be recognised by the competent authorities in other Member States within 90 days of receipt of the application and the assessment report from the reference Member State, and that that recognition is not dependant on the procedure followed by the reference Member State for granting that authorisation.*

It must then be pointed out that such an obligation of mutual recognition is strictly delineated by Article 28 of Directive 2001/83.

First, an application for mutual recognition must be held to be valid where, in accordance with the requirements of Article 28(2), it is accompanied by the information and particulars referred to in Articles 8, 10(1) and 11 of that directive, the dossier submitted is identical to the dossier accepted by the reference Member State, and any additions or amendments contained in the file have been identified by the applicant.

Second, it is clear from the wording of Article 28(4) of Directive 2001/83 that the existence of a risk to public health, within the meaning of Article 29(1) of that directive, constitutes the only ground that a Member State is entitled to rely on to object to the recognition of a marketing authorisation granted by another Member State. In addition, Article 29 provides that a Member State wishing to rely on such a ground is required to comply with a specifically prescribed procedure for provision of information, concerted action, and arbitration. "

35. In that case, the Court expressly rejected the argument that concerned Member States may be able to enter into their own assessment of the merits of an application for a MA, outside the scope of Article 29(1), holding that (§§31 – 32):

> "*…it cannot be accepted, as submitted by SKB and the governments of the United Kingdom and Norway, that the Member State in receipt of an application for mutual recognition is entitled – outside of the situation where there is a risk to public health referred to in Article 29 – to carry out a fresh assessment of the data on essential similarity which the reference Member State relied on in accepting an abridged application.*
>
> *As the Advocate General stated in points 100 and 101 of his Opinion, not only would such an interpretation run counter to the very wording of Articles 28 and 29 of Directive 2001/83, but it would render those provisions redundant. If a Member State which was asked to recognise an authorisation already granted by another Member State could make that recognition subject to a second assessment of all or part of the application for authorisation, that would deprive the mutual recognition procedure established by the Community legislature of all meaning and seriously compromise the attainment of the objectives of Directive 2001/83 such as, in particular, the free movement of medicinal products in the internal market, referred to in paragraph 25 above*."

36. In Ireland's submission, similar considerations apply to the decentralised procedure set out in Article 28(3). As with the mutual recognition procedure, the wording of Article 28(3) is "*unequivocal*":[8] the concerned Member State "*shall approve*" the draft assessment report of the reference Member State and "*shall adopt*" a decision accordingly. The sole exception to these obligations arises if the Article 29(1) exception is made out. According to the Order for Reference, no public health concerns were raised by the concerned Member States in the present case.

37. Second, the above analysis also follows from the scheme and purpose of the decentralised procedure. As the preamble to Directive 2001/83 makes clear, a key aim of that Directive is to remove hindrances to trade in medicinal products

[8] See the Opinion of AG Bot in *Synthon*, §62 (discussing the mutual recognition procedure).

within the EU (see recitals (4) – (6) thereof). The mutual recognition and decentralised procedures seek to further this aim. This can be seen in recital (12) of the Directive, which provides,

> *"With the exception of those medicinal products which are subject to the centralized Community authorization procedure established by Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (14) a marketing authorization for a medicinal product granted by a competent authority in one Member State ought to be recognized by the competent authorities of the other Member States unless there are serious grounds for supposing that the authorization of the medicinal product concerned may present a risk to public health. In the event of a disagreement between Member States about the quality, the safety or the efficacy of a medicinal product, a scientific evaluation of the matter should be undertaken according to a Community standard, leading to a single decision on the area of disagreement binding on the Member States concerned...."*

38. Similarly, recital (15) of Directive 2001/83 makes clear that the responsibility of preparing assessment reports falls solely on the Member State that has authorised or who is actively considering the medicinal product, and aims to prevent duplication of effort between Member State authorities,

> "*In order better to protect public health and avoid any unnecessary duplication of effort during the examination of application for a marketing authorization for medicinal products, Member States should systematically prepare assessment reports in respect of each medicinal product which is authorized by them, and exchange the reports upon request. Furthermore, a Member State should be able to suspend the examination of an application for authorization to place a medicinal*

product on the market which is currently under active consideration in another Member State with a view to recognizing the decision reached by the latter Member State."

39. In his Opinion in *Synthon*, Advocate General Bot offered a helpful and detailed analysis of the underlying rationale of the mutual recognition procedure, which is also highly relevant here (at §§65 – 73):

"first of all, on the unity of the law. In order for a marketing authorisation to be recognised, the various national regimes for marketing authorisations must in point of fact be concordant. The Community pharmaceutical legislation fully harmonises the conditions for marketing medicinal products, and in particular the conditions for issuing marketing authorisations. It fixes the rules relating to analytical, toxico-pharmacological and clinical norms and protocols which the Member States are to follow in order to enable the competent authorities to make assessments on the basis of uniform tests and according to common criteria. It also lays down the conditions in which medicinal products must be manufactured, imported and labelled.

Next, the procedure for mutual recognition is based on mutual confidence between the Member States.

Under this procedure, a marketing authorisation is no longer a decision handed down on the basis of the law of the Member State concerned. That Member State must in fact rely on the scientific examination and assessment conducted by the competent authorities of the reference Member State.

In this spirit, the Member State concerned has very limited discretion. Under the wording of Article 28 of Directive 2001/83, its role is limited to verifying that the application for mutual recognition satisfies the requirements laid down in Article 28(2).

> *The Member State concerned must therefore satisfy itself that the dossier submitted to it contains the documents and particulars referred to in Articles 8 and 10 of the Directive and a summary of the characteristics of the product. It must also check that the dossier is identical with that accepted by the reference Member State, and that any additions or amendments it contains have been identified by the applicant.*
>
> *Contrary to the role it plays in the context of examination of an application for marketing authorisation under Article 19 of Directive 2001/83, the powers of the Member State dealing with an application for mutual recognition are therefore reduced to the strictly legal aspect of the application. It cannot therefore, in my view, make a fresh examination of the substance of the application for marketing authorisation or repeat the investigations already conducted in this connection by the reference Member State…".*

40. In so concluding, AG Bot further relied upon the scheme of Directive 2001/83, and in particular on the fact that a special procedure existed in cases where concerns pursuant to Article 29(1) arose (at §§71 – 73):

> *Finally, the mutual recognition procedure limits the grounds on which a Member State may refuse to recognise a marketing authorisation, which prevents it exercising any discretionary power.*
>
> *72. Thus, under Article 28(4) of Directive 2001/83, the Member State concerned may rely on the exception in Article 29(1) of the Directive only in order not to recognise within the time-limit the marketing authorisation issued by the reference Member State. It must therefore show that 'there are grounds for supposing that the marketing authorisation of the medicinal product concerned may present a risk to public health'. (25)*

> *73. That proviso is the only exception to the principle of the mutual recognition of marketing authorisations."*[9]

41. It followed that the examination of the concerned Member State must be (§§90 – 91):

> *"…confined to ascertaining whether the application has satisfied the requirements set out in Article 28(2) of the Directive. In such a case, the Member State concerned cannot have recourse to fresh scientific evaluations of the product. Nor, in my view, can it repeat tests already carried out by the reference Member State or, in this connection, carry out a fresh examination of the essential similarity of the product to the reference product. Such conduct would, by its very nature, run counter to the principle of mutual recognition. It would, furthermore, render nugatory the consultation and arbitration procedure established by the Community legislature which seeks to ensure that scientific evaluation of areas of disagreement should be performed at Community level.*
>
> *91. In addition, the Member State to which such an application is made remains bound to recognise that authorisation unless it is able to invoke an objective reason concerning the protection of public health. In that case, Directive 2001/83 offers it no choice other than to initiate the procedure provided for in Article 29 of the Directive*."

42. Indeed, if it were otherwise, and concerned Member States could make a fresh examination of the application and reject it for a reason other than a potential risk to public health, the Advocate General noted that this would (§§99 – 102):

> *"render meaningless the principle of mutual recognition, which constitutes the keystone of Article 28 of Directive 2001/83.*

[9] See also, §80 of the Opinion in that case.

In fact, if we were to allow the Member State concerned to examine and assess the application for mutual recognition in the same way as it examines an application for marketing authorisation, that would deprive the mutual recognition procedure of all meaning. On that interpretation we would run the risk of divergent assessments by national authorities. Furthermore, recourse by the Member State concerned to fresh scientific evaluations of the product could be interpreted as a sign of mistrust with regard to the checks already carried out by the competent authorities of the reference Member State. Such an approach would therefore destroy the vital mutual confidence between the Member States.

Furthermore, if the Member State concerned could on its own initiative reject an application for mutual recognition, there would be no uniformity of national marketing authorisations, and such an approach would negate the effectiveness of the consultation and arbitration procedure established for this purpose by the Community legislature.

Finally, if we were to allow the Member State concerned to rely on a ground other than that expressly referred to in Article 29(1) of Directive 2001/83, in order not to recognise a marketing authorisation, such an approach would have the effect of limiting the scope of the obligation set out in Article 28(4) of the Directive."

43. As the Court recognised in Case C-527/07 *Generics (UK)* ECLI:EU:C:2009:379, the situation would be different in the event that no MA had been granted, such that the medicinal product cannot constitute a reference medicinal product (see §§33 – 34). This is not the case here, where it is common case that Ribomustin was authorised by the German authorities in July 2005, and that Levact® was granted a marketing authorisation in July 2010.

44. Rather, the question raised by the national court in the present case is essentially whether the Finnish authority may investigate and second guess the Danish authority's finding that the data exclusivity period has expired for Levact® (and,

as part of that, the Danish authority's finding that Ribomustin was to be treated as the reference medicinal product, and the MA issued for Levact® must be included within the global MA issued for Ribomustin).

45. The answer to the first question should therefore, in Ireland's submission, be that it is not open to the competent authorities of the concerned Member State in the decentralised procedure for MAs for generic medicinal products provided in Article 28(3) of Directive 2001/83 to determine, when issuing a national MA, the time from which the data exclusivity period for the reference medicinal product begins to run. Rather, the national authority of a concerned Member State is bound to adopt a decision in conformity with the assessment report and product information, as approved by the national authority of the reference Member State, unless the procedure envisaged by Article 29 of Directive 2001/38 has been invoked.

The second question referred

46. By its second question, the referring court asks whether, if its first question is answered in the negative, a court of the concerned Member State must determine the time from which the period of data exclusivity starts to run. The referring court specifically queries the relevance of the right to effective legal protection with regard to data exclusivity provided for in Article 47 of the Charter and Article 10 of Directive 2001/83, and asks whether this right requires the national court to examine whether the original MA (in this case, granted in Germany) was issued in accordance with Directive 2001/83.

47. In Ireland's submission, a national court of the concerned Member State reviewing the decision of the concerned Member State's authority to issue a MA has no competence to enter into a substantive analysis of the approach adopted by the reference Member State in its Article 28(3) assessment report, just as the authority has no such competence at first instance. Again, this is subject to one exception, namely, where the proviso of Article 29 of Directive 2001/83 applies.

48. Ireland submits that this follows logically from the role of the national court in any such appeal or judicial review procedure. In particular, it is the role of that court to assess whether the authority of the concerned Member State (in this case, Fimea) carried out its duties in accordance with its legal obligations. That authority cannot reasonably be criticised by a national court for failing to undertake a substantive assessment of the reference Member State's approach, in circumstances where, as explained in relation to the first question, it is specifically forbidden by Directive 2001/83 from carrying out such assessment.

49. The national court asks whether the requirement of an effective remedy, as provided by EU law, changes the above conclusion. In Ireland's view, it does not.

50. Article 47 of the Charter provides, insofar as relevant,

"*Everyone whose rights and freedoms guaranteed by the law of the Union are violated has the right to an effective remedy before a tribunal in compliance with the conditions laid down in this Article.*

Everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal previously established by law…"

51. In Case C-104/13 *Olainfarm* ECLI:EU:C:2014:2316, the Court of Justice held that Article 10 of Directive 2001/83, in conjunction with Article 47 of the Charter, itself conferred a right to an effective remedy on the MA holder for the reference medicinal product, in an application by for an MA of a generic product of another manufacturer pursuant to that Article.

52. Ireland notes that, in *Olainfarm*, the right to an effective remedy of the holder of the reference product to enforce the conditions of Article 10 could, logically, only be vindicated before the national courts of the Member State whose authority had granted the MA for the generic product. In that case, both the reference product MA and the generic product MA had been granted by the same Member State, Latvia. There was therefore no issue of mutual recognition of MAs granted by another Member State.

53. That is in contrast to the facts of the instant case, where the MA for Ribomustin was granted by the competent German authority, the BfArM, the MA for Levact® was granted by the French authorities, and the draft assessment report in the Article 28(3) procedure was prepared by the Danish authorities. Astellas Pharma now seeks to access the Finnish courts, as a concerned Member State, seeking to overturn Fimea's assessment of the data exclusivity period for Levact®.

54. Fundamentally, however, that claim seeks to overturn the assessment of the Danish authorities that the MA for Levact® must be regarded as being included within the global MA issued for Ribomustin and, as part of that, seeks to re-open the assessment of the German and French authorities in their MA decisions.

55. In Ireland's submission, such a claim runs counter to the system of trust and mutual recognition contained in Title III of Directive 2001/38, as set out above, and would impair achievement of that Directive's aim of removing hindrances to cross-border trade in medicinal products.

56. Rather, the natural forum for Astellas Pharma to challenge the assessment of the Danish authorities would be before the Danish courts, the natural forum to challenge the German MA would be before the German courts, and the natural forum to challenge the French MA would be before the French courts. Astellas Pharma is not, therefore, deprived of an effective remedy contrary to Article 47 of the Charter or any other provision of EU law. On this point, Ireland recalls that, as the Court of Justice has held, reasonable national limitation rules are compatible with Article 47 of the Charter as long as they satisfy the principle of effectiveness.[10]

57. For these reasons, Ireland submits that the response to the second question referred should be that the national courts of a concerned Member State are not

[10] Thus the Court has held, that, "*As regards the principle of effectiveness, the Court has stated that it is compatible with European Union law to lay down reasonable time-limits for bringing proceedings in the interests of legal certainty which protects both the individual and the authorities concerned. Such time-limits are not liable to make it in practice impossible or excessively difficult to exercise the rights conferred by European Union law*." See for instance Case C-542/08 *Barth* ECLI:EU:C:2010:193, at §28 and case-law cited therein.

competent to determine the time from which the period of data exclusivity starts to run, or whether the original marketing authorisation granted in another Member State was issued in accordance with the rules laid down by Directive 2001/83.

IV — Proposed answer to the questions referred

58. In the light of the foregoing, Ireland respectfully submits that the Court of Justice should answer the questions referred by the *Korkein hallinto-oikeus* as follows:

It is not open to the competent authorities of the concerned Member State in the decentralised procedure for MAs for generic medicinal products provided in Article 28(3) of Directive 2001/83 to determine, when issuing a national marketing authorisation, the time from which the data exclusivity period for the reference medicinal product begins to run. Rather, the national authority of a concerned Member State is bound to adopt a decision in conformity with the assessment report and product information, as approved by the national authority of the reference Member State, unless the procedure envisaged by Article 29 of Directive 2001/38 has been invoked.

The national courts of a concerned Member State are not competent to determine the time from which the period of data exclusivity starts to run, or whether the original marketing authorisation granted in another Member State was issued in accordance with the rules laid down by Directive 2001/83.

Dated 22 February 2017

Signed: Tony Joyce
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On behalf of Eileen Creedon, Chief State Solicitor

Signed: Lorraine Williams
Agent for Ireland
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