Reports of Cases

OPINION OF ADVOCATE GENERAL
JÄÄSKINEN
delivered on 23 October 2014[1]

**Case C-539/13**

**Merck Canada Inc.**
**and**
**Merck Sharp & Dohme Ltd**
**v**
**Sigma Pharmaceuticals PLC**
**(Request for a preliminary ruling from the**

**Court of Appeal (England and Wales) (Civil Division) (United Kingdom))**

(Intellectual Property — Trade marks — Parallel imports from Poland into the United Kingdom of a pharmaceutical product — Interpretation of the Specific Mechanism provided for in Chapter 2 of Annex IV to the Act of Accession of 2003 — Requirement to notify holders and beneficiaries of patents or supplementary protection certificates of an intention to import certain medicinal products from an acceding Member State where patent protection has been unavailable — Effect of the patent owner's failure to respond to notification — Entity bound to make notification and entity to whom the notification is to be addressed)

## I – **Introduction**

1. In this order for reference the Court of Appeal (England and Wales) seeks guidance on the interpretation of the Specific Mechanism in Chapter 2 of Annex IV to the Act of Accession of 2003 ('the Specific Mechanism').[2] This provision sets out a derogation from the principle of the free movement of goods, and is designed to protect the interests of holders and beneficiaries of patents and supplementary protection certificates (in the following 'patent owner') in the old Member States with respect to certain pharmaceutical products, in situations in which the product concerned could not have been effectively protected in the new Member State before its accession to the European Union.

2. In a nutshell, the Specific Mechanism allows patent owners to rely on their rights with respect to imports from the new Member States, even after their accession, and even if the product in question was put on the market in that new Member State for the first time by a patent owner or with his consent. However, this can occur in only a narrow set of circumstances. That is, when at the time of

1 — Original language: English.

2 — Annex IV, Chapter 2, to the 2003 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. 797.

filing of the application for the patent or supplementary protection certificate in question in an old Member State (Member State A), such protection could not be obtained in the relevant new Member State (Member State B), and importation of the pharmaceutical product concerned is intended from Member State B into Member State A.

3. This is exactly the situation that has arisen in the main proceedings. Merck Canada Inc., a company incorporated under the laws of Canada, and Merck Sharp & Dohme Limited, a company incorporated under the laws of the United Kingdom (in the following jointly 'Merck'), have brought proceedings in the United Kingdom in reliance on the Specific Mechanism. Merck seek, inter alia, damages and destruction of stock, due to the alleged unlawful parallel importation by Sigma Pharmaceuticals PLC ('Sigma') into the United Kingdom from Poland of quantities of a Merck drug called 'Singulair', the generic name of which is 'Montelukast', even though Sigma purports to have provided prior notification as required by the Specific Mechanism.

4. After the United Kingdom Patents County Court found in favour of Merck, Sigma appealed to the Court of Appeal. It sent questions for a preliminary ruling seeking guidance concerning the consequences of the patent owner not responding to a notification made pursuant to the Specific Mechanism, the entities who may give the notification, and to whom the notification must be given.

## II – **Legal framework, facts and the question referred**

### A – *Applicable provisions*

5. The Specific Mechanism in Chapter 2 of Annex IV to the Act of Accession of 2003 is formulated as follows:

'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 in order to prevent the import and marketing [3] 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.'

### B – *Facts and questions referred*

6. A commercial version of Montelukast, namely Singulair, protected by Supplementary Protection Certificate in favour of Merck, [4] was placed on the market in the European Union in Finland on 25 August 1997 under a first Community medicinal product authorisation. It received its medical product authorisations in the United Kingdom on 15 January 1998.

3 — When reference is made throughout this Opinion to importation of a product covered by the Specific Mechanism, it also includes the act of marketing it. Similarly, reference to importers of such products equally refers to those engaged in the marketing of the products.

4 — After an application made on 10 October 1991, a Supplementary Protection Certificate was issued to Merck Canada Inc. with respect to Montelukast with an expiry date of 24 August 2012. A six month paediatric extension was subsequently granted, bringing its expiry date to 24 February 2013.

7. On 22 June 2009, Pharma XL Limited, an associated company of Sigma, sent a letter addressed to the 'Manager, Regulatory Affairs' of Merck Sharp & Dohme Limited at its address in the United Kingdom giving notice of its intention to import Singulair from Poland to the United Kingdom and to apply for the necessary authorisation therein. There was no reference to Sigma in the letter, and nor did it refer to any potential importer other than Pharma XL. [5]

8. The letter was received by Merck Sharp & Dohme Limited, but no reply was sent as a result of an administrative oversight, and even though it was in accordance with Merck's policy to reply to letters objecting to importations of this kind. In addition, Pharma XL Ltd wrote four subsequent letters to the Manager, Regulatory Affairs, Merck, Sharpe & Dome Limited, stating their intention to import Singulair from Poland, enclosing copies of the intended presentation of the repackaged product, and asking whether Merck had any objection. None of these letters received a response.

9. On 14 September 2009, Pharma XL Ltd filed two applications with the competent United Kingdom government agency for parallel import licences of Singulair. Parallel import licences were granted for different dosages of Singulair in May and September of 2010. Thereafter Sigma began importing Singulair from Poland, which was repackaged by Pharma XL Ltd and sold in the United Kingdom market by Sigma.

10. However, on 14 December 2010 Merck informed Pharma XL Ltd, by letter, of their objection to the importation of Singulair from Poland under the Specific Mechanism. On 16 December 2010 the letter was received at Pharma XL Ltd's registered office, and Sigma immediately ceased further sales of Singulair from Poland. However, prior to receiving that letter, Sigma had already imported and sold in excess of £2 million of Singulair and was left in possession of over £2 million worth of stocks, the majority irreversibly repackaged for the United Kingdom market.

11. Merck instituted proceedings in the Patent County Court which found in its favour. On Sigma's appeal to the Court of Appeal, an order for reference, dated 18 April 2013 and received at the Court on 14 October 2013, was sent with the following preliminary questions:

'(1) May the holder, or his beneficiary, of a patent or supplementary protection certificate 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 supplementary protection certificate 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

5 — According to the order for reference, Sigma and Pharma XL are members of the same group of companies and have arranged their affairs so that Sigma carries on the activities of importing and marketing and Pharma XL addresses the necessary regulatory issues.

(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 supplementary protection certificate limited to persons who have a legal right under national law to bring proceedings to enforce that patent or supplementary protection certification?

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 supplementary protection certificate, 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 supplementary protection certificate 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?'

12. Written observations were submitted by Merck, Sigma, the Czech Republic and the Commission. Merck, Sigma, and the Commission participated at the hearing that was held on 4 September 2014.

## III – **Analysis**

### A – *Preliminary observations*

13. The subject matter of a patent consists of an exclusive right of the patent owner to exploit economically the protected invention during the validity of the patent.[6] This right is created by an administrative decision of the competent patent authority, and presupposes that the invention and the identity of the patent owner are disclosed, usually through official communication and inscription in a public registry.

14. Patent rights, including rights protected under a supplementary protection certificate, are intellectual property, and this is a form of property which is in turn protected by Article 17 of the Charter of Fundamental Rights ('the Charter').[7] Further, the Specific Mechanism must be interpreted in conformity with Article 17 of the Charter.

15. Pursuant to classic Court of Justice case-law, Treaty rules on the free movement of goods do not affect the existence of intellectual property rights or deprive them of their substance.[8] However, from this principle, and other fundamental rules of the internal market, follow restrictions concerning the right holder's capacity to exercise his rights in order to prevent importation of protected goods which have already been put on the market in another Member State by him or with his consent. This principle of exhaustion enables parallel importation of protected goods from other Member States without the right holder's consent under the abovementioned circumstances.

16. This principle does not affect the substance of patent rights as, in principle, the patent owner has been compensated adequately in the Member State from which the parallel importation originated, or at least he could have been compensated had he duly sought protection there.

17. However, it has often been the case that the level of patent protection in acceding States has, prior to the accession, been lower than the protection required by EU law, especially with respect to patents for pharmaceutical products.[9] In such a scenario, full application of internal market principles after the accession would lead to a situation in which the patent owner would be exposed to parallel imports from the relevant new Member States without having been able to protect his invention there and, as a result, without having received adequate compensation. Moreover, as the representative of Merck pointed out at the hearing, in such circumstances the patent owner would have a disincentive to market his product in the new Member States as this would generate re-importation of the product.

6 — Patent law is not harmonised within the European Union, but a common core of protection can be found in Article 28(1)(a) of Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement), binding both the Union and the Member States. According to this provision, a patent shall confer on its owner, where the subject matter of a patent is a product, exclusive rights to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product. The TRIPS Agreement forms Annex 1 C to the Agreement establishing the World Trade Organization, signed in Marrakesh on 15 April 1994 and approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multi-lateral negotiations (1986-1994), OJ 1994 L 336, p. 1.

7 — Judgments in *Laserdisken*, C-479/04, EU:C:2006:549; *Promusicae*, C-275/06, EU:C:2008:54; and *Metronome Musik*, C-200/96, EU:C:1998:172.

8 — E.g. judgments in *Deutsche Grammophon Gesellschaft*, 78/70, EU:C:1971:59; *Centrafarm and de Peijper*, 15/74, EU:C:1974:114; and *Donner*, C-5/11, EU:C:2012:370.

9 — Even though the European Union does not have substantive legislation on patents, with the exception of supplementary protection certificates, there is indirect harmonisation of some core elements of patent law through the requirement for the Member States to have acceded to the European Patent Convention, and through the provision of the TRIPS agreement, which binds the Member States as a matter of EU law. I recall that in accordance with Article 207 TFEU 'commercial aspects of intellectual property' form part of Common Commercial Policy. The external competence of the EU in this field is exclusive: see Article 3(1)(e) TFEU and judgment in *Daiichi Sankyo and Sanofi-Aventis Deutschland*, C-414/11, EU:C:2013:520, paragraph 52, but it is not internally, see judgment in *Spain* v *Council*, C-274/11 and C-295/11, EU:C:2013:240, paragraph 25. See also Opinion 1/94, EU:C:1994:384, paragraphs 57, 58, 60, 65, 68 and 71.

18. In order to achieve a balance between effective protection of patent rights and the free movement of goods, the Act of Accession of 2003, like the Act of Accession of 1985, adopted a Specific Mechanism. In substance, the mechanism enables the patent owner to rely on his exclusive rights against importers in situations in which these rights would otherwise be exhausted under the Court's case-law. The Specific Mechanism provided in the Act of Accession of 2003 has, however, in its second paragraph, introduced an obligation on the potential parallel importer to give prior notification to the patent owner. Questions 1 and 2 concern, in substance, the impact of this obligation on the legal position of the patent owner who seeks to rely on the Specific Mechanism.

19. Moreover, the second paragraph of the Specific Mechanism lays down a procedural requirement on importers to demonstrate to the competent authorities in the Member State where the product enjoys patent or supplementary protection that the patent owner has been given one month's prior notification before the application regarding that import.

B – *The answer to Questions 1 and 2*

20. At the outset I point out that there is no dispute between the parties in the main proceedings that, at the time of the filing for the relevant patent in the United Kingdom, namely 10 October 1991, Poland had not introduced patent protection for pharmaceutical products into its laws. Nor is it disputed that a supplementary protection certificate was unavailable under the laws of Poland at the time it was applied for in the United Kingdom, namely 8 July 1998. Thus, the order for reference hinges on the interpretation of the Specific Mechanism rather than whether or not it applies.

21. Pursuant to the first and second questions referred by the Court of Appeal, the Court is being asked to rule on the legal consequences flowing from silence on the part of the patent owner, and for a period of more than one month, once the notification provided for in the second paragraph of the Specific Mechanism has been provided. In my opinion, Questions 1 and 2 referred by the Court of Appeal are to be understood as an inquiry on the extent to which silence on the part of patent owners affects their legal position in the event of failure to respond to a notice provided pursuant to the second paragraph of the Specific Mechanism. This is the approach I will employ in the analysis that follows.

22. Here it is possible to sketch out two extreme positions. One of them is essentially advocated by Merck. According to this view, paragraph 1 of the Specific Mechanism cuts off the applicability of the exhaustion principle with regards to products falling within its scope, and thereby reinstates for the patent owner the legal position that he would normally enjoy in the absence of the EU internal market. In other words, his entitlement to rely on his patent or supplementary protection certificate in order to prevent the imports from Poland, and marketing in the United Kingdom, would be fully enforceable, internal market rules notwithstanding. As Merck acknowledged at the hearing, this would put imports from Poland and other Member States that acceded to the European Union in 2004 on the same footing as imports from third countries.

23. In practice, this interpretation of the Specific Mechanism would entitle a patent owner to seek redress and damages, *even retroactively* to the date when importation began, and there would be no obligation on the patent owner to warn importers of his intention to enforce his patent rights. Generally, a patent owner may seek legal redress regarding any infringements that took place before the infringer learned about the patent owner's intention to enforce his rights. Furthermore, the patent owner has no obligation to inform the infringer of his intention to enforce his rights before he takes the relevant legal action.

24. Thus, on the thesis advanced by Merck, the only supplement to the legal position of the patent owner introduced by the second paragraph of the Specific Mechanism would consist of the obligation on the potential importer to provide prior notification. In this respect the Specific Mechanism would give enhanced protection to the patent owner, because putative infringers do not ordinarily have a particular duty to inform the patent owner before they start importing the patented product without the patent owner's consent.

25. This latter point demonstrates, in my opinion, that the position put forward by Merck cannot be sound. It cannot be presumed that the negotiators of the Act of Accession of 2003 intended, in the context of the Specific Mechanism, to give the patent owner more protection than was usually available, and actually establish a kind of duty of 'self-incrimination' to potential infringers. Or, as the Commission pointed out at the hearing, the Specific Mechanism does not create a double privilege for patent owners.

26. The second extreme position is as follows: The Specific Mechanism only provides a window of opportunity for the patent owner to activate the protection against a specific potential importer. If he fails to do this, the parallel importer can rely on the ordinarily applicable internal market principles, and due to the principles of free movement of goods and exhaustion of patent rights no patent rights could be enforced against him later, given that the protected product was placed on the market in the new Member State by the patent owner or with his consent.

27. It was clear at the hearing that this latter position was not advocated by any of the parties appearing before the Court. Sigma, along with the Commission, have acknowledged that any failure to comply with the procedural requirements that stem from the second paragraph of the Specific Mechanism would only prevent enforcement of patent rights with respect to importation of the pharmaceutical product that occurred prior to the demonstration of the patent owner's intention to rely upon those rights. In other words, Sigma, has acknowledged that the Specific Mechanism could not be called in aid to allow them to continue to import Singulair after receipt of Merck's letter of 14 December 2010 objecting to it. On this interpretation of the Specific Mechanism, the patent owner can use his right to prevent parallel importations, but only with respect to activities taking place *after* his reliance on his rights was communicated to the importer.

28. Hence, the correct interpretation of the Specific Mechanism must be sought from between the two extremes described above. This requires determining what role, if any, the principle of free movement of goods plays in the context of the Specific Mechanism, the latter clearly giving preponderance to the patent rights protected by the fundamental right to property pursuant to Article 17 of the Charter.

### 1. Wording of the Specific Mechanism

29. In my opinion the wording of the first paragraph of the Specific Mechanism is not very helpful in this respect. The crucial issue is the meaning to be attributed to the words that the patent owner 'may rely' on the rights granted by the patent or the supplementary protection certificate.

30. According to Merck they simply mean that, under the Specific Mechanism, the patent owner, like any patent owner, may enforce his patent rights if he so wishes. According to the Commission, it is clear from the wording of the 2003 Specific Mechanism that the right to prevent the importation of products covered by that mechanism is not automatic and is dependent on the right holder exercising an option to restrict the parallel importation or marketing of the pharmaceutical product at issue. I agree with this view.

31. In fact, in *Generics & Harris Pharmaceuticals*, the Court, in interpreting the identical wording of the Specific Mechanism of the Act of Accession of 1985, according to which 'the holder, or his beneficiary, of a patent … may rely upon the rights granted by that patent in order to prevent the import and marketing of that product',[10] came to the same conclusion. The Court inferred from the optional character of the derogation that the provision is 'therefore inapplicable unless the proprietor of the patent demonstrates his intention to exercise that option.'[11]

32. In my opinion, this interpretation applies equally to the Specific Mechanism in the Act of Accession of 2003. It does not simply refer to the patent owner's usual entitlement to enforce patent rights. Rather, it refers to a separate matter, namely expression of the patent owner's *will to keep the protection in force* in relation to potential parallel imports from a new Member State. If that objection is furnished, any importation without a licence becomes illegal. It is a completely different issue as to whether and by which means the patent owner decides to enforce his patent rights, provided that the importation has taken place, even though he has demonstrated his intention to exercise that option. In other words the first aspect relates to the question whether the patent rights *become enforceable*, the second whether they *are in fact enforced*.

33. Therefore the Specific Mechanism is inapplicable unless the patent owner demonstrates his intention to exercise the option to object to parallel imports falling within its remit. If he fails to do so the protected products may be lawfully imported without his consent from the new Member State to the old Member State.

2. Purposive and systematic interpretation

34. This interpretation is confirmed by purposive and systematic interpretation of the Specific Mechanism. As pointed out in the written observations of the Commission, the notification requirement under the Specific Mechanism aims at ensuring that patent owners are duly informed in sufficient time of an intention to import protected products so that they may rely on the Specific Mechanism to prevent the proposed parallel import of pharmaceutical products enjoying patent or supplementary protection in the relevant Member State. Like the notification obligation under trade mark law, which may result in the imposition of limitations on parallel traders in the repackaging of trade-marked products, the Specific Mechanism seeks to ensure that the legitimate interests of the patent owner are safeguarded.

35. Indeed, in the *Boehringer*[12] case the Court held, in the domain of trade mark law, that the adequate functioning of such a notice system 'presupposes that the interested parties make sincere efforts to respect each other's legitimate interests'.[13] The Court further recognised the entitlement of a trade mark proprietor to a 'reasonable time' to react to a repackaging notice while 'consideration must be also be given to the parallel importer's interest in proceeding to market the pharmaceutical product as soon as possible after obtaining the necessary licence from the competent authority.'[14] In that case the Court indicated that 15 working days would be reasonable.[15]

10 — Judgment in *Generics and Harris Pharmaceuticals*, C-191/90, EU:C:1992:407, paragraph 33.

11 — Ibid., paragraph 42.

12 — Judgment in *Boehringer Ingelheim and Others*, C-143/00, EU:C:2002:246.

13 — Ibid., paragraph 62.

14 — Ibid., paragraph 66.

15 — Ibid., paragraph 67.

36. Like the Commission, I also point out that the patent protection provided for by the Specific Mechanism is broader than that supplied under EU trade mark law. In trade mark law, the trade mark proprietor may oppose parallel import of goods put on the market in the Union (EEA) by him or with his consent, only 'where there exist legitimate reasons … especially where the condition of the goods is changed or impaired after they have been put on the market'[16], particularly through repackaging.

37. By contrast, the Specific Mechanism does not impose any obligation on a patent owner to justify a refusal to permit the importation of products falling within the scope of that mechanism. This does not, however, mean that a patent owner could never have an obligation, supported by the fundamental principle of free movement of goods, to take due account of the legitimate interests of a potential parallel importer.

38. In view of the settled case-law of the Court, according to which 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 in order to attain its objective,[17] the potential parallel importer under the Specific Mechanism has a legitimate interest protected by EU law to know, in clear terms, his own legal position vis-à-vis the patent owner. Therefore, the entitlement of the latter to invoke and rely upon the rights provided for in the Specific Mechanism must be construed as being conditional on the patent owner having reacted to the notification received and having informed the notice provider that he opposes the proposed importation and marketing of the pharmaceutical product in issue.

39. This conclusion is reinforced by the fact that the Specific Mechanism in the Act of Accession of 2003 expressly requires importers to 'demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given' to the patent owner. No such requirement was present in the Act of Accession of 1985.

40. Thus, the existence of the one-month notification period implies, in the internal market context, where the free movement of goods is fundamental, a corresponding requirement for the patent owner to respond to that notification in the event that he wishes to prohibit the proposed importation and marketing of the pharmaceutical product in issue. The inclusion of the time-limit serves to ensure that the patent owner responds promptly and, in turn, respects the legitimate interests and expectations of the potential importer to receive a reply to the notice, with a view to being able to take informed investment decisions.

41. As a consequence, in the absence of a response within the one month time-limit from the patent owner, a potential importer who has complied with the obligation to notify is permitted to commence importing. An alternative interpretation would deprive the one month deadline of its intended effect.

42. Moreover, an interpretation according to which the patent owner were entitled to rely upon the rights provided for in the Specific Mechanism, without having responded to a notification, would deprive the intended importer of any legal certainty. He would have no way of knowing whether he could legally import or place on the market the protected pharmaceutical product. It is to be recalled that the principle of legal certainty constitutes a general principle of EU law, and EU law provisions like the Specific Mechanism must be interpreted in a manner that is consistent with general principles.[18]

16 — See Article 7(2) of Directive 2008/95/EC of the European Parliament and of the Council of 22 October 2008 to approximate the laws of the Member States relating to trade marks (Codified version), OJ 2008 L 299, p. 25.

17 — Judgment in *Apostolides*, C-420/07, EU:C:2009:271, paragraph 35 and case-law cited.

18 — Judgments in *Skoma-Lux*, C-161/06, EU:C:2007:773, paragraphs 38 and 51, *Ordre des barreaux francophones et germanophone and Others*, C-305/05, EU:C:2007:383, paragraph 28 and *UPC Telekabel Wien*, C-314/12, EU:C:2014:192, paragrahp 46.

43. That said, as I have already mentioned, it is necessary to note that the Specific Mechanism prevents only *retroactive* reliance on patent rights against parallel importers. In other words, any failure to respond to a notification only prevents the seeking of redress with respect to importation in the form of damages, or other remedies, for the period before the importer was informed of the patent owner's intention to rely on his patent rights. In other words the patent owner may, within the limits stemming from the principle of good faith, withdraw his acquiescence to parallel imports, but only with regard to the periods after the importer was duly informed. The Specific Mechanism protects patent rights, under certain circumstances, notwithstanding the internal market principle of exhaustion. Such a property right, protected by Article 17 of the Charter, cannot be considered to be completely forfeited simply because the patent owner failed to object to parallel imports in good time.

44. In the main proceedings Sigma has accepted that it could not and would not continue with parallel imports after it became aware of the opposition by Merck. This is consistent with the interpretation I am proposing. In contrast, any redress sought by Merck regarding imports that took place before this moment would, in my opinion, be incompatible with the Specific Mechanism.

45. As an intermediary conclusion, I am of the opinion that Questions 1 and 2 should be answered in the sense that a patent owner, duly notified, of an intention to import or market pharmaceutical products covered by the Specific Mechanism provided in Annex IV, Chapter 2, to the Act of Accession of 2003, is required to respond to such notification and demonstrate an intention to oppose the proposed import and marketing within the period prescribed in the second paragraph of the mechanism in order to be entitled to enforce any restriction on the importation of the products concerned. The patent owner is precluded from relying upon his rights with respect to any importation of the pharmaceutical product in a Member State that occurred prior to the demonstration of his intention to rely upon those rights.

### C – *Question 3: who is required to notify?*

46. The referring court inquires as to whether notification of the intention to import pharmaceutical products provided for in the second paragraph of the Specific Mechanism may only be given by the person actually intending to import the products concerned. If the answer to the question is in the negative, the court seeks guidance regarding the category of persons that may provide such notification.

47. The second paragraph of the 2003 Specific Mechanism states that, '[a]ny person intending to import or market … shall demonstrate … that one month's prior notification has been given …'. On the one hand, this provision suggests that it is the person intending to import the product at issue that must demonstrate compliance with the notification requirement. On the other hand, the provision does not specify that that is the person who must also actually carry out the notification. Hence, a literal interpretation of the Specific Mechanism does not provide a conclusive answer.

48. As to the purposive and systematic interpretation of the provision, as noted above, the Commission points out in its written observations that the objective of the notification requirement is to ensure that the patent owner is made aware of the intentions of the importer, so he can effectively address the notifying entity if he intends to rely on his rights under the Specific Mechanism to prevent the importation and marketing of the product. It thus ensures the protection of his legitimate interests.

49. In the field of parallel trade of trade marked products, the Court ruled in *Orifarm* [19] that the person notifying the repackaged product to the trade mark proprietor does not have to be the actual re-packager, provided certain conditions are fulfilled. It held that:

'… [the] interest of the proprietor is fully safeguarded where the name of the undertaking at whose order and on whose instructions the repackaging has been carried out, and which assumes responsibility for the repackaging, appears clearly on the packaging of the repackaged product … Moreover, because that undertaking assumes full responsibility for the repackaging operations, the proprietor can enforce his rights and, where appropriate, obtain compensation'. [20]

50. Trade mark and patent owners have in common their economic interest in exploiting their exclusive rights. In their respective contexts they both need to be able to enforce their rights and, where appropriate, obtain compensation when they have been infringed. However, due to the differences between trade marks and patents, I am not of the view that the criteria in the *Orifarm* judgment should guide the interpretation of the notification requirement pursuant to the Specific Mechanism. Unlike trade mark owners, in situations falling within the scope of the Specific Mechanism, the patent owners are not required to tolerate any parallel imports to which they object.

51. The Czech Republic rightly observes that the objective of the notification requirement under the Specific Mechanism is to give the patent owner the option of initiating, before the commencement of importation and marketing, judicial proceedings to prevent it. I add that in practice this often means seeking interim relief.

52. It follows that what is important for the patent owner is that the potential infringer, namely the person intending to import and place the pharmaceutical product on the market, is identified in the prior notification. However, precisely who provides the notification is irrelevant from a legal point of view. This is the sense in which I would answer the third question.

D – *Question 4: to whom must the notification be given?*

53. By its fourth question, the referring court seeks additional guidance as to the addressee of the notification provided for in the second paragraph of the Specific Mechanism. It essentially asks which persons are covered by the term 'beneficiary', and particularly whether a 'beneficiary' of a patent or supplementary protection certificate encompasses only persons who have a legal right under national law to bring proceedings to enforce that patent or supplementary protection certificate, or whether it includes the marketing authorisation holder of the pharmaceutical product concerned, when that market authorisation holder forms part of the same group of companies as the actual holder (or beneficiary) of the patent or supplementary protection certificate. The referring court further inquires as to whether or not a marketing authorisation holder, although not a beneficiary, can be a valid recipient of the notification for other reasons.

54. As the Commission points out in its written observations, unlike the notifying entity, the person(s) to whom prior notification shall be given is clearly identified by the second paragraph of the Specific Mechanism as 'the holder or beneficiary of such [patent or SPC] protection'. Whereas 'the holder' seems to refer to the proprietor of the patent or the supplementary protection certificate, the meaning of 'beneficiary' is less precise and is not a term generally used in the intellectual property *acquis*. Linguistic versions of the 2003 Specific Mechanism other than the English version, namely the French ('ayant-droit') and German ('der von ihm Begünstigte') versions, seem to more clearly indicate that the person referred to is a person who derives enforceable legal rights from the holder.

19 — Judgment in *Orifarm and Others*, C-400/09 and C-207/10, EU:C:2011:519.

20 — Ibid., paragraphs 29 and 30.

55. This is conclusions is confirmed by an interpretation of the second paragraph of the Specific Mechanism, read in the light of its first paragraph, which refers to 'the holder, or his beneficiary, of a patent or supplementary protection certificate' who 'may rely on the rights granted by that patent or supplementary protection certificate'.

56. Therefore, it seems, *on a literal interpretation*, that notification must be sent to one of the persons or entities which may rely on the said rights and take action to enforce them under national law.

57. In the present case, on the basis of the order for reference, these persons appear to be limited to the proprietor, or the exclusive licensee, of the patent or supplementary protection certificate. [21]

58. According to the Commission, literal interpretation of the second paragraph of the Specific Mechanism would be too restrictive, once viewed in the light of the objectives and the context of the provision. I do not share this position.

59. The Czech Republic rightly observes in its written observations that because the very purpose of the notification is to enable the patent owner to rely on his patent rights, the notification must be addressed directly to him, or to a person who in accordance with national law may enforce these rights.

60. Contrary to the oral submissions of Sigma, this cannot be considered to be an unreasonably difficult requirement. It follows from the terms of the second paragraph of the Specific Mechanism that the potential importer is expected to ascertain the identity of the right holder or his beneficiary. Moreover, as pointed out by Merck, their identities are easily available on public patent registers.

61. Paragraphs (b) and (c) of Question 4 reflect the fact that, in the United Kingdom, prior notifications in accordance with the second paragraph of the Specific Mechanism are made, and accepted as made, to group companies responsible for marketing authorisations or regulatory matters. In my opinion such a situation does not, as a matter of EU law, affect the interpretation of the second paragraph of the Specific Mechanism. [22]

62. It may be that in some Member States general civil law principles on legal representation and agency may mean that a notification is validly made when its addressee is a person who is linked to the holder, or his beneficiary, and the latter have by their own action created an expectation that the person concerned is legally authorised to represent them. However, no national law of this kind can affect the interpretation of the second paragraph of the Special Mechanism.

63. For these reasons I am of the opinion that Question 4 should be answered in the sense that the prior notification laid down in the Specific Mechanism must be made to the holder of the patent or the supplementary protection certificate or to a person who, in accordance with national law, may enforce these rights.

21 — The Patents Act of 1977, section 67(1), provides that: 'Subject to the provisions of this section, the holder of an exclusive licence under a patent shall have the same right as the proprietor of the patent to bring proceedings in respect of any infringement of the patent committed after the date of the licence ....'

22 — At the hearing the Commission argued that if the parallel importer has addressed its notice to an entity in the sphere of the patent holder, and there is no obvious mistake, then the notification requirements of the Specific Mechanism were satisfied. To this end the Commission relied on a case arising in the field of product liability, namely judgment in *Aventis Pasteur*, C-358/08, EU:C:2009:744, paragraph 59. However, given that this case arose prior to the advent of the Specific Mechanism, and relates to an entirely different legal context, it cannot assist in its interpretation.

## IV – **Conclusion**

64. On these grounds I propose the following answers to the questions referred by the Court of Appeal (England and Wales):

Questions 1 and 2 A holder of a patent or a supplementary protection certificate, or his beneficiary, duly notified of an intention to import and market pharmaceutical products covered by the Specific Mechanism provided for in Annex IV, Chapter 2, 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, is required to respond to the notification, so as to demonstrate an intention to oppose the proposed importation and placing on the market, within the period prescribed in the second paragraph of the Specific Mechanism, in order to be entitled to enforce any restriction on the import and marketing of the products concerned. A holder of a patent or a supplementary protection certificate, or his beneficiary, is precluded from relying upon his rights with respect to any import and marketing of the pharmaceutical product in a Member State that occurred prior to the demonstration of his intention to rely upon those rights.

Question 3 The notification required under the second paragraph of the aforementioned Specific Mechanism may be carried out by someone other than the potential importer and marketer provided that the identity of the latter is clearly identified by the notifying entity.

Question 4 Prior notification under the second paragraph of the aforementioned Specific Mechanism must be given to a person who has a legal right under national law to bring proceedings to enforce the patent or supplementary protection certificate.