



THE COURT OF APPEAL

CIVIL

Appeal No. 2015/278

**The President
Finlay Geoghegan J.
Peart J**

**IN THE MATTER OF IRISH PATENT No. EP (IE) 1379220 FILED ON THE
27TH MAY, 2002 AND REGISTERED IN THE NAME OF
BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG**

IN RESPECT OF AN ALLEGED INVENTION FOR "INHALATION CAPSULES"

AND

**IN THE MATTER OF THE PATENTS ACT 1992 AND
THE PATENTS (AMENDMENT) ACT 2006**

BETWEEN

BOEHRINGER INGELHEIM PHARMA GmbH AND CO KG

APPELLANT

AND

NORTON (WATERFORD) LIMITED t/a TEVA PHARMACEUTICALS IRELAND

RESPONDENT

Judgment delivered on the 26th day of February 2016 by

Ms. Justice Finlay Geoghegan

1. Boehringer Ingelheim Pharma GmbH and Co KG ("Boehringer") appeals against an order for discovery made by the High Court (Cregan J.) on the 19th May, 2015, in which he ordered discovery of five categories of documents. Boehringer appeals against the substance of the order made in respect of categories 1 to 4 and the timing of the required making of discovery in respect of category 5.

2. The order was made in a petition by Norton (Waterford) Limited t/a Teva Pharmaceuticals Ireland ("Teva") seeking revocation of Irish Patent No. EP(IE) 1379220 ("220 Patent").

3. At the time of the hearing of the discovery motion in the High Court (and upon the hearing of the appeal) the grounds of revocation were:

(i) Obviousness over three pieces of prior art referred to as "Maesen" (a study from 1995); "Ogura" (a paper from 1998) and "Barnes" (paper from 2001).

(ii) Lack of sufficiency and/or plausibility.

4. The 220 Patent is part of the protection in place for Boehringer Spiriva ® product. The priority date for the 220 Patent is the 1st June, 2001 which it derives from German patent number 1012694.

5. In the High Court the discovery application was heard in conjunction with applications for discovery in parallel proceedings relating to a Supplementary Protection Certificate (SPC) granted to another company in the Boehringer Ingelheim group. Teva also applied for revocation of the SPC in the parallel proceedings. The order for discovery made in those proceedings was appealed to this court, but by reason of developments in the High Court due to the proximate expiry date of the SPC subsequent to the hearing of the appeal it is no longer necessary to deal with the appeal in the SPC proceedings.

6. Prior to the discovery hearing in the High Court Teva had confirmed in replies to particulars that it was not making a claim of obviousness over common general knowledge. This is of some relevance to the issues on appeal. Also, Boehringer had, shortly before the hearing, made an application by motion of the 11th March, 2015, to amend the 220 Patent. Teva has indicated an intention to object to the amendment. The issue of Boehringer's entitlement to amend will not be determined until the hearing of the petition. Boehringer at the discovery hearing indicated that it will not at the trial hearing seek to defend the 220 Patent as granted, but will only defend an amended form featuring the bifurcation of claims as between PEG Gelatin claims and HPMC claims reflected in the amendment applied for. Teva has indicated that no challenge will be brought in respect of claims 1 or 4 of the amended 202 Patent (presumably if granted).

7. It also relevant to the issues on appeal that at the time of the High Court discovery hearing there were proceedings between related companies of Boehringer and Teva in the English High Court relating to the equivalent UK 220 Patent which were due to be heard in July 2015. At the time of the hearing of this appeal judgment had been reserved. The approach of the related parties to

disclosure in England following exchanges at a case management conference with Arnold J. were relied upon in the High Court and again on appeal by Boehringer.

8. Boehringer's Spiriva product is stated to be essentially a smooth muscle relaxant that is inhaled into the lungs and that yields bronchodilatory effects when it binds to the muscarinic receptors in the deep lung. The Spiriva product is currently taken in inhaler form by two methods. The 220 Patent is stated to protect the formulation of the medicinal product containing Tiotropium in a capsule for inhalation that ensures the stability of the active ingredient and the release of the active substance with high metering accuracy. It is also stated to protect the formulation when used with the Handihaler® device so that it is delivered to the lung.

9. The trial judge having had a four day discovery hearing based upon a number of affidavits; having delivered an extensive ex tempore judgment on the 27th March, 2015, and having heard further submissions over two days, delivered a supplemental written judgment on the 6th May, 2015, pursuant to all of which he made the following orders for discovery by Boehringer of documents which are or have been in its possession, power or procurement:

"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, for the period between 1 June 2001 and 21 December 2005, 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).

2. (a) (i) U Reports created during the period 1 June 1996 and 21 December 2005 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 during the period 1 June 1996 and 21 December 2005 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 during the period 1 June 1996 and 21 December 2005 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

2(b) Those portions of laboratory notebooks, for the period between 1 June 1996 and 21 December 2005, of 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).

3. All documents created during the period between 1 June 1996 and 21 December 2005, 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 to the prior art referred to and listed in the Particulars of Objection dated 23 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).

4. All documents created during the period between 1 June 1996 and 21 December 2005, 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.

5. 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."

Applicable principles

10. The basic principles applicable to the determination of the discovery application in the High Court and on appeal were and are not in dispute. The trial judge referred to and applied the well established principles as they were referred to previously in a series of judgments of the High Court relating to discovery applications in patent proceedings. These included: *Medtronic Inc. v. Guidant Corporation* [2007] IEHC 37; *Schneider (Europe) GmbH v. Connor Med Systems Ireland Limited* [2007] 2 ILRM 300 [2007] IEHC 63; *Medlinol Limited v. Abbott Ireland* [2010] IEHC 6; *AstraZeneca AB v. Pinewood Laboratories Limited* [2011] IEHC 159 and *AstraZeneca v. Patents Act* [2014] IEHC 189.

11. Those judgments in turn refer to the general principles set out or approved of by the Supreme Court in, amongst others, *Framus v CRH plc* [2004] 2 I.R. 20, approving of *Hannon v. Commission of Public Works* [2001] IEHC 59; *P.J. Carroll and Company v. Minister for Health and Children* [2006] 3 IR 431 approving of the judgment of Kelly J. in the High Court (Unreported, 9th December, 2005) in the same case; *Ryanair plc v. Aer Rianta CPT* [2003] 4 I.R. 264 and *Taylor v. Clonmel Healthcare Limited* [2004] 1 I.R. 169.

12. From the above the general principles in this jurisdiction may be summarised as follows.

1. The principles applicable to discovery in patent cases is not different to discovery in other types of cases.

2. The applicant for discovery must establish firstly relevance of the documents sought to the matters in question in the proceedings (O. 31, r. 12(1)) as a matter of probability and not only possibility (Hannon approved of in *Framus*). What are the matters in question must be determined by reference to the pleadings and particulars.

3. The formulation of Brett L.J. in *Compagnie Financiere et Commerciale du Pacifique v. Peruvian Guano Company* (1882) 11 QBD 55, remains the applicable test for relevance in this jurisdiction:

"It seems to me that every document relates to the matter in question in the action, which not only would be evidence upon any issue, but also which, it is reasonable to suppose, contains information which may – not which must – either directly or indirectly enable the party requiring the affidavit either to advance his own case or to damage the case of his adversary. I put in the words 'either directly or indirectly' because, as it seems to me, a document can properly be said to contain information which may enable the party requiring the affidavit either to advance his own case or damage the case of his adversary, if it is a document which may fairly lead him to a train of inquiry, which may have either of these two consequences."

4. In addition to relevance the applicant for discovery must show that the discovery sought is necessary for disposing fairly of the cause or matter or for saving costs (O. 31, r. 12(5)). The court is expressly precluded by order O. 31, r. 12(5) from making an order for discovery unless it is satisfied that discovery of the relevant documents is necessary for either such purpose.

5. The discretion given to the court to decide what is necessary has been referred to as a "broad discretion" per Fennelly J. in *Aer Rianta plc*. It requires the court to consider: "What is genuinely necessary for the fairness of the litigation" and introduces a concept of "proportionality between the extent or volume of the documents to be discovered and the degree to which the documents are likely to advance the case of the applicant or damage the case of his or her opponent". Per Murray C.J. in *Framus*. It requires the court to consider whether discovery of the documents sought is necessary for the fair disposal of the proceedings in a cost effective manner.

6. The continued test of relevance in this jurisdiction which includes the 'line of inquiry' test from *Peruvian Guano* goes beyond documents potentially admissible in evidence and is not confined to same (*Schneider*).

13. Whilst concerns have been expressed in several judgments in relation to the importance of reducing the cost of litigation and in particular costs attributable to discovery of documents nevertheless, as appears from the above, in this jurisdiction it remains the position that the test of relevance includes those documents which as a matter of probability may lead to "a line of inquiry". This is exemplified by the averment required in paragraph 8 of the affidavit of discovery required by O.31 r.13 as set out in Appendix C Form 10:

"8. I understand that the obligation on a party giving discovery is to discover all documents and electronically stored information within his/her/its possession, power or procurement within the categories agreed or ordered to be delivered that contain information which may enable the party receiving the discovery to advance its own case or to damage the case of the party giving discovery **or which may fairly lead to a train of inquiry which may have either of those consequences**" [emphasis added].

14. The averment required only relates, of course, to the categories ordered or agreed which must have already been considered necessary for the fair disposal of the proceedings. As stated by Kelly J in *Medtronic Inc. v. Guidant Corporation* [2007] IEHC

"37. The court should also consider the necessity for the documents having regard to all the relevant circumstances, including the burden, scale and cost of the discovery sought. It should also be willing to confine categories of documents sought to what is genuinely necessary for the fair disposal of the litigation".

15. The Court was not asked in submissions on appeal to depart from the above well established principles. Rather submissions were directed to their application to the matters in question in these proceedings, taking into account the approach of the related parties to the similar proceedings in England. Boehringer submits that certain of the categories ordered are not relevant and others are not necessary.

UK Proceedings

16. Before the High Court and again before this Court Boehringer relied upon what occurred before Arnold J. in the parallel proceedings brought by related companies in relation to the UK 220 Patent to submit that the documents in categories 1 to 4 were not relevant to the questions in issue in the proceedings and if relevant were not necessary for the just disposal of the proceedings.

17. The trial judge has set out in some detail in his judgment the evidence before him of what had occurred in the English High Court. It is sufficient for present purposes to note that in the English proceedings, Teva UK Limited sought revocation of Boehringer's UK 220 Patent upon the same grounds as in the Irish proceedings of obviousness and insufficiency. It appears at the time of the application before Arnold J. it was obviousness over two pieces of identified prior art and not over common general knowledge.

18. In accordance with the English Civil Procedure Rules Teva UK had included in draft directions provision for standard disclosure under Rule 31.6. This requires a party to disclose

(a) the documents on which he relies; and

(b) the documents which:

- (i) adversely affect his own case;
- (ii) adversely affect another parties case or
- (iii) support another parties case and

(c) the documents which he is required to disclose by a relevant practice direction.

19. Further according to CPR Rule 63.9 in patent invalidity actions, a four year disclosure window is specified which includes documents created two years before the priority date and two years thereafter.

20. Boehringer's UK lawyers, it is deposed, on an assumption that standard disclosure might be given by the English High Court, did not object to the proposal but proposed a staged approach with a defined and limited number of documents to be reviewed for relevance and potential disclosure under standard disclosure obligations as a first stage and provision for a possible second stage. Teva UK agreed to that and such directions were given at a case management conference on the 1st October, 2014. Boehringer prepared a draft disclosure report.

21. Subsequently a dispute arose in relation to confidentiality restrictions to be applied in respect of the documents to be disclosed by Boehringer and an application was brought by Teva UK before Arnold J. in the English High Court on the 19th October, 2014. The transcript of that hearing was exhibited in the affidavits before the trial judge. It appears that Arnold J. had on affidavit a general description of the documents intended to be disclosed by Boehringer and referred to as the "U-Reports".

22. Arnold J. took the view that the documents which Boehringer was proposing to disclose, but in respect of which there was a dispute concerning the confidentiality conditions, were not discloseable having regard to the issues in the case. He stated:-

"So far as the revocation claim is concerned [of the UK 220 Patent] the ordinary obviousness case, as I see it, the position is straightforward, viz that we have an allegation of obviousness over two prior art documents."

[Counsel agreed]

"It is expressly acknowledged that there is no claim of obviousness over common general knowledge alone and therefore your client's disclosure, the U-Reports that are talked about in Mr. Cordell's evidence, I cannot begin to see that they are of relevance. The only other validity plea is the AgrEvo plea also run on the basis of insufficiency which is all about plausibility on the face of the patent. So again the U-Reports are not relevant there. So far as I can see, the U-reports are simply not discloseable."

23. Later in the exchanges with counsel at the same hearing Arnold J. expressed concern that

"Time after time in the patents court, I see parties agreeing to give disclosure at considerable expense when it turns out it is of no relevance."

24. Following a break to allow counsel take instructions, counsel for Boehringer indicated insofar as the patent claim was concerned that they were adopting the judge's suggestion of not disclosing any of the U-Reports and counsel for Teva UK indicated his client's agreement.

25. The trial judge summarised the submissions made on behalf of Boehringer to him in reliance on the above at para. 27 of his judgment:

"The submission of Mr. Howard SC for the Respondent is this: Firstly, that the Petitioner is bringing identical proceedings in Ireland and the UK against the Respondent; secondly, the Petitioner in the UK has accepted in the 220 revocation proceedings that, in the light of Arnold J's comments, no discovery is relevant or necessary; thirdly, however, the Petitioner in this jurisdiction is not only seeking discovery, it is seeking discovery of a vast amount of documents; and, fourthly, that the court should take note of this situation and ask itself, is it the case that documents can be relevant in one jurisdiction and not in the other."

26. The trial judge then considered certain dicta of Clarke J. in *Ranbaxy Laboratories and Others v. Warner Lambert Company* [2007] IEHC 256 and of Barrett J. in *AstraZeneca* [2014] IEHC 189 and reached his conclusion as to the impact of what had occurred in the UK proceedings before Arnold J. and the views expressed by him in the following terms at paras. 31 and 32:-

"31. In my view, the words of Arnold J in the transcript exhibited in these proceedings should be treated with the greatest of respect as he is an eminent patent judge, but it should also be treated with caution in this case for a number of reasons: firstly, his dicta are not given in the context of an application for discovery where he made a decision not to grant discovery on grounds that it was neither relevant nor necessary; secondly, his dicta were given in the context of a confidentiality agreement in respect of certain documents; thirdly, it appears that his remarks may only have referred to a couple of documents; fourthly, the discovery rules in the UK and Ireland are different; fifthly, the case management procedures of such cases is different; sixthly, the petitioner in Ireland with its Irish legal advisors is entitled to run its case in the usual way and to seek discovery if it believes it is necessary to do so under the Irish rules of discovery.

32. However, having said that, I think a court in Ireland can have regard to the fact that identical proceedings in the UK are being run without any discovery being sought. In those circumstances I do not believe that it would be appropriate to order a vast amount of discovery in Ireland where no discovery at all is being sought in the UK."

27. On appeal the principal submission made on behalf of Boehringer in relation to what occurred in England in the parallel proceedings was that Teva decided to proceed with its revocation claim upon similar grounds of objection without seeking any disclosure from Boehringer. Further by the time of the appeal hearing, the English High Court trial hearing had taken place and Teva did not suggest that the absence of discovered documents had interfered with them obtaining a full and fair hearing of their claim in England. It was also stressed that whilst there is an acknowledged difference between the *Peruvian Guano* relevance test in this jurisdiction as including the 'line of inquiry' documents and the test for relevance in CPR standard disclosure in England, nevertheless it remains open in England to a party to apply for disclosure in addition to that obtainable pursuant to standard disclosure. It was not disputed on behalf of the Teva that such potential procedure exists. However I think it would be fair to take into account that from a number of English decisions opened to the Court the probability of getting any such broad discovery or disclosure in a claim for revocation based on obviousness over specified prior art and insufficiency would be low.

28. Counsel for Boehringer on appeal submitted that Cregan J. in considering relevance and more particularly necessity of the individual categories of documents had failed to take into account sufficiently the fact that Teva proceeded with its claim in England without seeking to obtain disclosure of any of the documents in categories 1 to 4.

29. Counsel for Teva on this issue stressed the difference in test for relevance between Ireland and certainly standard disclosure in England; the fact that the trial judge had limited the categories of documents sought in particular in categories 1 and 2 and also reduced the periods sought; the fact that similar categories of documents had been ordered by the High Court in the patent discovery judgments cited above (albeit some on consent) and the fact that Boehringer had sought discovery of similar categories of documents in the SPC proceedings. This last ground appears to me to be of no relevance.

30. It is self evident that the trial judge was obliged to consider the discovery application in accordance with the law and procedures in this jurisdiction. However, in my view in reaching his decision he gave insufficient weight to the fact that Teva UK decided to proceed with its claim for revocation of essentially the same patent upon the same grounds and where the substantive law to be applied is in substance the same in both jurisdictions without disclosure/discovery. In those factual circumstances, whilst he was correct to consider whether the categories of documents in respect of which discovery was sought were relevant in accordance with the *Peruvian Guano* test when he came to consider the necessity of discovery for the fair disposal of the proceedings in a cost effective manner it appears to me that in certain of the categories he insufficiently took into account the manner in which Teva proceeded with the English proceedings.

Categories ordered by the High Court

31. The trial judge concluded that each of the categories ordered were relevant to the matters in question in the proceedings in accordance with the *Peruvian Guano* test. Boehringer submits that he did not explain in some instances the reason for his conclusion on relevance. It must be recalled that the first judgment was an ex tempore judgment given at the end of a four day hearing in which the prior judgments, particularly those on discovery in patent cases of the High Court in which similar classes of documents had been either agreed or found to be relevant had been opened fully to him. Further he had considered the affidavits, the letters seeking voluntary discovery and responses thereto and other exhibits as I have done.

32. There is no dispute that the claim of obviousness or the issue of inventive step over the cited prior art must be determined in accordance with the well known statements of Oliver L.J. in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Limited* [1985] RPC 59 at 73. The primary evidence at trial will be that of properly qualified expert witnesses. Secondary evidence of contemporary events may not be totally excluded in accordance with the decision of the English Court of Appeal in *Molnlycke AB v. Proctor and Gamble Limited (No. 5)* [1994] RPC 49. However, as is clear from that judgment secondary evidence of that type must be kept firmly in its place and will vary from case to case. I do not understand Teva to have made any case in the High Court or before us that they were proposing to call secondary evidence of the type envisaged in *Molnlycke*. The fact that the claim is obviousness over cited prior art and not over common general knowledge may explain this. I have noted that Arnold J.'s in his comments identified that this was a case of obviousness over specified prior art and not over common general knowledge prior to expressing his view of lack of relevance of the proposed disclosure of what might be generically referred to as inventor's note books.

33. In the course of the hearing before this Court, counsel for Boehringer confirmed that they were not intending to call an inventor and counsel for Teva indicated likewise.

34. Insofar as the claim of lack of sufficiency or plausibility is concerned, it appears to be accepted that such claim falls to be determined by objective construction of the patent and that again expert evidence will be the only relevant evidence.

35. I now turn to individual consideration of categories 1 to 4 each of which the trial judge considered to be both relevant and necessary. It appears to me important to separate the two questions of relevance and necessity.

36. On the question of relevance Teva in their grounding affidavit and in submissions make an overall claim to relevance which affects all four categories. They contend in respect of each category 1 to 4 that the documents within the category will disclose analysis by Boehringer and the relevant individuals working on its behalf of the extent to which the alleged invention, the subject matter of the 220 Patent comprised an inventive step having regard to the prior art. They say that such analysis is relevant to the question of the issue of obviousness and in particular comes within the *Peruvian Guano* line of inquiry test for relevance. Boehringer's own analysis may lead to a line of inquiry which Teva may engage in with its own experts.

37. In my view the trial judge was correct in concluding that categories 1 to 4 include documents which as a matter of probability are relevant in accordance with the *Peruvian Guano* test as disclosing a line of inquiry which may assist Teva's case or damage that of Boehringer or indeed damage Teva's case or assist that of Boehringer. Each of the categories were categories which had been allowed in prior High Court decisions and for so long as in this jurisdiction we continue to apply the *Peruvian Guano* test for relevance it cannot be said that the High Court judge erred in his conclusion on the question of relevance. However it is important to note for the question of necessity that it does not appear that Teva has established that any of the categories as a matter of probability contain documents potentially admissible in evidence having regard to the claims made, the nature of the evidence to be adduced and the absence of any intention to call an inventor.

38. The conclusion reached by the trial judge on necessity of each category requires separate consideration. However, there is one general claim of necessity made by Teva which applies to all categories. Teva submits that once it is established that the documents are relevant, then the fair or just disposal of the proceedings requires that the documents be discovered to them. They submit that if this is not done, they are precluded from having documents available to them for the purpose of both instructing their own expert witnesses and cross examining the expert witnesses of Boehringer that are available to Boehringer in instructing its expert witnesses and giving instructions for the cross examination of Teva's expert witnesses. This, Teva submits, means there is not equality of arms or gives to Boehringer a litigious advantage if discovery is not ordered.

39. I accepted such a submission in *Schneider* as a second reason for which I considered discovery of the inventor's notebooks in that case as necessary for the fair disposal of those proceedings. I remain of the view that it is a matter properly to be taken into account by a trial judge in determining whether or not he should make an order for discovery of documents determined to be relevant. However, it is only a factor albeit an important one which must be taken into account and as is clear from the Supreme Court decisions in *Aer Rianta* and *Framus*, a judge, in considering whether or not an applicant for discovery has satisfied him or her that it is necessary to make an order for discovery of relevant documents, must also consider the proportionality of making the order sought having regard to the particular facts of the case and the reasons for which the applicants contend discovery is necessary and the grounds of objection made by the respondent to the application. Included in the latter are questions such as the numbers of documents sought, the cost of carrying out the discovery and potential confidentiality issues.

40. I would also add that in general in considering the necessity of the discovery of relevant documents the nature and potential strength of the relevance is a consideration to be taken into account.

41. Turning to category 1 which is in substance a portion of the patent file, in my view the trial judge was correct in making an order

of discovery and holding that the documents were both relevant and necessary for the fair disposal of the proceedings. He limited the category, following the second hearing to all documents contained in the patent application to the Irish and German Patents Office and all correspondence between Boehringer and European, German and Irish patent offices for the period between 1st June, 2001 to 21st December, 2005, "as disclosed the state of art prior to the priority date of the 220 Patent namely, the 1st June, 2001 (including, but not limited to the prior art documents needed by the petitioner)". For reasons already given, those documents are relevant within the *Peruvian Guano* test as they may disclose lines of inquiry from consideration of the specified prior art or other prior art and queries raised by patent offices in relation thereto. Teva justified the inclusion of prior art beyond the specified prior art on the basis that they would be entitled to apply to add further pieces prior to hearing. The entitlement to make such an application was not disputed and in a context where it has already specified three pieces it cannot be considered as simply "fishing". These documents are information which is available to Boehringer and it is in a position to use in instructing its own witnesses. Boehringer has not advanced any particular difficulties in identifying or discovering the list of such documents, any volume issue or any particular confidentiality issues in making discovery of same.

42. In deciding to uphold the decision ordering the discovery of this category I have taken into account that Teva was prepared in England to proceed to trial without seeking such documents. However, as previously indicated it does appear to me that the survival in this jurisdiction of the test of relevance in accordance with *Peruvian Guano* is such that necessity of discovery for the fair disposal of proceedings in this jurisdiction must be determined in accordance with the potential discoverability of documents considered relevant in accordance with that test. It is a matter for another day if a party argues that the court should change its approach to the test of relevance or a change is made to the Rules of Court. There may well be merit in a reconsideration of the current test for relevance. However, for so long as the *Peruvian Guano* test for relevance subsists, it appears to me that the trial judge was correct in circumstances where no particular difficulty or significant cost was advanced by Boehringer in discovering this category in concluding their discovery on the facts of this case was necessary for the fair disposal of the proceedings and in ordering discovery of category 1.

43. In relation to categories 2 and 3 I have formed the opposite view. It appears to me that the trial judge was in error on the facts herein in concluding that the discovery of categories 2 and 3 is necessary for the fair disposal of these proceedings. In reaching this conclusion I am fully conscious that on the facts of *Schneider* I reached the opposite point of view in relation to the inventor's notebooks on the facts therein and the trial judge relied in part upon my decision in *Schneider*. However, as I have already indicated an applicant must establish necessity having regard to the facts of the individual case. In *Schneider* the claim of obviousness was over two specified pieces of prior art and unlike this case also over common general knowledge. I have no recollection now of the facts other than as recorded in my judgment, from which it does not appear that the respondent in that case had made out any difficulty in providing the discovery sought in terms of cost or numbers or documents nor based its objection upon confidentiality concerns. It was a case where there was a claim for infringement with a counterclaim of invalidity.

44. Further it has been submitted in this appeal that in my reasoning in *Schneider* I was incorrect in accepting a submission in that case: "it will be of assistance to the defendant in cross examining the plaintiff's expert witnesses by reference to what at least one person admittedly skilled in the art (i.e. the inventor) actually did." On a reconsideration of the authorities in relation to the characteristics of a person skilled in the art for the purposes of the *Windsurfing* obviousness test, I accept that the notional person skilled in the art is a person who lacks inventiveness and thus I was incorrect in regarding the inventor as being an example of a notional "person skilled in the art".

45. The principal differences on the facts in this application for discovery and those before me in *Schneider* are first the objections grounded on the facts set out mainly in the affidavit of Mr. Jan-Christian Redel filed on behalf of Boehringer concerning the cost, volume of documentation and multiple data sources which would have to be searched over long periods and the complications of the confidentiality issues particularly having regard to the fact that Teva is a generic competitor and second the decision of Teva to pursue its similar claim in the UK without seeking disclosure or discovery of any of the documents included in categories 2 and 3. Those facts are such that notwithstanding that the categories may contain relevant documents which may assist Teva in giving instructions to its own experts or instructing counsel to cross examine experts from Boehringer I have concluded that the trial judge was in error on the facts herein in concluding that discovery of the very significant volume of documents potentially within categories 2 and 3 is necessary for disposing fairly of these proceedings. The proportionality between the potential advantage to Teva in obtaining these documents for use in these proceedings and the probable cost and time involved in Boehringer making discovery and taking into account the position in the UK proceedings is such that discovery of categories 2 and 3 is not necessary for the fair disposal of the proceedings.

46. I have formed a similar view in relation to category 4. Whilst I recognise that this category is of a more limited category of documents, nevertheless as Mr. Redel's affidavit discloses identifying the existence of such documents over a nine year period from multiple sources having regard to the facts set out would also involve significant time and money. Certain of the documents whilst relevant may be the subject of privilege. That is a lesser consideration than others. I have reached the conclusion that on the particular facts herein, that category 4 is not necessary for the fair disposal of the proceedings. Even assuming Teva might ultimately have had disclosed to them (if the discovery order were upheld) relevant documents which are not privileged and which refer to an issue of validity of the 220 Patent which may have assisted in instructing experts or instructing counsel for the purposes of cross examination I do not consider on the facts herein such discovery is proportionate or necessary. Again, in reaching this conclusion I have taken into account the fact that Teva proceeded in the UK, without claiming any unfairness without such documents. It is also relevant that both parties belong to major pharmaceutical groups with multiple resources available to obtain expert scientific and legal advice and hence Teva is in a position to independently obtain leading advice, both scientific and legal as to the validity of the 220 Patent and it is not necessary for the fair disposal of these proceedings that they be permitted to view any such non-privileged advice obtained by Boehringer in the course of the nine year period referred to in the High Court order.

47. Accordingly, I would vary the High Court order so as to refuse the application in respect of categories 2, 3 and 4.

48. The next issue relates to the timing of discovery of the documents in category 5. These are the documents upon which Boehringer will rely on to demonstrate that the 220 Patent is valid and should not be revoked whether on grounds of lack of inventive step and/or insufficiency or otherwise.

49. The only issue in dispute in the High Court and again on appeal is whether or not Boehringer should have to make discovery of these documents in advance of or after service of the witness statements of Teva. The normal practice in the Commercial list in the High Court is for the plaintiff's witness statements to be furnished in advance of the defendant's witness statements. The timing of the discovery of the documents in category 5 is essentially a question of case management. The trial judge in his *ex tempore* judgment at para. 70 referred to the submissions made by counsel on behalf of Boehringer for deferral until after the witness statements of Teva had been produced and indicated that in his view it was "not appropriate for the proper case management of these proceedings that it should wait until then".

50. The trial judge is best placed to determine matters of case management and in my view the Court of Appeal should be very slow to interfere with the discretion of a trial judge in case managing proceedings in the High Court. The trial judge was acting well within his discretion in determining that the documents which Boehringer had agreed to discover should be made available to Teva in advance of the preparation of its witness statements. Accordingly, I would reject the appeal against his determination of the timing of discovery in relation to category 5.

51. The only remaining matter is the submission made on behalf of the Boehringer that the trial judge failed to have regard to its application to amend the 220 patent and the position taken by both parties in relation to the existing claims in the patent and the amended claims if allowed, when making the orders for discovery. This is a complicated issue and it appears to me preferable that a full consideration of the question be left over to a case where it affects a significant order for discovery. The only disputed category which I propose allowing is category 1. Boehringer as I have indicated has not sought to advance any particular difficulties in relation to discovery of those documents. In general it appears to me that the trial judge was correct in considering the application for discovery in relation to issues in dispute in the proceedings on the pleadings as they stood at the date of application before him. It is the concessions made by Teva and Boehringer in relation to the position post a decision on the application for amendment and the fact that that application is left over to the trial which complicates the issue. It does not appear to me necessary to resolve same in relation to the order I would propose for category 1 only.

Order

The appeal will be allowed in part and the orders for discovery in relation to categories 2, 3 and 4 in the High Court order of the 19th May, 2015 vacated.