

Neutral Citation Number: [2016] EWHC 1896 (Pat)

Appeal No: CH-2016-000026

IN THE HIGH COURT OF JUSTICE

**CHANCERY DIVISION**

**PATENTS COURT**

Rolls Building

Fetter Lane, London EC4A 1NL

Date: 29 July 2016

**Before** :

MR JUSTICE ARNOLD

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**Between :**

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| --- | --- | --- |
|  | **MERCK SHARP & DOHME CORPORATION** | Appellant |
|  | **- and -** |  |
|  | **THE COMPTROLLER-GENERAL OF PATENTS, DESIGNS AND TRADE MARKS** | Respondent |

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**Thomas Hinchliffe QC** (instructed by **Hogan Lovells International LLP**) for the **Appellant**

**Nicholas Saunders** and **Malcolm Birdling** (instructed by the **Treasury Solicitor**) for the **Respondent**

Hearing date: 20 July 2016

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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MR JUSTICE ARNOLD

**MR JUSTICE ARNOLD :**

Introduction

1. This is an appeal by Merck Sharp & Dohme Corp (“MSD”) from a decision of Dr Lawrence Cullen, Deputy Director, acting for the Comptroller-General of Patents, Designs and Trade Marks dated 12 January 2016 (O/117/16) to refuse MSD’s application for a supplementary protection certificate SPC/GB14/062 (“the Application”) on the ground that it did not comply with Article 3(b) of European Parliament and Council Regulation 469/2009/EC of 6 May 2009 concerning the supplementary protection certificate for medicinal products (codified version) (“the SPC Regulation”). MSD contends that the application did comply with Article 3(b). In the alternative, MSD contends that, to the extent that the application did not comply with Article 3(b) at the application date, this was an irregularity which was capable of being rectified, and was rectified, subsequently pursuant to Article 10(3) of the SPC Regulation.
2. These issues arise because, as at the date of the Application, MSD did not have a United Kingdom marketing authorisation for its medicinal product Atozet. MSD had applied for marketing authorisations in a number of Member States of the European Union, including the UK, under the decentralised procedure established by European Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (“the Medicinal Products Directive”). MSD had been notified of the close of the procedure, but the time for the national competent authorities (“NCAs”) to adopt decisions to grant marketing authorisations had not yet expired, and the UK NCA, the Medicines and Healthcare Products Regulatory Agency (“MHRA”), had not done so. The MHRA subsequently granted MSD a marketing authorisation within the time limited for it to do so.

The decentralised procedure

1. There are currently three different procedures that can be used to submit a medicinal product for marketing authorisations in the EU. These are:
   1. the centralised procedure (“the CP”) established by European Parliament and Council Regulation 726/2004/EC of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;
   2. the mutual recognition procedure (“the MRP”) established by the Medicinal Products Directive; and
   3. the decentralised procedure (“the DCP”).
2. As its name suggest, the CP is a process whereby the application for a marketing authorisation is made to the European Medicines Agency and, if granted, the marketing authorisation permits the holder to market the medicinal product anywhere in the EU.
3. The MRP and DCP are both based upon the principle of mutual recognition. This principle requires that, where an application for marketing authorisation has been granted in one Member State for a particular medicinal product, the NCAs in all other Member States ought to recognise that grant and grant corresponding marketing authorisations for that medicinal product in their own countries. The two processes differ in that:
   1. The MRP applies when the medicinal product has already been approved in one Member State. Marketing authorisations in the other Member States are granted on the basis of recognition of the existing marketing authorisation.
   2. The DCP applies when the medicinal product has not yet been approved in any Member State. The DCP allows for applications for marketing authorisations to be made simultaneously in several Member States. One of these is designated by the applicant as the “reference member state” (“RMS”). The remaining member states are referred to as “concerned member states” (“CMSs”). The RMS coordinates the process for approval of the marketing authorisation application, as described below.
4. There are some products that are required to be authorised by the CP (see Regulation 726/2004/EC Article 3 and the Annex). If the product is not one that is required to be authorised centrally, the choice of whether the MRP or DCP should be used depends upon whether or not the medicinal product has already been authorised in any Member State.
5. Under the DCP, the process is as follows:
   1. the applicant applies simultaneously to the NCAs in multiple Member States. One of those states is nominated by the applicant as the RMS (see Article 28(1) set out below).
   2. The RMS must, within 120 days, prepare a draft assessment report, draft summary of product characteristics (“SmPC”) and draft labelling and packaging and send these draft documents to the CMSs (see Article 28(3)).
   3. The CMSs have a further 90 days to approve the draft documents and inform the RMS of their approval (see Article 28(4)).
   4. On agreement of all the CMSs, the RMS records the agreement of all parties, closes the procedure and informs the applicant accordingly (see Article 28(4)).
   5. Each Member State has 30 days from the closure of the procedure to adopt a decision (i.e. grant a marketing authorisation) in conformity with the approved assessment report, approved SmPC and approved labelling and packaging (see Article 28(5)).
6. Member States are required to take all appropriate measures to ensure that the procedure for granting a marketing authorisation (i.e. stages (ii), (iii) and (iv) above) is completed with 210 days after the submission of a valid application (see Article 17(1)). The additional 30 days in which to grant a marketing authorisation takes the total period to 240 days.

The facts

1. The Application concerns the product “ezetimibe and atorvastatin or pharmaceutically acceptable salts thereof, including atorvastatin as atorvastatin calcium trihydrate”. Ezetimibe and atorvastatin is the combination of active ingredients present in Atozet.
2. The basic patent on which the Application relied is European Patent (UK) No. 0 720 599, entitled “Hydroxy-substituted Azetidinone Compounds Useful as Hypocholesterolemic Agents” (“the Patent”). This was filed on 14 September 1994 with an earliest priority date of 21 September 1993 and granted on 19 May 1999. The Patent protected both ezetimibe and combinations of ezetimibe with certain other active ingredients. It is not disputed for present purposes that a pharmaceutical composition comprising ezetimibe and atorvastatin is protected by claim 17 of the Patent (which refers to atorvastatin by the code CI-981). The Patent expired on 13 September 2014.
3. On 4 April 2003 MSD obtained a marketing authorisation in respect of a medicinal product whose active ingredient was ezetimibe, and on 23 October 2003 MSD obtained an SPC in respect of that product. On 18 November 2004 MSD obtained a marketing authorisation in respect of a medicinal product whose active ingredients were ezetimibe and simvastatin, and on 30 June 2006 MSD obtained an SPC in respect of that product.
4. In September 2006 MSD began development of a fixed dose combination of ezetimibe and atorvastatin in tablet form. It encountered problems in establishing a satisfactory formulation, and this work continued until 2013.
5. In September 2013 MSD filed applications for marketing authorisations in a number of Member States in respect of Atozet under the DCP and designated Germany as the RMS. The NCA in Germany is the Bundesinstitut für Arzneimittel und Medizinprodukte (“BfArM”, the German Medicines Agency). It appears that it was not until 13 February 2014 that the BfArM accepted MSD had filed a valid application, however.
6. The Application was filed on 12 September 2014 i.e. a single day before the Patent expired. At that time MSD did not have a UK marketing authorisation for Atozet. That being so, MSD could not provide any details of any UK marketing authorisation in the Application. Instead, MSD relied upon an email from the BfArM described as the “End of Procedure communication of approval: Number: DE/H/3895-3898/001-004/DC Date: 10 September 2014” (“the EoP Notice”). A copy of the EoP Notice was provided with the Application.
7. In a covering letter accompanying the Application MSD contended that the effect of the EoP Notice was that all affected Member States, including the UK, had agreed to grant marketing authorisations for Atozet and that “each Member state ... will now carry out the formal step of granting the national marketing authorisations”. MSD requested that it be permitted to supplement the Application when the UK marketing authorisation was granted.
8. On 17 September 2014 the Intellectual Property Office’s examiner wrote to MSD raising two objections to the Application. The first objection was that the Application did not comply with Article 3(b) of the SPC Regulation since MSD did not hold a valid UK marketing authorisation: the EoP Notice did not satisfy this requirement as the UK marketing authorisation had not yet been granted.The second objection was that the Applicationdid not comply with Article 3(c) of the SPC Regulation. MSD was invited to make any representations in response on or before 18 November 2014.
9. On 10 October 2014 the MHRA granted a UK marketing authorisation for Atozet to MSD’s UK subsidiary Merck Sharp & Dohme Ltd.
10. On 17 November 2014 MSD submitted a copy of the UK marketing authorisation together with the first EU marketing authorisation for Atozet, which had been granted in France on 12 September 2014. These were provided under cover of a letter which asserted that these documents were submitted so as to rectify any irregularities in the Application.
11. The examiner maintained that the conditions for the grant of an SPC were not met, and after further exchanges of correspondence, the matter proceeded to a hearing before the hearing officer on 3 September 2015. In his decision the hearing officer concluded that the Application did comply with Article 3(c) of the SPC Regulation, but that it did not comply with Article 3(b) and that that was not an irregularity which could be cured under Article 10(3).

The legislative framework

*The SPC Regulation*

1. The SPC Regulation includes the following recitals:

“(4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

(5) This situation leads to a lack of protection which penalises pharmaceutical research.

(7) A uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market.

(8) Therefore, the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted is necessary. A regulation is therefore the most appropriate legal instrument.

(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.”

1. Articles 3, 7, 9 and 10 of the SPC Regulation provide, so far as relevant:

“*Article 3*

**Conditions for obtaining a certificate**

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

…

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

…

*Article 7*

**Application for a certificate**

1. The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted.

2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

3. The application for an extension of the duration may be made when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8(1)(d) or Article 8(2), respectively, are fulfilled.

4. The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate.

5. Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No 1901/2006, the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate.

*Article 8*

**Content of the application for a certificate**

1. The application for a certificate shall contain:

(a) a request for the grant of a certificate, stating in particular:

(i) the name and address of the applicant;

(ii) if he has appointed a representative, the name and address of the representative;

(iii) the number of the basic patent and the title of the invention;

(iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3(b) and, if this authorisation is not the first authorisation for placing the product on the market in the Community, the number and date of that authorisation;

(b) a copy of the authorisation to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC or Article 14 of Directive 2001/82/EC;

(c) if the authorisation referred to in point (b) is not the first authorisation for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication;

(d) where the application for a certificate includes a request for an extension of the duration:

(i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006;

(ii) where necessary, in addition to the copy of the authorisation to place the product on the market as referred to in point (b), proof of possession of authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.

2. Where an application for a certificate is pending, an application for an extended duration in accordance with Article 7(3) shall include the particulars referred to in paragraph 1(d) of this Article and a reference to the application for a certificate already filed.

3. The application for an extension of the duration of a certificate already granted shall contain the particulars referred to in paragraph 1(d) and a copy of the certificate already granted.

…

*Article 9*

**Lodging of an application for a certificate**

1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorisation referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.

The application for an extension of the duration of a certificate shall be lodged with the competent authority of the Member State concerned.

…

*Article 10*

**Grant of the certificate or rejection of the application for a certificate**

1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9(1) shall grant the certificate.

2. The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.

3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.

4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.

5. Member States may provide that the authority referred to in Article 9(1) is to grant certificates without verifying that the conditions laid down in Article 3(c) and (d) are met.

6. Paragraphs 1 to 4 shall apply mutatis mutandis to the application for an extension of the duration.”

*The Medicinal Products Directive*

1. Articles 17, 28 and 31 of the Medicinal Products Directive provide, so far as relevant:

“*Article 17*

1. Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of 210 days after the submission of a valid application.

Applications for marketing authorisations in two or more Member States in respect of the same medicinal product shall be submitted in accordance with Articles 28 to 39.

…

*Article 28*

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

…

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

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

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

*Article 31*

1. The Member States, the Commission, the applicant or the marketing authorisation holder shall, in specific cases where the interests of the Union are involved, refer the matter to the Committee for application of the procedure laid down in Articles 32, 33 and 34 before any decision is reached on an application for a marketing authorisation or on the suspension or revocation of a marketing authorisation, or on any other variation of the marketing authorisation which appears necessary.

…”

Issue 1: Did the Application comply with Article 3(b)?

1. MSD contends that, on a proper construction of Article 3(b) of the SPC Regulation, an EoP Notice sent pursuant to Article 28(4) of the Medicinal Products Directive is equivalent to a valid marketing authorisation for that purpose. The Comptroller disputes this.
2. Although the issue primarily concerns the interpretation of Article 3(b) of the SPC Regulation, it is necessary first to consider Article 28(5) of the Medicinal Products Directive. Counsel for MSD pointed out that Article 28(5) is expressed in mandatory terms (“shall adopt a decision in conformity with”). It does not give the Member States any discretion as to what to do. On the contrary, it requires them to grant a marketing authorisation and to do so within 30 days of the closure of the procedure under Article 28(4). Accordingly, he argued, what mattered was the closure of the procedure following the agreement of all the CMSs to approve the relevant documents. Once that had happened, the grant of the marketing authorisations pursuant to Article 28(5) was an administrative formality.
3. Counsel for the Comptroller disputed this. He submitted that the Medicinal Products Directive only harmonised the procedure for obtaining marketing authorisations. The actual grant of marketing authorisations remained a matter for the Member States acting in accordance with their national laws. Thus in the UK marketing authorisations are granted by the MHRA under the Human Medicines Regulations 2012, SI 1916/2012.
4. I was not shown any authorities on the interpretation of Article 28(5), and therefore I must approach it as a matter of first impression. I accept that it is expressed in mandatory terms. I do not accept that it follows that the grant of marketing authorisations pursuant to Article 28(5) is an administrative formality. I agree with counsel for the Comptroller that, even after the closure of the procedure under Article 28(4), it remains necessary for each Member State to decide to grant a marketing authorisation. If a Member State fails to do so within 30 days without good reason, the applicant may have remedies. Thus in this country the applicant might be able to obtain an order of mandamus compelling the MHRA to take the decision. The applicant might also be able to seek *Francovich* damages from the Member State.
5. But what if the Member State has good reason? Suppose, for example, new information concerning the efficacy or safety of the medicinal product in question became available during the 30 day period. Counsel for MSD argued that the Member State would still be obliged to grant the marketing authorisation, although in an appropriate case it could then refer the matter to the Committee for Medicinal Products for Human Use under Article 31(1) of the Medicinal Products Directive. I am not sure that this is correct, since it appears to me that Article 31(1) would permit a Member State to refer the matter to the Committee before taking a decision. But even if it is, the fact remains that it is for Member States to grant marketing authorisations, and Article 28(5) gives them 30 days from the close of the procedure in which to do so.
6. Turning to Article 3(b) of the SPC Regulation, Counsel for MSD argued that this should be interpreted having regard to the object and scheme of the SPC Regulation. The object of the SPC Regulation was to compensate a patentee for the loss of part of the period of exclusivity conferred by a patent while waiting for the grant of a marketing authorisation. The delay was caused by the need for the applicant for a marketing authorisation to prove the efficacy and safety of the medicinal product. Having regard to that object, an EoP Notice served the same purpose as a marketing authorisation, because it showed that the CMSs were in agreement that the medicinal product had the requisite efficacy and safety.
7. Counsel for MSD also argued that interpreting an EoP Notice as equivalent to the marketing authorisation was consistent, or at least was not inconsistent, with the scheme of the SPC Regulation. Since the EoP Notice required approval of the SmPC, it was sufficient to define the scope of protection of the certificate in accordance with Article 4. Although the provisions on the duration of a certificate were drafted by reference to the grant of the marketing authorisation, the present problem would only arise when an EoP Notice was issued within the last 30 days of the terms of the basic patent, and thus the term of the certificate would always be capped at five years in accordance with Article 13(2). It would still be the case that, if the marketing authorisation was withdrawn, the certificate would lapse in accordance with Article 14(d).
8. Counsel for MSD also argued that a strict insistence on the need for a marketing authorisation actually to be granted would give rise to problems. First, as the facts of the present case demonstrated, it meant that the right to an SPC depended on how quickly the NCAs issued marketing authorisations following the EoP Notice. Here the French NCA had moved quickly, and hence the French marketing authorisation had been granted before expiry of the Patent, while the MHRA had moved less quickly, and so the UK marketing authorisation was only granted after expiry. Thus there would be a lack of uniformity across the EU, contrary to the objective stated in recital (7). Secondly, this problem would be exacerbated if a Member State wrongly failed to comply with the 30 day time limit in Article 28(5). That would be particularly unfair to the applicant if the EoP Notice was issued more than 30 days before expiry of the basic patent, but one or more Member States only granted marketing authorisations after expiry of the basic patent.
9. It should be noted that the logic of MSD’s argument is that what matters is not the fact that an EoP Notice has been issued, but the fact that the CMSs have all agreed that the application for a marketing authorisation meets the requirements of the Medicinal Products Directive. As counsel for MSD accepted, it would follow that an application could comply with Article 3(b) even if no EoP Notice had been issued, if the applicant could prove by other means that all of the CMSs were in fact in agreement at the date of the application for the SPC.
10. Counsel for the Comptroller submitted that an EoP Notice was not equivalent to a marketing authorisation for four reasons. First, the SPC Regulation referred repeatedly to the requirement for a marketing authorisation to be granted: in addition to Article 3(b), see Articles 4, 7(1), 8(1)(a)(iv), (b) and (c), 9(1), (2)(d), 11(1)(d), 13(1) and 14(d). By contrast, there was no reference to EoP Notices in the SPC Regulation.
11. Secondly, applications for SPCs were made to national industrial property offices under Article 9(1). While they were competent to consider whether a product was protected by a basic patent within Article 3(a), they were not the NCAs under the Medicinal Products Directive and they should not be required to do more than ascertain whether or not a marketing authorisation had been granted.
12. Thirdly, an EoP Notice had no legal effect. It remained for each Member State to grant a marketing authorisation which then had legal effect. As discussed above, the grant of marketing authorisations was governed by national law.
13. Fourthly, a product could not be placed on the market until the marketing authorisation was granted. This demonstrated that it was the grant of the marketing authorisation which was the key event.
14. More generally, counsel for the Comptroller argued that MSD’s arguments amounted to an invitation to the court to bend the interpretation of the SPC Regulation in order to enable MSD to obtain an SPC in the present case. That approach to interpretation was unjustified. As recital (10) showed, the SPC Regulation was intended to strike a balance between the different interests at stake. Moreover, it was important that the system for obtaining SPCs was clear, straightforward and predictable. In any event, MSD was not particularly deserving of the sympathy of the court given that it had not filed the Application until the last year of the Patent. The fact that MSD would be able to get an SPC in France, where the NCA had granted a marketing authorisation extremely quickly, but not in other Member States where NCAs had moved less quickly, was simply a consequence of the late filing of the Application.
15. In my opinion, for the reasons given by counsel for the Comptroller, the hearing officer was correct to conclude that the Application did not comply with Article 3(b): as at the date of the Application, no valid authorisation to place Atozet on the market had been granted in the UK, and the EoP Notice was not equivalent to a marketing authorisation for this purpose.

Issue 2: Was the absence of a marketing authorisation an irregularity which could be cured under Article 10(3)?

1. Article 10(3) requires the competent industrial property office to give the applicant an opportunity to rectify the irregularity if the application does not meet the conditions laid down in Article 8. In a case such as the present, the conditions are those specified in Article 8(1). The relevant condition for present purposes is Article 8(1)(b), which requires the application to contain a copy of the marketing authorisation referred to in Article 3(b).
2. MSD contends that, if the marketing authorisation has not yet been granted at the date of the application, but is granted later, the failure to include a copy of the marketing authorisation in the application is an irregularity which can be cured subsequently pursuant to Article 10(3) by providing a copy of the authorisation when it becomes available. The Comptroller contends that it is not possible to rectify the irregularity in this way, because Article 8(3) requires a copy of the authorisation “as referred to in Article 3(b)” i.e. a marketing authorisation which had been granted as at the date of the application. A failure to provide such a marketing authorisation was not cured by providing a marketing authorisation granted at a later date.
3. In support of its argument, MSD relies on the decision of the Court of Appeal in *E I du Pont de Nemours & Co v UK Intellectual Property Office* [2009] EWCA Civ 966, [2010] RPC 6 (“*DuPont*”). *DuPont* concerned an application for a six month extension to the period of protection provided by an SPC in accordance with the provisions of European Parliament and Council Regulation 1901/2006/EC of 12 December 2006 on medicinal products for paediatric use (“the Paediatric Regulation”) and the SPC Regulation. As explained below, such applications must be made a certain time before the expiry of the SPC. DuPont did not have all of the materials which Article 8 of the SPC Regulation required it to submit with its extension application by the deadline. Although it had filed a paediatric investigation plan complying with Article 36(1) of the Paediatric Regulation, it did not have copies of updated marketing authorisations from all Member States, as required by Article 8(d)(ii). This was because the process for agreeing the variation to the marketing authorisations had not been completed by the CMSs by the deadline for applying for the extension. In addition, even when that process was completed, some Member States failed to update their marketing authorisation within the specified time period. The Court of Appeal held that, in these circumstances, the omission of the updated marketing authorisations was an “irregularity” which could be cured when they became available subsequently in accordance with Article 10(3).
4. Jacob LJ expressed his reasons for reaching this conclusion as follows:

“51. I see no reason for giving ‘irregularity’ such a restrictive meaning [as something missing from the application which could have been contained within it at the time] – and every reason to give it a wide enough meaning to encompass cases such as the present where the defect is cured after the date of application.

52.  Firstly and most tellingly, all the Recitals and the Explanatory Memorandum which Miss May [counsel for the Comptroller] deployed so effectively in persuading me on the first two points turn against her argument on this point. For they are all about the reward of an extension being made available if the applicant complies with its PIP and gets the necessary MAs.  The reward is for that, not for doing all that before the application is made.

53.  Most tellingly there is no Recital or other material indicating everything must be in the application or capable of being in the application by the date it must be made.

54.  Moreover if she were right, then the problem of the laggard Member State would be significant – and it would be unrealistic to think that the Community legislator was so innocent as to think that all Member States would be certain to get it right within the 90 days provided for. There is no indication of any intention that the reward should be contingent upon all Member States doing the right thing in time. And no indication that the legislator intended to draw a distinction between what might be called a ‘mere irregularity’ and something more fundamental.

55.  Nor do I think her point about the last dates for an application particularly telling. She sought to ally it with a point about certainty for third parties, submitting that competitors should be in a position to know where they stand at an early date. But there is nothing about that in either Regulation. The nearest Miss May could point to was the first sentence of [the] ninth Recital of the SPC Regulation – 10th of the codified version):

All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account.

That is far from saying that everything must be complete by the date of the application.

56.  The ‘third party certainty’ point is further undermined by the fact that there is no requirement that third parties shall be entitled to see sufficient of the details of the application to form a view as to whether it will succeed. Or any of the details of an application for an MA or a variation of an MA. Nor is there any requirement that a national authority must come up with a decision by a particular time after the application. So third parties must wait for an indeterminate time – which on any view may include an Art 10(3) time extension – before knowing the result of the application for an extension.

57.  Besides, on any rational view, the importance of research into paediatric uses of medicines stands ahead of the purely commercial interests of third parties. The importance of that research being conducted and the results disseminated is the whole point of the Paediatric Regulation. A narrow construction of ‘irregularity’ is inimical to that fundamental purpose.

58.  Miss May indicated that, for future guidance, it would be helpful for the Comptroller to know just how late an applicant can be in supplementing its application with missing material.  As at present advised (and of course this is strictly a question not before us) I would only say this:  that in setting the Article 10(3) period the Comptroller can and should take into account all relevant factors. These will include the reasons for the failure to include all the Article 8(1) materials in the application, the extent to which the applicant is guilty of unreasonable conduct or delay, and how close to the date of expiry of the SPC full compliance with Article 8(1) is expected.  The guiding principle is the purpose of the Regulation.   The upshot is that unless the applicant has behaved unreasonably, time should be extended so that it gets its reward.”

1. Stanley Burton LJ agreed for reasons which he expressed as follows:

“61. The crucial issue before us concerns Article 10(3), and the meaning of ‘irregularity’. There are a number of reasons for giving the word a wide meaning. First, its context. It takes its meaning from the first part of the sentence. The natural meaning of ‘irregularity’ is a respect in which the application for the certificate does not meet the conditions laid down in Article 8. There is no contextual indication of any different meaning, and no basis in the wording or Article 10 or, as Lord Justice Jacob has shown, in the Recitals to the Regulation to limit its meaning. More particularly, nothing in the Recitals or the substantive provisions of the Regulation suggests the distinction contended for by Miss May.

62.  Secondly, the requirements of Article 8 are documentary. If an applicant produces the right documents, he is entitled to his extension. An irregularity is a failure of the application to contain the requisite documents. An irregularity can be rectified under Article 10, by submitting the missing documents. There is nothing to indicate that rectification requires anything else, and in particular that the relevant authority must not only consider whether the documents are genuine and fulfil the requirements of the Regulation but also whether they came into existence or could have come into existence before the latest date for the submission of the application.

63.  Lastly, but by no means least important, there are the reasons given by Jacob L.J. in paragraphs 52 to 54 of his judgment for giving ‘irregularity’ the natural meaning derived from its context.”

1. Counsel for MSD submitted that much of this reasoning was equally applicable to the present case. In particular, he argued that, just as DuPont in that case had done everything that was required of it by the relevant date and was simply waiting for the Member States to process the paperwork, so too had MSD in the present case.
2. Counsel for the Comptroller submitted that there were a number of important distinctions between the two cases which made the reasoning in *DuPont* inapplicable here.
3. First, an application for an SPC is governed by Article 7(1) and (2) of the SPC Regulation, whereas an application for an extension is governed by Article 7(3), (4) and (5). Article 7(1) and (2) provide that an application for an SPC can only be made after two events have already occurred: first, the grant of the patent; and secondly, the grant of a marketing authorisation. The applicant has to wait until both events have occurred, and then it has a period of six months to apply for an SPC. By contrast, Article 7(3), (4) and (5) provide that an application for an extension to a certificate has to be before an event occurs. It must be made two years before the expiry date of the SPC (or, in the earlier transitional period considered in *DuPont*,six months before expiry of the SPC). Thus, in the case of an application for an extension, an applicant must apply by a specific date whether it has all the relevant materials or not. If no application is made by this date, no extension can be obtained.
4. Secondly, Article 3 of the SPC Regulation does not apply to an application for an extension. In the case of an application for an SPC, however, Article 3 is unambiguous. It is a condition of the grant of an SPC that there be a valid marketing authorisation “at the date of that application”. This is precisely what Jacob LJ noted at [53] was missing from the provisions relating to applications for extensions.
5. Thirdly, even if the absence of a valid marketing authorisation were considered an “irregularity”, this could only be cured under Article 10(3) of the SPC Regulation insofar as it related to a requirement set out in Article 8. In *DuPont,* the requirement in issue was that in Article 8(1)(d)(i) of the SPC Regulation, which cross-refers to Article 36(1) of the Paediatric Regulation. In the instant case, Article 8(b) cross-refers to Article 3(b) of the SPC Regulation which requires that there be a valid marketing authorisation at the time of the application. Thus, even if MSD were permitted belatedly to submit the marketing authorisation, this could not cure the defect in its application, namely the impossibility of satisfying a mandatory condition for the grant of an SPC. It would be different if a marketing authorisation had been granted by the date of the application, but for some reason the applicant had failed to include a copy: then the irregularity could be cured by supplying a copy subsequently.
6. In my opinion, for the reasons given by counsel for the Comptroller, the hearing officer was correct to conclude that the defect in the Application was not an irregularity which could be rectified under Article 10(3).

Should there be a reference to the CJEU?

1. Although I have expressed my opinion on the two issues raised by this appeal, I do not feel able to say that the answers I have given are *acte clair*. This is particularly so with regard to the second issue. Furthermore, I note that MSD’s applications for SPCs for Atozet have given rise to divergent decisions amongst the Member States. To date, applications have been refused in Portugal and Sweden on the same ground as in the UK. But applications have been granted in Denmark, Greece, Italy and Luxembourg. Furthermore, although MSD’s application has so far been refused in the Netherlands, the ground of refusal was non-compliance with Article 3(c). In its decision dated 3 May 2016 the Dutch Patent Office held there was no objection under Article 3(b). As I understand its reasoning, it accepted that an EoP Notice should be regarded as equivalent to a marketing authorisation for this purpose. In these circumstances, I consider that it is only by referring the matter to the Court of Justice of the European Union that an authoritative ruling can be obtained.

Conclusion

1. For the reasons given above, I shall refer two questions to the CJEU for a preliminary ruling. I will hear counsel as to the precise wording of the questions, but in essence the questions are as follows:
2. Is an end of procedure notice issued by the reference member state under Article 28(4) of the Medicinal Products Directive equivalent to a granted marketing authorisation for the purposes of Article 3(b) of the SPC Regulation?
3. If the answer to question (1) is no, is the absence of a granted marketing authorisation at the date of the application for a certificate an irregularity which can be cured under Article 10(3) of the SPC Regulation once the marketing authorisation has been granted?