Neutral Citation Number: [2023] EWHC 1471 (Ch)

Appeal no. CH-2022-000241

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)

ON APPEAL FROM THE UK INTELLECTUAL PROPERTY OFFICE

The Rolls Building
7 Rolls Buildings
London, EC4A 1NL

Date: [16 June 2023]

Before:

RECORDER DOUGLAS CAMPBELL KC

- -

Between:

NEWRON PHARMACEUTICALS SPA

Appellant

- and -

THE COMPTROLLER-GENERAL OF PATENTS, TRADE MARKS AND DESIGNS

Respondent

- -

Richard Davis KC (instructed by **Mathys & Squire**) appeared on behalf of the Appellant

Dr Stuart Baran (instructed by **the Treasury Solicitor**) appeared for the Respondent

Hearing date: 26 May 2023

- -

APPROVED JUDGMENT

This judgment was handed down remotely at 10.30am on Friday 16 June 2023 by circulation to the parties or their representatives by email and release to the National Archives.

RECORDER DOUGLAS CAMPBELL KC:

Introduction

1. This is the Appellant's appeal from the decision of Dr L Cullen, Deputy Director acting for the Comptroller, dated 1 December 2022. In that decision Dr Cullen ("the Hearing Officer") refused the Appellant's application for a supplementary protection certificate ("SPC") on the grounds that such application did not meet the requirements of Article 3(b) of Regulation (EC) No. 469/2009 ("the SPC Regulation").

2. The basic patent (EP 1 613 296 B) is entitled "Methods for the Treatment of Parkinson's Disease". It was granted on 1 July 2009 and expires on 7 April 2024. It is only necessary to consider claim 1, which is as follows:

> *"1. The use of a first agent selected from safinamide from 0.5 to 1, 2, 3, 4 or 5 mg/kg/day in combination with levodopa/PDI, for the preparation of a medicament as a combined product for simultaneous, separated or sequential use for the treatment of Parkinson's Disease."*

3. PDI is the abbreviation for a Peripheral Decarboxylase Inhibitor. As the Hearing Officer explained at [10] of his decision, the role of the PDI is to inhibit the breakdown of levodopa while travelling through the bloodstream of the body to the brain. Once the levodopa crosses the blood-brain barrier, which the PDI cannot, the levodopa exerts its therapeutic effect.

4. It is accepted by the Appellant that the use of levodopa with a PDI was already a known treatment for Parkinson's disease.

5. The Hearing Officer found at [14] of his decision that claim 1 relates to a combination of three active ingredients (ie safinamide, levodopa, PDI) for use to treat Parkinson's disease. It is this combination which is "the product" that is protected by the basic patent. The Hearing Officer also found that the SPC application is addressed to this combination: see [18] of the decision. None of this is disputed.

6. Thus, unlike in so many of the reported cases on the SPC Regulation, Article 3(a) is not in issue although it remains relevant. Articles 3(c) and 3(d) are not in issue either.

7. However the Hearing Officer held that the marketing authorisation ("MA") for the medicinal product XADAGO, which was relied upon in support of the SPC application, was not an authorisation for this combination. This was for two independent reasons. First, he held that such MA was for the active ingredient safinamide alone, and not for a combination of safinamide, levodopa, and a PDI. See paragraphs [43]-[54] of the decision. Secondly, he did not accept that the MA related to safinamide in combination with both levodopa *and* a PDI. See paragraphs [55]-[59] of the decision. Before me, the Appellant attacked both of these reasons, as it had to do, but much more time was spent on the first reason. I will start with that.

(1) Is the MA for the active ingredient safinamide alone

Legal context

8. The SPC application was filed on 16 July 2015, at a time when the UK was part of the European Union, and it is common ground that I should apply the relevant law that was in force at that time in the UK. I will begin by setting out some relevant parts of the SPC Regulation, including various recitals to which my attention was drawn (emphasis added):

> *"…(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.*
>
> *(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.*
>
> *(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.*
>
> *(6) There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection…*
>
> *(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…"*

9. The Appellant emphasised recitals 2-6, including the underlined words in recital 3. The Respondent emphasised recital 10, including the words underlined therein.

10. The parties also emphasised Articles 1, 3, and 8(1)(b):

> *Article 1 Definitions*
>
> *For the purposes of this Regulation, the following definitions shall apply:*
>
> *(a) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;*
>
> *(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product…*

…

> *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:

(a) the product is protected by a basic patent in force;

(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;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

…

Article 8 Content of the application for a certificate

1. The application for a certificate shall contain …

(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;

11. The Appellant suggested that the phrase "the product" might have a different meaning as between the 4 limbs of Article 3, and in particular that it might have a broader meaning under Article 3(b) compared to Article 3(a) given what the Appellant said was the purpose of Article 3(b). In support of this submission the Appellant relied on a number of passages in the Opinion of the Advocate-General in **Medeva v Comptroller-General of Patent**, Case C-322/10, [2012] RPC 25.

12. I reject this submission. I can see no reason why the phrase "the product" should have a different meaning in different parts of the same Article, or indeed in different parts of the same Regulation. Its meaning is defined in Article 1(b) and it has the same meaning throughout. I do not read the passages of **Medeva** relied upon as going so far as to say anything else. I also note that **Medeva** was largely a case about Article 3(a), not 3(b), and the Court's judgment in that case was significantly more limited than the Advocate-General's Opinion had been.

13. The Hearing Officer considered that the most relevant UK authority on Article 3(b) was **Yeda Research and Development Company Ltd v Comptroller General of Patents** ("Yeda") [2010] EWHC 1733 (Pat), a decision of Lewison J as he then was. I agree. However the Appellant criticised **Yeda** as being a decision which was reached "rather hastily", and which "might be wrongly decided on the facts". In response to this criticism Counsel for the Comptroller drew my attention to the comprehensive review of this area of the law by Arnold J, as he then was, in **Abraxis Bioscience v Comptroller-General of Patents** ("**Abraxis**") [2017] EWHC 2014; and the subsequent decision of the CJEU in **Santen**, Case C-673/18, 9 July 2020. **Santen** was decided during the Brexit transition period and as such is binding on me.

14. In short Counsel for the Comptroller's submission on the law was that **Yeda** was not hastily or wrongly decided at all. On the contrary **Yeda** was supported by a line of European authority, which was internally consistent save for a short lived excursion in **Neurim Pharmaceuticals** [2012] RPC 23, and that normality had been restored since **Neurim** in **Santen**. I consider that this submission (save for the reference to **Santen**) is supported by the analysis of Arnold J in **Abraxis** (see for instance paragraphs [37]-[38], [43]-[44] thereof) and the Appellant did not submit to the contrary. I will briefly summarise the key points of that European case law.

15. In **Pharmacia Italia** [2004] ECR I-10001 the application was based on a marketing authorisation for cabergoline which had been granted for a human medicinal product. However there had been an earlier marketing authorisation for cabergoline as the active ingredient of a veterinary medicinal product. In its judgment the Court of Justice held as follows, emphasis added:

> *20. It follows, first, that the decisive factor for the grant of the certificate is not the intended use of the medicinal product and, second, that the purpose of the protection conferred by the certificate relates to any use of the product as a medicinal product without any distinction between use of the product as a medicinal product for human use and as a veterinary medicinal product.*

Thus the important point was the product itself, not how it had been (or how it was intended to be) used.

16. In **MIT** [2006] ECR I-4089 the marketing authorisation relied upon was for a product containing carmustine as an active ingredient and polifeprosan as an excipient. Carmustine had already been the subject of a marketing authorisation, but only in combination with inert excipients whereas polifeprosan was said to permit the delivery of a higher but constant dose of carmustine.

17. The Court of Justice held that the presence of polifeprosan in the newer marketing authorisation was irrelevant because it had no therapeutic effect of its own. See below, emphasis added.

> *25. In the light of the foregoing, the inevitable conclusion is that a substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of "active ingredient", which in turn is used to define the term "product".*
>
> *26. Therefore, the alliance of such a substance with a substance which does have therapeutic effects of its own cannot give rise to a "combination of active ingredients" within the meaning of Art.1(b) of Regulation No 1768/92.*
>
> *27. The fact that the substance without any therapeutic effect of its own renders possible a pharmaceutical form of the medicinal product necessary for the therapeutic efficacy of the substance which does have therapeutic effects cannot invalidate that interpretation"*

18. Thus the definition of "product" did not include the new excipient, even though the presence of this new excipient improved the performance of the carmustine.

19. The next case is **Yissum** [2007] ECR I-2839. The applicant relied upon a second medical use patent relating to the use of calcitriol in skin disorders, but there were two earlier marketing authorisations containing calcitriol as the active ingredient. The Court disposed of these by reasoned order, and held as follows:

> *17 It is clear from **Massachusetts Institute of Technology**, and, in particular, from paragraphs 19, 21, 23 and 24 of that judgment, that the concept of 'product' referred to in Article 1(b) of Regulation No 1768/92 must be interpreted strictly to mean 'active substance' or active ingredient'.*
>
> *18 It follows that the concept of 'product' cannot include the therapeutic use of an active ingredient protected by a basic patent.*
>
> *19. Moreover, the same interpretation can be inferred from paragraph 20 of the judgment in Case C-31/03 **Pharmacia Italia** [2004] ECR I-10001, in which the Court held that 'the decisive factor for the grant of the certificate is not the intended use of the medicinal product and … the purpose of the protection conferred by the certificate relates to any use of the product as a medicinal product without any distinction between use of the product as a medicinal product for human use and as a veterinary medicinal product'*

20. Thus far it will be seen that the case law is relatively straightforward. The word "product" must be interpreted strictly to mean the relevant active ingredient, and does not include the therapeutic use of that product. Hence it is not relevant to consider whether any new therapeutic use of the product provides valuable benefits.

21. In **Abraxis**, Arnold J went on to consider the subsequent cases of **Neurim** [2012] RPC 23, **GSK** [2014] RPC 17, and **Forsgren** [EU:C:2015:13]. It is not necessary to do so for purposes of this judgment. Instead I note that in **Abraxis** itself, the question referred to the CJEU was essentially whether Article 3(d), the provision in issue in that case, permitted SPCs to be obtained for new formulations of old ingredients.

22. Arnold J's view was that the answer should be no, even though this might deprive meritorious inventions of extended protection, because (a) it was more important that the SPC Regulation should provide a simple and predictable system which could be operated by national patent offices in a uniform manner and (b) the SPC Regulation aimed to balance the interests of patentees with those of other stakeholders: see [63]. The first point is further supported by paragraph 16 of the Explanatory Memorandum which led to the SPC Regulation and the second is further supported by recital 10 of the SPC Regulation. The CJEU subsequently answered the question which was referred in **Abraxis** as Arnold J had suggested it should: see Case C-443/17.

23. Finally in **Santen** the marketing authorisation relied upon was for a product containing the active ingredient ciclosporin, used to treat severe keratitis in adult patients with dry eye disease. There was a previous marketing authorisation for a product containing ciclosporin as an active ingredient which was used for a range of indications including preventing organ rejection. The applicant relied on **Neurim**, but the Court held as follows, emphasis added:

> *43 Moreover, it follows from a reading of Article 1(b) of Regulation No 469/2009 in conjunction with Article 4 thereof that the term 'product' is understood, for the purposes of applying that regulation, to mean the active ingredient or combination of active ingredients of a medicinal product, without its being necessary to limit its scope only to one of the therapeutic applications to which such an active ingredient or combination of active ingredients may give rise.*
>
> *44 Under Article 4 of that regulation, the protection conferred on the product by the SPC, although it extends only to the product covered by the MA, covers, on the other hand, any use of that product as a medicinal product which was authorised before the expiry of the SPC. It follows that the term 'product' within the meaning of Regulation No 469/2009 is not dependent on the manner in which that product is used and that the intended use of the medicinal product does not constitute a decisive factor for the grant of an SPC (see, to that effect, judgment of 19 October 2004,* ***Pharmacia Italia****, C-31/03, EU:C:2004:641, paragraphs 19 and 20).*
>
> *...*
>
> *46 That strict view of the term 'product' was given concrete form in Article 1(b) of Regulation No 469/2009, which defines that term by reference to an active ingredient or combination of active ingredients and not by reference to the therapeutic application of an active ingredient protected by the basic patent or a combination of active ingredients protected by that patent.*
>
> *47 It follows from the foregoing considerations that Article 1(b) of Regulation No 469/2009 must be interpreted as meaning that the fact that an active ingredient, or a combination of active ingredients, is used for the purposes of a new therapeutic application does not confer on it the status of a distinct product where the same active ingredient, or the same combination of active ingredients, has been used for the purposes of a different, already known, therapeutic application."*

24. **Santen** also points out that not all pharmaceutical research leading to a patent will obtain an SPC (see [55]) and that the system should be simple and predictable (see [59]).

25. Against that background I now come to **Yeda**, This is a little complicated because there were two SPC applications, namely '037 and '038. Most of the reported case deals with '038 but the passage of interest for present purposes is that dealing with '037. The point is that the '037 application was for the active ingredients, cetuximab and irinotecan, in combination and the '038 application was for the active ingredient cetuximab alone. The same marketing authorisation was cited in support of both applications. That MA was for "Erbitux – cetuximab", where Erbitux was the name of the relevant medicinal product and cetuximab was the active ingredient.

26. At first instance in **Yeda** the Hearing Officer analysed the MA in some detail, including: its title, the active ingredient of the medicinal product, the physical form of the product; and the fact that most of the MA was silent as to irinotecan: see paragraphs [33], [40] of the Hearing Officer's decision, reported at BL O/066/10. This led him to the conclusion that the MA was for a single active ingredient, cetuximab: ibid. This in turn meant that the MA could not form a basis for the '037 application, which was accordingly invalid.

27. On appeal, Lewison J (as he then was) began by considering what was meant by a "product":

> *19 To my mind it is clear from recital (10) and from the case law that what constitutes a "product" is to be strictly construed:* ***Generics (UK) Ltd v Daiichi Pharmaceutical Co Ltd*** *[2009] EWCA Civ 646, [2009] R.P.C. 23, CA. In deciding what is a "product" one must focus, as the hearing officer put it, "on what the product is, rather than what it does". As the ECJ said in Case C-202/05* ***Yissum Research and Development Co v Comptroller-General*** *(§ 18): "It follows that the concept of "product" cannot include the therapeutic use of an active ingredient protected by a basic patent."*

28. Lewison J then went on to cited paragraphs [33], [40] from the first instance decision with approval and described them as a "compelling analysis". He concluded as follows, emphasis in original:

> *"26 … art.1 of the decision plainly identifies the medicinal product, "Erbitux—cetuximab" as the subject-matter of the authorisation. No other medicinal product is identified. The direction to enter that product in the Community Register of Medicinal Products is to the same effect. Art.3 specifies the form of the labelling and package leaflet. The outer packaging makes no mention of irinotecan at all. The package leaflet contains two brief mentions of irinotecan in explaining how cetuximab is used. The summary of the product characteristics likewise contains brief mentions of irinotecan in explaining how cetuximab is <u>used</u>. But as the case law shows, how a medicinal product is used does not form part of the identification of the product itself. In my judgment the brief references to irinotecan in explaining how cetuximab is used are wholly insufficient to amount to a marketing authorisation of a product consisting of both cetuximab and irinotecan. In short, I agree with the hearing officer for the reasons that he gave."*

29. Now that I have set out the European law in some detail, it can be seen that **Yeda** (which was decided in July 2010) is entirely consistent with it. In short, *"how a medicinal product is used does not form part of the identification of the product itself".* Hence it was neither hastily nor wrongly decided.

30. The Appellant also drew my attention to the scheme of medicines regulation, and in particular the Medicinal Products Directive (Directive 2001/83/EC): see also **Bayer plc v NHS Darlington** [2020] EWCA Civ 449. This forms part of the background, but it is not relevant to the construction of the SPC Regulation.

Analysis

31. In this case the Hearing Officer considered the relevant MA (EU/1/14/984) at paragraphs [33]-[65]. I will now summarise the matters he considered.

32. The first point is that the title, first recital, and Article 1 of the MA are all specific to *"Xadago-safinamide*", Xadago being the name of the medicinal product: see paragraphs [33]-[37]. No other product is identified, and there is no mention of any combination of safinamide with anything. See the following:

> *COMMISSION IMPLEMENTING DECISION of 24.2.2015*

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Xadago - safinamide", a medicinal product for human use

...

Whereas: (1) The medicinal product "Xadago - safinamide" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

…

Article 1

The marketing authorisation provided for in Article 3 of Regulation (EC) No 726/2004 is granted for the medicinal product "Xadago - safinamide", the characteristics of which are summarised in Annex I to this Decision. "Xadago - safinamide" shall be registered in the Community register of medicinal products under number EU/1/14/984.

33. At paragraph [37] the Hearing Officer said *"On this basis, there appears to be only one active ingredient, safinamide"*. If anything, this was an understatement. It seems to me that if the SPC system is intended to be a simple and predictable one, there is much to be said for the view that the product which is authorised by an MA is the product which is identified in Article 1 of that MA.

34. However both in **Yeda** and in the decision under appeal, the tribunal has gone deeper than this. For instance the Hearing Officer did not stop at his paragraph [37], but went on to consider Sections 1 and 2 of Annex 1 to the MA, namely the Summary of Product Characteristics (SmPC), at his paragraph [38]. These Sections are as follows:

1. NAME OF THE MEDICINAL PRODUCT

Xadago 50 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains safinamide methansulfonate equivalent to 50 mg safinamide. For the full list of excipients, see section 6.1.

Thus neither of them mentions anything other than safinamide, despite describing the name of the medicinal product and its physical form.

35. Section 4 is entitled "Clinical Particulars" and runs from pages 2 to 10 of the MA. The passage particularly relied upon by the Appellant is section 4.1, which says as follows:

4.1 Therapeutic indications

Xadago is indicated for the treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa (L-dopa) alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients.

36. This is the only reference to "add-on therapy" in the MA although there are other references to levodopa elsewhere, as the Hearing Officer pointed out at [39]-[42]. It will be noted that this paragraph 4.1 does not require any PDI to be used at all. The safinamide might be used with a stable dose of levodopa "alone", and there is no limitation or explanation as to how such stability is achieved.

37. Article 2 of the MA refers to Annex II, which sets out manufacturing conditions and conditions for safe use. The Hearing Officer found at [41] that there were no references to levodopa, or a PDI, in this Annex, and the Appellant did not challenge this finding. This reinforces the conclusion that neither levodopa nor a PDI forms part of the product which is authorised by the MA.

38. Article 3 of the MA refers to Annex III, which is the labelling and packaging leaflet. The Hearing Officer found that there were a number of references to levodopa here, but in the context of explaining how safinamide worked: see paragraphs [42], [43]. I was not shown the outer packaging of Xadago, but the Appellant told me that (as in **Yeda**) it made no mention of anything other than safinamide.

39. The Hearing Officer's conclusions on the materials described above went into some detail so as to deal with all of the Appellant's arguments but essentially his view was that, as in **Yeda**, the MA was for safinamide alone and not for the combination of safinamide, levodopa and a PDI. It followed that the MA was not for the same product as the patent, and hence the SPC application as failed.

40. Despite the Appellant's best efforts to persuade me that the Hearing Officer was wrong, I am in no doubt that his decision on this first issue is correct and that I should dismiss this appeal. This is for the following reasons.

41. First of all, I agree with the Hearing Officer's analysis of the MA which I have summarised above. It all points one way: the product is safinamide, not a combination of safinamide with anything.

42. The Appellant's central submission was that it had done valuable research, and that it must therefore be entitled to an SPC unless there was a good reason why not. I do not agree that this is the correct approach. As Arnold J pointed out in **Abraxis**, the SPC Regulation is a balance of competing interests and this means that some meritorious inventions do not qualify for extended protection. **Pharmacia, MIT, Yissum, Santen**, and **Yeda** are all examples of prima facie meritorious inventions where SPCs were refused.

43. The correct approach is to consider whether the requirements of the SPC Regulation are satisfied. These requirements go beyond the mere prevention of what the Appellant referred to as "evergreening". If the requirements are not satisfied, then that is a "good reason" why the application fails. There is no "must" about it.

44. The Appellant submitted that because safinamide is an add-on therapy, it would "always" be used in combination with levodopa/PDI. This was variously expressed as *"without the levodopa therapy there is no therapy"* and *"safinamide cannot work on its own without the levodopa/PDI"* : see paragraph [49] of the Hearing Officer's decision where he records such submissions being made below. The Hearing Officer doubted whether that proposition was correct on the facts (see ibid) whereas the Appellant was firm that it was. It does not seem to me that the correctness of the factual proposition matters, since all of these

ways of putting it are merely different ways of seeking to import the therapeutic use into the definition of the product. Such an approach is contrary to the case law analysed above, including in particular **Pharmacia, MIT, Yissum, Santen**, and **Yeda**.

45. The Appellant also made the point that because safinamide is an add-on therapy, the patient would already have a source of levodopa/PDI and need not source it from the Appellant. I accept that this may well be why the Appellant did not seek an MA for the combination of safinamide and levodopa/PDI. However these reasons are irrelevant. I have to consider the MA upon which the Appellant relies, not why it decided to apply for that MA.

46. At the outset of the hearing the Appellant applied to rely on fresh evidence, namely the expert report of Dr Joanna Tufnell. I refused that application for reasons I gave at the time. Essentially there was no reason why the evidence could not have been adduced below, and most of it was irrelevant anyway. However the Respondent consented to the admission of a document entitled "Guideline on clinical development of fixed combination medicinal products" dated 23 March 2017, prepared by the Committee for Human Medicinal Products, which had been exhibited to Dr Tufnell's report, and given that consent I allowed it to be admitted.

47. Having admitted it, I did not find this document to be of assistance. As the executive summary states, it relates to *"clinical development of fixed combination medicinal products containing two or more active substances with a single pharmaceutical form".* It did not seem to me that the MA is for a "fixed combination medicinal product" at all since I was not convinced by the Appellant's explanation that "fixed" in this context meant as little as "anything which has been proven in clinical trials". Nor can this document change the law which I have to apply.

48. The Appellant also sought to distinguish **Yeda** on the facts, but while I agree that the facts of **Yeda** are different I do not consider that this makes any difference to its logic.

49. Finally the Hearing Officer was criticised for taking an approach to construing the MA which *"effectively gave the applicant no route to success"*. I do not consider that to be a proper criticism. The Hearing Officer was obliged to apply the SPC Regulation, not to give the applicant a route to success.

50. In these circumstances it is not necessary to consider the second question but since it was argued I will do so briefly.

(2) Does the MA relate to safinamide in combination with both levodopa *and* a PDI?

51. The Respondent submitted that this part of the Hearing Officer's decision rested upon findings of fact which the Appellant could not properly challenge on this appeal. However upon examination it turned out that the factual findings which the Respondent had in mind were of the "on page X it says Y" type: see paragraphs [57]-[59] of the Hearing Officer's decision. The Appellant made it clear that it did not challenge anything of that nature. Instead it criticised the Hearing Officer's legal conclusions on the basis thereof. I agree that such criticism does not involve any attack on findings of fact.

52. However the Appellant then runs into the next problem which is as follows. The Hearing Officer's essential conclusion was that the references to use of a PDI were too few, too deeply buried in the MA, and too equivocal to permit a conclusion that the MA was for a

safinamide in combination with both levodopa and a PDI. I consider that this conclusion was one which was open to the Hearing Officer to reach, and moreover I agree with it. It is correct that references to a PDI can be located somewhere in the MA if one digs deep enough into what I was told was 6000 pages of material, but this is deeper than para 4.1 of the SmPC, for instance (which, as I have pointed out, did not say that a PDI was necessary). The existence of such references, once found, does not mean that "the product" of the MA is the combination of safinamide with both levodopa and a PDI. It merely means that one possible use of safinamide is as part of such a combination. I do not accept the Appellant's submission that the skilled addressee would somehow read the MA as containing an unspoken but vital requirement that a PDI must always be used in all cases.

53. It is therefore not necessary to consider the principle identified by Lady Hale of Richmond in **AH (Sudan) v. SSHD** [2007] UKHL 49, [2008] 1 AC 678 at [30], upon which the Respondent also relied. That principle is as follows:

> *"To paraphrase a view I have expressed about such expert tribunals in another context, the ordinary courts should approach appeals from them with an appropriate degree of caution; it is probable that in understanding and applying the law in their specialised field the tribunal will have got it right: see Cooke v Secretary of State for Social Security [2001] EWCA Civ 734, [2002] 3 All ER 279, para 16."*

54. Accordingly I consider that the Hearing Officer was right to refuse the SPC application for this further reason.

Other points

55. I have not found it necessary to consider some further arguments by the Comptroller, based on matters such as practicality and costs. In any event I agree with the Appellant that:

> (a) such points should have been in a Respondent's Notice, and there was no such Notice; and
>
> (b) they were unconvincing points anyway.

56. For instance the Comptroller suggested that it would have required additional resources if the Appellant's approach were correct in law. I agree with the Appellant that if its approach were correct and the Comptroller lacked resources to apply it properly, then the answer is more resources rather than for the Comptroller to do something which was wrong in law on the grounds that doing so was cheaper than acting lawfully.

Conclusion

57. The appeal is dismissed. I will hear counsel as to the form of order I should make.