Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

12 February 2015 *

(Reference for a preliminary ruling — 2003 Act of Accession to the European Union — Annex IV — Chapter 2 — Specific Mechanism — Importation of a patented pharmaceutical product — Prior notification requirement)

In Case C-539/13,

REQUEST for a preliminary ruling under Article 267 TFEU from the Court of Appeal (England and Wales) (Civil Division) (United Kingdom), made by decision of 13 May 2013, received at the Court on 14 October 2013, in the proceedings

Merck Canada Inc.,

Merck Sharp & Dohme Ltd

v

Sigma Pharmaceuticals plc,

THE COURT (Third Chamber),

composed of M. Ilešič, President of the Chamber, A. Ó Caoimh, C. Toader, E. Jarašiūnas and C.G. Fernlund (Rapporteur), Judges,

Advocate General: N. Jääskinen,

Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 4 September 2014,

after considering the observations submitted on behalf of:

— Merck Canada Inc., by D. Anderson QC, S. Bennett, advocate, and T. Hinchliffe, Barrister,

— Sigma Pharmaceuticals plc, by M. Howe QC, and I. Jamal, Barrister, instructed by J. Maitland-Walker, Solicitor,

— the Czech Government, by M. Smolek and J. Vitáková, acting as Agents,

— the European Commission, by F.W. Bulst, A. Sipos and G. Wilms, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 23 October 2014,

* Language of the case: English.

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of the specific mechanism provided for in Chapter 2 of Annex IV to the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ 2003 L 236, p. 33) ('the 2003 Act of Accession').

2 The request has been made in proceedings between Merck Canada Inc. ('Merck Canada') and Merck Sharp & Dohme Ltd ('MSD'), the claimants in the main proceedings, and Sigma Pharmaceuticals plc ('Sigma') concerning the importation into the United Kingdom of a pharmaceutical product called 'Singulair' from Poland.

Legal context

3 Chapter 2 of Annex IV to the 2003 Act of Accession, entitled 'Company law', is worded as follows:

'Specific Mechanism

With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia, the holder, or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate ('SPC') in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.

Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection ('the Specific Mechanism').'

The dispute in the main proceedings and the questions referred for a preliminary ruling

4 Merck Canada is the holder of European Patent EP UK No 480 717 in respect of 'Montelukast, or a pharmaceutically acceptable salt thereof, preferably montelukast sodium'. That patent led to the grant of an SPC, which expired on 24 February 2014.

5 Montelukast is used as an active ingredient of Singulair.

6 The first authorisation to place Singulair on the market in the European Union was granted by the competent Finnish authorities on 25 August 1997. It received its marketing authorisation in the United Kingdom on 15 January 1998.

7 Merck Sharp and Dohme (Ireland) Ltd, a company incorporated under Irish law, was the exclusive licensee of the patent and the SPC from 1 October 2007 to 1 December 2010.

8 On 22 June 2009, Pharma XL Ltd ('Pharma XL'), an associated company of Sigma, gave MSD notification, at its address in the United Kingdom, of its intention to import Singulair in 5 mg and 10 mg dosage forms from Poland to the United Kingdom. At that time, MSD held the marketing authorisation in the United Kingdom but had no rights in the patent or the SPC in force.

9 On 14 September 2009, Pharma XL filed two applications with the Medicines and Healthcare Products Regulatory Agency for parallel import licenses for Singulair in 5 mg and 10 mg dosage forms, respectively. By decisions of 21 May and 10 September 2010, the Medicines and Healthcare Products Regulatory Agency granted those licenses. Those decisions referred to Sigma as one of the authorised importers of the pharmaceutical product in question.

10 On three occasions between 4 June and 15 September 2010, Pharma XL gave MSD notification of its intention to import Singulair and to present the repackaged product in 5 mg and 10 mg dosage forms.

11 Following those notifications, Sigma began to import Singulair from Poland in a form repackaged by Pharma XL.

12 On 14 December 2010, Merck Canada and MSD wrote to Pharma XL objecting to the parallel imports of Singulair. Upon receipt of that letter on 16 December 2010, Sigma immediately ceased sales of Singulair from Poland. The value of Sigma's parallel imports of Singulair up to that date is estimated to be in excess of £2 million, as is the value of the Sigma's stocks of Singulair repackaged for the United Kingdom market.

13 On 10 June 2011, Merck Canada and MSD brought infringement proceedings before the Patents County Court. Their application was granted by judgment of 27 April 2012. Sigma appealed against that decision before the referring court.

14 It is apparent from the information provided by the referring court that the parties to the main proceedings accept that the Specific Mechanism applies to the patent and the SPC for Montelukast, so that, in principle, their protection may be invoked to prevent the parallel importation of Singulair from Poland. On the other hand, the parties disagree as to the manner in which that protection may be enforced. Sigma is of the view that it is incumbent on the holder, or beneficiary, of the patent or SPC to demonstrate his intention to rely on that protection, whereas Merck Canada and MSD consider that such protection is automatically applicable, without any prior formal requirements or declaration on the part of the holder or his beneficiary.

15 In those circumstances, the Court of Appeal (England and Wales) (Civil Division) decided to stay proceedings and refer the following questions to the Court of Justice for a preliminary ruling:

'(1) May the holder, or his beneficiary, of a patent or [SPC] rely upon his rights under the first paragraph of the Specific Mechanism only if he has first demonstrated his intention to do so?

(2) If the answer to Question 1 is yes:

(a) How must that intention be demonstrated?

(b) Is the holder, or his beneficiary, precluded from relying upon his rights with respect to any import or marketing of the pharmaceutical product in a Member State that occurred prior to the demonstration of his intention to rely upon those rights?

(3) Who must give the prior notification to the holder or beneficiary of a patent or [SPC] under the second paragraph of the Specific Mechanism? In particular:

(a) Must the prior notification be given by the person intending to import or market the pharmaceutical product?

or

(b) Where, as permitted by the national regulatory system, an application for regulatory approval is made by someone other than the intended importer, can prior notification given by the applicant for regulatory approval be effective if that person does not itself intend to import or market the pharmaceutical product but where the intended importation and marketing will be carried out under the applicant's regulatory approval?; and

(i) Does it make any difference if the prior notification identifies the person that will import or market the pharmaceutical product?

(ii) Does it make any difference if the prior notification is given and the application for regulatory approval is made by one legal person within a group of companies which form a single economic unit, and the acts of importation and marketing are to be carried out by another legal person within that group under licence from the first legal person, but where the prior notification does not identify the legal person that will import or market the pharmaceutical product?

(4) To whom must prior notification be given under the second paragraph of the Specific Mechanism? In particular:

(a) Is the beneficiary of a patent or [SPC] limited to persons who have a legal right under national law to bring proceedings to enforce that patent or [SPC]?

or

(b) In a case where a group of companies forms a single economic unit comprising a number of legal entities, is it sufficient if the notification is addressed to a legal entity which is the operating subsidiary and marketing authorisation holder in the Member State of importation rather than the entity within the group that has a legal right under national law to bring proceedings to enforce that patent or [SPC], on the basis either that such legal entity may be characterised as a beneficiary of the patent or SPC, or that it is to be expected that such notification in the ordinary course of events will to come to the attention of the persons who make decisions on behalf of the patent or SPC holder?

(c) If the answer to Question 4(b) is yes, is a notification which is otherwise compliant rendered non-compliant if it is addressed to the "the Manager, Regulatory Affairs" of a company when that company is not the entity within the group that has a legal right under national law to bring proceedings to enforce that patent or [SPC] but is the operating subsidiary or marketing authorisation holder in the Member State of importation and when that Regulatory Affairs department in practice regularly receives notifications from parallel importers regarding the Specific Mechanism and other matters?'

Consideration of the questions referred

Questions 1 and 2

16 By its first two questions, which it is appropriate to examine together, the Court of Appeal is asking, in essence, whether the Specific Mechanism requires the holder, or beneficiary, of a patent or SPC to give notification of his intention to oppose the proposed importation before invoking his rights under the first paragraph of the Specific Mechanism and, if so, to specify exactly how such prior notification is to be given.

17 In particular, by its questions, the referring court is seeking to ascertain whether the Specific Mechanism precludes the holder, or beneficiary, of a patent or SPC from the possibility of relying on his rights under the first paragraph of that mechanism with respect to the importation and marketing of a pharmaceutical product protected in a Member State in which the product in question enjoys patent or supplementary protection where, as in the main proceedings, the importation and marketing took place before the holder, or beneficiary, of the patent or SPC demonstrated his intention to rely on those rights, that intention not having been demonstrated during the one-month period laid down in the second paragraph of the mechanism.

18 Merck is of the view that that question must be answered in the negative. The sole purpose of the requirement to give prior notification laid down in the second paragraph of the Specific Mechanism is to afford the person enjoying the protection conferred by the patent or SPC the opportunity to take preventive measures, where necessary. That is why the Specific Mechanism imposes obligations only on the parallel importer. Merck claims that it is not possible, on the basis of the Court's case-law, to answer the first question in the affirmative. In particular, it maintains that the judgment in *Generics and Harris Pharmaceuticals* (C-191/90, EU:C:1992:407) is irrelevant.

19 Merck submits that there is no justification for the argument that the Specific Mechanism imposes an obligation to give prior notification, which is never imposed on the holder, or beneficiary, of a patent or SPC seeking to enforce his rights. Merck considers that the interpretation that it advocates places no undue burden on parallel importers. On the other hand, a requirement for prior notification would have undesirable consequences where, for practical reasons, the patent holder did not receive the parallel importer's notification or failed to reply to it. More generally, Merck submits that if there were an obligation to give prior notification, the Specific Mechanism would have to define precisely how such an obligation is to be discharged, which is not the case.

20 The European Commission and, in essence, Sigma are of the view that it is clear from a purposive and systematic interpretation of the Specific Mechanism that the holder, or beneficiary, of a patent or SPC is required, within the period prescribed in the second paragraph of that mechanism, to reply to a notification and to demonstrate his intention to oppose the proposed importation.

21 Sigma and the Commission consider that the functioning of the Specific Mechanism presupposes that each of the parties concerned is to make a sincere effort to respect the other's legitimate interests (see, by analogy, judgments in *Boehringer Ingelheim and Others*, C-143/00, EU:C:2002:246, paragraph 62, and *The Wellcome Foundation*, C-276/05, EU:C:2008:756, paragraph 34). That conclusion is supported by the fact that the Specific Mechanism expressly provides that a one-month period is to elapse before the importation can be carried out.

22 That period implies, for the holder, or beneficiary, of the patent or SPC, a requirement to respond to the notification and to state whether he intends to prohibit the marketing of the product in question. The purpose of the one-month period is to ensure that the holder or beneficiary responds promptly, so as to protect the legitimate interests and expectations of the potential importer or marketer, who

cannot be left in a state of legal uncertainty. As a consequence, a duly notified holder, or beneficiary, of a patent or SPC who fails to reply and does not demonstrate his intention to rely on the rights provided for in the Specific Mechanism is precluded from retroactively relying on those rights.

23 In order for the reply to be given to the national court to be a useful one, it should be recalled that, under Article 2 of the 2003 Act of Accession, as from the date of accession, the provisions of the original Treaties and the acts adopted by the institutions and the European Central Bank before accession are binding on the new Member States and apply in those States under the conditions laid down in those Treaties and in that act.

24 It follows that, as from the date of accession, the principles laid down by the Court on the basis of Treaty articles relating to the free movement of goods are applicable to trade between the new Member States and the other EU Member States. The Court has consistently held that the proprietor of an industrial or commercial property right protected by the legislation of a Member State cannot rely upon that legislation to prevent the importation of a product which has been lawfully marketed in another Member State by the proprietor himself or with his consent. The Court has inferred from that principle that an inventor, or someone deriving rights from him, cannot invoke the patent which he holds in one Member State to prevent the importation of a product freely marketed by him in another Member State where the product is not patentable (judgments in *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraphs 11 and 12; *Merck*, 187/80, EU:C:1981:180, paragraphs 12 and 13; and *Generics and Harris Pharmaceuticals*, C-191/90, EU:C:1992:407, paragraph 31).

25 However, the Specific Mechanism provides for a specific derogation from that principle. It is the Court's well established case-law that provisions in an Act of Accession which permit exceptions to or derogations from rules laid down by the Treaties must be interpreted restrictively with reference to the Treaty provisions in question and must be limited to what is absolutely necessary to attain the objective pursued (judgment in *Apostolides*, C-420/07, EU:C:2009:271, paragraph 35 and the case-law cited). As the Advocate General observed at point 18 of his Opinion, the Specific Mechanism seeks to achieve a balance between effective protection of patent or SPC rights and the free movement of goods.

26 The first paragraph of the Specific Mechanism provides that the holder, or beneficiary, of a patent or SPC 'may rely on' the rights granted by that patent or SPC 'in order to prevent the import and marketing' of the protected product, but gives no further details.

27 The second paragraph of the Specific Mechanism adds that '[a]ny person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection.'

28 The Specific Mechanism does not go so far so as to impose on a person intending to import a protected pharmaceutical product an obligation to obtain the express prior consent of the holder, or beneficiary, of a patent or SPC. However, any person contemplating importing a protected pharmaceutical product is required to comply with a number of obligations and formalities before he may import such a product.

29 First, such a person is required to give notification of his intention to the holder, or beneficiary, of the patent or SPC, so as to enable the latter, where appropriate, to invoke the rights conferred by the patent or SPC to prevent the importation and marketing of the product concerned, in accordance with the conditions which form the subject-matter of the third and fourth questions referred. Next, once such notice has been duly given, there is a waiting period of one month. Finally, it is only upon expiry of that period that the person in question may apply to the competent authorities for authorisation to import the protected pharmaceutical product. It follows from the above that the

proposed import operation cannot go ahead without the prior authorisation of the competent national authorities, which cannot be sought before the expiry of the one-month waiting period following receipt of the notification by the person enjoying the protection conferred by the patent or SPC.

30 Accordingly, the Specific Mechanism added to national authorisation procedures for the importation of pharmaceutical products a requirement to give prior notification of the proposed operation to the holder, or beneficiary, of the patent or SPC, to which a one-month waiting period is attached. The purpose of that period is to enable the person enjoying the protection conferred by the patent or SPC to prevent any importation and the importer to be apprised of any such decision as soon as possible so that he may draw the relevant conclusions.

31 It is true that no provision in the Specific Mechanism expressly requires such a holder or beneficiary to communicate, before commencing any legal proceedings to that end, his intention to oppose a proposed importation of which he has been duly notified. However, if the holder, or beneficiary, of the patent or SPC fails to take advantage of that period in order to indicate his objection, the person proposing to import the pharmaceutical product in question may legitimately apply to the competent authorities for authorisation to import the product and, where appropriate, import and market it.

32 Nevertheless, in such a situation, the holder, or beneficiary, of the patent or SPC cannot be regarded as having forfeited the right to rely on the Specific Mechanism. Although he may not obtain compensation for the loss suffered as a result of the parallel imports which he failed to oppose in good time, such a holder or beneficiary remains, in principle, free to oppose future importation and marketing of the pharmaceutical product protected by the patent or SPC.

33 In the light of the foregoing, the answer to Questions 1 and 2 is that the second paragraph of the Specific Mechanism must be interpreted as not requiring the holder, or beneficiary, of a patent of SPC to give notification of his intention to oppose a proposed importation before invoking his rights under the first paragraph of that mechanism. However, if such a holder or beneficiary does not indicate such an intention during the one-month waiting period laid down in the second paragraph of the mechanism, the person proposing to import the pharmaceutical product in question may legitimately apply to the competent authorities for authorisation to import the product and, where appropriate, import and market it. The specific mechanism thus denies that holder or his beneficiary the possibility of relying on his rights under the first paragraph of the mechanism with regard to any importation and marketing of the pharmaceutical product carried out before such an intention was indicated.

Question 4

34 By its fourth question, the referring court is asking, in essence, to whom must the notification provided for in the second paragraph of the Specific Mechanism be given.

35 It is apparent from the clear wording of that mechanism that the notification must be given to the ‘holder’ or ‘beneficiary’ of the protection conferred by a patent or SPC. The term ‘holder’ must be understood, according to its generally accepted meaning, as referring to the person identified by the patent as the recipient of the protection conferred by the patent.

36 Similarly, the term ‘beneficiary’ (‘ayant droit’ in the French version and ‘der von ihm Begünstigte’ in the German version) must be understood, according to its generally accepted meaning, as designating any person who enjoys rights conferred by law on the holder of the patent, inter alia by virtue of a licence agreement.

37 It therefore follows from a literal interpretation of the Specific Mechanism that the notification referred to in the second paragraph of the mechanism must be given to the holder of the patent or SPC or to any other person enjoying rights conferred by law by that patent or SPC.

38 Sigma and the Commission are of the view that that literal interpretation is at odds with the purpose of the Specific Mechanism. They contend that the term 'beneficiary' refers to any company which, within a group, may reasonably be regarded as acting on behalf of the patent holder. That would be the case, for example, as regards a company which holds the marketing authorisation for the relevant pharmaceutical product. Sigma maintains that to make parallel importers responsible for determining which entity, within a group of companies, is the patent holder for a pharmaceutical product would be unreasonable and artificial where the group operates as a single economic unit. The Commission accepts, however, that the possibility cannot be ruled out that, in certain exceptional cases, if notification were given to such a person, that would be insufficient for the purpose of protecting the interests of the holder or his beneficiary.

39 However, it should be recalled that the purpose of the notification requirement is to enable the holder, or beneficiary, of a patent or SPC to prevent the import and marketing of a protected product by being informed, in advance, of any proposed parallel importation from one of the new Member States in which it was not possible to obtain such protection before its accession to the EU. By imposing that notification requirement, the EU legislature made clear its intention to strike a balance between the risk of imposing too many formal requirements on the parallel importer and the risk of placing the person enjoying the protection conferred by a patent of SPC, or his beneficiary, in a position of legal uncertainty.

40 It should be noted in that regard that patents and SPCs are, by their nature, subject to rules on public disclosure under which any person may easily ascertain the name of the patent or SPC holder. As a consequence, to require the parallel importer to first identify the holder of the patent or SPC cannot be regarded as imposing an unduly onerous burden on the importer. It is quite conceivable that a third party may encounter some difficulty in identifying with the requisite degree of certainty the entity which, within a multinational group, enjoys the rights conferred by law by a patent or SPC. However, as the Specific Mechanism does not systematically require such identification, it is always open to the person seeking to import the goods in question to give notification to the patent or SPC holder.

41 To accept that notification may be given to other persons on the ground that such persons form, together with the holder, or beneficiary, of the patent or SPC, a single undertaking, or that, as a result of their conduct or status as holder of the marketing authorisation for the relevant pharmaceutical product, those persons give the appearance of being the holder's beneficiary, would be liable to undermine the effectiveness of the Specific Mechanism, which is based on prior notification being given of the proposed importation. Such an interpretation might place the person enjoying the protection conferred by the patent in a position of legal uncertainty, at odds with the objective pursued by the Specific Mechanism.

42 In addition to the fact that it fails to have due regard for the letter of the Specific Mechanism, it would not be possible, on the basis of the interpretation advocated by Sigma and the Commission, to maintain the balance which that mechanism seeks to achieve.

43 The answer to Question 4 is therefore that the second paragraph of the Specific Mechanism must be interpreted as meaning that the notification must be given to the holder, or beneficiary, of the patent or SPC, the latter term designating any person enjoying the rights conferred by law on the patent or SPC holder.

Question 3

44 By its third question, the referring court is asking, in essence, who must give the notification required under the second paragraph of the Specific Mechanism.

45 Sigma and the Commission contend that the Specific Mechanism does not require the potential importer to give notification personally or require that the notification should specify precisely the identity of the potential importer.

46 As observed by the Advocate General at point 47 of his Opinion, it should be noted that while the Specific Mechanism provides that it is the person intending to import the product at issue that must demonstrate compliance with the notification requirement, that provision, due to its use of the passive voice in the majority of the language versions, does not state unequivocally that that is the person who is personally required to carry out the notification ('[a]ny person intending to import … shall demonstrate … that one month's prior notification has been given').

47 In view of that ambiguity, that provision must be interpreted in the light of its purpose and context. As observed at paragraph 39 above, the purpose of the notification requirement is to enable the holder, or beneficiary, of a patent or SPC to prevent the import and marketing of a protected product.

48 As submitted, in essence, by the Czech Government, in order for the holder, or beneficiary, of the patent or SCP to be able to make an informed decision as to whether to oppose the importation, where necessary by commencing infringement proceedings, it is essential that the notification should identify clearly the person proposing to carry out the importation. The interests of the person enjoying the protection conferred by the patent or SPC, or his beneficiary, would not be adequately protected if the notification did not contain that information.

49 On the other hand, it would be too formalistic to interpret the terms of the Specific Mechanism as going so far as to require that the person who is to carry out the notification must be the person intending to import or market the product in question, bearing in mind that the Specific Mechanism does not expressly lay down such a requirement.

50 The answer to Question 3 is therefore that the second paragraph of the Specific Mechanism is to be interpreted as meaning that that provision does not require the person intending to import or market the pharmaceutical product in question to give notification himself, provided that it is possible from the notification to identify that person clearly.

Costs

51 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Third Chamber) hereby rules:

1. **The second paragraph of the Specific Mechanism provided for in Chapter 2 of Annex IV to the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded must be interpreted as not requiring the holder, or beneficiary, of a patent or supplementary protection certificate to give notification of his intention to oppose a proposed importation before invoking his rights under the first paragraph of that**

mechanism. However, if such a holder or beneficiary does not indicate such an intention during the one-month waiting period laid down in the second paragraph of the mechanism, the person proposing to import the pharmaceutical product in question may legitimately apply to the competent authorities for authorisation to import the product and, where appropriate, import and market it. The Specific Mechanism thus denies that holder or his beneficiary the possibility of relying on his rights under the first paragraph of the mechanism with regard to any importation and marketing of the pharmaceutical product carried out before such an intention was indicated.

2. **The second paragraph of the Specific Mechanism must be interpreted as meaning that the notification must be given to the holder, or beneficiary, of the patent or the supplementary protection certificate, the latter term designating any person enjoying the rights conferred by law on the holder of the patent or the supplementary protection certificate.**

3. **The second paragraph of the Specific Mechanism is to be interpreted as not requiring the person intending to import or market the pharmaceutical product in question to give notification himself, provided that it is possible from the notification to identify that person clearly.**

[Signatures]