Neutral Citation Number: [2013] EWCA Civ 326

Case No: A3/2012/1150

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE PATENTS COUNTY COURT
HHJ BIRSS QC
[2012] EWPCC 18

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 18/04/2013

Before:

LORD JUSTICE PATTEN
LADY JUSTICE BLACK
and
LORD JUSTICE KITCHIN

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Between:

(1) Merck Canada Inc **(a company incorporated under the laws of Canada)** **(2) Merck Sharp & Dohme Ltd** **(a company incorporated under the laws of England)**	**Claimants** **Respondents**
- and -	
Sigma Pharmaceuticals plc	**Defendant/** **Appellant**

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- -

David Anderson QC and Thomas Hinchliffe (instructed by Hogan Lovells International LLP)
for the Claimants/Respondents
Martin Howe QC and Isabel Jamal (instructed by Maitland Walker LLP)
for the Defendant/Appellant

Hearing dates: 7/8 February 2013

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Approved Judgment

Lord Justice Kitchin:

1. This appeal concerns the parallel importation from Poland into the United Kingdom of patented pharmaceuticals and the proper interpretation of a special derogation from the normal free movement rules which was negotiated as part of the accession arrangements of Poland and a number of other countries to the EU in 2004.

The background

2. The first respondent ("Merck Canada") is the registered proprietor of EP UK No 0 480 717 ("the patent") and a related Supplementary Protection Certificate SPC/GB98/025 ("the SPC"). The patent expired on 10 October 2011 and the SPC expired on 24 February 2013. The second respondent ("MSD") became the exclusive licensee under the patent and the SPC by an agreement dated 27 May 2011. Merck Canada and MSD (together "Merck") are members of the well known Merck pharmaceutical group of companies.

3. The patent and the SPC protected a chemical called montelukast sodium. This is the active ingredient of a pharmaceutical product sold by Merck under the name Singulair for the treatment of asthma. It is one of Merck's most successful products.

4. The appellant ("Sigma") is a parallel importer of pharmaceutical products and, like other such traders, deals in a large number of different product lines. Between June and December 2010, Sigma imported into and sold in the United Kingdom quantities of Singulair which had been put upon the market in Poland by MSD BV, another company in the Merck group, and so, under the normal EU rules governing the free movement of goods, Merck would have exhausted its rights and could not have relied upon the patent or the SPC to prevent their parallel importation.

5. It is, however, common ground that the normal rules do not apply in this case for the following reasons. A number of the Member States which acceded to the EU in 2004 historically had not permitted the patenting of pharmaceutical products; they had only permitted the patenting of processes for making such products. This is an important distinction because it is recognised that the protection afforded by a process patent is often less effective than that afforded by a product patent since the former only protects the particular claimed process whereas the latter protects the claimed product however it is made.

6. By 2004, all of these accession States did permit the patenting of pharmaceutical products but there remained a number of cases where patents or SPCs had been granted in other Member States in respect of pharmaceutical products at a time when no such protection was available in one or more of the accession States. It was considered that this placed pharmaceutical companies at a disadvantage because they were obliged to put their pharmaceutical products on the market in the accession States where only limited patent protection was available at prices which were lower than they would have been if they had been able to enjoy full product patent protection. A special derogation from the normal free movement rules was therefore negotiated as part of the accession arrangements for these States. It is called the Specific Mechanism and is set out in Annex IV, Chapter 2 to the Act of Accession. It reads:

> "2. COMPANY LAW
>
> Treaty establishing the European Community: Part Three, Title I Free Movement Of Goods
>
> 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 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."

7. It can be seen the Specific Mechanism has two parts. In broad terms, the first allows an owner of a patent or an SPC which protects a pharmaceutical product to prevent the parallel importation of that product from one of the accession States if, at the time of filing, it was not possible to obtain such protection in that accession State. The second requires the person intending to import the product to demonstrate to the relevant national authority that he has given notice of that intention to the holder or beneficiary of the protection ("the patent holder").

8. The applications for the patent and for the SPC were each filed at a time when it was not possible to obtain patent protection in Poland for montelukast sodium. Accordingly Sigma accepts that the patent and the SPC may in principle be invoked under the Specific Mechanism to oppose the importation into and sale in the United Kingdom of the Singulair it bought in Poland. But, as I shall explain, it says that, once properly notified, the patent holder must elect to enforce his rights before he can take the benefit of the derogation.

9. On 22 June 2009, Pharma XL Limited ("Pharma XL"), an associated company of Sigma responsible for applying for parallel import authorisations for the Sigma group of companies, sent a letter to the Manager, Regulatory Affairs of MSD at its premises in Hoddesdon in Hertfordshire stating that it intended to import Singulair from Poland, mentioning the Specific Mechanism and asking whether Merck had any reason to object to that importation. MSD did receive that letter but did not reply to it.

10. On 14 September 2009, and having received no response to the letter of 22 June, Pharma XL proceeded to apply to the Medicines and Health Regulatory Agency ("the MHRA") for parallel importation licences for Singulair in 5mg and 10mg form.

11. These licences, referred to as PL(PI) licences, are a special form of marketing authorisation which allow a parallel imported pharmaceutical to be marketed in the United Kingdom. In appropriate circumstances, the MRHA will grant such a licence in accordance with the obligations resting on Member States under the Treaty on the Functioning of the European Union ("the TFEU"), formerly the EC Treaty, as interpreted by the Court of Justice in Case C-104/75 *Officier van Justitie v de Peijper* [1975] ECR 613. The MRHA is concerned with the efficacy of medicinal products and patient safety. Accordingly, a PL(PI) will normally have conditions attached to it which regulate the manner in which a parallel imported drug is repackaged. For example, the wording and appearance of the packaging itself must be approved; the entity responsible for the parallel importation must be identified so that the product can be traced if necessary; and the patient information leaflet must contain all appropriate warnings and contra-indications necessary to ensure patient safety. Further, operations such as repackaging which could prejudice the integrity of the product must be carried out in suitable premises and under properly controlled conditions.

12. It is a feature of the United Kingdom system that the actual importer of the product need not be the holder of the PL(PI) provided that any re-labelling and repackaging operations are conducted under the control of the licence holder and in accordance with the licence conditions. The MHRA therefore accepts the filing of the names of one or more permitted importers under the PL(PI) but, in such a case, it is the holder of the PL(PI) who must ensure its terms are complied with.

13. PL(PI)s are granted without consideration of whether patent rights would be infringed by importation. Nevertheless, in the case of an intended importation from one of the accession States and in the light of the second part of the Specific Mechanism, the form of application for a PL(PI) includes a requirement that the applicant must state that the Specific Mechanism does not apply to the product in question or verify that one month's prior notification of the proposed importation has been given to the patent holder. The MHRA does not, however, check whether this information is correct. Further, if the relevant formalities have been complied with, the PL(PI) will be granted irrespective of whether the patent holder or beneficiary agrees to the parallel importation, objects to it, or does nothing.

14. In this case, the application form filed by Pharma XL indicated that one month's prior notification had indeed been given and on 21 May 2010, the MHRA granted to Pharma XL a PL(PI) in respect of the 5mg dosage form of Singulair.

15. On 4 June and 13 July 2010, Pharma XL wrote letters to the Manager, Regulatory Affairs of MSD in order to meet the trade mark requirements explained by the Court of Justice in Joined Cases C-427/93, C-429/93 and C-436/93 *Bristol-Myers Squibb v Paranova* [1996] ECR I-3457, stating its intention to import 5mg Singulair from Poland and enclosing copies of the intended presentation of the repackaged products. MSD received these letters but did not respond to them. As it happens, Merck has no objection to these repackaged products from a trade mark point of view.

16. Thereafter Sigma began importing 5mg Singulair from Poland. The product was repackaged by Pharma XL under the PL(PI) and sold in the United Kingdom by Sigma.

17. On 10 September 2010, the MHRA granted to Pharma XL a PL(PI) in respect of the 10mg dosage form of Singulair.

18. On 15 September 2010, Pharma XL wrote two further trade mark notification letters to the Manager, Regulatory Affairs of MSD indicating its intention to import 10mg Singulair from Poland and again enclosing copies of the intended presentation of the repackaged products. MSD received these letters too, but did not respond to them. As in the case of the 5mg products, Merck has no objection to these repackaged products from a trade mark point of view.

19. Thereafter Sigma began importing 10mg Singulair from Poland. The product was again repackaged by Pharma XL under the PL(PI) and sold in the United Kingdom by Sigma.

20. It was not until 14 December 2010 that solicitors acting for Merck wrote to Pharma XL at its registered office objecting to the importation of Singulair from Poland under the Specific Mechanism and asserting that acts of importation and sale already carried out amounted to an infringement of Merck's patent rights. They sought undertakings, damages and other relief. That letter was received by Pharma XL on 16 December 2010, and Sigma immediately ceased further sales. By that time, Sigma had imported and sold in excess of £2 million of Singulair and was left in possession of over £2 million of stock, most of which had been repackaged for the United Kingdom market.

The proceedings and the judgment below

21. On 10 June 2011, Merck commenced these proceedings alleging infringement of the patent and the SPC.

22. Sigma admitted that the patent and SPC were valid and that the Singulair it had imported and sold fell within their scope. It also accepted that the Specific Mechanism was capable of applying to the patent and the SPC because they were each applied for at a time when equivalent protection was not available in Poland.

23. Sigma's primary defence was that the Specific Mechanism merely confers upon a patent holder the option of preventing imports of the kind in issue. It argued that the derogating provisions are therefore inapplicable unless and until the patent holder demonstrates his intention to exercise that option, and such intention was not demonstrated by Merck until it sent the letter of 14 December 2010. Its secondary case was that, having failed to respond to the series of letters to which I have referred, Merck was estopped under national law from asserting its rights.

24. For its part, Merck accepted that the letters sent by Pharma XL and relied upon by Sigma had been sent to and received by MSD's Regulatory Affairs Department, and explained that, although it was its policy to reply to notices received under the Specific Mechanism about imports from Poland, the letter of 22 June 2009 had been overlooked as a result of an administrative error. However, it disputed that the importation and sale of Singulair was lawful until it elected to oppose such dealings.

It also contended that the letter of 22 June 2009 was not, in any event, a sufficient notification in accordance with the second paragraph of the Specific Mechanism because it was not sent to the patent "holder or beneficiary" which, it contended, should have been Merck Canada and not MSD, and because it was sent by Pharma XL and not by Sigma.

25. The case came on for trial before HH Judge Birss QC on 13 and 14 March 2012. In his judgment dated 27 April 2012, the judge rejected both of Sigma's defences. He held the Specific Mechanism does not require the patent holder to demonstrate his intention to oppose importation before that activity is rendered an infringement, and he declined to refer any issue concerning the proper interpretation of the Specific Mechanism to the Court of Justice. He also found that, on the facts of the case, Merck was not estopped from relying on its patent rights. In the circumstances, it was not necessary for the judge to address the issues concerning the adequacy of Sigma's notice and he did not do so.

26. In the light of his judgment, the judge granted an injunction and ordered an inquiry as to the damage suffered by Merck or an account of the profits made by Sigma. He also ordered Sigma to deliver up its unsold stocks of Singulair, although he stayed this part of his order pending appeal.

The appeal

27. On this appeal Sigma contends the judge fell into error in the following respects. First, it submits that the judge ought to have held that, on its proper interpretation, the Specific Mechanism confers upon the patent holder an option to invoke its protection and that in order to do so, he must demonstrate his intention to exercise that option. Only after that intention has been demonstrated does the derogation apply.

28. Second, Sigma argues that the letter sent by Pharma XL to MSD on 22 June 2009 was sufficient to satisfy any obligation to give notice of the intention to import, and the judge ought to have so held.

29. Third, Sigma contends the judge wrongly failed to find that Merck was estopped from asserting its causes of action for patent or SPC infringement against the acts which Sigma carried out prior to notification by Merck of its objections.

30. Fourth, Sigma argues that the judge's decision to order the destruction of stock which could be lawfully sold after the expiry of the SPC was based upon erroneous principles of national law, contrary to EU law and a perverse exercise of discretion.

31. Finally but importantly, Sigma argues that the correct interpretation of the Specific Mechanism is fundamental to this case and that it is therefore appropriate to refer the issues to which it gives rise to the Court of Justice. Moreover, as for estoppel and delivery up, it recognises that these involve issues of national law but says that the starting point for the consideration of its arguments is the correct analysis of the legal duties under and consequences of the Specific Mechanism and whether the judge's approach goes beyond what can be regarded as justified and proportionate under Article 36 TFEU. It therefore invites us to refer a series of questions on these issues too.

32. I turn then to address each of the substantive issues to which this appeal gives rise.

The Specific Mechanism

33. The Specific Mechanism must be seen in context so I begin with some basic principles. It has long been established that a patentee cannot exercise a right given to him by the law of a Member State to prohibit the marketing in that State of products protected by the patent which have been put on the market in another Member State by him or with his consent: see Articles 34-36 TFEU (previously Arts 30 and 36 EEC) as interpreted in, for example, Case 15/74 *Centrafarm v Sterling Drug* [1975] FSR 161. This is the free movement rule and it was described by the Court of Justice in *Centrafarm* at [8] as one of the fundamental principles of the European single market.

34. The free movement rule has even been held to preclude the right of the holder of a patent for a pharmaceutical product to oppose importation by a third party of that product from another Member State in circumstances where that holder first put the product on the market in that State after its accession to the EU but before the product could be protected by a patent in that State: see Case 187/80 *Merck v Stephar* [1981] ECR 2063; [1981] 3 CMLR 463; and Joined Cases C-267/95 and C-268/95 *Merck v Primecrown* [1996] ECR I-6285; [1997] FSR 237. In the *Primecrown* case, the Court explained at [25] that any derogation from the rule must be interpreted strictly.

35. The severity of the rule has, however, been tempered on occasion. In particular, the accession arrangements for Spain and Portugal contained a derogation in very similar terms to the first paragraph of the Specific Mechanism. According to Articles 47 and 209 of the Iberian Act of Accession, the holder of a patent for a pharmaceutical product filed in a Member State at a time when a product patent could not be obtained in Spain or Portugal could rely upon the rights granted by the patent in order to prevent the importation of that product into the existing Member State where the product enjoyed patent protection, and that was so even if the product was put on the market in Spain or Portugal for the first time by him or with his consent.

36. This Iberian derogation was considered by the Court of Justice in Case C-191/90 *Generics and Harris v Smith Kline and French* [1992] ECR I-5335. In that case Smith Kline and French ("SKF") was the proprietor of two patents for cimetidine, a pharmaceutical which it marketed under the name Tagamet for the treatment of ulcers. Under the provisions of the Patents Act 1977 ("the 1977 Act"), the life of these patents had been extended from 16 to 20 years but they were treated as having been endorsed "licences of right". The 1977 Act also provided that in the case of a patent so endorsed, any person was entitled as of right to a licence on such terms as might be settled by agreement or, in default of agreement, by the Comptroller. A question arose as to whether it was permissible for the Comptroller to include in the licence a term restricting importation from Spain and Portugal. This question and two others were referred by this court to the Court of Justice.

37. Observations were submitted by the Commission, by the Spanish and United Kingdom Governments and by all the parties. The Commission, the Spanish and United Kingdom Governments and Harris and Generics all argued that patents endorsed licences of right were "weak" patents and so necessarily excluded from the derogation. The Spanish Government also contended that it was not permissible for a

national authority – here the Comptroller - to include a term restricting importation from Spain and Portugal because the right to give effect to the derogation was vested solely in the patentee or his beneficiary. Moreover, it continued, the exercise of the right was merely optional.

38. The Court of Justice held that application of the free movement rules meant that SKF could ask for a restriction against importation by the licensee from third countries, but not against importation from other Member States. However, these rules were displaced by the Iberian derogation, which meant that SKF could rely upon their rights under national law to restrict importation from Spain and Portugal and could therefore ask for a corresponding restriction in the licence.

39. In reaching this conclusion the Court explained (at [37]-[38]) that its own jurisprudence did not establish a Community definition of a "weak" patent from which it would follow that a patent endorsed licences of right was necessarily excluded from the derogation. Further, it emphasised (at [38]) that in interpreting Articles 47 and 209 it was necessary to have regard to their actual wording, according to which the proprietor of a patent "may rely upon the rights granted by the patent" to prevent importation of the patented product.

40. The Court continued that there were two conditions for the application of the derogation. The first was that the patent should grant to its proprietor the right to prevent importation as a matter of national law. As the Court explained:

> "[41] Such an interpretation is consistent with the purpose of Articles 47 and 209 of the Act of Accession, namely to derogate in a limited area from the Community rules governing the free movement of goods and not to create new rights exceeding the protection conferred on the patent by national law."

41. The Court addressed the second condition in this important paragraph:

> "[42] The second condition governing the prohibition on importing patented products from Spain and Portugal concerns the fact that the provisions of Articles 47 and 209 of the Act of Accession merely confer upon the proprietor of the patent the option of preventing such imports. Those derogating provisions are therefore inapplicable unless the proprietor of the patent demonstrates his intention to exercise that option. Contrary to the view expressed by the Spanish Government in its written observations, the effect of that condition is not to prohibit the authorities of the Member States from applying those provisions themselves. However, for the provisions to apply in such a case the proprietor of the patent must have demonstrated his intention to exercise the right conferred upon him by Articles 47 and 209.

42. The Court then gave its answer to the third question:

> [43] Consequently, the reply to the third question must be that Articles 47 and 209 of the Act of Accession of Spain and Portugal must be interpreted to the effect that the authorities of the Member States competent to settle, in the absence of agreement, the terms of licences of a right may, on the basis of those provisions and in derogation from the principles laid down by Articles 30 and 36 EEC, prohibit the licensee from importing from Spain and Portugal a patented pharmaceutical product if national law confers upon the proprietor of the patent the right to prevent imports and if the proprietor exercises the right conferred upon him by Articles 47 and 209."

43. The Specific Mechanism has clearly been modelled upon the Iberian derogation and so it may reasonably be assumed that it was intended to have the same essential meaning. There are differences, however. For present purposes the most important of these is the inclusion in the Specific Mechanism of the second paragraph and the obligation it imposes upon the person intending to import the product to give notice to the patent holder. This is a matter upon which Sigma particularly relies, as I shall explain.

44. Sigma contends it is clear from the reasoning of the Court of Justice at [42] that the Iberian derogation merely conferred upon the proprietor of a patent the option of preventing imports from Spain and Portugal. Further, the derogation was inapplicable unless the proprietor had demonstrated his intention to exercise that option.

45. Against this background, Sigma says that the meaning of the Specific Mechanism is clear and that its second paragraph makes perfect sense. It provides the patent holder with an option to rely upon his patent rights to oppose the importation and marketing of products falling within the scope of the derogation. So he must first elect to exercise that option and then demonstrate that he has done so. The second paragraph provides the machinery to allow this to happen because it requires anyone intending to import or market a protected product to give at least one month's notice to the patent holder.

46. Merck responds that the question addressed by the Court at [42] was whether a national authority could insert an import prohibition into a licence of right. The answer given by the Court was that it could, but the patentee must first have indicated his intention to exercise the right conferred by Articles 47 and 209. Without such an indication the Comptroller would have no basis upon which to act. Merck continues that nothing in the decision of the Court supports Sigma's suggestion that in an ordinary (that is to say, not a licence of right) case, the intention to exercise the right must be communicated before the act of importation.

47. As for the Specific Mechanism, Merck contends that Sigma is seeking to read into it words which are simply not there. The words "may rely" make it clear that the rights are private rights which the patent holder can enforce by bringing legal proceedings if he so chooses. Further, the second paragraph concerns the person seeking the PL(PI); requires that person to tell the relevant authority that notice has been given to the patent holder; but imposes no requirement of any kind upon the patent holder and says nothing at all about a counter-notice. Moreover, the Specific Mechanism does not

create new rights, it only permits the exercise of existing rights, and they do not require the satisfaction of any special conditions.

48. Merck also says that imposing a requirement upon a patent holder to give notice of his intention to oppose parallel importation makes no sense because it is something he will always wish to do. In this connection it relies upon evidence given by Mr Shah, the Finance Director of Sigma, that he could think of no commercial reason why a patent holder would ever wish to consent to parallel importation.

49. Finally, Merck points to various practical problems. For example, it asks, what would happen if the application for the PL(PI) indicates that the importer has given notice to the patent holder but he has in fact failed to do so? It also says that the Specific Mechanism contains no guidance as to the length of the notice period, or as to the identity of the parties who are to give or receive that notice.

50. In assessing these rival submissions, I think it important to have well in mind the basic principles to which I referred at the outset of my consideration of this issue. The free movement rule is one of the core principles of the European single market and any derogation from it must be interpreted strictly.

51. Second, the Specific Mechanism was modelled upon and must, in my view, be interpreted in the light of the Iberian derogation and the guidance given by the Court of Justice in Case C-191/90 *Generics and Harris.* In that regard I believe Merck is entirely right to say that the relevant question addressed by the Court in that case was whether a national authority could insert an import prohibition into a licence of right. But in my judgment Merck is on much weaker ground in suggesting that there is nothing in Case C-191/90 *Generics and Harris* which supports Sigma's position. The Court framed the first two sentences of [42] in general terms, and did so before coming to the question of a licence of right. It explained that Articles 47 and 209 merely conferred upon the proprietor an option of preventing such importation, and that these provisions were therefore inapplicable unless the proprietor demonstrated his intention to exercise that option. No doubt the proprietor might do that in a variety of ways, for example, by writing a letter or by commencing proceedings. But I believe it to be strongly arguable that the Court here declared that unless and until the proprietor did so, the provisions were inapplicable.

52. Third, I come to the Specific Mechanism itself. Here I find Merck's submissions persuasive as a matter of pure linguistic analysis. But that is not the correct approach. A provision such as this must be considered in the light of the overall scheme and objectives of which it forms part. In this regard, Merck's submissions do not seem to me fully to address the purpose of the second paragraph; nor do I believe they engage with the exposition by the Court of Justice of the purpose and meaning of the Iberian derogation. Now it is clearly true to say that the obligation to notify the patent holder serves the function of bringing to his attention a potential infringement by the parallel importation of pharmaceutical products from one of the accession States. But I find the suggestion that this is the only purpose of the paragraph rather unsatisfactory, for a potential infringer is not generally obliged to notify a patent holder of his intention to import and market a product to which objection may be made.

53. Moreover, a further purpose of the paragraph is not difficult to discern. Seen against the need to interpret any derogation from the free movement rule strictly and the

reasoning of the Court of Justice in Case C-191/90 *Generics and Harris*, it is to give the patent holder the opportunity to decide whether to oppose the proposed importation and, if he forms the intention to do so, to demonstrate that intention.

54. I accept that a patent holder who has relevant patent or SPC rights in which he has confidence is unlikely to consent to the parallel importation of pharmaceutical products to which he can properly object. But I am not persuaded that will always be so and, in any event, the patent holder is likely to be in the best position to assess whether he has any relevant rights, the strength of those rights, and the risk of damage to his business from the proposed importation having regard to all the relevant circumstances, including the nature of the product in issue, its cost and the nature of the market into which it will be sold. If he does not object then there will be no unnecessary interference with the free movement of goods between Member States.

55. Finally, I must have regard to the practical problems to which Merck refers. So far as the parties to these proceedings are concerned, this is a matter to which I must return in addressing the next issue. As for the other suggested problems, it seems to me that, on analysis, they rather melt away. If the appropriate notice is not given, the patent holder will be under no obligation to demonstrate his intention to exercise the option. Turning to the notice period, the second paragraph of the Specific Mechanism makes clear this must be at least one month.

56. I therefore lean in favour of Sigma's position on this issue but I recognise the position is far from clear. It is therefore necessary to consider whether to make a reference to the Court of Justice. This is a matter to which I shall return after addressing the other issues which arise.

Notification

57. It will be recalled that the letter of 22 June 2009 was sent by Pharma XL, not Sigma; indeed, it made no reference to Sigma. Further, it was sent to the "Manager, Regulatory Affairs" at MSD, the marketing authorisation holder for Singulair, but, at the time, neither the owner of nor the exclusive licensee under the patent or the SPC. MSD only became the exclusive licensee under the patent and SPC on 27 May 2011.

The notifier

58. I begin with the issue of the notifier. Merck contends that the second paragraph of the Specific Mechanism is clear: it is the person intending to import or market the product who must give notice of that intention to the patent holder. This is important so that the patent holder knows whom to sue if he believes the proposed importation will infringe his rights. Here Sigma was intending to import, not Pharma XL.

59. Sigma responds that the second paragraph of the Specific Mechanism must be applied in the context of the United Kingdom's system of regulatory control. This permits an application for a PL(PI) to be made which prospectively covers a number of actual importers. Prior notification by the applicant for the PL(PI) is therefore sufficient to cover subsequent importations conducted under the PL(PI), since such prior notification fulfils the purpose of the second paragraph by allowing the patent holder to express his objection to the proposed importation if he has one.

60. The parties are therefore all agreed that at least one purpose of the second paragraph is to give the patent holder reasonable warning of a proposed importation. But the mechanism it embodies to give effect to this purpose is rather cumbersome for it focuses on a demonstration to the competent authority that notice has been given to the patent holder rather than upon the notice itself.

61. In the case of a jurisdiction with a simple regulatory system this may not matter. The person who intends to import or market the product will make the application for regulatory approval. So it makes some sense for him to demonstrate in his application to the competent authority that he has given notice of his intention to the patent holder. The position in the United Kingdom is, however, quite different. As I have explained, a person who makes an application for PL(PI) may identify a number of permitted importers, and need not necessarily import himself. Moreover, some of those importers may have no idea they have been included in the application. How then does the second paragraph apply in such a case?

62. I have to say I entertain some doubt as whether notification by an applicant for a PL(PI) could be an effective notification in respect of importation of products by persons who have no connection with the applicant but are named in the application as permitted importers. Such persons may be wholly unaware they had been included. Indeed, they may even be competitors of the applicant and, at least at that stage, have no settled intention to import the products in issue at all.

63. By contrast, Sigma and Pharma XL are members of the same group of companies and have so arranged their affairs that Sigma carries on the activities of importing and marketing and Pharma XL addresses the necessary regulatory issues. There can be no doubt that the group had made a decision to import and so Pharma XL made the application for the PL(PI) licence. At least one month before doing so, it notified Merck of the intention to import. Now it is true that Sigma did not itself notify Merck of that intention. Nor did Sigma demonstrate to the competent authority that it had done so. But did this amount to a failure to comply with the second paragraph? In answering this question I believe the following matters are relevant.

64. First, this is another question which must be considered in the light of the overall scheme and objectives of which it forms part. Here the purpose of the scheme is to ensure the patent holder has notice of the proposed importation at least one month before the regulatory application is filed so that, on Sigma's case, he can demonstrate his intention to exercise the right conferred by the Specific Mechanism and, on Merck's case, take action against the importer.

65. Second, it was entirely appropriate for Pharma XL to make the application for the PL(PI) licence. It was the entity to which the licence was, in due course, granted and it was the entity responsible for ensuring that its terms and conditions were complied with. Further, it was required by the regulatory system to indicate whether notice of the proposed importation had been given to the patent holder.

66. Third, Merck was in a position to object to the proposed importation at any time after receipt of the letter of 22 June 2009, and to demonstrate that objection to Pharma XL. As Sigma accepts, Merck could then invoke its rights under the Specific Mechanism against any person operating under the licence. I recognise that Merck was not notified of the name of the particular group company which it was proposed would

actually carry out the acts of importation. However, it may be questioned whether this could ever have caused Merck any real difficulty because Pharma XL could have been required to disclose the name of the proposed importer if it declined to do so voluntarily. Moreover, and as a practical matter, as soon as Pharma XL received Merck's letter of 14 December 2010, Sigma terminated its trade.

67. Once more, therefore, I favour Sigma's position on this question. But again, I believe the answer is not clear and in due course I must therefore consider whether to make a reference on this issue too.

The party notified

68. Merck says that Sigma's case fails for the further reason that notice has to be given to the patent proprietor or his beneficiary, that is to say, someone who has a right to sue for infringement and Pharma XL's letter of 22 June 2009 was written to MSD which, at that time, had no such right.

69. Sigma responds that this approach is highly artificial and that the term beneficiary should be given a more purposive interpretation and that it encompasses a person who benefits from the protection of the patent.

70. Sigma also contends that is clear from the evidence at the trial that Merck operates as a single organisation regardless of the divisions between legal entities and that the notice which was given was, or ought to have been, effective notification to the patent holder. In support of its contentions, Sigma relies upon the following factual matters.

71. First, MSD is part of the same undertaking as the patent holder because both are controlled by the same ultimate parent group company, Merck & Co Inc. Further, MSD was the Merck operating subsidiary in the United Kingdom, was the holder of the marketing authorisation for Singulair and was operating with permission under the protection of the patent.

72. Second, Dr Rollins, an employee of MSD, was described as "Managing Counsel, European Patents" and he acted in patent matters on behalf of the group as a whole. He therefore had authority to assert a patent which belonged to Merck Canada.

73. Third, if a notification letter had been sent to Merck Canada, it would have been referred to Dr Rollins at MSD in order for MSD to decide whether or not it wanted to object. Dr Rollins was the person responsible for deciding on behalf of the group companies how to respond to such letters.

74. Finally, the Merck group receives numerous notifications every year from parallel importers under the Specific Mechanism. Analysis of correspondence disclosed by Merck in relation to Singulair revealed that over 90% of these were sent to MSD's Hoddesdon address and a significant proportion of these were directed to the Manager, Regulatory Affairs or the Regulatory Affairs Department.

75. I recognise that the Specific Mechanism does not create a right to sue for infringement where none existed as a matter of national law. I also acknowledge that the Specific Mechanism does not use the term "undertaking" to describe the person to whom notice must be given. So also, it is important to note that Dr Rollins was working in

the Patent Department, not the Regulatory Affairs Department. Nevertheless, it seems to me that the points developed by Sigma do raise a real issue as to the meaning of the term "beneficiary" in the Specific Mechanism and I consider it at least arguable that MSD, as the operating company in the United Kingdom, falls within the scope of that term upon its proper interpretation. Further, I consider that, in all the circumstances of this case, notice to MSD did not deprive Merck Canada of an opportunity to invoke its rights under the Specific Mechanism. To the contrary, it was sufficient to enable Merck Canada to respond, but it failed to do so as a result of an administrative oversight. The question therefore turns upon the true meaning of the Specific Mechanism, how strict the notice requirement is and whether it can only be satisfied by the importer providing notice directly to the patent holder. This is therefore a further issue in relation to which I must consider a reference to the Court of Justice.

Estoppel

76. Sigma contends that it relied upon Merck's failure to respond to any of the letters sent by Pharma XL on 22 June 2009, 4 June 2010, 13 July 2010 and 15 September 2010 and if, contrary to its primary case, importations of Singulair made before it received Merck's letter of 14 December 2010 were unlawful, it would be unjust and inequitable for Merck to claim any relief in respect of them and it is estopped from so doing.

77. The judge heard evidence on this issue from Mr Shah. He explained, and the judge accepted, that Sigma believed that Merck did not object to its importation of Singulair. That misunderstanding arose from two things: first, Mr Shah understood that Polish Singulair was already on the market in the United Kingdom and Merck had no made no complaint about it; and second, Merck did not respond to the various notices it was sent by Pharma XL. But importantly, it was the former which induced Sigma's belief. Merck's failure to respond to Pharma XL's letters simply allowed that misunderstanding to continue.

78. The relevant legal principles were not in dispute before the judge and the parties invited him to consider this issue on the basis that the doctrine requires three elements namely, a representation made by one person to another; reasonable reliance by the other person upon that representation; and that the other person has suffered detriment in consequence of that reliance. It was, however, emphasised by Sigma that these elements cannot be separated one from another, that the quality of the representation might influence the issue of reliance, and that reliance and detriment are often intertwined; see *Gillett v Holt* [2001] Ch 210 per Robert Walker LJ at page 225.

79. In the present case the nature of the alleged representation is rather unusual in that it is said to have arisen from Merck's failure to respond to the letters from Pharma XL or, in short, from silence or inaction. In *Youell v Bland Welch & Co Ltd (the "Superhulls Cover" case) (No.2)* [1990] 2 Lloyd's Rep 431, Phillips J explained at page 452:

> "In the context of estoppel silence differs from a positive representation in that its effect will not normally be to induce a misunderstanding but to permit a misunderstanding that has already been induced to persist. In such circumstances a party who has remained silent may be estopped from asserting that the facts are other than those which they were mistakenly

> assumed to be. But such an estoppel will only arise if the party estopped was under a legal duty to dispel the other party's misunderstanding. "

80. In such a case the question is, therefore, whether the relationship between the parties is such that, in all the circumstances, the court will impose a positive duty to speak out.

81. The judge rejected the estoppel argument for three reasons. First, he held that Merck's failure to respond to Pharma XL's letters was not operative in the sense that it did not induce Sigma's belief that Merck had no objection to its importation of Polish Singulair.

82. Second, he held that Merck had no duty to respond to the letter of 22 June 2009; nor, he considered, did Merck have any duty to respond to the four subsequent letters dealing with the trade mark issues, for the reason that Merck had no objection to the repackaging of the products from a trade mark point of view.

83. Third, he held that any reliance that Sigma placed upon Merck's failure to respond was not reasonable in any event. This finding was based upon the fact that the letter of 22 June 2009 was sent to the Manager, Regulatory Affairs at MSD, that is to say, in the judge's view, the wrong person at the wrong company. It ought to have been sent to the owner of the patent, Merck Canada, or to the address for service given for the patent in the United Kingdom patent register, namely "the European Patent Department" at MSD's Hoddesdon premises. The judge also thought that Mr Shah ought to have checked whether his letter of 22 June 2009 had ever been received, that being what a prudent businessman would have done.

84. On this appeal Sigma contends, as it has to, that the judge fell into error at all stages of his reasoning. It says the judge ought to have found that Merck's conduct was at least causative of Sigma's belief; that Merck did have a duty to respond both in order to invoke its rights under the Specific Mechanism and generally as a matter of EU law; and that the judge erred in concluding that any reliance placed by Sigma upon Merck's failure to respond was unreasonable.

85. In my judgment this aspect of the appeal falls at the first and second hurdles. There is no challenge to the judge's finding that the failure to respond to the letter of 22 June 2009 did not induce any misunderstanding on Sigma's part because Sigma thought that Polish Singulair was already on the market and that Merck had no objection to it. At most, the failure to respond to that letter allowed Sigma's misunderstanding to persist. The crucial question, therefore, is whether Merck was under a legal duty to respond to the letter of 22 June 2009 or to any of the later letters dealing with the trade mark issues.

86. In addressing this question, I begin with some general observations. First, there is no suggestion that Merck was or ought to have been aware of Sigma's existing state of mind and, in particular, the misunderstanding which it had already formed as to Merck's attitude to the importation of patented pharmaceutical products from Poland. Second, it cannot be said that any action by Merck fostered that misunderstanding. Third, there was no contractual or other relationship between Sigma and Merck outside the scope of the Specific Mechanism which could be said to have generated an

obligation upon Merck to respond to letters from Pharma XL or Sigma. Fourth, standing by and taking no steps to pursue a claim for infringement of patent does not in general make it unconscionable to bring a claim at a later time but still within the limitation period. It follows that, absent any consideration of the Specific Mechanism or a general principle of EU law, there is no basis for saying that Merck is estopped from asserting its rights in this case.

87. I come then to the Specific Mechanism and EU law relating to the free movement of goods. I have explained the parties' respective contentions in relation to the Specific Mechanism in some detail earlier in this judgment. If Sigma is right as to its meaning and effect then Merck cannot enforce its rights against Sigma's activities in relation to Polish Singulair prior to December 2010, and that is so because Pharma XL's letter of 22 June 2009 was sufficient to satisfy the requirement contained in the second paragraph and yet it was not until December 2010 that Merck demonstrated an intention to oppose importation. If, on the other hand, Merck is right as to its meaning and effect, then either Pharma XL's letter was not sufficient to satisfy the requirement contained in the second paragraph, or it was never necessary to demonstrate an intention to oppose importation before that activity was rendered an infringement. But whatever the correct interpretation of the Specific Mechanism, I find it quite impossible to extract from it some more general obligation which applies outside its scope. Nor can a general appeal to EU law assist Sigma. In particular, if Merck is entitled to rely upon the derogation then it must follow, one way or another, that it was not obliged to reply to the letter of 22 June 2009. It must also follow that it was under no duty to do so, and is guilty of no failure which could found an estoppel as a matter of domestic law.

Delivery up

88. I can deal with this quite shortly. The judge having found infringement, he made a consequential order that Sigma must destroy the infringing products which it held. The question which arises is whether he fell into error in so doing, on the assumption that his finding of infringement was correct.

89. The jurisdiction to make an order for the destruction of infringing products is conferred by s.61(1)(b) of the 1977 Act. This is consistent with Article 10 of the Enforcement Directive 2004/48 EC which reads:

> "Corrective measures
>
> 1. Without prejudice to any damages due to the rightholder by reason of the infringement, and without compensation of any sort, Member States shall ensure that the competent judicial authorities may order, at the request of the applicant, that appropriate measures be taken with regard to goods that they have found to be infringing an intellectual property right and, in appropriate cases, with regard to materials and implements principally used in the creation or manufacture of those goods. Such measures shall include:
>
> (a) recall from the channels of commerce,

(b) definitive removal from the channels of commerce, or

(c) destruction."

90. The purpose of such an order was explained by Jacob LJ in *Mayne v Pharmacia* [2005] EWCA Civ 294:

> "4. Furthermore, it is important to remember what the jurisdiction to grant an order for delivery up is for. It is not anything more than a way of making sure that the injunction is obeyed. Einfield J in *Rousel Uclaf & Another v Pan Laboratories Limited* [1994] 51 FCR 316, in the Federal Court of Australia, on 17th May 1994, dealing with a very similar case, said this:
>
> > "In this case the products cannot, while they remain outside the jurisdiction, infringe the Australian patents of the applicants. Nor is there any evidence that, unless ordered to do so by the Court, the respondents intend to re-import them. All that can be said in support of such an order is that while in Australia the products infringed the patents and that the respondents should not be allowed to "gain a benefit" by "sneaking" them out of the jurisdiction. But an order for delivery up is not for punishment of the infringer or compensation to the patentee. It is to protect the patentee's rights. As I see it, the presence of the products in Papua New Guinea does not place the rights of the applicants at risk and in need of protection. See further Blanco White, Patents for Inventions 1974 4th ed para 12-128; Terrell on the Law of Patents 13th ed, para 14.178-14.180."
>
> 5. The order for delivery up therefore being ancillary to the injunction, one always has to ask whether it is necessary to be made. Sometimes the court refuses to make it simply on the basis that a particular machine which has been found to infringe can be modified. In that case the court makes the alternative order of modification upon oath. There is no case for delivery up of material which may have had a temporary presence in this country."

91. In this case the judge ordered delivery up for five reasons. First, he thought the best way to ensure compliance with the injunction was to order delivery up. Second, Sigma's retention of unlawfully imported products would give it an unwarranted advantage when the SPC expired because it might well be able to sell those products into the market more quickly than would have been the case had it not infringed. Third, the fact the products were perfectly marketable was neither here nor there; their relevant characteristic was that they were infringing. Fourth, the remedy was proportionate because the products ought never to have been imported. Fifth, there were no third party interests which required consideration.

92. On this appeal, Sigma contends the judge fell into error. It says that the effect of the order is that the products must be destroyed even though it is now perfectly lawful to sell them in the United Kingdom. This, it says, is senseless and punitive. It continues that it should also be borne in mind that the products were imported and repackaged in good faith and in the belief that Merck did not object; that the products were in fact made by Merck; and that the order has had the effect of preventing the sale of products in the United Kingdom after the expiry of the SPC and so also allowing Merck to maintain price differentials between the market in the United Kingdom and the markets of other Member Sates.

93. In considering these submissions I would emphasise as the outset that an order for delivery up is a discretionary remedy and so Sigma must show the judge has erred in principle or that he has exceeded the generous ambit within which reasonable disagreement is possible. It must also be noted that, as Sigma fairly accepted, the question whether the judge has fallen into error must be considered as at the date he made his order.

94. I turn then to consider the various matters relied upon by Sigma. As for the first point, it is of course true that Merck no longer has any relevant rights but, as I have said, the matter must be judged as at the date of the order, and this was made some nine months before the SPC expired. I also accept that Sigma has acted in good faith and in the belief that Merck did not object. But this is far from determinative; Sigma had been found to infringe and the products it had imported were all infringing goods. So also, the fact that the products were originally made by Merck is beside the point. They were bought in a jurisdiction that did not offer protection at the relevant time and, on the assumption the judge was right, their importation into the United Kingdom amounted to an infringement. Finally, it is true that the effect of the order is to prevent the sale of the products in the United Kingdom after the expiry of the SPC, but this is because the judge found them to be infringing products. As he held, to allow Sigma to sell them after the expiry would have been to confer upon it an unwarranted advantage.

95. For all these reasons I am satisfied that the judge was entitled to make the order he did, on the assumption his finding of infringement was correct. It cannot be said he erred in principle or made an order which was plainly wrong.

Reference to the Court of Justice

96. Under Article 267 of the TFEU this court may submit a request to the Court of Justice for a ruling on a question concerning the interpretation of a rule of EU law if it considers it necessary to do so in order to resolve a dispute before it. In my judgment this case raises three groups of questions concerning the proper interpretation of the Specific Mechanism which must be answered for this court to decide this appeal.

97. The first concerns the conditions which must be satisfied before a patent holder may bring infringement proceedings under the Specific Mechanism and, in particular, whether the derogation confers upon the patent holder an option of preventing imports falling in its scope; and whether the derogation is inapplicable unless and until the patent holder demonstrates his intention to exercise that option.

98. The second concerns the identity of the person who must give the notice under the second paragraph of the Specific Mechanism and, in particular, whether a notification is compliant if it is given by an applicant for regulatory approval in the Member State into which the products are to be imported; and whether it makes any difference if the notification is given and the application for regulatory approval is made by one legal entity within a group of companies which form a single economic unit, and the acts of importation are to be carried out by another legal entity within that group under licence from the first legal entity.

99. The third concerns the identity of the person to whom the notice must be given under the second paragraph of the Specific Mechanism and, in particular, whether, in a case where a group of companies form a single economic unit comprising a number of legal entities, it is 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 which has legal ownership of or an exclusive licence under the patent. A subsidiary question also arises as to whether a notification which is otherwise compliant is rendered non-compliant if it is addressed to the "the Manager, Regulatory Affairs".

100. I recognise that this court is not obliged to make a reference but I believe it is appropriate to do so for the following reasons. First, these questions are not *acte clair*. Second, the Specific Mechanism has not yet been considered by the Court of Justice and, although its Iberian predecessor was considered by the Court in Case C-191/90 *Generics and Harris Pharmaceuticals*, there is uncertainty as to how the decision of the Court in that case should be understood. Finally, the parties helpfully provided to us after the hearing an agreed table which shows that the Specific Mechanism will continue to be relevant until 2019. In all these circumstances I believe it to be desirable that the questions raised in this case are answered authoritatively as soon as possible.

101. I would therefore make a reference to the Court of Justice for a preliminary ruling on each of the three groups of questions posed at [97], [98] and [99] above. They are currently formulated in general terms on the basis of questions originally proposed by Sigma. We have not had the benefit of any comments from Merck. Accordingly, I would invite the parties to consider them further in the light of this judgment and to propose draft questions and a draft reference for our consideration.

Lady Justice Black:

102. I agree.

Lord Justice Patten:

103. I also agree.