Neutral Citation: [2016] IEHC 540

THE HIGH COURT

COMMERCIAL

[2015 No. 10250 P.]

BETWEEN

BRISTOL MYERS SQUIBB COMPANY ONO PHARMACEUTICAL COMPANY LIMITED AND TASUKU HONJO

PLAINTIFFS

AND

MERCK SHARP AND DOHME CORP AND SCHERING PLOUGH (IRELAND) COMPANY TRADING AS S/P BRINNY COMPANY AND MSD INTERNATIONAL GMBH TRADING AS MSD (CARLOW) AND MERCK SHARP AND DOHME IRELAND (HUMAN HEALTH) LIMITED AND MERCK SHARP AND DOHME LIMITED

DEFENDANTS

JUDGMENT of Ms. Justice Costello delivered on the 5th day of October, 2016.

1. These proceedings are patent infringement proceedings in which the defendants have counterclaimed for revocation of the patent relied upon by the plaintiffs. The patent at issue is patent no. EP (IE) 1 537 878 entitled **"Immunopotentiating compositions" ("the Patent").** The invention comprises the use of antibodies which inhibit an immunosuppressant receptor known as PD-1 for the treatment of cancer. The plaintiffs issued these proceedings as they say that the manufacture and supply of a product called "*KEYTRUDA*" in Ireland involves the defendants in activities amounting to infringement of the Patent in Ireland. KEYTRUDA comprises an anti PD-1 antibody called Pembrolizumab.

2. The first named plaintiff is a company incorporated in the State of Delaware in the United States. The second named plaintiff is a Japanese company which is engaged in the research development and manufacture of pharmaceuticals and the third named plaintiff is the inventor of the invention, the subject of the Patent.

3. The invention had been patented in many countries including the United States, as well as Ireland, the United Kingdom and other contracting States of the European Patent Convention ("the EPC"). The Patent and the UK patent are identical in that they both devolve from the central application process afforded by the EPC. The specification in drawings of the related US patents are identical to the Patent and the UK patent, since all patents devolved from the same international patent application, but the claims of the US patents differ in some respects. The Patent is co-owned by the second and third named plaintiffs and licensed exclusively to the first named plaintiff.

4. The defendants are all members of the same group of companies ultimately owned and controlled by Merck & Co. Inc, a company incorporated in the United States. They are all involved in healthcare and in the manufacture and supply of pharmaceuticals. The first named defendant is a company incorporated under the laws of the State of New Jersey. The second and fourth named defendants are companies incorporated in Ireland, carrying on business in Ireland. The third named defendant is a company incorporated in Switzerland but registered in Ireland as an external company having a branch situated in Carlow. The fifth named defendant is a company incorporated in the United Kingdom carrying on business in the area of healthcare and pharmaceuticals.

5. The plaintiffs have taken patent infringement proceedings in respect of the manufacture and use by various Merck companies of KEYTRUDA and the antibody of which it is composed, Pembrolizumab, in certain countries under the specific patent register for those countries, including the United States of America and the United Kingdom. These proceedings were issued in circumstances where it became apparent to the plaintiffs that Schering Plough (Ireland) and MSD International were making the KEYTRUDA product in Ireland and were held out as doing so for or on behalf of, or in conjunction with, the first named defendant. The fifth named defendant is the holder of a European marketing authorisation for KEYTRUDA and the fourth named defendant is named as the local representative for the fifth named defendant for supply of KEYTRUDA in Ireland.

6. In advance of issuing the proceedings, solicitors for the plaintiffs wrote to all five of the then intended defendants on 25th November, 2015, notifying them of the intended proceedings and seeking clarification in respect of the activities connected with KEYTRUDA and/or Pembrolizumab in Ireland, so that the infringement claim could be framed precisely in respect of each of the Merck companies in question as to which acts of making, offering, putting on the market, or using KEYTRUDA and/or Pembrolizumab were being carried out by each defendant (whether singly or jointly) and which acts of stocking and importing for those purposes they were concerned with. As of the date of the hearing of the motion, most of these questions remained unanswered.

7. The proceedings issued on 8th December, 2015, and the plaintiffs delivered a statement of claim and particulars of infringement on 18th December, 2015, setting out the plaintiffs' case for infringement of the Patent against each of the five defendants. In paras. 11 – 15 of the statement of claim, they plead as follows:-

> *"11. The defendants, whether singly or jointly, or by the respective servants or agents, have infringed and continue to infringe the Patent by making, offering, putting on the market, using or importing, or stocking for those purposes, an anti-PD-1 antibody for use in the treatment of cancer falling within claims 1 to 4 of the Patent, as more particularly set out in the Particulars of Infringement delivered herewith, and/or by supplying the means for putting the invention the subject of claims 1 to 4 of the Patent into effect.*
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> *12. Further, or on the alternative and without prejudice to the foregoing, the infringing acts of each of the defendants pleaded herein and particularised in the Particulars of Infringement delivered herewith have been and are being carried out by the defendants in question acting as agent of one, or other, or all of the other defendants.*
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> *13. Further, or on the alterative and without prejudice to the foregoing, the infringing acts of each of the defendants pleaded herein and particularised in the Particulars of Infringement delivered herewith have been and are being carried out as a result of having been procured by the defendants and any of them, or as part of a common design between the defendants to do the said acts, and the defendants have acted in furtherance of that design by the doing of the said acts and the defendants are thereby jointly liable in respect of the acts of infringement of the Patent.*

14. Further or in the alternative and without prejudice to the foregoing, the defendants or one or more of them have knowingly supplied or offered to supply one or more of their number in the State with means, relating to an essential element of the invention the subject of the Patent, for putting it into effect in the State."

8. They say that the defendants have, therefore, infringed and are infringing rights conferred on the plaintiffs under ss. 40 and 41 of the Patents Act, 1992 (as amended) and they seek a declaration that the Patent has been infringed by the defendants and each of them (and their servants or agents) and other reliefs.

9. The defendants delivered a defence and counterclaim and particulars of objection on 29th February, 2016. The defendants challenge the validity of the Patent and counterclaim for its revocation. They seek revocation of the Patent on multiple grounds including lack of novelty, obviousness and sufficiency as well as asserting that the Patent, as granted, adds matter over the application filed. Specifically, there is an allegation that the invention goes no further than the prior art and/or that the claims of the Patent should be read as an invention encompassing the treatment of every anti PD-1 antibody of every cancer, that this is not plausible and that the Patent should, therefore, be condemned as not inventive or sufficient in respect of some of its scope.

10. As part of the defence, the defendants admit that KEYTRUDA is the brand name for the medicine containing an anti-PD-1 antibody called Pembrolizumab currently used in and approved for the treatment of advanced unresectable/metastic melanoma; that the manufacture of KEYTRUDA is carried out in the State by the second and third named defendants; that the fifth named defendant supplies KEYTRUDA in the State for compassionate use on a named patient basis without charge; that the fifth named defendant holds the marketing authorisation for the supply of KEYTRUDA (Pembrolizumab) product in the State and that the fourth named defendant is specified as the local representative. The rest of the pleas of infringement are denied.

11. The plaintiffs delivered a reply and defence to counterclaim on 11th March, 2016, putting the alleged grounds of invalidity into issue. Thus, the issues to be determined at the trial have been defined by the pleadings.

Scope of the trial
12. The plaintiffs seek a declaration that the Patent is invalid and a finding that the defendants have infringed the Patent. Given the nature of the Patent, they are not seeking an injunction restraining the defendants, all or any of them, from supplying KEYTRUDA or Pembrolizumab within the State but rather are seeking a declaration pursuant to s. 47(1)(e) of the Patents Act 1992 (as amended) that the Patent is valid and has been infringed by the defendants. They are also seeking damages in respect of the alleged infringement. They allege that the defendants, all or each of them, have been making, offering, putting on the market or using a product which is the subject matter of the Patent or importing or stocking the product for those purposes or offering, putting on the market, using or importing or stocking for those purposes the product obtained directly by a process which is the subject matter of the Patent within the meaning of s. 40 of the Act. It is also alleged that the defendants, or one or more of them have been supplying or offering to supply in the State, a person other than a party entitled to exploit the patented invention with means, related to an essential element of that invention, for putting it into effect in the State within the meaning of s. 41 of the Act.

13. As already stated, the defendants have denied infringement and denied the validity of the patent and sought its revocation. Specifically, for the purposes of this judgment it is important to note that they challenge the validity of the Patent on the basis of obviousness by reference to certain specified prior art and common general knowledge. They reserve the right to adduce additional prior art as against the Patent.

14. By letter dated 9th March, 2016 the plaintiffs' solicitors wrote to the defendants' solicitors proposing that issues of liability and quantum be split and that therefore discovery necessary to the liability issues on infringement and validity would only be needed at this stage. On 11th March, 2016 the defendants' solicitors agreed to the "*bifurcation of the trial*" and sought confirmation that the first module of the trial would be "*confined to (i) the issue of validity and (ii) the issue of whether the product infringes your client's patent (if valid), with all other issues left over to the second module should it be required*."

15. On 14th March, 2016 an application was made to Court for a split trial and these letters were exhibited. The court made an order in the following terms:-

*"By Consent **IT IS ORDERED** that the trial of this action be bifurcated, that the first module be confined to (i) the issue of validity of the Patent and (ii) the issue of infringement (if any) and that all other issues including the damages claim be left over to the second module should it be required."*

The parties were given liberty to apply.

16. On the basis of this order the parties proceeded to seek voluntary discovery. In the course of the exchange of correspondence it became clear that the parties disagreed as to the scope of the first module of the trial. The plaintiffs argued that all issues of infringement were for determination. The defendants argued on the basis of their consent, as set out in the letter of 11th March, 2016, that the issues in the first module were confined to the issue of validity and the issue of whether the product infringed the Patent **and no more**. They submitted that they did not agree to try other matters of infringement at this stage and they were to be held over to a subsequent module.

17. The parties were given liberty to apply by the order of McGovern J. dated 14th March, 2016, but, despite the dispute as to the scope of the issues for trial of the first module, no application was made to McGovern J. to resolve the dispute one way or another. I cannot go behind the wording of the order of the High Court. The order makes no reference to the product (KEYTRUDA) and it does not limit the issues of infringement in any way. It is clear that the scope of the claim advanced by the plaintiffs in these proceedings in relation to infringement is wider than the question of whether or not the product is capable of infringing the Patent. If the product does not infringe the Patent, that is the end of the issue of infringement. However, if the product does infringe the Patent, then further evidence must be adduced before infringement by any one of the defendants can be established. The issue of infringement can only be dealt with in the first module of the trial, in accordance with the order of the High Court of 14th March, 2016, if evidence as to these other matters is also adduced. I therefore do not accept that the infringement issues for hearing in the first module of the proceedings are confined to whether or not the product KEYTRUDA is capable of infringing the Patent. All aspects of the alleged acts of infringement are for trial in the first module.

Applications for Discovery
18. In accordance with the directions of the High Court, the plaintiffs and the defendants each sought voluntary discovery from the other. Very considerable agreement has been reached between the parties but they were unable to resolve all of their issues. Two motions were brought, and were heard by me in July 2016, and this judgment is my ruling in respect of those motions. There were three categories in dispute in respect of the plaintiffs' request for discovery and two in respect of the defendants' request for

discovery.

Relevant Legal Principles
19. The Court of Appeal recently considered the question of the principles applicable in an application for discovery in a patent action in the case of *Teva v. Boehringer* [2016] IECA 67. Finlay Geoghegan J. summarised the general principles as follows:-

> *"12. From the above the general principles in this jurisdiction may be summarised as follows.*
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> *1. The principles applicable to discovery in patent cases is not different to discovery in other types of cases.*
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> *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.*
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> *3. The formulation of Brett L.J. in Compagnie Financiere et Commerciale du Pacifque 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.'*
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> *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.*
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> *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).*

20. She also reaffirmed the court's approval of the observations of Kelly J. in *Medtronic Inc v. Guidant Corporation* [2007] IEHC 37 where he stated:-

> *"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."*

21. I emphasise, because it formed the subject of some debate at the hearing of the motion, that the onus lies on the applicant for discovery to establish that the category or categories of discovery sought are both relevant and necessary for disposing fairly of the cause or matter or for saving costs.

The Plaintiffs' Application for Discovery

Category 1: All documents relating to the mode of action of KEYTRUDA, the defendants' medicinal product containing an anti PD-1 antibody called Pembrolizumab.
22. Under s. 45 of the Patent Act 1992, as amended, the extent of the protection conferred by a patent or a patent application is determined by the terms of the claims. The claims of the Patent comprises an anti PD-1 antibody which inhibits the immunosuppressive signal of PD-1 for the treatment of cancer. The plaintiffs plead that the defendants' KEYTRUDA product comprises a medicine containing an anti PD-1 antibody called Pembrolizumab which inhibits the immunosuppressive signal of PD-1 for the treatment of cancer, as claimed in the Patent, thereby infringing the Patent.

23. While the defendants have made certain concessions in their defence and counterclaim, they have not conceded that Pembrolizumab, the anti PD-1 antibody comprised in the KEYTRUDA product, inhibits the immunosuppressive signal of PD-1.

24. Initially, the defendants proposed supplying the plaintiffs with samples of the product so that the plaintiffs could carry out their own experiments to make out their case on the issue. This offer was not acceptable as an alternative to discovery to the plaintiffs. The defendants then offered to carry out new electronic searches of the documents which were originally collected by the defendants for review during the US discovery process against certain specified key words. There were various conditions and caveats attached to the offer. The US discovery went up to 4th September, 2014. The plaintiffs wanted to extend the temporal limitation up to the present day as 4th September, 2014, was an arbitrary cut off point. The defendants were concerned at the burden of extending the US discovery exercise in respect of certain types of documents. By way of a compromise they offered to update their US discovery exercise in respect of the category by going back to those electronic document sources which were still active from which documents were collected for the purposes of the US discovery exercise. However, they objected to discovering publicly available third party documents and marketing materials.

25. The plaintiffs' solicitors required that the US discovery of the defendants be appropriately updated and that it include publicly available third party documents and marketing materials.

26. When the matter came on for hearing, the situation pertaining in the affidavits had been overtaken by the narrowing of the issues that occurred in the correspondence. The result was that neither the plaintiffs nor the defendants had affidavit evidence specifically addressing either the need for these specific refinements of the category or the details of the burden of making the further discovery

if so ordered. I make this by way of observation rather than criticism of the parties as they are to be commended for continuing, up until the morning of the hearing of the motion, to attempt to resolve the outstanding issues. In the circumstances, it would not have been possible to set out up to date affidavits dealing with the matter, much less possible for the opponents to furnish any replying affidavit thereto. It is for this reason that I have been prepared to accept submissions from counsel which were not supported by verifying affidavits and I have not dismissed arguments solely on the basis that they were not supported by affidavit evidence.

27. The plaintiffs argue that there was no real dispute about the relevance of the category of discovery as sought and that the objection was on the grounds of necessity and proportionality. The plaintiffs argue that the documentation is necessary to enable the plaintiffs to meet the case that the defendants will advance that KEYTRUDA does not infringe the Patent in relation to the denial that KEYTRUDA inhibits or stimulates the immunosuppressive signal of the PD-1 antibody. The plaintiffs submitted that if the defendants had a legitimate concern about the proportionality and volume in respect of the marketing materials captured by the category, they suggested that discovery of a representative sample would be sufficient.

28. The defendants' solicitors pointed out that the US discovery process involved the collection and review of approximately one terabyte of data, which is one trillion bytes of data, comprising approximately 1.8 million items and which was conducted within the specific parameters agreed to by the plaintiffs in the US proceedings. Going outside the US discovery exercise amounts to requiring the defendants to carry out a new discovery process entirely afresh. It was submitted that it was completely unnecessary and wholly disproportionate and unjustifiably burdensome in terms of the time and costs for the defendants. Counsel submitted that while it would be possible to conduct additional searches on documents in the possession and procurement of the defendants' post 4th September, 2014, the real difficulty was the time, effort and expense that would be incurred in reviewing the documents thrown up following the electronic searching. He objected to requiring the defendants to discover third party articles which might be thrown up by such a search on the basis that the articles would have to be reviewed by experts and not just lawyers in order to determine whether or not they fell within the scope of Category 1. He objected to discovering marketing material on the basis that it would involve a huge volume of documents and the probative value of these documents in relation to the relevant issue i.e. the mode of operation of KEYTRUDA, would be very slight.

29. In assessing the defendants' argument I have balanced the likely burden of searching for the electronic marketing materials against the likely benefit to accrue to the plaintiffs from such discovery. The burden is undoubtedly considerable. It is, therefore, necessary to consider the possible benefit to the party seeking the discovery. It must be borne in mind that vast discovery is to be made in these proceedings. These are secondary materials sent out to professionals dealing in specialist cancer treatment. While the materials might well specify the mode of operation of KEYTRUDA, it is highly improbable that none of the other documents which are to be discovered, will not also specify the mode of operation of KEYTRUDA. In other words, it is highly improbable that this category of discovery will add something new which is not already to be found in the other documents to be discovered to the plaintiffs. On that basis, I believe that it would be disproportionate to order that a fresh discovery exercise be conducted in respect of these materials for the period post-dating the US discovery.

30. I am of the opinion that the situation is different with regard to third party articles. It is to be borne in mind that the defendants will be searching their own database in respect of these keywords. The keywords may throw up third party articles written during the two years since 4th September, 2014. I have been given no indication of the possible or likely number of such papers by either party. However, it is to be inferred that, relatively speaking, this will not be a large number of documents. The defendants will already be very familiar with these papers both from the point of view of their own business and also from the point of view of the litigation in the United States, United Kingdom and elsewhere. I accept that the documents will have to be reviewed in order to ascertain whether or not they fall within Category 1, but I do not believe that this would be such an onerous task in all the circumstances. I am not satisfied that the defendants have made out a proportionality argument sufficient to rebut the plaintiffs' argument that discovery of these documents is necessary for fairly disposing of this action.

31. I am, therefore, prepared to direct that the discovery of this category should include publicly available third party documents within the defendants' updated US discovery.

Category 3: All documents relating to hBAT, CT-011 and/or the subject matter of EP0742795 and WO03/099196 including, but not limited to, all documents relating to the mechanism of action of hBAT, CT-011 and/or the subject matter of EP0742795 and WO03/099196, including, but not limited to, all experiments relating to any such mechanism of action.
32. In their defence and counterclaim, the defendants plead that the Patent is anticipated by, among other things, the prior art referred to in this category. The essential allegation is that these documents disclose an antibody referred to as hBAT and CT-011 and the defendants will allege that this antibody anticipates the invention of the Patent. This category is sought in connection with the defendants' claim that the Patent is invalid and it should be revoked.

33. The only dispute between the parties when the matter came on for hearing related to the search term "*BAT*". Counsel on behalf of the plaintiffs accepted that if it was not possible to search the term "*BAT*" for technical reasons, his clients would accept that but would seek to have the fact verified on affidavit. I am satisfied that the defendants were correct in declining to include the word "*BAT*" in the search terms they offered in respect of this category. A very significant targeted list has been offered and the inclusion of the generic search term "*BAT*" is likely to yield a whole host of irrelevant words which will have to be reviewed at considerable time and expense but with very little prospect of revealing anything which has not already been captured by the agreed key words. It would be disproportionate to order the defendants to search their databases with the term "*BAT*" and I refuse that part of the application. I require that the defendants swear an affidavit setting out the technical difficulty in searching the term "*BAT*" as submitted to the Court and this should be furnished at the same time as discovery is furnished.

Category 2: All documents relating to and/or evidencing the dealings and/or arrangements made as between the defendants and each or any of them and/or as between the defendants and any of them and any third party – whether member of the Merck group or otherwise – in relation to: the manufacture and/or supply and/or offering of the KEYTRUDA product and/or Pembrolizumab in the State and/or the importation and/or stocking of KEYTRUDA and/or Pembrolizumab for those purposes; and/or the supply of the means for the making in the State of the KEYTRUDA product and/or Pembrolizumab, including but not limited to any and all:-

a. technology transfer agreements;

b. intellection property licences or assignments (including Patent, know-how, technology and/or trademark licences);

c. agreements to supply goods or services;

d. distribution agreements;

e. manufacturing (including contract manufacturing), sale or supply agreements;

f. revenue recognition or Revenue, profit or royalty arrangements,

relating to the manufacture, offering or putting on the market of the KEYTRUDA product and/or Pembrolizumab in the State and/or the supply in the State of the means of manufacturing the KEYTRUDA product and/or Pembrolizumab.
34. The plaintiffs argued that this category was relevant and necessary in order to establish the precise acts of the alleged infringement which each of the defendants had and continued to engage in. They referred to the fact that they had written to the then intended defendants on the 25th November, 2015 seeking clarification of the activities connected with KEYTRUDA and/or Pembrolizumab in Ireland so that the infringement claim could be framed precisely in respect of each of the Merck companies in question. The defendants had not provided the information sought. In a notice for particulars delivered on behalf of the defendants, the plaintiffs were required to provide particulars in respect of each individual defendant of the acts of infringement alleged against each particular defendant. The plaintiffs submitted that this category was necessary in order to enable them to be specific about the matters set out in the statement of claim and the particulars of infringement.

35. The defendants opposed this category of discovery on the grounds that it was not necessary at this stage. This was based upon the defendants' argument that they had agreed to a split trial on the basis that the issue of validity and the issue of infringement of the product KEYTRUDA alone formed part of the first module. I have already determined that the order of the High Court of the 14th March, 2016 directs the trial of all issues of infringement in the case in the first module. Given that decision, the defendants' argument that these documents are neither relevant nor necessary must be rejected.

36. The second ground upon which they objected to this category of discovery was the ground of confidentiality. They pointed out, and it was indeed not contested, that the defendants and the plaintiffs are commercial competitors. These documents will contain highly sensitive commercial information. They submit that their discovery would afford the plaintiffs an unfair commercial advantage over the defendants. They rely upon the decision of Barrett J. in *Nutrimedical B.V. v. Nualtra Ltd*. [2016] IEHC 261 where the defendants sought discovery of certain documents "*… relating to the planning of, institution of or conduct of, these proceedings*." This was in the context of the plaintiffs having ultimately admitted to sending poison pen letters, among other things, to third parties, with a view to discrediting the product of the defendant. In other words, they were documents which were highly likely to be privileged and related to the conduct of the actual proceedings. Barrett J. held:

> *"…such discovery as is sought in the additional category, were it to be granted, would afford Nualtra, even in the mere recital of privileged correspondence in an affidavit of discovery, so great an insight into the plaintiffs' conduct of its trade mark infringement proceedings as to completely skew the state of play between the parties, giving Nualtra a litigious advantage over the plaintiffs that no party to proceedings could or should as a matter of fair procedures be allowed, even in the peculiar circumstances here presenting."*

37. I do not believe that this case is of assistance to the defendants. The documents sought in Category 2 do not relate to the conduct by the defendants of these proceedings. They are the documents necessary to establish the various acts of infringement alleged against the individual defendants. Their discovery would in no way confer upon the plaintiffs an undue litigious advantage which was the basis of the refusal of the category in *Nutrimedical*.

38. The defendants also relied upon the decision of Clarke J. in *Independent Newspapers (Ireland) Ltd. v. Murphy* [2006] 3 I.R. 566. In that case Clarke J. acknowledged that confidentiality *per se* was not a ground for the refusal to discover and produce non-privileged material. At para. 23 of the judgment he stated:

> *"it seems to me that the balancing of the rights involved also requires the application of the doctrine of proportionality. To that extent, it seems to me to be appropriate to interfere with the right of confidence to the minimum extent necessary consistent with securing that there be no risk of impairment of a fair hearing. In the unusual circumstances of this case it is far from clear (for the reasons analysed above) as to whether any of the disputed documentation will become necessary. As pointed out relevance will depend on the case which the plaintiff makes, the facts and evidence led in support of that case and the legal submissions of the parties. The balance is, therefore, between a possible relevance and a high probability of a breach of confidence."*

39. The defendants argue that these documents may never become relevant because the Court might hold that the Patent is invalid or that the product KEYTRUDA does not infringe the Patent. However, this argument is predicated on the assumption that the first module of this trial will not include the wider elements of infringement. Therefore, the argument that these documents may not in fact become relevant must fail in light of the order of 14th March, 2016. Furthermore, far from being peripherally relevant to an issue that might not arise in the case, they are central and essential to the claim of infringement against each of the defendants. Indeed the defendants do not truly contest this, they merely argue that discovery of these documents is premature. That being so, it seems to me that there is a risk of impairment of a fair hearing if discovery of this category is not made. On that basis, the argument of the defendants based upon *Independent Newspapers v. Murphy* must also be rejected.

40. That is not to say that the concerns raised by the defendants in relation to confidentiality are not well made and that they do not have various interests which require to be protected as far as possible by the Court. I note that in relation to the proceedings in the United States, a confidentiality club has been established. A similar arrangement will be required to be made in relation to this litigation and in particular in relation to this category of discovery documents. Furthermore, it seems to me that it is appropriate that the defendants be permitted to redact confidential material within documents discovered in this category which do not relate to the category *per se*. On that basis, I make an order for discovery in terms of Category 2.

The defendants' motion for discovery
41. By the time the motion came on for hearing most issues in relation to the defendants' application for discovery had been resolved. The plaintiffs agreed to provide the entire discovery made in the United States proceedings as discovery in these proceedings. They did so on the basis that while there might well be discovery material which was not strictly speaking relevant or necessary in the context of these proceedings, nonetheless they were anxious to avoid the expense of carrying out a separate exercise to comply with specific discovery sought in respect of these proceedings. There was one area of dispute which the parties could not resolve. The discovery in the United States terminates at 4th September, 2014. The issue in dispute was whether the period for discovery in respect of categories 30 and 33 should be extended beyond that date.

Category 30

Documents containing or evidencing any queries raised by licensees or potential licensees of the Patent in relation to the

pleaded issues of invalidity of the Patent and any responses provided thereto.
42. The plaintiffs objected to making discovery of this category on the grounds that it was both irrelevant and not necessary. The defendants argued that it was both relevant and necessary and that the plaintiffs had not established that the burden of making the discovery sought was disproportionate.

43. In the defendants' letter seeking voluntary discovery they say that this category is relevant to the issues of the validity of the Patent and in particular to their particulars of objection including novelty, obviousness, insufficiency, plausibility and added matter. The letter stated "*These documents are directly relevant to the pleaded issues of invalidity in dispute*" and that the plaintiffs should discover "*all documentation in its power, possession or procurement in relation to or in connection with the validity of the Patent including the novelty, obviousness, plausibility and sufficiency of the Patent*." It justified the category by stating that it may assist the defendants in advancing their attack on the validity of the Patent, in preparing evidence, briefing their experts and in cross-examining witnesses.

44. In the grounding affidavit of Ms. Collette Brady sworn on 30th May, 2016 on behalf of the defendants she relies upon paras. 23, 24 and 25 of her affidavit as dealing with the relevance and necessity of this category of documentation. Those paragraphs do not in reality elaborate upon the reasons set out in the letter seeking voluntary discovery. Ms. Brady was more concerned with addressing the technical difficulties and burden that may face the plaintiffs in re-interrogating the US discovery in order to comply with the discovery sought by the defendants. This was because at the time of the swearing of the affidavit, the plaintiffs had offered to provide the entire discovery made in the United States discovery as discovery in these proceedings, while reserving their position as to the relevance or necessity of such discovery. The defendants had sought assurances that the US discovery did not exclude documents relating to the Patent (given that it was concerned with the US patents). At the time of the swearing of the affidavit such assurance had not yet been provided.

45. In relation to the burden of discovering documents that may have been created after the cut-off date for US discovery she states at para. 49:

> *"I believe that it would not be an unduly burdensome task to go back to the relevant document sources originally identified [in the US discovery] as being potentially relevant and, in so far as electronic documents are concerned, to apply the same search terms as were originally applied to those document sources and further refining those searches by date limitation so as to ensure that US documents already discovered were not returned as "hits"."*

46. At the hearing of the motion, counsel on behalf of the defendants argued that the documents in this category were relevant on the line of inquiry test. It was urged that it might lead the defendants upon an inquiry to relevant prior art of which they were unaware and that this was therefore relevant to the issue of the validity of the Patent. Counsel for the defendants submitted that the discovery was necessary for the reasons set out by the defendants' solicitors in their correspondence and affidavit. He said that once an applicant for discovery has established that a category of documents is relevant then the Court will presume that the discovery is also necessary. He submitted that an applicant was required to do no more than to verify the fact that the category of documents was necessary. In this regard, he relied upon the Supreme Court decision of *Taylor v. Clonmel Healthcare Limited* [2004] 1 I.R. 169. Geoghegan J., following the judgment of Fennelly J. in *Ryanair Plc. v. Aer Rianta* [2003] IESC 62, stated:

> *"If a party is entitled to a document on grounds of relevance to assist him in his case, on the ordinary discovery principles it will usually be "necessary". Save in exceptional cases, a formal verification of this in the affidavit will be sufficient on a prima facie basis."*

47. Counsel submitted that the defendants had satisfied this requirement and that therefore the onus had shifted to the plaintiffs to say why it was disproportionate to order the discovery sought. Any objection advanced by a party seeking to resist discovery must be based upon evidence and must be based upon more than a bare assertion that the burden is unduly onerous. He referred to the decision of Kelly J. in *AstraZeneca AB v. Pinewood Laboratories Limited* [2011] IEHC 159 where the learned trial judge rejected an objection in the following terms:

> *"The only remaining opposition is a rather lacklustre statement at para. 7 of the replying affidavit which confirms a statement contained in a letter of 8th March, 2011, to the effect that this category would result in the production of millions of documents. That assertion was made in the letter on the basis of information provided by Ms. Jenny Lidander, an official of Astra. No further information is forthcoming and no explanation is given."*

48. Counsel submitted that the plaintiffs had advanced no evidence whatsoever to support their opposition to this category of discovery based on the burden or unfairness of complying. This was in marked contrast to the situation in the *Boehringer* [2016] IECA 67 case where a representative of that company swore a very detailed affidavit setting out precisely all the difficulties that would be faced in complying with the discovery sought by the plaintiff in that case.

49. The plaintiffs objected to this category of discovery on the basis that the defendants had not made out a case that the category sought was either relevant or necessary. The burden was on the applicant, for discovery, to satisfy the Court that the documents sought were both relevant and necessary. It followed that the plaintiffs were not required to set out on affidavit detailed explanations as to why discovery of this category of documents, for the period post the US discovery, would be disproportionate in the circumstances. She submitted that the defendants were seeking to reverse the onus of proof in relation to discovery and that this was contrary to the rules. It was contended that the Court should balance the relevance of the documentation to be sought against the high probability of a breach of confidence; the discovery sought was unnecessary given the scale of the US discovery and compliance with the request would be unduly burdensome.

50. It is quite clear that it is for the applicant for discovery in the first place to establish that the category of documents sought are both relevant and necessary to an issue or issues arising from the pleadings in the case. Furthermore, if the applicant does not establish that the documents sought are necessary for a fair disposal of the cause or matter or for the saving of costs then the Court may not order the discovery sought.

51. The plaintiffs objected that these documents would only produce subjective opinions and the case law established that the validity of the Patent has to be determined by objective evidence. Furthermore, the evidence would at best be secondary evidence and would not be probative or would be very much peripheral to the trial and therefore were not relevant. However, this argument does not take account of the sixth point identified by Finlay Geoghegan J. in *Boehringer* :

> *"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)."*

On this basis I reject the plaintiffs' argument that this category is not relevant.

52. The real difficulty in this case was the issue of necessity. In *Boehringer*, Finlay Geoghegan J. identified the following as matters which may be properly taken into account by a trial judge in determining whether or not to make an order for discovery of documents which he or she has determined to be relevant:

> (i.) Whether the producing party will be afforded a litigious advantage if discovery is not ordered. If the documents are not discovered then the applicant for discovery will not have them for the purposes of instructing their own witnesses and cross-examining the expert witnesses of their opponent, while they will be available to the expert witnesses of the opponent and for giving instructions for the cross examination of the applicants' expert witnesses.
>
> (ii.) The court must consider the proportionality of making the order sought having regard to the particular facts of the case.
>
> (iii.) The reasons for which the applicants contend discovery is necessary.
>
> (iv.) The ground of objections made by the respondent to the application. Included in the latter are questions such as the number of documents sought, the cost of carrying out the discovery and potential confidentiality issues.

53. Neither side adduced detailed evidence addressing the issue of necessity in relation to this category specifically. I do not accept that *Taylor v. Clonmel Healthcare Ltd*. is authority for the proposition, as contended by the defendants, that necessity is to be presumed once relevance has been established. Geoghegan J. made it clear that there may be cases where the formal verification that the documents are necessary will not be sufficient and he acknowledged that there would be cases where it will not be necessary to discover relevant documents. While the evidence of the defendants was rather general in nature and did not really address the issue why documents post 4th September, 2014 were necessary in respect of Category 30, I have reached the conclusion that the defendants have established that discovery of this category of documents post 4th September, 2014 is necessary. In so doing, I am conscious of the fact that in *Boehringer* Finlay Geoghegan J. acknowledged the importance of instructing experts and counsel and these are grounds upon which the defendants have relied in this case.

54. The question then is whether or not the plaintiffs have established that discovery of the category nonetheless would impose a disproportionate burden on the plaintiffs and therefore ought to be refused. Counsel relied upon the judgment of Clarke J. in *Independent Newspapers v. Murphy* and said that the Court must balance the question of relevance with the high probability of a breach of confidence. However, this issue was simply not addressed in either the correspondence or the grounding affidavit of Ms. Brady and accordingly there was no evidence to support this submission which I therefore reject.

55. In respect of the United States discovery, it was submitted that this would cover everything that could ever be said in any way about any aspect of validity of the Patent for 12 years up to September, 2014. It was submitted that undoubtedly this would encompass everything relevant to the validity issues in these proceedings and accordingly it was disproportionate to direct further discovery over and above that already being made through furnishing the vast US discovery.

56. This is the same argument that was made by the defendants against the plaintiffs in respect of Category 1 in relation to marketing materials. I accepted that argument and rejected the plaintiffs' request for discovery of the marketing materials in view of the fact that it would be a vast exercise yielding very little benefit. Here, the Court has not been told: what would be involved in complying with the discovery sought; the potential number of documents involved; the cost of the likely exercise; and the time it was likely to take. This is not something that arose just before the hearing of the motion. The plaintiffs could have set out this information had they so wished. This contrasts with what occurred in the *Boehringer* case. While I am not holding that it is necessary in each and every case to present the kind of evidence that was adduced in *Boehringer* in order to resist an order for discovery on the grounds that it is disproportionate and therefore not necessary, there must be some effort made by the party who seeks to advance this argument to establish the facts and to give the Court a picture of precisely what is involved. The Court cannot properly assess how disproportionate a request for discovery is in the absence of this information. The plaintiffs have not made out their case on this ground.

57. Finally, it was argued that the discovery sought *simpliciter* was unduly burdensome. However there was no evidence before the Court as to the possible number of licensees or possible licensees who may have engaged with the plaintiffs since 4th September, 2014. There was no indication of the scale of the burden involved in complying with this request for discovery and no particular technical difficulty was identified. I have therefore reached the conclusion that the defendants are entitled to an order for discovery in respect of this category.

Category 33

Documents recording, setting forth or evidencing any analysis, reverse engineering of, attempts to reverse-engineer or any other attempts to determine whether or not the substance or product complained of by the plaintiff in these proceedings infringes the Patent or comes within the claims of the Patent or any equivalent patent or to determine the structure or operation of any aspect of the said substance or product.

58. The plaintiffs accepted the relevance of this material and agreed to make extensive discovery via the US discovery of documents within this category. The defendants sought to extend the period of discovery after the cut-off date for the US discovery on 4th September, 2014. The plaintiffs objected on the basis that it was inconceivable that the documents that their clients would have under this category, post the institution of the US proceedings in September, 2014, would not be covered by privilege and the imposition of a separate duty to list them in addition to the discovery already agreed would amount to the imposition of cost on the plaintiffs without any benefit to the defendants. The defendants justified this category as being both relevant and necessary because it is concerned with the practical investigation of whether the plaintiffs' case on infringement has any substance or may be undermined. In view of the fact that the defendants are seeking this discovery after the date of the initiation of the US proceedings on 4th September, 2014, it is difficult to conceive of any document which would fall within this category which would not be covered by a claim of privilege. It is accepted that privilege is not *per se* a valid ground upon which to object to discovery. The plaintiffs object to discovery of this extended category on the grounds of necessity. They say that since privilege will undoubtedly cover material within this category (if any) created since the plaintiffs sued the defendants in the US proceedings, there is nothing to be gained by the defendants by requiring discovery to be made of any such material on the one hand and such a requirement will merely pose unnecessary costs on the plaintiffs on the other hand.

59. I accept this submission. A category of discovery must be necessary for the fair disposal of the cause or matter or for the saving of costs. This category, if ordered, will undoubtedly increase costs and I do not accept that the defendants have established that it

is necessary for the fair disposal of the trial. I do not believe that the listing of documents in the privileged section of an already extensive affidavit of discovery will assist the defendants in their conduct of the proceedings sufficiently so as to justify the additional expense, which must be incurred if discovery of these documents post 4th September, 2014 is ordered by the Court. On that basis, I hold that the discovery sought is not necessary and I refuse this category of discovery.

Result

60. The defendants will make discovery of the documents comprised in Category 1 by updating the US discovery to include publically available third party documents, but not marketing materials and Category 2. In respect of Category 3 they shall swear an affidavit setting out that it was not possible to search the term "BAT" without producing many words including those letters in the body of the word. The plaintiffs will make discovery of the documents in Category 30 by updating the US discovery. They are not required to make updated discovery of Category 33.