

THE HIGH COURT

[2014 No. 2 PAP]

IN THE MATTER OF IRISH PATENT NUMBER EP (IE) 1379220 FILED ON THE 27th DAY OF MAY 2002 AND REGISTERED IN THE NAME OF BOEHRINGER INGELHEIM PHARMA GMBH & CO KG IN RESPECT OF AN ALLEGED INVENTION FOR "INHALATION CAPSULES"

BETWEEN

NORTON (WATERFORD) LIMITED T/A TEVA PHARMACEUTICALS IRELAND

PETITIONER

AND

BOEHRINGER INGELHEIM PHARMA GMBH & CO KG (No.2)

RESPONDENT

[2014 No. 1 PAP]

IN THE MATTER OF IRISH PATENT NUMBER 622528 FILED ON THE 14th DAY OF SEPTEMBER 1990 AND REGISTERED IN THE NAME OF BOEHRINGER INGELHEIM INTERNATIONAL GMBH IN RESPECT OF AN ALLEGED INVENTION FOR "NOVEL THIENYLCARBOXYLATES OF AMINO ALCOHOLS, THEIR QUARTERNARY PRODUCTS AND THE PREPARATION AND USE OF THESE COMPOUNDS"

AND

IN THE MATTER OF SUPPLEMENTARY PROTECTION CERTIFICATE NUMBER 2002/021 FOR THE SAID PATENT FILED ON THE 14th DAY OF AUGUST 2002 AND DUE TO EXPIRE ON THE 13th DAY OF MARCH 2016 FOR A PRODUCT IDENTIFIED AS "QUARTERNARY SALT FORMS OF SCOPINE DI- (2-THIENYL) GLYCOLATE, ESPECIALLY SALTS OF TIOTROPIUM- PREFERRED TIOTROPIUMBROMIDE MONOHYDRATE"

BETWEEN

NORTON (WATERFORD) LIMITED T/A TEVA PHARMACEUTICALS IRELAND

PETITIONER

AND

BOEHRINGER INGELHEIM INTERNATIONAL GMBH (No. 2)

RESPONDENT

JUDGMENT of Mr. Justice CREGAN delivered on 6th day of May, 2015

Introduction

1. On Friday 27th March 2015, having heard the Petitioner's two discovery motions over a period of four days, I gave an *ex tempore* judgment in two different proceedings. The first was in the proceedings with record number 2014/2 PAP. The second was in proceedings with the record number 2014/1 PAP. This judgment should be read in conjunction with, and as supplemental to, that judgment.

2. In record number 2014/2 PAP the Petitioner sought five categories of documents; In record number 2014/1 PAP the Petitioner sought twelve categories of documents.

3. In my *ex tempore* decision I set out the categories sought, the arguments made by both parties and my decision on each category. However I adjourned the matter to allow the parties to agree on the exact wording of each category in the light of my judgment and/or for further consideration of any issues which might arise in relation to the exact wording of the order for discovery. I also adjourned submissions in relation to the time periods for the categories of documents sought.

4. These matters came back before me for further hearing on Monday 27th April 2015 and Thursday 30th April 2015. The Respondent's solicitors had sent to the Petitioner's solicitors documents with red-lined versions of their suggested wording for the orders for discovery in the light of my decision and also a clean copy of such wording.

5. However despite the best efforts of both parties, there was some element of disagreement between the parties about the exact wording for each category. That is perhaps not surprising given the complexity of the issues in these proceedings.

The first proceedings – Record no. 2014/ 2 PAP

Category 1

6. The first category of documents sought by the Petitioner was as follows:

"All documents relating to the patent application filed with the European Patent Office and with the Irish Patents Office as a designated State in respect of European Patent number EP 1379220, together with the relevant national designated equivalent, referred to as the 220 patent, and for German patent application 10126924 from which the 220 patent claims priority as disclosed the state of the art prior to the priority date of the 220 patent, namely 1st June 2001 including, but not limited to, the prior art documents pleaded by the Petitioner."

7. In the light of my judgment on 27th March 2015, the Respondent suggested the following wording in relation to this category as follows (with the exception of the words in brackets):

"[All documents relating to] the patent application filed with the European Patent Office in respect of European patent number EP 1379220 (the 'European 220 patent'), the application filed with the Irish Patents Office in respect of the Irish designation of the European 220 patent (the '220 patent') and the German patent application number 10126924 filed with the German Patents Office from which the European 220 patent claims priority and all correspondence between the Respondent and/or its agents with the European Patent Office, the Irish Patents Office and the German Patents Office in relation to the said patent applications as disclose the state of the art prior to the priority date of the 220 patent namely 1st June 2001 (including but not limited to the prior art document pleaded by the Petitioner)."

8. In my view, this form of wording – subject to the issue of the phrase "all documents relating to" fairly reflects the decision I made in relation to this category.

9. The Applicant seeks to add the words "All documents relating to". However, an issue has arisen between the parties as to what is the precise meaning of the words "all documents relating to" the patent application filed with the European and other patent offices.

10. The Petitioner sought to argue that it meant all documents which might have pre-dated or pre-existed any decision even to make an application for a patent.

11. The Respondent by contrast argued that the phrase "all documents relating to" before the words "patent application" should be deleted. In its view that was the intention of the court order.

12. The ambiguity therefore arises in relation to "all documents relating to the patent application" and what is meant by that phrase.

13. In my earlier judgment (at page 150 of the transcript) given on Friday, 27th March 2015, I stated:

*"I note however in the **Medtronic** decision, Kelly J. noted at one of the categories sought by the defendant, that the plaintiff had agreed to make discovery of the complete file in respect of their application before the Irish Patents Office and the European Patent Office. However the Court held in that case that the defendant had failed to establish why any documents beyond that limited category were necessary in order to have a fair trial and he refused discovery in respect of that category."*

14. I went to say that:

"However, in my view this patent file is clearly relevant and necessary and must be discovered. However I am not satisfied that any of the documents beyond the patent application file are necessary and I will therefore limit it to this."

15. I then went on to say that:

"I believe that what should be discovered in category 1 is 'all documents relating to the patent application filed with the European Patent Office and with the Irish Patents Office as a designated State in respect of the European patent number 220 and for German patent application number 924 from which the 220 patent claimed priority'"

16. And I went on to say:

"And I will hear further submissions from the parties on the exact wording in that regard."

17. What I intended was that there should be discovery of the complete file by the Respondent in respect of its application before the Irish Patents Office and the European Patent Office etc. So it relates to all documents in the file. It does not relate to any documents which might precede any application to the Patents Office. In my view, this category of documents would commence with the first document that would be sent by the Respondent to the relevant patent office.

18. The intent of my order was to direct discovery not of "all documents relating to" the patent file but of all documents "contained in" the patent application.

19. Thus an order will be made in the following terms:

Category 1.

All documents contained in the patent application filed with the European Patent Office in respect of European patent number EP1379220 (the "European 220 patent"), the application filed with the Irish Patents Office in respect of the Irish designation of the European 220 patent (the "220 patent") and the German patent application number 10126924 filed with the German Patents Office from which the European 220 patent claims priority and all correspondence between the Respondent and/or its agents with the European Patent Office, the Irish Patents Office and the German Patents Office in relation to the said patent applications as disclosed the state of art prior to the priority date of the 220 patent namely 1st June 2001 (including but not limited to the prior art documents pleaded by the Petitioner)"

Category 1

Disclosure period

20. I am using the term "disclosure period" to indicate the time period within which the relevant documents must be discovered. There were submissions from both parties as to the relevant disclosure period for this category of documents. It was suggested that the UK rule (i.e. a period of two years before the priority date and two years after the priority date) should be the relevant disclosure period. However the Petitioner argued that the Irish rules on discovery were quite different to the English rules and that it was not

appropriate to follow a similar time period in Ireland because the rules were different. It was submitted that as the Irish discovery rules had evolved in a different way and mandated a category by category approach, that the UK disclosure period suggested above might not be appropriate. It was also submitted by the Petitioner that each category of documents was different and therefore the disclosure period might emerge more clearly from each particular category of documents. In my view that is a persuasive submission.

21. Thus in relation to category 1, given that the documents which are to be discovered are all documents contained in the patent application filed with the European and other Patent Offices, it has been suggested by the Respondent that the appropriate period is 1st June 2001 – the date of the first application to the patent office until 21st December 2005 (the date of the grant of the patent).

22. In my view this is an appropriate disclosure period and I will order disclosure of all documents within that time period.

Category 2

23. The second category sought by the Petitioner was as follows:

"All documents so however described concerning the conception, development and reduction to practice of the subject matter disclosed or claimed in the 220 patent and for the avoidance of doubt the earlier related German application number 10126924 from which the priority of the 220 patent is derived, including (but not limited to) all laboratory notebooks of the named inventors: Mr. Michael Trunk, Michael Walz, Ms. Karoline Bechtold-Peters, Dieter Hochrainer and their laboratory technicians, correspondence, files, memoranda, notes, calendars and research of the said inventors and any co-worker who directly assisted them with regard to the subject matter of the 220 patent in respect of each feature of the 220 patent or any other equivalent patent."

24. In relation to this category 2, I had in my earlier judgment of 27th March, 2015, divided category 2 into three constituent parts as follows:

(a) "All documents concerning conception, development and reduction to practice of the subject matter disclosed or claimed in the 220 patent from which the priority date of the 220 patent is derived"

(b) "The laboratory notebooks of the named inventors and their laboratory technicians"

(c) "The correspondence of the said inventors and any co-worker who directly assisted them".

Category 2(a)

25. My conclusion in relation to 2(a) was as follows:

"I think therefore the documents which are relevant and material and proportionate to this part of the discovery are those documents identified in the defendant's disclosure reports i.e. 1. The U reports; 2. The Spiriva project folders; 3. The hard copy documents at para. 2. 19 of the defendant's disclosure reports."

26. William Fry in its letter of 27th April 2015 set out a red line category and a clean category of the categories of discovery sought. Category 2 – because of the manner in which I broke it down - and also because of my decision - has been redrafted as follows in relation to category 2(a):

1. *"U reports created which relate to the conception, development and reduction to practice of the subject matter disclosed or claimed in the 220 patent (and for the avoidance of doubt in the European 220 patent and the German patent number 1012694)."*

2. *"Documents created contained within the two specific Spiriva project folders held by the Respondent's drug delivery department which relate to the conception development and reduction to practice of the subject matter disclosed or claimed in the 220 patent (and for the avoidance of doubt in the European 220 patent and German patent number 1012694)."*

3. *"Documents created contained within the 20 hard copy files identified at paragraph 2.19 of the Respondent's UK Disclosure Report which relate to the conception development and reduction to practice of the subject matter disclosed or claimed in the 220 patent (and for the avoidance of doubt in the European 220 patent and German patent number 1012694) from which the priority date of the 220 patent is derived."*

In my view, this accurately reflects the substance of what I had directed to be discovered under category 2.

Category 2 (b)

27. In relation to category 2 (b), the essential element of this was the laboratory notebooks of the main inventors and their laboratory technicians. In my earlier decision [of 27th March 2015] I had said that *"in relation to the second element of category 2, the laboratory notebooks, I am of the view that these laboratory notebooks of the named inventors and their laboratory technicians are relevant and material and should be discovered and I note in this regard that Finlay Geoghegan J. in Schneider made discovery of this category."*

Category 2(c)

28. In relation to the third element, the correspondence and files of the inventors and any co-worker who directly assisted them, I am of the view that most if not all of these documents could well be captured in the category above at 2 (b).

Respondent's suggested wording

29. The Respondent's suggested wording of this category is

"Those portions of hard copy laboratory notebooks written up during the disclosure period by the named inventors: Mr. Michael Trunk, Michael Walz, Karoline Bechtold-Peters, Dieter Hochrainer and their laboratory technicians who directly assisted them with regard to the subject matter of the 220 patent which relate to the conception, development and reduction to practice of the subject matter of the 220 patent (and for the avoidance of doubt disclosed in the European 220 patent and German patent number 1012694)."

30. In relation to the words underlined the Petitioner makes two objections. These are that the words "hard copy" laboratory note books have been inserted whereas these formed no part of the application for discovery. (Mr. Howard S.C. for the Respondent however clarified that there was no issue on this and that all electronic copies would also be discovered.)

31. Secondly, the Petitioner objected that the words "written up" also appeared in the draft order. I am satisfied that these words also are not necessary.

32. In the circumstances therefore I would make the following order in relation to discovery in relation to category 2:

Category 2

- (a) (i) U Reports created which relate to the conception, development and reduction to practice of the subject matter disclosed or claimed in the 220 patent (and for the avoidance of doubt in the European 220 patent and German patent number 1012694);**
(a) (ii) Documents created contained within the two specific Spiriva project folders held by the Respondent's drug delivery department which relate to the conception, development and reduction to practice of the subject matter disclosed or claimed in the 220 patent (and for the avoidance of doubt in the European 220 patent and German patent number 1012694).
(a) (iii) Documents created contained within the 20 hard copy files identified at para 2.19 of the Respondent's UK disclosure report which relate to the conception, development and reduction to practice of the subject matter disclosed or claimed in the 220 patent (and for the avoidance of doubt in the European 220 patent and German patent number 101 2694 (from which the priority date of the 220 patent is derived) and
(b) Those portions of laboratory notebooks of the named inventors Michael Trunk, Michael Walz, Karoline Bechtold-Peters, Dieter Hochrainer and their laboratory technicians who directly assisted them with regard to the subject matter of the 220 patent which relate to the conception, development and reduction to practice of the subject matter of the 220 patent (and for the avoidance of doubt disclosed in the European 220 patent and German patent number 1012694)"

Category 2

The disclosure period

33. It appears as if no disclosure period arises in relation to category 2 (a).

34. In relation to category 2 (b) the Petitioner sought discovery of all laboratory notebooks going right back to the very beginning of the keeping of such notebooks. The Respondent argued that the disclosure period should be a period of two years before the priority date (from 1st June 1999) to a period of two years after the priority date (i.e. 1st June 2003). It argued that the inventive process had been going on for a considerable period of time and that the notebooks had been intermingled with experiments on other products and that this invention took place within a wider context.

35. Having considered the submissions of both parties I believe that the relevant disclosure period should commence a period of five years before the priority date (i.e. five years prior to 1st June 2001) which is 1st June 1996. I believe that a period of two years before the priority date is too restrictive but I believe that a period beyond that is too burdensome and not proportionate.

36. Moreover I do not believe that the end date of two years after the priority date i.e. 1st June 2003 is appropriate. I believe that all laboratory notebooks up to the grant of the patent on 21st December 2005 should be discoverable. This may disclose notebooks which may assist the Petitioner in advancing their case or damaging the case of the Respondent. Thus the disclosure period for this category shall be 1st June 1996 until 21st December 2005.

Category 3

37. The third category of documents sought by the Petitioner is as follows:

"All documents which disclose or evidence the consideration (if any) given by the inventors of the 220 patent, Mr. Michael Trunk, Mr. Michael Walz, Ms. Karoline Bechtold-Peters, and Mr. Dieter Hochrainer and/or their laboratory technicians and/or by or on behalf of the Respondent to the prior art referred to or related to that listed in the Particulars of Objections dated 23rd October 2014, including any documents disclosing or evidencing any considerations or evaluation by the inventors and/or their technicians and/or by and on behalf of the Respondent as to the potential effect of any such alleged prior art on the patentability of the subject matter disclosed in the 220 patent or any other equivalent patent".

38. In my earlier judgment I noted that category 3 in this case is similar, if not identical to, a category of documents ordered to be discovered in *Schneider v. Conor Medsystems*.

39. I was of the view that these documents were relevant and necessary and should be discovered.

40. The Respondent sent a suggested draft wording for this category 3 of the order.

41. The Petitioner objects to this suggested rewording on the grounds that, it says they are intended to narrow the scope of the order I had already made and to reargue matters which had already been decided by the court.

42. Similar objections were made by counsel for the Respondent against some of the Petitioner's submissions.

43. However, in my view, these submissions are not accurate. Having made my decision on each of the categories in substantive terms, I held over for further consideration the exact wording of each category of discovery. In a case of this complexity and magnitude - which is clearly hard fought - it is not unexpected that there would be differences of view over the exact wording of the order.

44. There were two particular issues which arose in relation to the wording of this category. Michael Howard S.C. for the Respondent argued that, whilst documents which refer to the prior art were clearly caught within the order, he was of the view that documents "related to the prior art" should not be discoverable on the grounds that this formulation was inherently vague and difficult for the Respondent to know how to properly comply with same.

45. Counsel for the Petitioner argued that the wording used was exactly the same as that which had been approved by Ms. Justice Finlay Geoghegan in *Schneider*.

46. However each case is different and I have significant affidavit evidence about the enormous difficulties discovery will occasion the Respondent in this case. The substance of what is being sought by the Petitioner in this category of documents is all documents which show the consideration given by the inventors to the prior art. That is the essence of the matter. It is those documents which should be discovered. In my view, directing discovery of documents which evidence the consideration given by the inventors to "matters related to" the prior art listed in the Particulars of Objection is too vague a formulation in the circumstances of this case. Moreover I do not believe that such documents are relevant or necessary. Even if they were to be relevant and necessary I do not believe they are proportionate. I believe that the Petitioner will obtain all the necessary documents which it needs to prosecute its case by discovery of all documents which show consideration of the prior art referred to in the particulars of objection.

47. The second issue is that Mr. Howard S.C on behalf of the Respondent submitted that the evaluation of the inventors (and their laboratory technicians) of such prior art on the patentability of the subject matter was all that was required to be discovered and that it was not necessary to direct discovery of any documents which evidence any consideration or evaluation "by or on behalf of the Respondent company" as to the potential effect of such alleged prior art on the patentability of the subject matter.

48. In addition, it was argued by Mr. Howard that such documents were caught under category 4. Mr. Coughlan for the Petitioner argued that these documents were not caught under category 4 (which he said related to external consideration) – but that these documents related to internal consideration within the company apart from the inventors.

49. I am of the view that the Respondent's submissions on this are well founded. In particular I have had regard to the structure of the category sought. Thus, what is sought in category 3, in essence, is all documents which show the consideration given by the inventors to the prior art. The category then goes on to say "including any documents" which show any consideration or evaluation by the inventors and/or the laboratory technicians and/or on behalf of the Respondent as to the effect of such prior art on the patentability of the subject matter". The use of the word "including" in that context means that such documents were intended to be a subset of the more general category sought in the first sentence. The general category of documents only relates to the inventors and their laboratory technicians; it does not relate to any consideration given "by or on behalf of the Respondent".

50. However I would not want to decide this issue on such a narrowly technical analysis of the structure of the sentence. One should not analyse a sentence in a letter seeking discovery as one would analyse a statute. The substance of the issue is that the Petitioner is seeking all documents which show the consideration given by the inventors of the product to the prior art. That should include any documents which show any consideration by the inventors/laboratory technicians of the effect of such prior art on the patentability of the subject matter. That is the essence of the discovery sought under this category. The phrase "and/or by or on behalf of the Respondent" broadens the category of documents out to an unacceptable level. It is difficult to see – even if it is relevant – how it is proportionate to the issues to be decided in these proceedings. I am also of the view that such documents would, in any event, probably be captured by category 4.

51. In those circumstances I believe that the appropriate order in respect of category 3 should be as follows:

"All documents created which disclose or evidence the consideration (if any) given by the inventors of the "220 patent, Mr. Michael Trunk, Mr. Michael Walz, Ms. Karoline Bechtold-Peters, and Mr. Dieter Hochrainer and/or their laboratory technicians and/or by or on behalf of the Respondent to the prior art referred to and listed in the Particulars of Objection dated 23rd October 2014 including any documents disclosing or evidencing any consideration or evaluation by the inventors and/or their laboratory technicians (who directly assisted them with regard to the subject matter of the 220 patent) as to the potential effect of such an alleged prior art on the patentability of the subject matter disclosed in the 220 patent (and for the avoidance of doubt disclosed in the European 220 patent and German patent number 1012694)."

Third Category – disclosure period

52. Both parties agreed that similar considerations applied to this category as applied to category 2.

53. In the circumstances I will order discovery of documents for the same period as category 2 i.e. from 1st June 1996 until 21st December 2005.

Category 4

54. I note that there is no dispute in relation to the proposed wording of the order for category 4 and I therefore propose to make an order under category 4 that the Respondent make discovery of

"All documents created which concern or refer to the issue of validity of the 220 patent which have been shown to, provided to, sent to or received from any expert, consultant or in-house counsel and/or patent attorneys who are or have been retained by the Respondent in respect of such an issue."

Category 4 – disclosure period

55. The disclosure period sought by the Petitioner was all documents between the date the Respondent started to devise the alleged invention and 21st December 2005, the date of the patent. The Respondent sought to limit it to two years before and after the priority date.

56. Having considered the submissions of the parties and having regard to the nature of the document sought I believe that an appropriate and proportionate disclosure period would be a period of five years before the priority date (i.e. 1st June 1996) until the grant of the patent – 21st December 2005.

Category 5

57. I note that there is no issue in relation to this and therefore I will make an order that the Respondent discover

"All documents that the Respondent will rely on to demonstrate that the 220 patent is valid and should not be revoked whether on the grounds of lack of inventive step and/or insufficiency or otherwise."

Category 5 – Disclosure Periods

58. I note that there is no time limit in relation to this category of documents.

The second proceedings – Record no. 2014/ 1 PAP

Category 1

59. There is a broad agreement between the parties about the exact wording of an order for discovery in respect of category 1 in these proceedings.

60. The only dispute arises again in relation to the phrase “all documents relating to” the patent application. However this debate mirrored the debate in respect of category 1 in the other set of proceedings. In my view what should be discovered is “all documents contained in the patent application”.

61. Therefore the discovery of category 1 shall be as follows:

“All documents contained in the patent application filed with the Irish Patents Office in respect of Irish patent number 65528 (the base patent), the patent application filed with the European Patent Office in respect of the European Patent EP 0418716 (the 716 patent) and the patent application filed with the German Patents Office for German patent application number 3931041.8 (the German patent) and all correspondence between the Respondent and/or its agents with the Irish Patents Office, the European Patent Office and the German Patents Office in relation to the said patent applications as disclosed, whether all or any of the following are claimed, identified, specified, under, or otherwise protected by the basic patent (or for the avoidance of doubt the 716 patent or the German patent)

1. Tiotropium bromide monohydrate

2. Salts of tiotropium

3. Scopine di – (2-thienyl) glycolate in the form of quaternary salts; and/or

4. Any other product not listed in 1 to 3 above.

Disclosure period

62. The agreed disclosure period is from 16th September 1989 – (the priority date) until 12th October 1995 (the grant of the patent).

Category 2

63. Again there seems to be agreement between the parties in respect of the wording of this category.

64. In respect of the disclosure period the Petitioner suggested or submitted that the appropriate disclosure period was 16th September 1987 (i.e two years before the priority date) until 12th October 1995 – the grant of the patent. The Respondent by contrast suggested that it should be two years before the priority date until two years after the priority date. However, in my view, given this category, I believe that the disclosure period should be that suggested by the Petitioner i.e. 16th September 1987 – two years before the priority date until 12th October 1995 (the grant of the basic patent).

65. Therefore the order in respect of this category will be as follows

“Those portions of laboratory notebooks created during the disclosure period by the named inventors, Dr Ralph Banholzer, Dr Rudolph Bauer and Dr Richard Reichl and their laboratory technicians who directly assisted them with regard to the subject matter of the basic patent that relate to each feature of the basic patent (or for the avoidance of doubt the 716 patent or the German patent)”. The disclosure period shall be 16th September 1987 until 12th October 1995.

Category 7

66. The wording of this category is agreed subject to the addition of the words “all documents contained in” at the start of the category.

67. The disclosure period commences with the date of the application on 14th August 2002 and will run until the date of the grant of the patent on 20th October 2004.

68. Therefore the order for category 7 will be made in the following terms:

“All documents contained in the application filed with the Irish Patents Office for SPC 2002/021 (the Irish SPC) and all correspondence between the Respondent and/or its agents to/from the Irish Patents Office in relation to the said application which discloses whether any or all of the following are claimed, identified, specified, under, or otherwise protected by the basic patent and/or covered by the marketing authorisation relied upon in respect of such application for the SPC.

1. Tiotropium bromide monohydrate

2. Salts of tiotropium

3. Scopine di – (2-thienyl) glycolate in the form of quaternary salts; and/or

4. Any other product not listed in 1 to 3 above.”

69. The disclosure period shall be from 14th August 2002 until 20th October 2004.

Category 8

70. A form of wording in respect of this category has been agreed.

71. Moreover no time period arises in respect of this.

72. Thus an order will be made in the following terms:

A copy of Irish marketing authorisation number PA 775/21 and Dutch marketing authorisation RVG 26191 as granted.

Category 9

73. The wording on this category has been agreed.

74. In relation to the disclosure period both parties agree that it raised the same issues on the disclosure period as were raised in the analogous category in the PAP 2 proceedings. In those proceeding I had directed the disclosure period of five years before the priority date until the grant of the patent. In my view an analogous disclosure period should be ordered here.

75. As the SPC was granted on 20th October 2014 it will run until the grant of the SPC.

76. Thus I will make an order as follows in respect of category 9

**"All documents created which concern or refer to the issue of validity of the Irish SPC which have been shown to provided to, sent to or received from any expert consultant or in house counsel and/or patent attorneys who are, or had been, retained by the Respondent in respect of such issue.
The disclosure period shall be from 14th August 1997 being five years before the SPC application until 20th October 2004 being the date of the grant of the SPC.**

Category 12

77. I note that there is no dispute between the parties as to the wording and no disclosure period is required.

78. I will therefore make an order in terms of category 12 as follows

"All documents that the Respondent will rely on to demonstrate that the SPC is valid and should not be revoked."