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IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice

Strand, London, WC2A 2LL

Date: 22nd May 2009

Before :

Mr John Baldwin QC

(sitting as a Deputy Judge of the Chancery Division)

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IN THE MATTER OF Council Regulation (EEC) No.1768/92 (as amended) and Council Regulation (EC) No.1901/2006 (as amended)

AND IN THE MATTER OF Application No. SPC/GB/95/010 by E I du Pont Nemours & Co for an extension of an SPC

AND IN THE MATTER OF an appeal from the decision of the Comptroller of Patents Dated 9 April 2009 (BL/O/096/09)

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Mr Peter Prescott QC (instructed by **Lovells LLP**) for the **Appellant**

Miss Charlotte May (instructed by **Treasury Solicitor**) for the **Respondent**

Hearing dates: 12, 13 May 2009

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JUDGMENT

Dated 22 May 2009

1.
This is an appeal from the decision of the Comptroller General of Patents given by Hearing Officer Cullen on 9 April 2009 in which he found that an application by E I du Pont de Nemours & Co (Dupont) to the Intellectual Property Office (IPO) for a six month extension to the period of protection provided by a supplementary protection certificate (SPC) in respect of the product marketed as Cozaar contained irregularities and therefore was not acceptable.

2.
In order to understand this appeal it is necessary to rehearse some of the background to SPCs and the applications for extensions thereof. It is also necessary to understand some of the requirements that are in place before medicinal products can be marketed in the EC and it is convenient to deal with this latter first.

3.

Medicinal products cannot be marketed in the EC unless the manufacturer or supplier has obtained a Marketing Authorisation (MA) from the competent authority, and there are three ways in which an application for such can be made (i) by the mutual recognition procedure (MRP), (ii) by the centralised procedure (CP) and (iii) by the decentralised procedure, only the first two of which are relevant to this appeal.

4.
The MRP is regulated by Directive 2001/83/EC (the MRP Directive) and enables an MA granted in one Member State (called the Reference Member State or RMS) to be recognised by one or more other Member States (called the Concerned Member States or CMS). Once an MA is granted in the RMS, applications can proceed through the relevant national authorities and the result is a bundle of national MAs in respect of the same product.

5.
The CP is regulated by Regulation (EC) No 726/2004 (the CP Regulation) and provides for a single application to a Community authority (the European Medicines Agency or EMEA). The application is dealt with Community-wide and, if granted, results in an MA valid throughout the Community.

6.
MAs resulting from use of either the MRP or the CP must contain the essential medical information relating to the product and, in particular, will include a summary of the product characteristics (Art 11 of the MRP Directive) and the requisite labelling and packaging information (Arts 54, 55, 59 and 63 of the MRP Directive).

7.
A manufacturer can only market a medicinal product in accordance with the terms of its MA. However, once a medicinal product is on the market, it can be used or prescribed according to the judgment of the relevant health professional. Thus the MA does not limit the use to which a medicine can in fact be put. But it does limit the way the manufacturer can market the product. And if the manufacturer wishes to change the way the product is marketed, for example, sell it in a different physical form or for a different indication, then it must apply for a variation of its MA.

8.
Both the MRP Directive (and Regulation (EC) No 1084/2003) and the CP Regulation (and Regulation (EC) No 1085/2003) provide for variations to existing MAs and relevant to this appeal is the class of variation known as Type II, which includes a different use and dosage. Pursuant to the application to vary, the summary of product characteristics and labelling and packaging information must be updated to reflect the variation and to ensure that the same information is presented in all Member States in which the medicinal product is to be sold.

9.
MAs take time to acquire and, if the active ingredient of the potential product is protected by a patent, this time may eat into the period during which the manufacturer is protected by its patent from others who may want to make and sell the same drug. This is where SPCs come in.

10.
SPCs were created by Council Regulation (EEC) No 1768/92 (the SPCR) and their function is to extend the term of patent protection for products which are the subject of an MA beyond the date when the underlying patent would otherwise expire. The purpose of the extension of term is to provide a means whereby the patentee may be compensated for the time and expense it spent in

obtaining an MA (during which time its product was not on the market). Article 7 of the SPCR provides for the timing of the application for an SPC.

11.
Recently, those concerned with these matters reached the conclusion that the paediatric population (being all those under the age of 18) were not being served as well as they might be by the then current procedures. More particularly, a Council Resolution of 14 December 2000 called on the Commission of the European Communities to make proposals in the form of incentives, regulatory measures or other supporting measures in respect of clinical research and development to ensure new medicinal products for children and medicinal products already on the market are fully adapted to the specific needs of children. Such proposals were presented on 29 September 2004 (COM(2004) 599) (and included an Explanatory Memorandum) and on 12 November 2004 the Council decided to consult the European Economic and Social Committee (EESC) who gave its Opinion at a meeting on 11/12 May 2005. The position of the European Parliament adopted at first reading on 7 September 2005 included some new proposals and in particular, so far as this appeal is concerned, indicated that the reward of a 6 month extension to the SPC should be granted if all the measures in the agreed paediatric investigation plan had been complied with and procedures for obtaining marketing authorisation were in progress.

12.
The Commission considered these proposals and on 10 November 2005 issued an amended proposal for a Regulation (COM(2005) 577). It rejected the position of the European Parliament in these terms:

The Commission does not accept amendments 14 and 51 which aim to remove the requirement for a medicinal product to be authorised in all Member States as a prerequisite for the extension of the supplementary protection certificate. The paediatric regulation aims to ensure that children throughout the EU are provided with safe and effective medicines, and this is achieved through the requirement that an extension of the supplementary protection certificate is available only if the product is authorised in all Member States. Experience has shown that market forces alone do not ensure the availability of medicines for children. Medicinal products are frequently not authorised in Member States where there is no patent or where the population is small.

Amendment 51 proposes that the supplementary protection certificate be granted in Member States were [sic] marketing authorisation procedures are still in progress. However, Article 36, in relation to Article 29, provides that the extension of the supplementary protection certificate is only granted if information on the paediatric studies conducted is included in the product information when an authorisation is granted. For this reason, marketing authorisation procedures should be completed for the extension of the supplementary protection certificate to be granted.

Furthermore, in the operation of the mutual recognition and decentralised procedures of Directive 2001/83/EC as amended by Directive 2004/27/EC, Member States have only 30 days from the assessment by the reference Member State to grant marketing authorisations. Differences in the operation of national competent authorities should therefore not lead to significant variation in the authorisation date in the different Member States.

13.
The upshot was Regulation (EC) No 1901/2006 (the PR) which came into force on 26 January 2007 and established a system of obligations and rewards and incentives in order to stimulate and improve the research, development and authorisation of medicinal products for the paediatric population. The

rewards include a 6 month extension of the duration of an SPC and the issue on this appeal is whether or not Dupont is in a position to claim that reward in the case of Cozaar.

14.
The PR amended the SPCR, including Article 7 thereof, to provide for applications for an extension of the duration of an SPC. Article 7 (4) provides that such an application shall be lodged not later than two years before the expiry of the SPC but Article 7(5) provides that, notwithstanding Article 7(4), for 5 years following the entry into force of the PR the application for an extension of the duration of an SPC already granted shall be lodged not later than six months before the expiry of the certificate.

15.
It was common ground between counsel, and I accept, that certainty with respect to these dates is important to industry and to consumers since they inform the patentee as well as third party manufacturers and consumers about the times during which a product is the subject of patent protection and possible monopoly rights. Certainty with respect to dates enables companies to plan ahead. Moreover, interested persons ought to be able to determine the term of patent protection (including any extended term) from publicly available documents.

16.
Miss May, counsel for the IPO, also pointed out that the SPCR envisaged a simple and transparent system which could easily be applied by the parties concerned and did not lead to excessive bureaucracy, relying on [39] of Gilead v The Comptroller [2008] EWHC 1902 (Pat) and paragraph 16 of the Commission Proposal (COM(90) 101) which led to the SPCR. She said that it was no function of the local patent offices to inquire into the science behind any application; that it was and was intended to be an administrative system which could easily be implemented in those offices.

17.
Mr Prescott QC reminded me that neither the travaux préparatoires nor the recitals can trump the operative parts of the Regulation and that

“the travaux préparatoires are an ancillary tool in legislative interpretation. They cannot in themselves be used to contradict the clear wording of the legislation”;

(C-280/07 Hauptzollamt Bremen v. Tyson Perketthandel [48] per A-G Sharpston). He also drew my attention to Aerotel Ltd v. Telco Holdings Ltd [2006] EWCA Civ 1371 [11], per Jacob LJ, referring to travaux préparatoires:

“Only a bull's-eye counts” (per Lord Steyn in Effort Shipping v Linden Management [1988] AC 605 at 625),

and to Higgs v. R [2008] EWCA Crim 1324, [34], again per Jacob LJ, quoting more fully from Lord Steyn:

“I would be quite prepared, in an appropriate case involving truly feasible alternative interpretations of a convention, to allow the evidence contained in the travaux préparatoires to be determinative of the question of construction. But that is only possible where the court is satisfied that the travaux préparatoires clearly and indisputably point to a definite legal intention: see Fothergill v Monarch Airlines Ltd., per Lord Wilberforce, at p.278c. Only a bull’s-eye counts. Nothing less will do.”

18.

The reason for that, Mr Prescott QC submits, is that unless one is satisfied that the makers of the legislation had the precise point present to their minds (and not merely that we can read the language of the travaux and, with hindsight, make it read on to the problem a quo), the travaux are of no relevance. From a consideration of the materials put before me, I am satisfied that the makers of the legislation did have the present problem in mind and that, accordingly, it is legitimate for me to consider what was said in those documents.

19.
The SPC for Cozaar expires on 1 September 2009 and thus, pursuant to Article 7 (5) of the SPCR, the deadline for the application for an extension was 1 March 2009. Dupont lodged its application on 18 February 2009, so the issue on this appeal becomes refined to whether that application was proper in form and content and, if not, whether it can be subsequently amended such that it can be regarded as having been in proper form before the deadline of 1 March.

20.
Article 8 of the SPCR, as amended by the PR, specifies the content of the application for an SPC and the relevant part is in these terms:

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) .....

(b) a copy of the authorization 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 authorization

and the summary of the product characteristics listed in Article 4a

of Directive 65/65/EEC or Article 5a of Directive 81/851/EEC;

(c) .....

(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 authorisations to

place the product on the market as referred to in point (b), proof

that it has 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.

1a. 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) and a reference to the

application for a certificate already filed.

1b. 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.

21.
It will be seen that reference is made to Article 36 of the PR and this, in TITLE V, is in these terms:

REWARDS AND INCENTIVES

Article 36

1. Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92 [the SPCR].

The first subparagraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

2. The inclusion in a marketing authorisation of the statement referred to in Article 28(3) shall be used for the purposes of applying paragraph 1 of this Article.

3. Where the procedures laid down in Directive 2001/83/EC [the MRP Directive] have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States.

4. Paragraphs 1, 2 and 3 shall apply to products that are protected by a supplementary protection certificate under Regulation (EEC) No 1768/92 [the SPCR], or under a patent which qualifies for the granting of the supplementary protection certificate. They shall not apply to medicinal products designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

5. .....

Article 28(3) of the PR is in these terms:

3. If the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, the competent authority shall

include within the marketing authorisation a statement indicating compliance of the application with the agreed completed paediatric investigation plan. ……..

22.
The IPO's contention is that the grant of the reward identified in Article 36(1) of the PR can only be made if the application for it, i.e. for an SPC extension, includes the Article 28(3) Statement and, if the MRP procedure was being used, there are authorisations, following on from an application under Article 7 or 8 of the PR, in all Member States. But this leads to a difficulty for Dupont and the difficulty is this. The Article 28(3) Statement indicating compliance with the agreed paediatric investigation plan (PIP) is included within the MA and therefore does not come into existence prior to the grant of the MA. Dupont, as of the date of its application for an extension of the SPC, had not been granted an MA by the RMS (Holland) in respect of the relevant variation and therefore could not and did not include the 28(3) Statement within its application. Since there was no MA from the RMS, there was no MA from the other Member States either. And Dupont would not have been in a better position had its application for the MA been made using the CP (so that Article 36(3) was not engaged) since there would still have been no 28(3) Statement.

23.
Counsel for Dupont (Mr Prescott QC) submitted that this was far too narrow an approach and that since Dupont had in fact done all the relevant required studies regarding the paediatric population, it should be entitled to the 6 months reward. He accepted that the summary of product characteristics had not been agreed, but he said this was a minor consideration in the context of the time and money spent on paediatric research and one must be careful not to let the tail wag the large dog of clinical trials. His argument was that Article 8(1)(d)(i) of the SPCR needs some interpretation as Article 36(1) of the PR does not refer to any statement at all, but to the fact that where an application under Article 7 or 8 of the PR includes the results of the required studies, the holder of the SPC shall be entitled to the 6 month extension. He says that Dupont's application for an MA did indeed contain the results of those studies and accordingly the entitlement to the extension follows. He contended that the 28(3) Statement was one way of satisfying the competent authority that Article 36(1) was satisfied, but it was not the only way. As for the Article 36(3) point, he argued that the product there referred to was the active ingredient (see Article 1(b) of the SPCR) and that, as a matter of fact, there was an MA for the active ingredient of Cozaar in all Member States (being the initial MA obtained without reference to and before the coming into effect of any regulations about the paediatric population). He contended that Article 36(3) was not concerned with a requirement that any MA resulting from paediatric studies extend to all Member States. He submitted that this must be the right construction as, otherwise, his clients could not hope to comply with Article 36(3) in time, in part because some of the Member States do not timeously comply with their obligations under the MRP.

24.
It would be unfortunate indeed if manufacturers were denied their reward under Article 36 because one or more Member States could not get round to doing what they ought to be doing in a timely manner. But that problem has not escaped the attention of the relevant authorities. Miss May drew to my attention a letter from the European Commission dated 21 January 2009 to the Heads of Medicines Agencies which addressed this particular problem and urged the relevant national authorities to respect their obligations. The last two paragraphs of the letter are in these terms:

Given that the extension of the SPC under the Paediatric Regulation is based on authorisation having been obtained in all Member States, companies may face practical obstacles to receive the reward for their investment in paediatric research as a direct result of non-compliance with the legal deadlines

by the Member States' authorities. This may entail delays in the granting of the SPC extension and even the complete unavailability of the reward in cases whether the delay to grant marketing authorisation runs beyond the expiry of the SPC whose extension is intended.

I would like to stress that the situation described creates a clear risk to the achievement of the main aim of the Paediatric Regulation "to facilitate the development and accessibility of medicinal products for use in the paediatric population" (Recital 4). I would therefore urge all responsible national competent authorities which currently fail to meet their legal obligation of respecting the above deadline, to do their utmost to remedy this situation.

The fact that the Commission wrote in these terms does not, of course, indicate that they have properly construed the PR. But it is an indication that the problems of authority non-compliance identified by Mr Prescott are being addressed at Community level.

25.
In support of the contention that the 28(3) Statement was only one of the available methods of satisfying the competent authority of the Article 36(1) requirements, Mr Prescott QC drew my attention to what he referred to as Google automatic translations into a number of European languages of Article 36(2). He said that these supported his proposition that 'shall be used' in Article 36(2) does not mean 'must be used' or 'shall be used to the exclusion of anything else' but instead means 'may be used' and that other statements would suffice for the purposes of applying Article 36(1), so long as they contained the detail required under Article 36(1). I am bound to say I have never found Google automatic translations very satisfactory; they are notoriously acontextual and I would be reluctant to place much weight on them. The exercise also assumes I can retranslate for myself the automatically translated version and reach a proper understanding of what Article 36(2) means in the context of the PR. I do not regard this as a satisfactory way of proceeding.

26.
Mr Prescott QC also drew my attention to the Opinion of Advocate General Fennelly and the decision of the ECJ in Biogen Inc v Smithkline Beecham Biologicals SA Case C-181/95. In that case the patentee applying for an SPC was unable to include within its application, as required by the SPCR, a copy of the MA and the reason was that it, not being the MA holder, did not possess such a copy. The ECJ said this failure did not matter as the relevant national authority could get hold of a copy from the national authority which issued it, this being by virtue of the mutual cooperation which was incumbent on the various national authorities. But the Advocate General went further. In his Opinion, he said that the purpose of the relevant provision of the Regulation was to prove the existence of certain facts about the marketing authorisation (as referred to and specified in Article 3 of the SPCR), and that if these could be proved from some other reliable source, that should be sufficient (§§59 and 63 of his Opinion) for the grant of an SPC.

27.
By analogy, Mr Prescott QC submitted that provision from a reliable source of all that is substantively required by Article 36(1) of the PR should entitle his client to a six month extension (at least as far as Article 36(1) is concerned). This begs the question of what is substantively required by Article 36(1) and why the 28(3) Statement is referred to in Article 36(2).

28.
Mr Prescott QC's answer to this was short and simple. Article 36(1) itself said what was substantively required for the 6 month extension to an SPC, and the 28(3) statement was a convenient but not the only way of an applicant demonstrating that substantive requirement.

29.
Counsel's original submission was that the 'statement indicating compliance with an agreed paediatric investigation plan as referred to in Article 36(1) of the [PR]' required by Article 8(1)(d)(i) of the SPCR (see paragraph 20 above) was sufficiently provided by the opinion of the Paediatric Committee as to whether or not the studies conducted by the applicant were in compliance with the agreed plan (see Article 23(2) of the PR).

30.
In my judgment it is plain that an Opinion as to whether studies conducted by an applicant are in compliance with an agreed plan cannot possibly be a reliable source for a conclusion that the results of all studies conducted in compliance with that plan are included within the application. The Opinion simply does not address the relevant question, and it may be for that reason that the Opinion obtained in this case states on its face that 'This Opinion does not entitle to the rewards and incentives referred to in [Article 36(1)]', but there may be other reasons for this as well.

31.
During the course of Miss May's argument on behalf of the IPO, Mr Prescott QC abandoned reliance on the Opinion of the Paediatric Committee to satisfy the statement of compliance with Article 36(1) and pointed instead, or in addition, to the statement from the Dutch Regulatory Authority (Holland being the RMS in this case) dated 13 February 2009 to the effect that Article 24 of the PR did not provide a bar to Dupont being eligible for, inter alia, the rewards in Article 36. Miss May then accepted on behalf of the Comptroller that the compliance requirements of Articles 23 and 24 of the PR had been satisfied by Dupont in its application. But she did not accept that this was sufficient for the purposes of Article 36. She contended that Articles 23 and 24 were only about compliance with the PIP and that the rewards under Article 36 did not follow unless the product information requirements (i.e. the summary of product characteristics and the labelling and packaging content) were also satisfied and that there was an MA as a result of an application under Articles 7 or 8 of the PR in all Member States.

32.
Mr Prescott QC drew my attention to the principle of proportionality and to Lord Hoffmann's summary in CR Smith Glaziers Ltd v. Commissioners of Customs and Excise [2003] UKHL 7:

25. The Advocate General did not enlarge upon what kind of conditions might be regarded as appropriate for this purpose. But in general European law would require them to satisfy the principle of proportionality in its broad sense, which, following German law, is divided into three sub-principles: first, a measure must be suitable for the purpose for which the power has been conferred; secondly, it must be necessary in the sense that the purpose could not have been achieved by some other means less burdensome to the persons affected and thirdly, it must be proportionate in the narrower sense, that is, the burdens imposed by the exercise of the power must not be disproportionate to the object to be achieved. In the particular instance of conditions for allowing a VAT exemption, the Court of Justice has recently said that such conditions must be "necessary for the attainment of the specific objective which [the legislation] pursues and have the least possible effect on the objectives and principles of the Sixth Directive": Ampafrance SA v Directeur des Services Fiscaux de Maine-et-Loire (Joined cases C-177 and 181/99) [2000] ECR I-7013, 7074, para 60.

Mr Prescott QC submitted that the Comptroller's interpretation of the Regulation would violate the principle of proportionality. It would mean that, even though an applicant had done the PIP studies to the satisfaction of the competent authority (perhaps, so he said, at the expense of a good deal of

money), and even though the information considered relevant to the interested public was made accessible to the whole world through the database by the EMEA itself, and even though the applicant had applied for a variation to his basic marketing authorisation in all Member States, he would nevertheless be denied his 6 month reward if even one Member State did not grant a variation to his basic marketing authorisation in sufficient time.

33.
Mr Prescott QC also submitted that Miss May's construction of the PR served no useful purpose whereas his provided that the requisite agreed clinical studies would be completed and reported to the satisfaction of those competent to judge, which satisfied the rationale behind the PR.

34.
In reaching a conclusion as to whether Dupont's construction of Article 36 of the PR is the right one it is appropriate to consider that Article in the wider context of the PR as a whole and what it set out to achieve. Counsel for both sides relied upon the recitals to the PR as an aid to its interpretation and there is benefit from their consideration.

35.
Recitals 1 to 3 note the requirements before medicinal products may be placed on the market and point out that appropriate studies may not have been done on the paediatric population with the result of problems in some cases due to adverse reactions, ineffective treatment and the like. They also record that market forces alone have proved insufficient to stimulate adequate research into the development and use of medicinal products for the paediatric population.

36.
Recital 4 sets out the aims and objectives of the PR. It is important and is in these terms.

(4) This Regulation aims to facilitate the development and accessibility of medicinal products for use in the paediatric population, to ensure that medicinal products used to treat the paediatric population are subject to ethical research of high quality and are appropriately authorised for use in the paediatric population, and to improve the information available on the use of medicinal products in the various paediatric populations. These objectives should be achieved without subjecting the paediatric population to unnecessary clinical trials and without delaying the authorisation of medicinal products for other age populations.

37.
Recital 5 makes reference to differences between national legislative, regulatory and administrative provisions which tend to hinder intra-Community trade and states that action to promote the development of paediatric products is justified with a view to preventing these hindrances. This gives some support to Miss May's argument that Article 36(3) does indeed refer to the MA which includes paediatric information and not some earlier MA (as contended for by Dupont).

38.
Recital 6 refers to the establishment of a system of obligations and rewards and incentives in order to achieve the objectives in Recital 4. Recitals 8 to 11 provide for the creation of a Paediatric Committee within the EMEA and the concept of paediatric investigation plans (PIPs) aimed at ensuring that the development of medicinal products that are potentially to be used on the paediatric population become an integral part of the development of medicinal products generally. Recital 11 refers to a requirement for the results of studies in the paediatric population to be presented at the time of filing

an application for an MA and states that the PIP should be the basis upon which compliance with this requirement is judged.

39.
Recital 17 is important in the present context and is in these terms:

(17) To provide healthcare professionals and patients with information on the safe and effective use of medicinal products in the paediatric population and as a transparency measure, information on the results of studies in the paediatric population, as well as on the status of the paediatric investigation plans, waivers and deferrals, should be included in product information. When all the measures in the paediatric investigation plan have been complied with, that fact should be recorded in the marketing authorisation, and should then be the basis upon which companies can obtain the rewards for compliance.

This suggests to me that the MA containing all the relevant product information should be the basis upon which companies can obtain rewards. If Dupont is correct in its submissions, the objectives in this Recital would not be achieved.

40.
Recital 21 is also important in the present context. It provides that the PR should include measures to maximise access by the Community population to new medicinal products tested and adapted for paediatric use, and to minimise the chance of Community-wide rewards and incentives being granted without sections of the Community paediatric population benefitting from the availability of a newly authorised medicine. Again, if Dupont is correct, the objectives in this Recital would not be achieved. Thus, for example, if there is no requirement to obtain an MA in all Member States, there would be no incentive on a company to go through the hoops of applying for such an authorisation in all Member States with the result that sections of the paediatric population would not have proper access to the new medicine.

41.
Recital 22 states that where a PIP has led to an MA including a paediatric indication for a product already marketed for other indications, there should be an obligation to place the product on the market, taking into account the paediatric indication, within 2 years. Mr Prescott QC relied on this to indicate that the putting onto the market of the product with the paediatric indication was not very important; otherwise the period of 2 years would have been much shorter. He also suggested that relevant information about the paediatric studies would be placed on the EMEA database more quickly than that. I did not find this submission very persuasive, there being no material upon which I could assess the significance or reasons for this 2 year period and no material in relation to how quickly or otherwise information gets in to the EMEA database. True it is that Article 41(3) of the PR refers to further consultation as to the nature of the information which will be entered onto the database and the fruits of that have recently been published (COM 2009/C 28/01). It is apparent that there is an intention to set up a dedicated website to which the public will have access. However, I have no further information about this or about when it will be operational.

42.
Recital 26 is also important in the present context. It is in these terms:

(26) For products falling within the scope of the requirement to submit paediatric data, if all the measures included in the agreed paediatric investigation plan are complied with, if the product is authorised in all Member States and if relevant information on the results of studies is included in

product information, a reward should be granted in the form of a 6-month extension of the supplementary protection certificate created by Council Regulation (EEC) No 1768/92 [6]. Any decisions by Member States' authorities as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes have no bearing on the granting of this reward.

This appears to me to suggest that the reward should only follow if the medicinal product in issue (i.e. the one in connection with which there has been a requirement to submit paediatric data and not the just the active ingredient) is authorised in all Member States and the results of the paediatric studies are included in the product information (including that presented on labels and packaging). The natural reading of this recital is that there will be product information available to the paediatric population throughout the Community, and not just in those Member States where the marketing might be the most profitable to the manufacturer.

43.
Recital 28 makes clear that the rewards under the PR are for carrying out studies in the paediatric population and not for demonstrating that there is a safe and effective usage for that population and accordingly should be granted even when a paediatric indication is not authorised. In line with the purpose of disseminating relevant information, the recital goes on to provide that relevant information on use in paediatric populations should be included in authorised product information. This is relevant to the present case in two respects. Firstly it is further support for Miss May’s argument that the MA needs to be granted before rewards can be obtained. Secondly, the studies on Cozaar led to refusal of an authorisation for a paediatric indication, precisely the circumstance contemplated by this recital.

44.
Miss May took me through the relevant travaux préparatoires as well as the Articles of the PR itself and submitted that the intention of the PR was that there were three substantive requirements to be fulfilled before a company became entitled to the reward of an extension to an SPC. These were:

(i) all the measures in the agreed PIP must have been completed and complied with (see especially Recitals 9-11, 17, 26; Articles 7-8, 28(3), 36; the Explanatory Memorandum (see paragraph 11 above), particularly the paragraph in the middle of page 6);

(ii) the authorised product information must include relevant information on the results of studies (see especially Recitals 17, 26, 28; Articles 28(3), 36; the Explanatory Memorandum)

(iii) the medicinal product which was subject to the PIP must be authorised in all member states (see especially Recitals 17, 21, 26; Article 36; all travaux).

45.
The paragraph in the Explanatory Memorandum to which Miss May drew particular attention is in these terms:

Extension of the duration of the supplementary protection certificate

For new medicines and for products covered by a patent or a Supplementary Protection Certificate (SPC), if all the measures included in the agreed paediatric investigation plan are complied with, if the product is authorised in all Member States and if relevant information on the results of studies is included in product information, the six-month SPC extension will be granted. The mechanism for this will be the inclusion of a statement in the marketing authorisation that these measures have been met. Companies will then be able to present the marketing authorisation to patent offices that will

then award the SPC extension. The need to have a marketing authorisation in all Member States is to prevent a Community-wide reward without Community-wide benefits to child-health. Because the reward is for conducting studies in children and not for demonstrating that a product is safe and effective in children, the reward will be granted even when a paediatric indication is not granted. However, relevant information on use in paediatric populations will have to be included in authorised product information.

It provides support for Miss May's argument.

46.
With respect to the construction of Article 36(3) of the PR, Miss May directed my attention to Article 8(1)(d) of the SPCR (see paragraph 20 above) and submitted that the 'product' there referred to was the one referred to in Article 36(3) which must be the one in respect of which the studies in the PIP have been conducted. She said that Article 36(3) is referring in terms to 'product' in the context of the MRP Directive which in Article 1(2) refers to medicinal products, and therefore Article 36(3) was referring to a medicinal product. Finally, she drew to my attention official translations of the PR into a number of European languages and pointed out that the word used in the SPCR for medicinal product in those texts was the same word as that used in Article 36(3) of the PR (and a different word from that used for 'product' in the SPCR).

47.
Dupont did not accept Miss May's analysis. Dupont's submission was that the purpose of the PR was to provide for a reward when a company agreed to and completed and complied with a PIP to the satisfaction of the competent authorities. Mr Prescott QC acknowledged the references to the supply and dissemination of product information in the source material and he referred to Recital 31 of the PR which makes reference to a database provided for by Article 11 of the Clinical Trials Directive (2001/20/EC). As I have already mentioned, he submitted that this was the mechanism whereby product information could be accessed. However, I have no reason to think that this database was intended to be the primary means by which product information be disseminated when the more effective means would be by the documents referred to in paragraph 6 above. I accept that the database will increase the availability of information on the use of medicinal products in the paediatric population, especially when the dedicated web site is up and running, and will avoid the unnecessary repetition of studies which do not add to the core of assembled knowledge, but product information distributed with the product itself is effective for disseminating information relevant to the treatment of patients.

48.
Mr Prescott also submitted that Article 36(2) applied only to applications under the CP and that, since Cozaar was proceeding under the MRP, it was irrelevant or, if not irrelevant, merely an indication of the sort of document which would establish that the application for the MA included the results of all studies, as referred to in Article 36(1).

49.
My first thoughts were that Article 28 (and therefore Article 28(3)) concerned only applications for an MA using the CP and that Article 29 concerned applications using the MRP. My reason for this was that Article 28 begins with a reference to the CP and Article 29 with a reference to the MRP and the articles read as though each is dealing with one procedure only. If this were right, then this would track into Article 36 with Article 36(2) being restricted to applications made pursuant to the CP and

Article 36(3) to the MRP. This might help Dupont if the MAs referred to in Article 36(3) were in respect of the basic ingredient only.

50.
However, I am satisfied that this is a superficial approach and is the wrong one. Firstly, and as Miss May pointed out, Article 29 deals only with applications under Article 8 of the MRP and that would leave a lacuna for Article 7 applications. Secondly, I can see no reason in principle or logic, and none was put to me on behalf of Dupont, why the requirements of Article 28(2) and Article 28(3) should only apply to applications for an MA using the CP and not apply to applications using the MRP.

51.
Mr Prescott QC also pointed out that, for those companies who already had an MA, there was no obligation to agree and comply with a PIP and that no company would do so unless it had a reasonable assurance of getting a paediatric extension. He submitted that an entitlement to an extension should follow the completion and compliance with a PIP, otherwise companies would not bother and the paediatric population would suffer. The trouble with this approach is that it is contrary to the purpose of the Regulation as I understand it, in particular that there be a marketing authorisation for the product pursuant to the implementation of a PIP in each Member State. If Mr Prescott QC is right that companies will not do anything unless there is a promise of a reward, there must be a real likelihood that, if his construction of the PR is correct, companies will complete the PIP, obtain an MA in Member States where they are likely to make a significant profit and simply not bother with the task of completing MA applications in other Member States. That was one of the situations the Commission contemplated when rejecting the Opinion of the European Parliament of 7 September 2005 (see paragraph 12 above).

52.
In my judgment Miss May correctly identified the substantive requirements of the PR with respect to the availability of the reward of an extension to an SPC. And I think she is right that Article 36 must be considered as a whole; that it is incorrect and impermissible to consider the first subparagraph of Article 36(1) in isolation. Indeed, the second subparagraph of Article 36(1) itself, which clearly requires a completed MA application before a reward is available, is further support for the proposition that the MA application must always have been completed before the rewards are available. Article 36(2) through its reference to the Article 28(3) Statement provides for the second substantive requirement. And Article 36(3) provides for the third substantive requirement where the MRP has been used (it being satisfied in any event where the CP is used and the MA granted).

53.
Thus, in my judgement an application for an extension to an SCP which did not satisfy all the requirements of Article 36 of the PR would be a defective application.

54.
However, I accept Mr Prescott QC’s submission that the requirement for an Article 28(3) statement is merely informative. But in my judgment information equivalent to such a statement from a properly reliable source would be the only substitute for it. I was not addressed on and have no material to comment on what might be an equivalent to the 28(3) statement and, although I was asked to give guidance on it by the IPO, cannot take the matter any further.

55.
I was also asked to give guidance as to the circumstances, if any, where an application for extension should be accepted prior to an MA having been granted in all Member States. Again I was not

addressed on what might be suitable circumstances. But consider a situation where an MA has been granted in a reference state. The company then has a certain number of days in which to submit translations of the product information to the CMSs and, after the receipt of that information, and if the translations are adequate, the CMSs should grant MAs in their States within 30 days of receipt of the translations. Assume that they do not do so because of administrative inadequacy. I would have thought these might well be circumstances where a national patent office could, upon being satisfied by reliable sources that the only matter outstanding was the rubber stamp of the errant Member State, lawfully grant a six month extension.

56.
Returning to the facts with respect to Cozaar it is common ground that at the date of application for the extension of the SPC (18 February 2009) the procedure for obtaining an MA in the RMS was not complete and accordingly, if my interpretation of the PR and SPCR is correct, that there was no entitlement to an extension of time as at that date. The deadline of an extension application in respect of Cozaar was 1 March 2009 and by that date the RMS had not granted an MA either. So Dupont's application must be refused unless the 18 February application can be subsequently amended and the amendments back dated in some way, or, alternatively, an application for an extension of the duration of an SPC under Article 7(5) is not required to be complete on the date it is made.

57.
I would find it surprising if it be the case that a company can lodge a seriously incomplete application for an extension of an SPC, more than six months before the expiry of the SPC (incomplete because some of the essential conditions for such an extension had not, by the 6 month date, been satisfied) and then complete it thereafter as and when those conditions were fulfilled (assuming they ever were). If that is the law, then the 6 month time limit in Article 7(5) would appear to be effectively meaningless. More importantly, there would no be certainty for third parties; even though the 6 month deadline had passed, they would have no way of anyone knowing whether or not an extension of the SPC was likely to be granted.

58.
However, my attention was drawn to Article 10 of the SPCR, the material parts of which are in these terms:

Article 10

Grant of the certificate or rejection of the application

.....

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.

Dupont submit that any deficiency in their application for an extension of the SPC for Cozaar is an irregularity within Article 10(3) and that it should be given time to put it right. I understand that what it has in mind is sufficient time, after the deadline in Article 7(5) has passed, for it to acquire a MA in all Member States, or for it to reach the situation that it would have acquired such MAs if each Member State complied with its obligations under the MRP [1] .

59.
There is little guidance in the authorities as to what amounts to an irregularity within Article 10(3) although Advocate General Fennelly in Biogen, Case C-181/95, [63] observed that this provision:

provides for a degree of flexibility on the part of the competent national industrial property office, to ensure that applications are not needlessly obstructed by procedural difficulties.

Miss May submitted that Article 10(3) permitted time to correct formalities in an application should any need correction, but was not concerned with substantive deficiencies.

60.
In my judgment the failures and deficiencies in the application for an extension of the SPC in respect of Cozaar were not such as can be described as irregularities within Article 10. They were deficiencies which arose because, by the time the deadline prescribed by Article 7(5) of the SPCR had passed, Dupont was not in a position to satisfy the relevant criteria. The application for an extension did not meet the conditions laid down for the grant of an extension because Dupont was unable to meet them. Dupont remained unable to meet those conditions at the time the deadline prescribed had passed. This was not because there was what could be called an irregularity with the application; it was because a series of crucial events had not happened. Dupont may have been entitled to the reward of an SPC extension if Article 7(5) of the SPCR said three months and not six months, but it does not.

61.
Finally I have reflected upon whether my conclusions offend the principle of proportionality relied upon by Mr Prescott QC. I do not think they do and, furthermore, I do not accept that the construction urged upon me by the IPO and which I have accepted serves no useful purpose.

62.
As a result, the appeal must be dismissed. I am much obliged to counsel for the assistance they have given me in this matter.

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[1] The position as of 18 May 2009 is that MAs have been granted in 13 out of 27 Member States and the required translations were provided to all of them by 22 April 2009. The 30 day period during which Member States can consider these translations may just have elapsed when this judgment is delivered. Dupont’s deadline for its Article 7(5) SPCR application was 1 March 2009.