THE HIGH COURT

2017 No. 4024 P

Between:

BIOGEN INC.,

F HOFFMANN-LA ROCHE AG

and

GENENTECH INC.

Plaintiffs

– and –

CELLTRION INC.,

CELLTRION HEALTHCARE HUNGARY KFT.,

MUNDIPHARMA INTERNATIONAL LIMITED

and

MUNDIPHARMA PHARMACEUTICALS LIMITED

Defendants

JUDGMENT of Mr Justice Max Barrett delivered on 4th May, 2018.

I

Background

1. These proceedings concern an action for infringement of (1) Irish Patent No. 1 951 304 entitled 'Method for treating Joint Damage' which protects rituximab in the MabThera label use for the treatment of arthritis (valid until 14th November, 2026) (the '304 Patent'); and (2) Irish Patent No. 2 055 313 entitled 'Treatment of hematologic malignancies associated with circulating tumor cells using chimeric anti-CD20 antibody' which protects rituximab in the MabThera label use for the treatment of chronic lymphocytic leukaemia (valid until 9th November, 2019) (the '313 Patent').

2. The substance of the dispute between the parties can be stated briefly. On or about 17th February, 2017, the European Medicines Agency granted a marketing authorisation to Celltrion Healthcare Hungary KFT for a biosimilar of the plaintiffs' medicinal product MabThera (rituximab) under the designation 'Truxima®'. Truxima is intended for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis. It is the plaintiffs' case that Truxima infringes the 304 Patent and the 313 Patent. The defendants contend that each of the 304 Patent and the 313 Patent is invalid. Accordingly, the defendants have counterclaimed for invalidity and seek orders revoking each of the said patents, on grounds of added matter, lack of novelty and insufficiency. The prior art documents relied on by the defendants are specified in the particulars of objection.

3. The within application comprises an application for discovery made by the defendants in the context of the above-titled proceedings. The defendants sought discovery of 15 categories of documents by letter dated 27th November, 2017. Of those 15 categories, Categories 1, 2, 10, 11, 12, 13, 14, and 15 (ii)-(v) (but not 15(i)) have been agreed either as sought or in an amended form. Categories 3, 4, 5, 6, 7, 8, 9, and 15(i) are in dispute. The position as regards each of the categories in dispute at the time of the hearing is as follows:

No.	Original Request	Counter-Offer (if any).
3	All documents created in the period between 15.12.00-22.10.14 howsoever described concerning the conception, development and reduction to practice of the subject-matter disclosed or claimed in the 304 Patent and for the avoidance of doubt the earlier related US patent application 737291P (from which the priority date of the 304 Patent is derived), including (but not limited to) all laboratory notebooks of the named inventors, Mark Totoritis, Timothy Mark Shaw, Sunil Agarwal, David Yocum and Ariella Kelman and their laboratory technicians, correspondence, files, memoranda, notes, calendars and research of the said named inventors and any co-worker who directly assisted them with regard to the subject-matter of the 304 Patent in respect of each feature of the 304 Patent or any other equivalent patent.	

4	All documents created in the period between 09.11.93 and 29.04.15 howsoever described concerning the conception, development and reduction to practice of the subject-matter disclosed or claimed in the 313 Patent and for the avoidance of doubt the earlier related US Patent application 107658P (from which the priority date of the 313 Patent is derived), including (but not limited to) all laboratory notebooks of the named inventors, Antonio J. Grillo-Lopez and Christine A White and their laboratory technicians, correspondence, files, memoranda, notes calendars and research of the said named inventors and any co-worker who directly assisted them with regard to the subject-matter, of the 313 Patent in respect of each feature of the 313 Patent or any other equivalent patent.	
5	All documents relating to the decision to undertake the trial of rituximab for use to treat chronic lymphocytic leukaemia as described within the claims of the 313 Patent, which came into existence at any time between 09.11.96-09.11.00.	
6	All documents created in the period between 15.11.00-22.10.14 which disclose or evidence the consideration (if any) given by the inventors of the 304 Patent, Mark Totoritis, Timothy Mark Shaw, Sunil Agarwal, David Yocum and Ariella Kelman, and/or their laboratory technicians and/or by or on behalf of the first-named plaintiff to the prior art referred to or related to that listed in the particulars of objections dated 11.09.2017, including any documents disclosing or evidencing any consideration or evaluation by the inventors and/or their technicians and/or by on behalf of the plaintiffs as to the potential effect of any such alleged prior art on the patentability of the subject-matter disclosed in the 304 Patent or any other equivalent patent.	
7	All documents created in the period between 09.11.93-29.04.15 which disclose or evidence the consideration (if any) given by the inventors of the 313 Patent, Antonio J Grillo-Lopez and Christine A White, and/or their laboratory technicians, and/or by or on behalf of the plaintiffs to the prior art referred to or related to that listed in the particulars of objections dated 11.09.2017, including any documents disclosing or evidencing any consideration or evaluation by the inventors and/or their technicians and/or by or on behalf of the plaintiffs as to the potential effect of any such alleged prior art on the patentability of the subject matter disclosed in the 313 Patent or any other equivalent patent.	
8	All documents created in the period between 15.11.00 and 22.10.14 which concern or refer to the issue of validity of the 304 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 had been retained by the Plaintiffs in respect of such issue.	
9	All documents created in the period between 09.11.93 and 29.04.15 which concern or refer to the issue of validity of the 313 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 had been retained by the plaintiffs in respect of such issue.	

15(i)	Documents and communications concerning the study described in the O'Brien Study [1], including but not limited to (i) any communications between the plaintiffs and the authors of the O'Brien Study (Susan O'Brien, Emil J Freireich, Michael Andreef, Michael J Keating and/or Susan Lerner) relating to the O'Brien Study… [1] *I.e.* the publication entitled "*Phase I/II Study of Rituxan in Chronic Lymphocytic Leukaemia (CLL)*" (*Blood*, Vol 92 at page 105A by S O'Brien *et al*, which was published on 09.11.98) as cited in the defendants' particulars of objections.	Plaintiffs' letter dated 14.12.17: In respect of category 15(i), plaintiffs offered: (i) "*an electronic search utilising appropriate search terms of the discovery previously made by them in the US Massachusetts proceedings, with the search confined to the documents disclosed in those proceedings and search terms being selected with a view to locating documents which would fall within this category.*"

II

Some Introductory Observations

4. The court turns to a consideration of applicable case-law later below and brings same to bear in its consideration of the categories of discovery now sought. However, it may be useful to commence with a number of introductory observations.

(1) in the general course of events it is untypical to have a discovery application applicable to 14 and 22-year periods; such a lengthy period of discovery requires very explicit justification.

(2) the proper approach to every discovery application, whether in the patent law context or otherwise, is to look at each category sought and to assess same by reference to a trinity of criteria (relevance, necessity and proportionality). It is necessary to note this because in the course of hearing the court was presented with a grid of past discovery applications in which certain categories of discovery were granted. The most that can be said of such a grid is that it shows that (a) discovery of Category X was granted in the context of some other Case A and/or B and/or C, and so (b) it is not unheard of for discovery of Category X to be granted. But in terms of assessing relevance, necessity and proportionality when it comes to Case D, E, *etc*., such an assessment falls always to be done on case-by-case basis by relevance to the individual circumstances at hand. (The grid furnished to the court in the within proceedings was in any event slightly unusual in that it omitted consideration of the decision of the Court of Appeal in *Boehringer Ingelheim Pharma GmbH v. Norton (Waterford) Ltd* [2016] IECA 67, a case which, as will be seen hereafter, is of no little importance when it comes to determining the application now at hand).

(3) the court was repeatedly referred to the actions of the plaintiffs in certain United Kingdom proceedings that correspond to those at hand. Those United Kingdom proceedings were compromised at the point where standard disclosure was to be made, which disclosure would apparently have yielded documentation akin to, though not quite as wide as, that now sought in Category 5. For what it is worth, the court notes in passing that none of Categories 3, 4, 6, 7, 8, 9, and 15(i) were sought by way of discovery in the United Kingdom proceedings.

(4) as regards dealings between the parties in the United States (which related to certain proceedings in the Netherlands), the court notes that (i) the plaintiffs have offered in respect of Category 15(i) what was offered in the United States but is being met with the response that in Ireland more is needed, (ii) in respect of Category 3, what was sought and agreed by defendants in the United States in this regard was far narrower than what is now being sought by way of Category 3.

III

Some Applicable Law

5. The general principles applicable to an *inter partes* application for discovery such as that now presenting are identified in the decisions of the Court of Appeal in *BAM PPP PGGM Infrastructure Cooperatie UA v. National Treasury Management Agency* [2015] IECA 246, para. 29, as echoed in *Boehringer Ingelheim Pharma GmBH v. Norton (Waterford) Ltd,* op. cit., para.12. As noted by Finlay Geoghegan J. in the latter judgment, at para.12, "*The principles applicable to discovery in patent cases*…[are] *not different to discovery in other types of cases*". It did not seem to the court that when it comes to the general legal principles applicable there was much dispute between the parties. What was in issue was the import and consequences of those principles in the context of the application at hand.

IV

This Case and the Decision in Boehringer

(i) Similarities and Distinctions.

a. Similarities.

6. Categories 3, 4, 6, 7, 8 and 9 in the within proceedings appear to have been quite closely modelled on what was sought in *Boehringer*. In this regard the following points seem of especial note: (i) Categories 3, 4, 6 and 7 (a) embrace and go beyond the so-called 'inventor's files' in respect of each of the 304 Patent and the 313 Patent, (b) are in almost identical terms to the Categories 2 and 3 that were refused by the Court of Appeal in *Boehringer*; (ii) Categories 8 and 9 (a) seek documents concerning the validity of

the 304 Patent and the 313 Patent and (b) are in almost identical terms to Category 4 which was refused by the Court of Appeal in Boehringer.

b. Distinctions.

7. The defendants note that (1) the within proceedings are infringement proceedings whereas those in *Boehringer* were revocation proceedings, (2) the cost of making discovery has not been identified with the same clarity as in *Boehringer*. As to (1), there is also in the within proceedings a counterclaim for invalidity, so the distinction which it is sought to make in this regard is of no practical consequence. As to (2), the court does not accept that this is so when it has regard to the averments of Ms Murphy as considered in Part VI below.

(ii) Inventors' Notebooks.

8. When it comes to the so-called 'inventors' notebooks', the court notes as follows:

> (1) as in *Boehringer* the defendants' claims concerning lack of inventive step will be determined by reference to objective evidence from expert witnesses; consistent with *Boehringer*, para. 32, "[s]*econdary evidence of contemporary events may not be totally excluded…* [but] *must be kept firmly in its place*";
>
> (2) the defendants have not manifested an intention to call one or more inventors by way of secondary evidence; the plaintiffs have indicated that they do not anticipate calling any inventors as witnesses (another key similarity with *Boehringer* where the fact that no inventor/s was/were to be called was considered material);
>
> (3) as in *Boehringer*, the evidence before the court is that (a) the burden in terms of assembling the documents specified in the disputed categories is great (see further the consideration of the affidavit evidence of Ms Murphy in Part VI below), (b) that burden is accentuated by the lengthy periods in respect of which discovery is sought, (c) that burden is disproportionate when one has regard to the limited relevance of what is sought. (In passing, and without prejudice to any of the foregoing, the court notes that it does not accept that an attempt made by defendants pre-hearing to elicit from the plaintiffs what temporal period the plaintiffs could 'live with' is tacit acknowledgement of the excessive temporal scope of the discovery sought; it was simply an attempt to see if some agreement could be reached without having recourse to the court, something that is to be encouraged).

(iii) Category 5.

9. Category 5 concerns the so-called 'inventors' notebooks' (and certain other documents that concern the alleged inventions that are the subject-matter of the impugned patents). As regards the so-called 'inventors' notebooks', the points just made apply with equal vigour.

V

The Compromised Proceedings

10. The defendants submit that the plaintiffs had agreed to make discovery of Category 5 in the United Kingdom. However:

> (1) Ms Murphy avers that such agreement as was reached in this regard was "*to conduct a reasonable and proportionate search for such documents and to disclose what was identified*", adding that "*It was never the case that the Plaintiffs agreed to disclose **all** such documents"* [emphasis in original];
>
> (2) the court notes in passing that Carr J., a judge of the High Court of England and Wales, appears to have been quite sceptical as to the relevance of the standard disclosure, observing on 25th February, 2016, in the later-compromised United Kingdom proceedings (at p.40 of the transcript submitted to this Court) that *"I have already expressed my concern about this potentially vast disclosure exercise, which may well produce virtually nothing of any relevance….If that is what the parties have agreed, fair enough, but you might reconsider it";*
>
> (3) the said proceedings, as mentioned, were eventually compromised; the court does not consider that it adds anything for it to join the defendants in their conjectures as to why the plaintiffs elected in their absolute discretion to compromise the United Kingdom proceedings.

VI

A Category-by-Category Consideration

11. In addition to the general points touched upon in the preceding pages, the following points might also be made in respect of the individual categories of discovery sought.

(i) Category 3.

12. Category 3 is a wide category of a type which the Court of Appeal in *Boehringer* viewed as of such limited relevance that its necessity and proportionality had to be carefully considered. The key point made in *Boehringer* was to point out that this material is in principle of secondary significance. It was also considered a significant factor in *Boehringer* that this material was not sought in corresponding proceedings in the United Kingdom (which is the same position here). Relevant too in *Boehringer* was that it was going to be a very significant burden on the maker of discovery to make the discovery and that probity had to be assessed in that context. Category 3 has been referred to as the so-called 'inventors' notebooks' category; however, on close inspection it is considerably wider than that. Thus it embraces everything concerning conception, development, and reduction to practice. When it comes to the relevance of this category, its relevance is asserted in the context of inventiveness (with the test for inventiveness being as identified by Oliver L.J. in his renowned judgment in *Windsurfing Intenational Inc. v. Tabur Marine (Great Britain) Ltd* [1985] RPC 59, 73, as approved by Finlay Geoghegan J. in *Schneider v. C Medsystems* [2007] 2 ILRM 300, 310).

13. Turning again to *Boehringer*, the Court of Appeal was concerned there with categories that were more narrowly cast than the ones sought in the within application. They were categories of a nature that had been considered and in some instances ordered in

previous cases, and while the Court of Appeal in *Boehringer* did not change the principles applicable, it reconsidered the appropriateness of discovery in the context of the existing principles. So if one goes to *Boehringer*, 4-6, and has regard to the categories of discovery identified there, one can see that it concerns categories which are very similar to the ones sought here. The general principles are set out by the Court of Appeal, at 7, with some emphasis being placed on proportionality. Then it is noted at page 9 that in *Medtronic Inc. v. Guidant Corporation* (Unreported, High Court, 23rd February, 2007) Kelly J. emphasised the importance of considering "*the necessity for the documents having regard to all the relevant circumstances, including the burden, scale and cost of the discovery sought".* Then, from 9, some emphasis was placed by the Court of Appeal on what had happened in parallel United Kingdom proceedings, it being noted, at 11, that in the United Kingdom:

> *"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 disclosable having regard to the issues in the case. He stated:-*
>
> *'So far as the revocation claim is concerned…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.'*
>
> *…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….*
>
> *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.'"*

(As noted previously above, a similar comment to the last-quoted observation of Arnold J. was made by Carr J. in the United Kingdom proceedings corresponding to the within proceedings, though only in respect of Category 5 (because the other disputed categories were not sought in the United Kingdom proceedings)).

14. Moving on with the consideration of the Court of Appeal's judgment in *Boehringer*, Finlay Geoghegan J., at 15–17, addresses precisely the arguments invoked by Celltrion in the support of the within application, observing:

> *"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*….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 in* Molnlycke AV v. Proctor and Gamble Limited (No 5) *[1994] RC 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."*

15. The secondary evidence in *Boehringer* was testimony of the inventor. In the within case it is not presently anticipated that the inventors will be giving any evidence.

16. Finlay Geoghegan J. continues:

> *"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* [i.e. evidence of inventors] *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.* [Court Note: the same applies here.] *I have noted that…*[Arnold J.] *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."*
>
> *…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.*
>
> *…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.*
>
> *…*
>
> *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...".*

17. The last-mentioned point applies with equal rigour in the context of the within proceedings.

18. Finlay Geoghegan J. continues:

> *"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.*
>
> *…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."

19. These, the court notes in passing, are precisely the points that are made in the affidavit evidence furnished by the defendants.

20. Finlay Geoghegan J. continues:

> *"This, Teva submits, means there is not equality of arms or gives to Boehringer a litigious advantage if discovery is not ordered….*
>
> *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* [Ryanair plc v.] Aer Rianta [CPT [2003] 4 IR 264] *and* Framus [v. CRH plc [2004] 2 IR 20], *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."*

21. At hearing, some criticism was made of Ms Murphy's affidavit to the effect that she does not address the burden of making discovery under Category 3, even though in her affidavit evidence she avers that the issues she has outlined bear on all the categories of discovery (and this is borne out by a consideration of the substance of her evidence).

22. Finlay Geoghegan J. continues, at 17-20:

> *"I would also add that in general in considering the necessity of the discovery of relevant documents the nature and the potential strength of the relevance is a consideration to be taken into account.*
>
> *…*
>
> *In relation to categories 2 and 3 I have formed the opposite view* [*i.e.* the Court of Appeal will not allow discovery.] *It appears to me 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.* [Court Note: this has not been established in the within application]. *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."*

23. What one can see from the foregoing is that a key factor, from Finlay Geoghegan J.'s point of view, was proportionality.

24. Finlay Geoghegan J. continues:

> "[I]*t has been submitted in this appeal that in my reasoning in Schneider I was incorrect in accepting a submission in that case*…[that] *'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."*
>
> 25. Finlay Geoghegan J. immediately moves on to correct the error in the foregoing, viz the notion that an inventor, being an inventive person, could be the unimaginative skilled worker. Yet there is suggestion in the defendants' affidavit evidence that, *inter alia*, discovery of Category 3 "*will also be of assistance to the Defendants in cross-examining the Plaintiff's expert witness(es) by reference to what at least one or more persons admittedly skilled in the art (*i.e*. the inventors) actually did…".* That clearly just cannot be right.

26. Finlay Geoghegan J. continues, at 20:

> "*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. Jean-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.* [Court Note: that is exactly the same position in the within application, the sole distinction being that there are no confidentiality issues raised; however Ms Murphy has testified as to the complications and the volume of documentation that has to be sought, which goes, of course, to proportionality]. *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 the 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.* [Court Note: this, it seems to the court, is a critical statement in explaining the approach of the Court of Appeal: (as here) there is testimony as to the probable cost and time involved in making discovery and the position in the United Kingdom has been taken into account (and in the within case, when one looks to the United Kingdom one finds that Category 3 was not sought; what was sought was disclosure of material bearing on category 5)]."

27. Finlay Geoghegan J. continues, at 20-21:

> *"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.* [Court Note: the within case sits 'four square' with Boehringer in this regard. This is a case where the disputed categories other than Category 5 were not sought in the United Kingdom and it does not appear that there was any disadvantage perceived to arise in the United Kingdom that matters proceeded so.]

28. Leave to appeal the judgment of the Court of Appeal to the Supreme Court was refused by way of determination of 5th May, 2016, with, *inter alia*, the following observations being made by the Supreme Court:

> *"1.This determination relates to an interlocutory application for discovery of documents….*[T]*he case should be determined in accordance with the pleadings in the case and any discovery order should be strictly limited to what is relevant to the issues pleaded, provided same is relevant and necessary for the disposal of the case, and the order made is not disproportionately burdensome to either side.*
>
> *2.What is at issue is a claim by Teva that the patent granted is invalid due to, firstly, lack of sufficiency and/or plausibility in the patent and, secondly, that 3 pieces of prior art which are specifically pleaded mean that the patent was obvious to those skilled in the area and, thus, did not constitute an inventive step. The 3 pieces of prior art* [are cited]….*Obviousness over common general art was not pleaded.*
>
> *3.There needs to be a refocusing in this case on issues which concern, firstly, the interpretation of the patent itself and what it teaches* [*i.e.* the first step in the Windsurfing test] *and, secondly, what level of knowledge the team considering the pleaded prior art would have had as to the state of science at the time of the patent and whether an inventive step was required in order to arrive at what is alleged by Teva to have been obvious, and therefore not patentable. Where patent cases are focused in this way, lengthy discovery applications, lengthy submissions and the exchange of vast quantities of documentation become unnecessary. Furthermore, the issues in the case will be addressed within a limited timescale by the court of trial and expert witnesses will not be called repetitively on each side….*
>
> *6. Turning then to the issues on this application, Cregan J. in the High Court originally ordered 5 categories of discovery….*
>
> *8. The Court of Appeal upheld the order of the High Court in relation to category 1. In relation to categories 2 and 3, while partly claimed by one side to have been influenced by the decision of Arnold J of the High Court of England and Wales, a different view was taken* [by the Court of Appeal]*…in relation to category 4. At paragraph 43 Finlay Geoghegan J stated:*
>
> > *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 was 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….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.*
>
> *….11…..It is pleaded that discovery has been 'equated with admissibility' in the judgment of the Court of Appeal, where the assertion is that discovery has nothing to do with admissibility in evidence. Another complaint is that what has been set by the Court of Appeal is 'a proportionality test with an unduly low threshold' enabling the burden of discovery to be pleaded by an opponent in order to defeat 'the interests of justice'. Finally, the Court of Appeal is said to have fallen into error in a manner which impacts generally on the public interest in refusing discovery in relation to issues of confidentiality.*
>
> *….12….If, as is clear, the issue is whether an inventive step was taken by the team considering the eventually patented product, the entire focus of litigation should be on the nature of the prior art and whether the step or steps leading to what was patented could properly be analysed as being inventive. Of course, the patenting of medicines is an important issue for society generally. The invention of medicines is also important as is the relevant legislation which seeks to define a proper balance between the needs of society and a proper reward for innovative research and development. Something to do with patent registration of medicinal products does not of itself make the case of one of general public importance."*

29. Reasonable people might perhaps reasonably differ in their views as to the approach adopted by the Court of Appeal in *Boehringer* and whether there was merit to the substance of the appeal advanced before the Supreme Court (to the extent that the substance of same is known). However, the court does not get to entertain such views or engage in such debate. It is bound and accepts itself to be bound by the decision of the Court of Appeal, which decision in any event enjoys a degree of endorsement from the Supreme Court insofar as no issues of public importance were perceived to arise from the decision of the Court of Appeal, the Supreme Court urging a refocusing by the parties in *Boehringer* on the central issues at play (what might be styled 'the *Windsurfing* issues').

30. Turning then from the lengthy but worthwhile consideration of the decision of the Court of Appeal undertaken in the preceding pages and returning once more to the text of Category 3, as set out in the table previously above, there are a few points which it seems to the court are worthy of note:

(1) this is a remarkable request for a 14-year period of documentation which was not sought in the United Kingdom.

(2) the priority date of the 304 Patent is 15th November, 2005. This being so, it is not clear why documentation is being sought for a remarkable eight years after the priority date. Of course, discovery for some period after a priority date can satisfy the criteria for discovery but eight years is a strikingly long period.

(3) the court's attention has been drawn to certain e-mail correspondence in the United States between or for the parties (an e-mail of 25.01.2017 from Mr R Cerwinski to Mr G Frischling (others copied); and an e-mail of 27.01.2017 from Mr G Frischling to Mr R Cerwinski (others copied)) as in effect pointing to the Category 3 documentation having been, to use a colloquialism, 'ready to roll' in the United States, the point being that the Category 3 documentation should therefore be readily discoverable in this jurisdiction (*i.e*. assuming relevance and necessity being satisfied, it should be readily capable of production and so, at least in that (limited) sense, discovery would be proportionate. However, there are a couple of problems with this logic. First, the e-mail correspondence, on examination, does not point to the Category 3 documentation as being 'ready to roll'. Second, as counsel for the plaintiffs noted in his submissions at hearing, in fact this line of contention rather backfires on the defendants because what becomes apparent from a consideration of the evidence before the court is that the defendants when it came to what, for ease of reference, might be described as the Category 3 realm, was satisfied to accept a much narrower disclosure in the United States in this regard. In fact, the defendants remain willing to give United States-style disclosure on this basis, should that be asked for, in respect of both patents, subject to slight variation as to dates. But, for reasons best known to them, this is not acceptable to the defendants; they want discovery of all of the Category 3 documentation and for the reasons identified in the within judgment that is something to which they are not entitled as a matter of law.

(4) the defendants face real difficulties when it comes to establishing the relevance of Category 3. The first affidavit of Mr. Kelly struggles to justify, save by reference to its possible role as secondary evidence, what the utility of the Category 3 documentation will be. Thus Mr Kelly avers, *inter alia*, that:

> – "*they may lead to a line of inquiry in that they will disclose the actual experiments and other steps taken by the inventors",* but this was viewed by Finlay Geoghegan J. in *Boehringer* as being of secondary significance.
>
> – "[s]*uch documents may also address the issue of added matter and/or insufficiency*". In this last regard the court struggles to see how what the inventors actually did has anything to do with added matter. Added matter is seeing whether there is something new in the patent as granted as compared to the patent application. It is a comparative exercise between the two that has nothing to do with what the inventor did. As to "*insufficiency*" that is the allegation that the patent does not disclose the invention so that it can be practised. But again what the inventor did has nothing to do with that question. That is a question of expert evidence on the point 'does this or does this not tell me how I am going to perform the invention?'
>
> – "*such documents…may be used to assist the Plaintiffs in briefing its own expert witness(es) and providing the Plaintiffs' legal team with relevant documents for the purpose of cross-examining the Defendants' expert witness(es)*". But briefing and cross-examining by reference to what the inventors actually did is, as explained in *Boehringer*, only of secondary significance because an inventor (being inventive) cannot equate to an unimaginative skilled worker. As to the cross-examination point, that was rejected by Finlay Geoghegan J. in *Boehringer*, her point being that to cross-examine somebody by reference to what the inventor did does not really progress the issues very much because, again, an inventor (being inventive) cannot equate to an unimaginative skilled worker.

(5) it does not follow inevitably that because there was a form of discovery in the United States that this has the effect of reducing the burden of what is now sought because there is not a mirroring between what was then sought and what is now sought.

(6) the court does not accept the proposition averred to by Mr Kelly in his affidavit evidence that the issue of proportionality falls to be gauged by reference to the profitability of the relevant product, rather than the probity of the evidence. So, for example, he avers that "*The Second-Named Defendant (F Hoffman-La Roche AG) made approximately €22 million from sales of rituximab was worth in excess of €200 million a year. Whenever proportionality is raised as a reason to refuse to make discovery, it is important to bear in mind what the cost of discovery is proportional to.*" That, with respect, is not a correct understanding of the proportionality test. The proportionality test requires a court to look at the burden of making discovery and to assess whether it is proportionate to the probative or likely probative value of the documentation sought. In a nutshell, proportionality in this regard checks for 'probative versus burden', not 'profitability versus burden'.

(7) when it comes to the evidence as to disproportionate burden, the court notes, in particular, the following averments of Ms Murphy, a solicitor acting for the plaintiffs in the within proceedings:

> *"Category 3 as drafted is far broader than the reasons proffered in support of the discovery. Firstly, it spans a period of 14 years, which in itself represents an extremely heavy burden in terms of searching for documents. As such, it seeks discovery of documentation created five years before the priority date. Further, it seeks documentation for circa. 8 years after the filing date",*

and also

> *"I am instructed* [as to] *the following regarding the third-named Plaintiff ('Genentech'). I am instructed that the following are very rough estimates.*
>
> ☐ *I am instructed that Genentech stores many documents in a form of off-site storage called DataSafe.*

☐ *When a DataSafe search was carried out solely in respect of the individuals whose names appear in the Defendants' discovery requests, approximately 1,448 potentially relevant documents were identified, involving potentially millions of pages of documents.*

☐ *The documents stored with DataSafe do not include other documents held in other forms of storage that could potentially be implicated, for example documents held by Genentech employees and former employees.*

☐ *Regarding the time it would typically take to review this amount of material, Genentech has made a conservative estimate of 4,000 hours. This does not include the number of hours that would be required to search and review documentation held by Biogen and La Roche.*

☐ *Regarding the typical cost of reviewing this amount of material, Genentech's current conservative estimate is $200,000 USD assuming contract attorneys were used. This would increase substantially if Genentech's standard outside counsel were used.*

…Furthermore, I am instructed the following regarding the first-named Plaintiff ('Biogen'):

☐ *Former Idec employees, Drs White, Grillo-Lopez, and Totoritis all left the company more than a decade ago. The San Diego facility where they worked was shut down in 2011….*

☐ *Biogen has a collection of archival materials from the San Diego site in the form of computer back-up tapes. These tapes are maintained off-site by a records management service called Iron Mountain.*

☐ *There are 12,676 computer tapes in this archive, going back to 1999. Biogen does not have the internal capability to read these old tapes, and Biogen's understanding is that the tapes are likely in a variety of different formats, increasing the burden of reading them all. A discovery vendor would likely need four or five different types of systems to read the tapes.*

☐ *Biogen often has no record of what is on a given tape. Thus, for many of these thousands of tapes, to determine what is on it would likely require loading and reviewing it. This would dramatically increase the burden of reviewing the archives. In particular, Biogen has no reliable information about the contents of any tapes from before 2005.*

☐ *Physical deterioration of tapes would further impact a search like this. For tapes older than five years (which these are), it is likely that tape content will be lost or very difficult to access. For tapes going as far back as 1999, it is likely that most of the tape content will have deteriorated.*

☐ *Biogen estimates that the vendor process with regard to these tapes would cost at least hundreds of thousands of US dollars even assuming that none of the tapes are encrypted. If tapes are encrypted, as seems likely, that would cost an additional US$100 per tape. This same process would take approximately four months.*

☐ *In my firm's letter of 19 January 2018, it was further noted that this request as it standards refers to 'any communications' between anyone at either Biogen Inc., F Hoffman La-Roche and Genentech Inc., three large companies, and any of five separate individuals, relating to a study that was run over two decades ago, since which we are instructed a variety of corporate transactions and records-disrupting events have occurred.*

☐ *By way of example:*

– *Roche Holdings Ltd acquired a majority holding in Genentech in 1990.*

– *The partnership between Genentech and Idec Pharmaceuticals Inc to market Rituximab was in 1997.*

– *[in] 2003 Biogen Inc merged with Idec Pharmaceuticals Inc to become Biogen Idec Inc (subsequently reverted to Biogen Inc)*

– *[in] 2009 Roche and Genentech merged….*

I am instructed that Roche has been engaged in numerous acquisitions over the years also in the pharmaceutical business. The storage of files belonging to the patent department has been transferred in 2014 to an outside vendor. This makes it difficult to locate files not being part of a specific case folder. The pharmaceutical research and development at Welwyn Garden City has been closed in 2001. Numerous documents have been transferred to the Basel storage facilities and are burdensome to be tracked down. In addition, there has been quite some change with regard to the employees (retirement, change of workplace or change of employer). The patent files handled in Basel basically reflect a part of the documents at Genentech. The majority (roughly 40 folders) are related to ongoing invalidity actions and worldwide litigation….

For the avoidance of doubt, the significant practical difficulties arising in respect of Category 15(i) also arise generally in respect of all the categories of discovery remaining in dispute."

(ii) Category 4.

31. The detail of Category 4 has been identified previously above. The same points arise to be made, *mutatis mutandis*, concerning Category 4 as have been made by the court in respect of Category 3, save to note that the documentation in this category is being sought in respect of a 22-year period.

(iii) Category 5.

32. The detail of Category 5 has been identified previously above. The same reasons are offered for this category as was offered for the previous categories, with the additional averment that Category 5 had been deemed by the plaintiffs to be relevant to the issues in the UK proceedings. A number of points might usefully be made in this regard:

– first, the court notes Ms Murphy's averments in this regard, as referenced previously above, *viz*:

> *"In the Grounding Affidavit, the Defendants assert that it is noteworthy that the Plaintiffs have refused to make discovery of the Defendants' requested category 5 despite the same category in relevant proceedings in the UK ('UK proceedings') forming the subject-matter of the UK Disclosure report….*
>
> *I have been informed by Mr Aaron Hayward, Senior Associate of Herbert Smith Freehills LLP (who were directly involved in the UK proceedings) that it is correct that the Plaintiffs initially agreed to provide standard disclosure in the UK proceedings confined to the 4-year window (2 years either side of the priority date). However, three significant points bear emphasis in this regard….*
>
> *First, we are instructed that standard disclosure is subject always to proportionality and reasonableness of search based on the factors set out in the Civil Procedure Rules (CPR 31.7(2)), including the nature and complexity of the proceedings, the ease and expense of retrieval of any particular document and the significance of any document that is likely to be located during the search. As such, at its height, the Plaintiffs agreed only to conduct a reasonable and proportionate search for such documents and to disclose what was identified. It was never the case that the Plaintiffs agreed to disclose* ***all*** *such documents. The initial agreement was only to conduct a reasonable and proportionate search for such documents and disclose what was identified….*
>
> *Second, it became apparent in the UK proceedings that even standard disclosure would be extremely onerous and disproportionate. In this regard, I am further instructed by Mr Hayward that, during the course of the UK proceedings, the Plaintiff's advisors became aware that Biogen/Genentech had collated documents onto a database in or about 2011 (the 'US Database') in the context of US infringement proceedings brought by Biogen/Genentech against GSK. In the said proceedings Biogen/Genentech against GSK. In the said proceedings Biogen/Genentech had alleged that GSK's Arzerra product infringed its US 7 682 612 Patent (US equivalent of EP 1 616 572). The US Database was at that time managed by DLA Piper (though has since been migrated to Deloitte). We are instructed by Mr Hayward that it was initially hoped that the US Database would provide a short cut to the disclosure process in the UK. However, the US Database contained a vast amount (1.3 TB) of material and it was not possible to ascertain what documents were collared into the database(or how the documents had been identified). DLA Piper had indicated to Herbert Smith Freehills LLP that they thought the documents recording that process had since been destroyed. Given this development we are instructed that this option was put on hold in favour of exploring other options, including a targeted search of source documents, rather than using the US database, significantly curtailed disclosure or no disclosure at all….*
>
> [W]*e are instructed that at the Case Management Conference that took place in the UK proceedings on 25 February 2016, Mr Justice Carr* [of the High Court of England and Wales] *expressed doubts as to the relevance of standard disclosure at all. In particular, he expressed the view that the Plaintiff's solicitors in the UK proceedings were '…*very, very obliging souls'*for agreeing to make standard disclosure. He went on to state:*
>
> > 'I have already expressed my concern about this potentially vast exercise, which may well produce virtually nothing of any relevance. I appreciate it was your proposal that was then agreed that there should then be standard disclosure. If that is what the parties have agreed, fair enough, but you might reconsider it.'
> >
> > [Court Note: Like comments were made by Arnold J. in Boehringer and the Court of Appeal had regard to this fact in that case.]
>
> *…Third, the UK proceedings were ultimately compromised and document production did not eventually occur….*
>
> *In the circumstances, the Plaintiffs are of the view that the Defendants' attempts to draw parallels between the UK disclosure process and the Irish discovery request are misleading. Whilst we are instructed that the Plaintiffs did agree to make standard disclosure at a point in time, the order for standard disclosure itself imparts a proportionality and reasonableness test in terms of the searches to be conducted. Consequently the Plaintiffs in the UK proceedings agreed only to conduct a reasonable and proportionate search for such documents and disclose what was identified. Moreover, as outlined above, it subsequently transpired that standard disclosure would be unworkable and the English High Court questioned the 'potentially vast' disclosure request, which it noted might produce 'virtually nothing of any relevance'."*

– second, the court notes the following details that feature under the heading "*Disclosure*" in the third witness statement delivered by Mr Moore, a solicitor acting for the plaintiffs in the (compromised) corresponding UK proceedings:

> "I understand from my colleagues that the following was confirmed [in a telephone call between the parties]…on 17 February 2016:
>
> *(a) Both sides agree to standard disclosure;*
>
> *(b) There are vast amounts of documents on a US database which may or may not be relevant;*
>
> *(c) Given (ii), my firm may work with Biogen to do a targeted search of source documents, rather than utilising the US database; and*
>
> *(d) If so, the estimated costs of disclosure may be less than the initial cost estimate provided in the disclosure report; however*
>
> *(e) at this stage, we are not ruling out that a keyword search of the US database may be the preferable, along with a potentially significant document review exercise in relation to the results….*

Standard disclosure is subject always to proportionality and reasonable of search…based in the factors set out in CPR 31.7(2). [It is useful to quote both CPR 31.(7)(1) and (2):

"(1) When giving standard disclosure, a party is required to make a reasonable search for documents falling within rule 31.6(b) or (c) [i.e. documents which (per rule 31.(6)(b)) (i) adversely affect his own case, (ii) adversely affect another party's case, or (iii) support another party's case, and (per rule 31(6)(c)) (iv) documents which he is required to disclose by a relevant practice direction].

(2) The factors relevant in deciding the reasonableness of a search include the following:

(a) the number of documents involved;

(b) the nature and complexity of the proceedings;

(c) the ease and expense of retrieval of any particular document; and

(d) the significance of any document which is likely to be located during the search."]

Included in those factors are the nature and complexity of the proceedings, the ease and expense of retrieval of any particular documents and the significance of any document that is likely to be located during the search….

If the only way to find certain categories of potentially relevant documents is to search the US database, it may well be a substantial exercise that cannot be conducted by the deadline requested by Celltrion for a September trial date….

Additionally, it is currently not clear to me that disclosure will be at all probative in this action. For example, unpublished materials available to my client in the relevant disclosure window relating to clinical trials are unlikely to have been available to the skilled person, and are therefore not probative to the analysis of the skilled person's knowledge or attitude at the priority date…."

– third, it is for the defendants (as applicants in the within application) to identify the relevance of the Category 5 documentation; however, all they have been able to do is point towards the UK disclosure report. There is no explanation in the affidavit evidence before the court as to the significance of the documentation. And the Category 5 documentation would actually be somewhat wider than was sought in the United Kingdom because it is not subject to a reasonable search restriction at all.

33. It seems to the court that:

(i) the plaintiffs cannot get around the fact that what might be styled a 'substantial chunk' of what, in the within proceedings, is the Category 5 documentation, was acknowledged (or effectively acknowledged) by the plaintiffs in England and Wales proceedings to be relevant (albeit that this acknowledgement came in the context of the proportionality and reasonableness test which applied to the searches that fell to be conducted in that jurisdiction);

(ii) the defendants, on whom the burden falls in this regard, have failed to establish the relevance of the Category 5 documentation beyond the (narrower) Category 5-like documentation that would have been provided in England and Wales.

34. The foregoing being so: (a) the court will order discovery of the Category 5 documentation; but (b) to ensure that the requirements of relevance, necessity and proportionality are satisfied, will order that the plaintiffs conduct only the reasonable search of the type contemplated by rule 31.7 of the Civil Procedure Rules of England and Wales.

(iv) Categories 6 and 7.

35. The detail of Categories 6 and 7 has been identified previously above. Both categories are in similar terms. Both categories were refused in *Boehringer*. Both raise the same issues of proportionality and in this regard, like points arise to be made, *mutatis mutandis*, as have been made in respect of Category 3 above.

(v) Category 8.

36. The detail of Category 8 has been identified previously above. This category was rejected in *Boehringer* because of its scale (an aspect of matters which is equally applicable here), and the improbability of it containing anything of assistance given that all of it was likely to be

privileged. [The court's attention has been drawn in this regard to s.94 of the Patents Act 1992, as amended, which provides as follows:

"(1) A communication to which this section applies shall be privileged from disclosure in any proceeding (including a proceeding before the Controller or competent authority under the European Patent Convention or the Treaty) to the same extent as a communication between client and solicitor is privileged in any proceeding before a court in the State.

(2) This section applies to a communication— (a) between a person, or person acting on his behalf and a solicitor or patent agent, or person acting on his behalf, or (b) for the purpose of obtaining, or in response to a request for, information which a person is seeking for the purpose of instructing a solicitor or patent agent in relation to any matter concerning the protection of an invention, patent, or technical information or any matter involving passing off.

(3) In this section 'patent agent' means (a) a person registered as a patent agent in the register of patent agents, (b) a company or partnership lawfully practicing as a patent agent in the State (c) a person to whom section 106(3) applies, or (d) a person or partnership who satisfies the condition mentioned in subsection (1) or (3) of section 125."]

(vi) Category 15(i).

37. The detail of Category 15(i) has been identified previously above. The court notes that an offer has been made by the plaintiffs in respect of this category, that offer being to make discovery of what was offered and accepted in the United States. However, there has been no explanation as to why this offer is not sufficient. The category is sought on the basis that the defendants wish to enquire what is the O'Brien study connection to the 313 Patent. The plaintiffs point to the fact that if it is to be granted as sought it would involve a disproportionate exercise. To satisfy the requirements of relevance, necessity and proportionality, the court will order discovery on the terms offered by the defendants.

VII

Conclusion

38. For the reasons identified above:

(i) the court respectfully refuses to make an order of discovery in respect of Categories 3, 4, 6, 7 and 8;

(ii) (a) the court will order discovery of the Category 5 documentation; but (b) to ensure that the requirements of relevance, necessity and proportionality are satisfied, will order that the plaintiffs conduct only a reasonable search of the type contemplated by rule 31.7 of the United Kingdom's Civil Procedure Rules; and

(iii) the court will order discovery of Category 15(i) on the terms offered by the defendants.