THE HIGH COURT

COMMERICAL

2017 No. 1 PAP

IN THE MATTER OF European Patent (IE) 2 233 474 entitled "Condensed Aminodihydrothiazine Derivative" filed on 16 January 2009 and registered in the name of Eisai R&D Management Co. Ltd

IN THE MATTER of the Patents Acts 1992 (as amended)

JUDGMENT of Mr. Justice Denis McDonald delivered on the 31st day of July 2018

Introduction

1. In these patent revocation proceedings, the patentee, Eisai R&D Management Co. Ltd ("Eisai") seeks an order staying these proceedings pending the determination of European Patent Office ("EPO") opposition proceedings which are currently pending before the Technical Board of Appeal ("TBA") in Munich.

2. The proceedings in Ireland relate to Patent No. (IE) 2 233 474 ("the Patent"). The Patent is entitled "*Condensed Aminodihydrothiazine Derivative*". The Patent was granted on 5 August, 2015. The Patent devolves from a European patent (EP 2 233 474) pursuant to the arrangements established under the European Patent Convention ("EPC") by means of its designation for protection in Ireland. As such, under Section 119 of the Patents Act, 1992 (as amended) (the "Act"), the Patent takes effect under Irish law as an Irish national patent.

3. The subject matter of the Patent comprises compounds that are said to potentially treat Alzheimer's disease by inhibiting the production of amyloid-beta (amyloid-P). This is a protein found in the brain that is associated with Alzheimer's disease. The compounds are claimed in the Patent as a treatment for neurodegenerative diseases, including Alzheimer's disease.

4. The Revocation Petition was presented on behalf of Eli Lilly & Company ("Eli Lilly") on 27 October, 2017. Shortly thereafter, a motion was brought seeking to enter the proceedings into the Commercial List. The pleadings have been closed since 5 March, 2018. The present motion seeking a stay of the proceedings was subsequently issued on 11 April, 2018. There have also been exchanges of requests for discovery on both sides which have led to motions for discovery by both parties. The motions for discovery have not yet been heard. They were listed for mention only before me at the hearing of the present motion which took place over a period of two days on 5 and 6 July, 2018.

The proceedings before the EPO

5. Eli Lilly filed with the EPO a Notice of Opposition in respect of the European Patent on 5 May, 2016. It should be noted at this point that there is a nine month window from the date of grant of a patent in which to file a Notice of Opposition. The opposition is restricted to claims 1-8 and dependent claims 12-14 of the European Patent. An oral hearing was held on 26 January, 2018 by the Opposition Division of the EPO. Following that oral hearing, a written decision was issued by the Opposition Division on 13 February, 2018 maintaining the European Patent as granted. That decision has now been appealed by Eli Lilly to TBA. According to Dr. Jan Carl Zillies, a European patent attorney who has sworn an affidavit on behalf of Eisai, a request could be made by Eli Lilly for an expedited hearing of the appeal before TBA and Dr. Zillies has said (based on conversations he had with the Registrar of TBA) that a hearing in or about one year from the date the TBA agrees to accelerate the proceedings would be "possible".

The application for a stay of the Irish proceedings

6. In support of its application for a stay, Eisai has drawn attention to the undoubted fact that the hearing of these proceedings will involve a consideration of complex technical scientific matters in relation to at least four specialist fields, namely:-

(a) medicinal chemistry;

(b) synthetic organic chemistry;

(c) computational chemistry; and

(d) biological assays.

7. Eisai has also drawn attention to the fact that when previous revocation proceedings were commenced in London in May 2016 in respect of the equivalent U.K. patent, the Patents Court gave each party permission to call four expert witnesses, one in each of these fields. For completeness it should be noted that the proceedings in London were resolved on 6 April, 2017 when an order was made on Eisai's own application seeking the amendment of the U.K. equivalent patent and the dismissal of its own claim. This involved the deletion of claims 1-8 of the U.K. Patent together with consequential amendments to claims 9-14. According to Dr. Kevin Stansfield (the Head of Intellectual Property at Eisai Europe) in his affidavit sworn on 9 April, 2018, this was done by Eisai for purely commercial reasons, and in particular for the purposes of avoiding significant litigation costs. It appears from the subsequent affidavit sworn on behalf of Eli Lilly by Andrew Smith on 10 May, 2018 that Eisai also agreed to pay Eli Lilly's costs of the English proceedings. I should record, at this point, that the attack on the U.K. designation of the Patent by Eli Lilly focused exclusively on claims 1-8 and on certain aspects of claim 9-14. As Mr. Smith explains in his affidavit, the voluntary application by Eisai to delete all the claims under challenge and to pay Eli Lilly's costs rendered the action in London "*nugatory*" as Eli Lilly had obtained all that it had sought in those proceedings.

8. In support of its application for a stay, Eisai maintains that a tremendous amount of resources will need to be invested by both Eisai and Eli Lilly in these proceedings in engaging experts and preparing the matter for hearing. It is suggested that this is not a cost effective or an appropriate use of the resources of the court where, if an accelerated hearing is granted in respect of the appeal before TBA, the proceedings before the EPO should be finally concluded prior to the determination of these proceedings at first instance by the court. In the course of the hearing before me, it was suggested by counsel on behalf of Eisai that, by the time discovery is completed in this case, and by the time appropriate experiments have been agreed and carried out, it would be unrealistic to think that a hearing could be assigned to the case prior to Michaelmas Term 2019. This was not seriously challenged by counsel on behalf of Eli Lilly. While counsel for Eli Lilly suggested that the court might be in a position to give judgment in the matter also within Michaelmas Term 2019, I made it clear that in my view (and this remains my view), this is unrealistic. In a complex case of this kind (which both parties estimate could last in excess of six weeks and which may well require the appointment of an expert assessor to

assist the court), it is simply not feasible to think that the court would be in a position to give judgment in the matter prior to the end of Michaelmas Term 2019. In my view, the earliest that the court would be in a position to give a decision in the matter would be in Hilary Term 2020.

9. In addition to drawing attention to the significant costs and resources that will have to be invested in the Irish proceedings, Eisai also suggests that, in any event, it is unreal to suppose that Eli Lilly needs to have these proceedings determined as speedily as it suggests. In particular, Eisai suggests that the launch date of any product by Eli Lilly is unlikely to occur until several years in the future. This is in circumstances where Eli Lilly is still undertaking clinical trials and some of those trials have not been successful. Eisai highlights the fact that Eli Lilly has abandoned its Phase II clinical trials with its lead BACE 1 inhibitor compound as a monotherapy. Eisai suggests that the most advanced trial that Eli Lilly has in progress is the Phase II combination therapy trial which will not be completed until December 2020. In this context, Eisai has also drawn my attention to the provisions of Section 42(1)(g) of the Act (as amended) under which the carrying out of studies, tests and trials with a view to obtaining a marketing authorisation in respect of a medicinal product for human use will not be regarded as an infringement of a patent. Thus, Eisai argues that Eli Lilly will be free to carry out preliminary work notwithstanding any stay which the court may place on the revocation proceedings.

The position taken by Eli Lilly

10. The application for a stay is strongly opposed by Eli Lilly. Before addressing the grounds on which Eli Lilly opposes the application for a stay, I should first identify the grounds on which Eli Lilly seeks to revoke the patent. These are:-

> (a) by reference to Section 58(b) of the Act, Eli Lilly relies on insufficiency as a ground. Eli Lilly claims that the patent does not enable the skilled person to achieve the invention to the extent of its claimed scope without undue effort; the skilled person is not taught how to synthesise all of the claimed compounds falling within the claims of the Patent and not all of the compounds claimed in the Patent have amyloid-P inhibiting effects or would be able to cross the blood-brain barrier in order to have those effects and it is clear that many of the compounds coming within the claims could not have those effects or could not cross the blood brain barrier in order to do so;
>
> (b) by reference to Section 58(a) of the Act, Eli Lilly challenges the validity of the Patent substantially on the same basis, namely that in the circumstances the claimed invention does not make a technical contribution and is not amenable to industrial application;
>
> (c) Eli Lilly also seeks revocation on the basis that it was not anyway plausible at the priority date that the invention claimed was attainable.

11. Eli Lilly wishes to engage in its own independent development of amyloid-P inhibiting compounds and wishes to be free to make and supply new treatments for Alzheimer's disease from its plant in Kinsale, Co. Cork.

12. In his first affidavit sworn on 10 May, 2018, Mr. Andrew Smith explains that Ireland is the intended global manufacturing site for the amyloid-P inhibiting compounds that Eli Lilly has in development. Mr. Smith says that the key question for Eli Lilly in making its commercial plans is not the landscape of rights at the date of launch, but many years prior to launch, at the point in time when it is necessary for Eli Lilly to decide on spending significant resources to develop its manufacturing facilities at its intended manufacturing site in Kinsale. For this reason, Mr. Smith explains that Eisai is mistaken in thinking that Eli Lilly's concern is that it should be free to carry out studies, tests and trials.

13. In paragraph 39 of his first affidavit, Mr. Smith says that it is of the utmost importance for pharmaceutical companies (and for patients) that new, potentially life-changing medicines, can be supplied to patients as soon as the necessary marketing authorisations are granted. Mr. Smith says that in order to ensure that patients receive rapid access to new medicines, pharmaceutical companies have to make key commercial decisions many years in advance of launch.

14. In paragraph 40 of his first affidavit, Mr. Smith says that to be in a position to launch a new medicine, a pharmaceutical company must not only have a medicine which has succeeded in clinical trials and obtained the necessary marketing authorisations, but that it must also have a commercial manufacturing facility capable of producing the medicine in question and approved by the regulatory authorities for the purposes of manufacture. The case made by Eli Lilly is not that the Patent needs to be revoked in order to carry out the preliminary work required in terms of studies, tests and trials. Eli Lilly stresses that it is the preparation of a suitable manufacturing plant that requires significant investment decisions to be made years in advance of any proposed launch.

15. Mr. Smith says that to mitigate the risk of a manufacturing site not meeting the strict regulatory and quality requirements in good time, Eli Lilly aims to ensure that its manufacturing sites reach a state of readiness and compliance well in advance of the need for commercial supply of a new medicine. Mr. Smith says that in order to achieve this, it is necessary to make preparations many years in advance of the potential supply of any new medicine.

16. According to Mr. Smith, the steps which a pharmaceutical manufacturer must carry out include:-

> (a) evaluation of existing facilities and equipment;
>
> (b) evaluation of potential suppliers (in relation to both the redevelopment of an existing site and the manufacturing processes planned for the site);
>
> (c) investment in facilities;
>
> (d) investment in equipment; and
>
> (e) investment in personnel and training.

17. Mr. Smith also says that even if the date of launch in Ireland for any new Alzheimer treatment by Eli Lilly is no earlier than 2024 or 2025 (Eisai suggests it could be as late as 2026), Eli Lilly is anxious to be in a position to begin making significant commercial preparations and investments in relation to its intended manufacturing site "*as soon as possible and, at latest, in 2019*". Mr. Smith says that a delay of even one year would potentially delay the supply to patients of a potentially life changing treatment for Alzheimer's disease, and would also have serious implications for Eli Lilly commercially, including loss of revenue.

18. Eli Lilly seeks to make the case that the current revocation proceedings in Ireland are of critical importance in terms of "*path clearing*". Mr. Smith explains in paragraph 46 of his affidavit that in circumstances where Kinsale is the intended site for the global

commercial manufacture of the proposed new compounds (currently under development), it is "*of the utmost importance for Lilly that it obtain as much commercial certainty as possible, as soon as possible in relation to the manufacture of any such medicine in the State".* Mr. Smith concludes his affidavit by saying that the concerns expressed by Eisai must be balanced against the implications of the commercial uncertainty and potential revenue losses that would be engendered by the grant of a stay. Eli Lilly submits in such circumstances that the balance of justice favours the refusal of a stay.

19. It will be necessary, at a later point in this judgment, to consider in more detail the respective contentions advanced by the parties (and the evidence which both parties have placed before the court) in relation to the application for a stay. I should flag at this point that there is a significant dispute between the parties as to the validity of their respective positions. The summary which I have set out above does not represent the entire of the positions adopted by both sides.

20. Before addressing the positions adopted by the parties, it may be helpful to address in the first instance the relevant principles to be applied in cases where a stay is sought of domestic revocation proceedings pending the determination of parallel opposition proceedings in respect of the same patent at the EPO.

Relevant case law

21. The test to be applied in the context of a stay of this kind was considered by McCracken J. in *Merck & Co. Inc. v. G.D. Searle & Co*. [2002] 3 IR 614. In that case, there were (as here) co-pending proceedings in Ireland and at the EPO. Merck had brought proceedings in Ireland for the revocation of an Irish patent which was derived from a European patent. At the same time, opposition proceedings were filed at the EPO. The patentee (Searle) sought a stay of the Irish proceedings pending the determination of the opposition proceedings before the EPO. At the time of the application to McCracken J., the pleadings had closed and discovery had been made by the patentee in identical terms to that made in parallel proceedings in the United Kingdom.

22. McCracken J. considered a number of the relevant English authorities (as they then existed). In particular, he drew attention to a number of observations of Aldous L.J. in the Court of Appeal of England & Wales, and to a decision of Laddie J.:-

(a) in the first place, he considered the observations of Aldous L.J. in *Beloit Technologies Inc. v. Valmet Paper Machinery Inc.* [1997] RPC 489 at p 503 where he said:-

> *"The fact that there may be proceedings both in the national courts and before the* [EPO] *is inevitable as patent rights both under the Convention and under the Act, are national rights to be enforced by the national courts with revocation and amendment being possible in both the national courts and in certain circumstances before the* [EPO]. *That overlap can mean that there are parallel proceedings in this country and the* [EPO] *with the potential for conflict. It is desirable for that to be avoided. Therefore, the Patents Court will stay the English proceedings pending a final resolution of the European proceedings, if they can be resolved quickly and a stay will not inflict injustice on the party or be against the public interest. Unfortunately that is not always possible as a resolution of opposition proceedings in the* [EPO] *takes from about 4 to 8 years";*

(b) McCracken J. then referred to what was said by Aldous L.J. in *Kimberly-Clarke Worldwide v. Proctor & Gamble* [2000] FSR 235 at p 245:-

> *"It is not sensible for a court in this country to allow proceedings to be heard in this country which duplicate those in the* [EPO] *unless justice requires that to happen. At the time that the 1977 Act was enacted, it was envisaged that proceedings before the* [EPO] *would be concluded with reasonable expedition. The consequence would be that any overlap between* [EPO] *proceedings and national actions could be prevented by staying the proceedings in this country for a short period. In some cases, the Patents Court has refused to stay proceedings in this country, despite the obvious desirability of taking that action, because of the injustice that a stay would cause";*

(c) the third case cited by McCracken J. was the decision of Laddie J. in *Unilever plc v. Frisa N.V.* [2000] FSR 708 at p 716 where Laddie J. said:-

> *"The reason, it appears to me why Aldous L.J. has said what he has said in Kimberly-Clarke concerning the desirability of stays where there are co-pending opposition proceedings, is in large part a reflection of the undesirability of litigating here on a patent monopoly which may be held not to exist or may be changed by alteration to the claims in the course of the* [EPO] *proceedings. There is great sense in saying that, if it is possible to do so without injustice, proceedings here should be stayed until such time as the final form of the patent is determined by the* [EPO]".

23. McCracken J. effectively adopted a similar approach in *Merck*. He said at p 618:-

> "*As the State has recognised the right of the* [EPO] *to determine applications for the grant of a patent which would extend to this jurisdiction, including the right to allow amendments to and to hear objections in relation to such patent, it would seem somewhat illogical, unless there was very good reason, for revocation proceedings to be heard in this country before the final determination of the existence and form of the patent by the* [EPO]".

24. McCracken J. said that, in considering the application for a stay in that case, the court should start from the premise that, if possible, the stay should be granted. However, this is always subject to a consideration of the reasons that are advanced by the opposing party as to why a stay should be refused. At p 619, he explained that what the court has to do on an application of this kind is to balance the arguments against a stay and decide whether, on the facts of any particular case, the "*scales are sufficiently weighted in favour of the petitioners so as to outweigh the basic preference for granting a stay".*

25. On the facts, McCracken J. came to the conclusion that the balance in that case lay in favour of the grant of a stay. He came to the conclusion that the arguments put forward by *Merck* were not sufficient to outweigh the basic preference for granting a stay.

26. I believe it is fair to say that the approach taken by McCracken J. was straightforward. One starts from the premise that a stay should be granted. However, one also has to consider the competing reasons put forward as to why it would be unfair or unjust to grant a stay. Ultimately, it is a question of balancing any prejudice to the petitioner arising as a consequence of the grant of a stay against the desirability of ensuring that there is a final decision of the EPO on the validity and form of the patent before any hearing takes place in Ireland in relation to what is essentially the same patent.

27. It appears to me to be clear that the reason why it was considered desirable by McCracken J. that a stay should be granted (save where the balance of justice lies with the petitioner) is the concern that an Irish court should not, in the absence of strong reasons, embark on what could well be a lengthy and costly hearing as to the validity of an Irish patent derived from a European patent until the EPO has finally determined both the question of the existence (i.e. validity) of the patent and also the form of the patent. This appears to me to be clear from the observations made by McCracken J. at p 618 (quoted in paragraph 23 above). It is also consistent with the views expressed by Aldous L.J. and by Laddie J. in the English authorities cited by McCracken J. As Laddie J. said in the *Unilever case*, it is undesirable that there should be litigation in relation to a national patent which may be held not to exist or which may be changed (by alteration to its claims) in the course of proceedings before the EPO. The underlying rationale appears to be that, in the absence of strong reasons, the parties will be put to significant cost and the resources of the court will be taken up with a hearing that may transpire to be wholly unnecessary (in the event of revocation of the patent at the EPO) or to have been based on an incorrect or incomplete premise (in the event that the form of the patent is amended at the EPO).

The European patent system

28. The rationale for favouring a stay (as described by McCracken J. in *Merck*) must be seen in the particular context of the European patent system under the European Patent Convention ("EPC"). Curiously, the EPC permits parallel proceedings to be taken before the national courts and before the EPO. Under Article 138 of the EPC, a European patent may be revoked by a national court even where its validity has previously been upheld by the EPO. In such circumstances, the revocation by the relevant national court will apply solely to the designation of the patent in the relevant contracting state in which such proceedings are brought. However, an opponent of a European patent can also seek to invalidate the patent by means of what is described as the "*opposition procedure*" in the EPO. As Jacob L.J. explained in *Unilin Beheer v. Berry Floor N.V.* [2007] EWCA Civ 364 at paragraph 14, such opposition proceedings are in reality proceedings for revocation. They can only be brought after the grant of the patent by the EPO. As noted in paragraph 5 above, the opposition proceedings must be brought within nine months from the date of the grant of the patent by the EPO. Such opposition proceedings will be determined by the Opposition Division of the EPO following which there is the availability of an appeal to TBA.

29. While the outcome of a patent revocation action before a national court will only have effect in the jurisdiction in which the national court determination is made, a decision of the EPO will have effect in each of the contracting states for which the European patent is designated - subject, however, to the ability of an individual national court (in those cases where the EPO does not itself decide to revoke the patent) to reach its own decision as to whether the national designation of the patent should be revoked. At the conclusion of the opposition proceedings, the EPO may not only uphold the validity of the patent, but it may also amend the patent by, for example, narrowing the claims of the patent in question. The ability of the EPO to amend the patent appears to have featured in the thinking of both McCracken J. in Ireland in *Merck* and in the thinking of Laddie J. in England in *Unilever plc v. Frisa* that it is undesirable to litigate in a national court on a patent monopoly that may not only be held not to exist, but which may be changed by alteration to the claims in the course of the proceedings before the EPO.

30. At the same time, it must be borne in mind that, as noted above, a determination by the EPO that a patent is valid does not bind the national courts. The national courts can still decide to revoke a patent derived from the European patent in their jurisdiction even where the validity of that patent has been upheld by the EPO following opposition proceedings. In any such proceedings, the petitioner will have available to it all of the procedural tools available under national law. This is, in fact, one of the points which is addressed by Mr. Smith on behalf of Eli Lilly in paragraph 34 of his affidavit sworn on 10 May, 2018. In that paragraph, Mr. Smith draws attention to the fact that opposition proceedings before the EPO are very different from national revocation proceedings. Mr. Smith suggests that the availability of pre-trial procedures such as discovery and interrogatories and the oral evidence given by experts at trial (following cross-examination) can make a difference to the ultimate outcome of revocation proceedings before U.K. courts or Irish courts as against the outcome of opposition proceedings in the EPO. The quite different approach taken by the EPO to opposition proceedings was also confirmed by counsel on behalf of Eisai in his closing submissions where he drew attention to the procedural differences that exist. As counsel for Eisai explained, EPO proceeding are not normally founded upon expert reports. Unlike a court, the EPO is a specialist tribunal. There is no cross-examination of experts. Nor is there discovery of documents in the manner available in Ireland. Counsel for Eisai, Mr. Newman S.C., drew attention to the fact that, in the current proceedings before the EPO, there is only one expert report in respect of computer modelling. As counsel said, this is likely to have arisen in circumstances where the one expertise potentially missing from the EPO is expertise in such modelling.

31. For the reasons outlined in paragraphs 28-30 above, it is an inherent part of the structure created by the EPC that there may, at the same time, be parallel proceedings before both the EPO and the national courts. This was the point made by Aldous L.J. in *Beloit Technologies* at p 503 which was, in turn, cited by McCracken J. in *Merck* at p 616. The EPC itself does not give priority to the proceedings before the EPO save that, where the EPO decides to revoke a patent, that will have effect in all of the Contracting States for which the patent is designated. On the other hand, a finding by the EPO that the patent is valid will not (as outlined above) deprive the national court of the ability to reach a contrary decision in respect of a national designation of the same patent. Thus, in this case, if the EPO were to uphold the validity of the patent (either in its original or in some amended form), that will not prevent Eli Lilly from pursuing these revocation proceedings in Ireland.

32. Mr. Smith in paragraph 34 of his first affidavit has confirmed that even if a stay is granted in the present case, and the validity of the patent is finally upheld at the EPO (whether in its entirety or in some amended form), Eli Lilly will seek to rely on its right to continue with these revocation proceedings in Ireland. As explained above, the EPC system permits this.

33. Before addressing the competing considerations in this case, I should, in the first instance, refer to some more recent developments which have taken place in England & Wales in relation to applications for stays of patent proceedings.

Developments in England & Wales

34. Since the decision of McCracken J. in *Merck*, there have been a significant number of judgments given by the English courts in relation to applications for stays of proceedings before the Patents Court there pending the determination of opposition proceedings at the EPO. It is unnecessary for present purposes to review all of the case law. It is sufficient, in my view, to draw attention to three cases in particular. In the first of these cases, namely *Glaxo Group Ltd v. Genentech Inc.* [2008] EWCA Civ 23, the English Court of Appeal (in a detailed judgment delivered by Mummery L.J.) gave detailed guidance as to how the discretion of the Patents Court should be exercised on an application to stay patent proceedings in England & Wales on the ground that there were parallel proceedings pending in the EPO. The guidance given by Mummery L.J. in that case has since been significantly revised (as described in more detail below) such that no useful purpose would be served by setting it out in full here. Nonetheless, there are a number of features of the judgment of Mummery L.J. which might be noted.

35. In paragraph 84 of his judgment, Mummery L.J. suggested that, in exercising its discretion, the factor which should carry most weight with the Patents Court is the length of time that it will take for the respective proceedings in the national court and in the EPO to achieve certainty on the issue of the validity of the patent *"so that business knows where it stands".* In paragraph 88 of his

judgment, Mummery L.J. indicated that although other factors are also relevant, they are of lesser importance than achieving "*some commercial certainty somewhere sooner*". At the time this decision was given, it appears that the opposition proceedings then pending before the EPO could possibly take as much as another four years. This is clear from paragraph 8 of the judgment of Mummery L.J.

36. In a somewhat surprising passage, Mummery L.J. also suggested (at paragraph 85 of his judgment) that there were no grounds to grant a stay of proceedings merely on the basis of a presumption against duplication of legal proceedings. He said:-

> *"…..there are no grounds justifying the application by the Patents Court of a presumption that the duplication of legal proceedings in it and in the EPO is, without more, a ground for a stay of the proceeding in the Patents Court, as the EPC system allows for parallel proceedings contesting the validity of the patent in both the international court (which is what the EPO in substance is) and in the national court".*

37. As I understand it, the predominant approach taken in the English courts at that time was that if the question of validity would be likely to be resolved more quickly in the English court than in the EPO, the court would normally refuse to grant a stay of the English proceedings.

38. I have to say that I have found it difficult to understand how this observation by Mummery L.J. (as quoted in paragraph 36 above) can be said to be consistent with the pre-existing case law which suggested that it was the undesirability of the duplication of legal proceedings that gave rise to what McCracken J. described as the "*premise that, if possible*, [a stay] *should be granted*" unless there was "*very good reason*" for national revocation proceedings to be heard before the final determination as to the existence and form of the patent by the EPO. This is clear from p 618 of his judgment in *Merck*. It also seems to me to be clear from the observations of Aldous L.J. in *Beloit Technologies Inc.* and the judgment of Laddie J. in *Unilever plc v. Frisa,* both of which were cited with approval by McCracken J.

39. At this point, it should be noted that, at the time of the decision of the Court of Appeal in *Glaxo v. Genentech*, the English courts had come to the conclusion that if the English court had upheld the validity of the patent prior to a subsequent decision of the EPO to revoke it, the decision of the English court would nonetheless operate to bind the parties to the decision of the English court notwithstanding the revocation of the patent by the EPO. (See the judgment of Jacob L.J. in *Unilin Beheer B.V. v. Berry Floor N.V.* [2007] FSR 635.

40. This approach was, however, subsequently held to be erroneous by the U.K. Supreme Court in *Virgin Atlantic Airways Ltd v. Zodiac Seats U.K. Ltd* [2013] UKSC 46. In that case, the principal judgment was given by Lord Sumption who said at paragraph 7:-

"The effect of [the EPC] *is that the English courts have the same jurisdiction to determine questions of validity and infringement in the case of a European patent as they have for domestic patents, but that concurrent jurisdiction over questions of validity is exercisable by the EPO. There is, however, an important difference between the legal effect of a decision in the two jurisdictions. Both are decisions in rem. They determine the validity of the patent not only as between the parties to the proceedings, but generally. But the English court's jurisdiction over the question of validity is purely national. A decision of an English court declaring a patent invalid, or (which will normally follow) revoking it, will have effect in the United Kingdom only, whereas a corresponding decision of the EPO, which was the authority by which the patent was granted, will have effect in all the states for which the patent was granted. These considerations make it highly desirable to avoid inconsistent decisions if it can be done. National procedures for achieving this differ from one contracting state to another. In England, there are established procedures for staying English proceedings in which the validity of a European patent is in issue, if there are concurrent opposition procedures in the EPO. However, the value of these procedures is somewhat diminished by the current practice of the High Court, which is based on dicta of Jacob L.J. in Unilin Beheer B.V. v. Berry Floor N.V. ….and on the subsequent decision of the Court of Appeal in Glaxo Group Ltd v. Genentech Inc. ….Their effect is that the primary consideration on an application for a stay is the probable duration of the proceedings before the two tribunals. If the question of validity would be likely to be resolved quicker in the English court than in the EPO, it would normally be appropriate not to stay the English proceedings. The consequences of this practice are particularly serious in a case where the English courts "win" the race to judgment if, as the Court of Appeal decided in Unilin, the effect is to bind the parties to a decision of the English court that the patent is valid notwithstanding that the EPO which granted it subsequently decides that it should be revoked or amended ab initio. …".*

41. Lord Sumption then reviewed the basis on which the English Court of Appeal had come to the conclusion in *Unilin* that the parties to the English revocation proceedings would be bound by the result of those proceedings even if the EPO subsequently decided to revoke the patent. He came to the conclusion that *Unilin* was wrongly decided. Lord Sumption also called for revision of the guidelines previously given by Mummery L.J. in the Court of Appeal in *Glaxo v. Genentech*. He said at paragraph 38:-

> *"I add a brief observation on the procedural implications. If I had concluded that the defendant was estopped from relying on the revocation or amendment of the patent once the court had adjudged it to be valid, that would have had important implications for the question whether English proceedings should be stayed pending a decision in concurrent opposition proceedings in the EPO. On that footing, it would in my opinion have been essential to stay the English proceedings so that the decision of the EPO would not be rendered nugatory by the operation of the law of res judicata. On that hypothesis, it would have been difficult to defend the guidance given by the Court of Appeal in Glaxo Group Ltd v. Genentech Inc. …..to the effect that the English court should normally refuse a stay of its own proceedings if it would be likely to resolve the question of validity significantly earlier. The effect of that guidance is to put more litigants in the impossible situation in which successive decisions of the Court of Appeal placed the parties in this case. As it is, the problem has not gone away, even on the footing that those decisions are overruled. In the first place, a similar problem may well arise if the patent is revoked by the EPO after a judgment has been given for a liquidated sum. Second, that problem is aggravated by the fact that a decision of the English court on validity is directly effective only in the United Kingdom, whereas the EPO's decision, being the decision of the authority which granted the patent, is directly effective in every country for which the patent was granted. Third, even if the EPO opposition proceedings are concluded in time to affect the English proceedings, the uncertainty and waste of costs involved do little credit to our procedures".*

42. In light of those observations, Lord Sumption suggested that the Court of Appeal in England & Wales should revise its guidelines. Very shortly afterwards, that court took the opportunity to do so in *IPCom GmbH & Co. v. HTC Europe Co. Ltd* [2013] EWCA Civ 1496. The judgment of the court on this occasion was given by Floyd L.J. who addressed the observations made by Lord Sumption in paragraph 7 of his judgment and also at paragraph 38 (both quoted above). In relation to paragraph 7 of Lord Sumption's judgment, Floyd L.J. said at paragraphs 50-51:-

> *"…It is clear that* [Lord Sumption] *considers that the guidelines should be designed to "avoid inconsistent decisions if this*

can be done". Avoiding inconsistent decisions is of course not easily achieved in a system which expressly allows for concurrent jurisdiction, a characteristic …which Lord Sumption expressly recognises …. As it is not suggested that the national court could stay the EPO, the elimination of any risk of inconsistent decisions would require a mandatory stay of all national patent proceedings, something which I am sure Lord Sumption would have said if he had meant. A mandatory stay of all national validity proceedings pending the resolution of validity in the EPO would mark the end of the ability of the national court to give judgments "clearing the way" for those who have products to launch and businesses to conduct in this jurisdiction, provided only that the EPO proceedings had not reached their conclusion. It would also make a significant hole in the ability of a party to enforce a patent for a very large proportion of its life.

I do not believe that Lord Sumption was suggesting such a radical change. I read Lord Sumption's observations as taking on board and accepting the difficulty of avoiding inconsistent decisions in the system created by the EPC. If the risk can be eliminated, so much the better, but failing that, matters should be arranged so that the impact of inconsistent decisions does not cause injustice".

43. It will be recalled that in paragraph 7 of his judgment in the *Virgin Atlantic case* (quoted in paragraph 40 above), Lord Sumption had called into question the approach taken in Glaxo v. Genentech that the primary consideration on an application for a stay is the probable duration of the proceedings before the competing tribunals. Floyd L.J. took this on board. At paragraph 53 of his judgment, Floyd L.J. said that Lord Sumption:-

"….is of course right that likely duration should not be seen as the only or even the principal reason for granting or refusing a stay. Delay must be considered in combination with other factors. A delay which causes neither side any real prejudice may justify a stay".

44. Floyd L.J. then considered the observations made by Lord Sumption at paragraph 38 of his judgment (quoted in paragraph 41 above). It will be recalled that one of the points highlighted by Lord Sumption in that paragraph was that a decision of the English court on validity has only limited effect – being directly effective only within the United Kingdom. With regard to that point, Floyd L.J. said at paragraph 55:-

"It is clear that Lord Sumption had in mind the fact that the decision of the EPO revoking the patent is directly effective in every country for which the patent is granted. This is, of course, a factor to bear in mind. But a large number of oppositions fail. In those cases, the decision of the EPO has no effect at all in any of the member states. Even in cases where the patent is upheld or upheld with some amendment, the need for full national infringement proceedings remain. In such proceedings, the defendant will be free to challenge the validity in the national court as well. In the long period before the EPO decides, one cannot predict that it will resolve the dispute between the parties: it remains no more than a possibility".

45. With regard to the possibility that the ultimate decision by the EPO will resolve the dispute between the parties, Floyd L.J. suggested that it must nonetheless be borne in mind that national proceedings have the potential to deliver "*some degree of certainty*". Floyd L.J. noted at paragraph 56 of his judgment that the decision of the national court that a patent is invalid cannot be undone by the EPO. He also suggested in the same paragraph that a rapid decision of a "*respected national court*" may promote early settlement of the dispute as a whole, bringing to an end proceedings everywhere.

46. Floyd L.J. also dealt with the statement made by Lord Sumption in paragraph 38 of his judgment that, even in cases where the EPO opposition proceedings are concluded in time to affect the English proceedings, "*the uncertainty and waste of costs involved do little credit to our procedures".* With regard to this point, Floyd L.J. said at paragraph 57 of his judgment that, while wasted costs are an unattractive feature of any litigation system, it nonetheless has to be borne in mind that a system which allows for concurrent proceedings (such as the EPC system) is more likely than others to involve some wasted costs in some cases. While the court should seek to arrange matters to avoid wasted costs, the court should recognise that, unless stays are to become mandatory, the risk of wasted costs will be outweighed in some cases by other factors. He also observed in the same paragraph that costs are:-

"…not necessarily wasted if the steps in the national proceedings can produce some commercial certainty for the parties or advance the case towards settlement".

47. Having considered the observations made by Lord Sumption, Floyd L.J. then turned to the guidance previously given in *Glaxo v. Genentech*. At paragraph 59 of his judgment, he rejected the submission made that *Glaxo v. Genentech* somehow did away with the presumption in favour of a stay. At paragraph 62, he stressed that a stay is the "*default position*" and that:-

"It is for the party opposing a stay to demonstrate why it should not be granted. The guidance should more clearly reflect that position".

48. This seems to me to be precisely the position which was taken by McCracken J. in *Merck* more than 12 years previously. It also seems to me to be entirely consistent with some of the older English cases such as *Beloit Technologies* and *Unilever plc v. Frisa*.

49. Having regard to the approach taken by the U.K. Supreme Court in *Virgin Atlantic* and the submissions made to the English Court of Appeal in the *IPCom* case, Floyd L.J. then recast the *Glaxo v. Genentech* guidance in the following terms at paragraph 68 of his judgment:-

"68. In the light of the observations in Virgin and the arguments on this appeal I would recast the Glaxo guidance as follows:

1. The discretion, which is very wide indeed, should be exercised to achieve the balance of justice between the parties having regard to all the relevant circumstances of the particular case.

2. The discretion is of the Patents Court, not of the Court of Appeal. The Court of Appeal would not be justified in interfering with a first instance decision that accords with legal principle and has been reached by taking into account all the relevant, and only the relevant, circumstances.

3. Although neither the EPC nor the 1977 Act contains express provisions relating to automatic or discretionary stay of proceedings in national courts, they provide the context and condition the exercise of the discretion.

4. It should thus be remembered that the possibility of concurrent proceedings contesting the validity of a patent

granted by the EPO is inherent in the system established by the EPC. It should also be remembered that national courts exercise exclusive jurisdiction on infringement issues.

5. If there are no other factors, a stay of the national proceedings is the default option. There is no purpose in pursuing two sets of proceedings simply because the Convention allows for it.

6. It is for the party resisting the grant of the stay to show why it should not be granted. Ultimately it is a question of where the balance of justice lies.

7. One important factor affecting the exercise of the discretion is the extent to which refusal of a stay will irrevocably deprive a party of any part of the benefit which the concurrent jurisdiction of the EPO and the national court is intended to confer. Thus, if allowing the national court to proceed might allow the patentee to obtain monetary compensation which is not repayable if the patent is subsequently revoked, this would be a weighty factor in favour of the grant of a stay. It may, however, be possible to mitigate the effect of this factor by the offer of suitable undertakings to repay.

8. The Patents Court judge is entitled to refuse a stay of the national proceedings where the evidence is that some commercial certainty would be achieved at a considerably earlier date in the case of the UK proceedings than in the EPO. It is true that it will not be possible to attain certainty everywhere until the EPO proceedings are finally resolved, but some certainty, sooner rather than later, and somewhere, such as in the UK, rather than nowhere, is, in general, preferable to continuing uncertainty everywhere.

9. It is permissible to take account of the fact that resolution of the national proceedings, whilst not finally resolving everything, may, by deciding some important issues, promote settlement.

10. An important factor affecting the discretion will be the length of time that it will take for the respective proceedings in the national court and in the EPO to reach a conclusion. This is not an independent factor, but needs to be considered in conjunction with the prejudice which any party will suffer from the delay, and lack of certainty, and what the national proceedings can achieve in terms of certainty.

11. The public interest in dispelling the uncertainty surrounding the validity of monopoly rights conferred by the grant of a patent is also a factor to be considered.

12. In weighing the balance it is material to take into account the risk of wasted costs, but this factor will normally be outweighed by commercial factors concerned with early resolution.

13. The hearing of an application for a stay is not to become a mini-trial of the various factors affecting its grant or refusal. The parties' assertions need to be examined critically, but at a relatively high level of generality."

50. In the course of their submissions, both sides have placed reliance on certain aspects of the guidance given by the Court of Appeal in *IPCom*. As I sought to explain in the course of the hearing, I do not believe that the guidance given in that case can necessarily be adopted in its entirety in this jurisdiction. While the guidance was obviously adopted following significant debate, it must be borne in mind that such debate took place in an English context, and, moreover, took place against a background where there had previously been a departure (so it seems to me) from the approach taken in the earlier case law which preceded the decision of McCracken J. in Ireland in *Merck* and with which McCracken J. expressly agreed. This is the issue addressed by me in paragraph 38 above. I therefore made it clear to the parties, in the course of the hearing, that while undoubtedly deserving great respect, I believe that the guidance must be treated nonetheless with some degree of caution in Ireland. For instance, for reasons which I consider in more detail below, I am not at all sure that an Irish court would take the same view of "*wasted costs*" as Floyd L.J. (as summarised in paragraph 46 above). Moreover, it seems to me that if guidance is to be given on this issue in an Irish context, this would more appropriately be done by the Court of Appeal or the Supreme Court after a very full debate about the nature of the guidance to be given.

51. I acknowledge that the guidance given by a very experienced patents judge such as Floyd L.J. may be of assistance in considering, for example, the weight to be given to some of the factors that fall to be considered in deciding where the balance of justice lies. That is ultimately the fundamental issue which falls for determination here. In my view, I must begin from the premise that it is desirable that a stay should be granted. I do not believe that Floyd L.J. was overstating things by suggesting that a stay is the default position. In essence, that is the approach taken in *Merck* by McCracken J. In fact, paragraphs 5 and 6 of the *IPCom* guidelines appears to me to be a reiteration of the principle applied in *Merck*. What I must consider is whether there are good reasons as to why the default position should not be taken in the present case. In assessing that issue, I must inevitably involve myself in an assessment of where the balance of justice lies. It is to that issue that I now turn.

The competing contentions of the parties in relation to the balance of justice

52. Having regard to the approach taken by McCracken J. in *Merck*, I am of the view that I must assess whether Eli Lilly has advanced good reasons as to why a stay should not be granted in the present case. I must also weigh those good reasons (if any) against the desirability of imposing a stay (and any other factors in support of a stay) in deciding where the balance of justice lies. The first step in this weighing exercise is to consider the reasons advanced by Eli Lilly in opposition to the stay. I must at the same time consider the competing contentions advanced by Eisai by way of criticism of these reasons.

53. At the outset, I must make very clear that, in my view, some of the matters outlined in paragraph 43 of the first affidavit of Mr. Smith on behalf of Eli Lily are not appropriate considerations on an application of this kind. In that paragraph, Mr. Smith states that Eli Lilly has been manufacturing at its site at Kinsale, County Cork since 1981, and that it currently has over 500 people employed at the site. Mr. Smith also says in the same paragraph that Eli Lilly has invested over €800 million in new manufacturing and support facilities at the Kinsale site. In the course of the hearing, it was stressed by counsel for Eli Lilly that this information is by way of background only. However, it is contained in the section of Mr. Smith's affidavit where he deals with the implications of a stay for Eli Lilly. I have to say that I am left with the impression that Eli Lilly was in some way seeking to place this evidence before the court with a view to influencing the outcome of the present application. I wish to make it very clear that such evidence has no role whatever to play in any consideration of the balance of justice. I find it difficult to see any basis upon which it could be said that it was appropriate to include this material in the affidavit.

54. The principal ground relied upon by Eli Lilly is summarised in paragraphs 12-18 above. In short, it is Eli Lilly's case that it can obtain crucial commercial certainty in the jurisdiction in which it proposes to commence manufacture of the new compound (assuming

future clinical trials are successful and a marketing authorisation is granted) by continuing with the proceedings in Ireland. Eli Lilly says that it needs to have commercial certainty as to its position in its intended place of manufacture as soon as possible. Eli Lilly maintains that even in circumstances where the validity of the patent is upheld at the EPO, the only way for it to ensure commercial certainty as early as possible is to continue with these proceedings. This must be seen against the backdrop that, as explained above, Eli Lilly intends to pursue the revocation proceedings in Ireland even if the validity of the patent is upheld by the EPO. As Mr. Smith has explained, Eli Lilly will be in a position to use all of the procedures available in Ireland (including the calling of expert testimony, discovery of documents and cross-examination of witnesses) to mount a form of attack on the validity of the patent that is not available under the processes and procedures of the EPO.

55. As noted in paragraph 17 above, Mr. Smith has deposed that Eli Lilly is anxious to be in a position to begin making significant commercial preparations and investments in relation to its intended manufacturing site as soon as possible and "*at latest, in 2019*". The reason put forward by Eli Lilly in support of its contention that path clearing of the patent in Ireland is crucial to its plans is explained in paragraph 45 of Mr. Smith's affidavit in the following terms:-

> "[The] *manufacturing site at Kinsale is currently the sole commercial manufacturing site, worldwide, within the Lilly group for small molecule active pharmaceutical ingredient manufacture. Lilly's strong preference is to manufacture their pharmaceutical ingredients "in-house", allowing Lilly to directly control quality and regulatory compliance, reducing risk to the patient and to the company. Accordingly, the Kinsale site is the strongly preferred option for the commercial manufacture of the ……compounds in development by Lilly. The alternatives to manufacturing at Kinsale would be for Lilly to develop an entirely new facility outside of the State for the manufacture of small molecule active pharmaceutical ingredients or for Lilly to contract with a third party to manufacture any future medicine for the treatment of Alzheimer's disease on Lilly's behalf. The former option would cause significant delay and would be prohibitively expensive, significantly more costly than making the necessary alterations and investments to the site at Kinsale. The latter option necessarily carries significant counterparty risk as Lilly would not ultimately be in control of quality and compliance and thus would be open to significant supply chain and regulatory risk at the hands of a third party".*

56. In paragraphs 48-57 of his affidavit, Mr. Smith seeks to make the case that even if a request for an expedited hearing is granted by the EPO, there is still significant potential that it will take substantially longer than 12 months to complete the proceedings before the EPO. Mr. Smith expresses the concern that, for example, TBA may remit the case back to the Opposition Division for further consideration. He also draws attention to the fact that Eisai has not only requested the Opposition Division to uphold the claims of the patent as granted, but also requested that the patent be maintained on the basis of amended claims which are the subject of eleven separate auxiliary requests. According to Mr. Smith, this increases the possibility that TBA may decide to remit proceedings back to the Opposition Division in the event that, for example, TBA decides that the main request is invalid, but that if the patent was amended by reference to one or more of the auxiliary requests, there could be potential to uphold its validity in such amended form. If, subsequently, the Opposition Division decide to maintain the European patent on the basis of one of those auxiliary requests, there would be a further right of appeal to TBA. Against this background, Mr. Smith suggests that it is difficult to estimate the time that will be needed for the opposition proceedings at the EPO to be finally determined.

57. In response to Mr. Smith's affidavit, Dr. Kevin Stansfield swore a further affidavit (his second) on 23 May, 2018 in which he sought to call into question the case made by Eli Lilly that there is an urgent need to obtain commercial certainty in Ireland. In his affidavit, Dr. Stansfield contends that Eli Lilly has not shown any urgency at all either in pursuing a revocation claim in Ireland, or in seeking an expedited hearing of the appeal currently pending before TBA. Dr. Stansfield draws attention to the way in which Eli Lilly commenced revocation proceedings in London on 27 May, 2016 just over three weeks after the filing by Eli Lilly of its opposition proceedings in the EPO. Dr. Stansfield highlights that Eli Lilly waited another year and five months before commencing proceedings in Ireland on 27 October, 2017.

58. In paragraph 8 of his affidavit, Dr. Stansfield refers to what he describes as a "*glaring inconsistency apparent in Eli Lilly's stance*". While resisting Eisai's application for a stay of the revocation proceedings in Ireland on the grounds of a "*supposedly pressing commercial imperative*", Eli Lilly "*has not made the slightest effort to obtain an expedited hearing*" from TBA so that there can be certainty as to the final form of the patent as granted by the EPO.

59. Dr. Stansfield accepts that one of the possible outcomes of the proceedings before the EPO is that some amendment to the patent may be made. Dr. Stansfield makes the point that the potential for amendment is important in the context of Eli Lilly's contention that it will proceed with revocation proceedings in Ireland even if the validity of the patent is upheld by TBA. Dr. Stansfield says that if there is an amendment of the patent as a consequence of the EPO proceedings, it is "*quite possible that what has gone before in these proceedings* [in Ireland] *in terms of pleadings, discovery and the preparation of expert reports and submissions may have to be revisited, which will obviously entail a huge waste of time and costs in respect of a case that is already destined to be technically complex and likely to place some considerable pressure on the parties and the Court".*

60. Dr. Stansfield also suggests that if Eli Lilly's appeal to TBA is successful in its entirety, and if in the meantime there is no stay of the Irish proceedings, the expenditure of resources involved in moving the Irish proceedings towards trial (or in a lengthy and technical complex trial) will have been "*for nought*".

61. In paragraph 14 of his affidavit, Dr. Stansfield suggests that the auxiliary requests should not result in any delay. He expresses the view that TBA would, if necessary, engage with the terms of the auxiliary requests rather than referring them back to the Opposition Division. However, it has to be said that Dr. Stansfield's evidence in relation to this issue is in very broad-brush terms. The reasons for his view have not been spelt out in any detail, and I am therefore in no position to form a view that there is no risk that TBA will not refer the matter back to the Opposition Division to deal with one or more of the auxiliary requests.

62. With regard to Eli Lilly's case that it needs commercial certainty about the position in Ireland by early 2019, Dr. Stansfield makes the following points:-

> (a) having regard to the timeline before Eli Lilly would be in a position to commence commercial manufacture of the compound, he says that in 2019, Eli Lilly would only need to manufacture batches of compound for Phase III studies, and he says that there is no reason why this work could not be undertaken even in the event that a stay is granted. As noted in paragraph 9 above, Section 42(1)(g) of the Act (as amended) expressly permits the carrying out of studies, tests and trials with a view to obtaining a marketing authorisation in respect of a medicinal product for human use. Such activity will not be regarded as an infringement of a patent;
>
> (b) while it would be usual that Phase III batches would be prepared at the site where the final product is manufactured, this is not essential. The additional cost incurred would be "*relatively small compared to the overall investment required*

to bring a development compound to market";

(c) the manufacturing costs for Phase III batches would at most be around €2 million, and the additional costs involved (should it ultimately be necessary to perform commercial manufacturing at a different site) would "*relatively speaking, not be high".* Dr. Stansfield adds that such manufacturing costs are likely to be broadly within the same range of what it would cost Eli Lilly to bring this case to trial based on a 4-6 week hearing.

63. A second affidavit was, in turn, made by Mr. Smith on behalf of Eli Lilly. In paragraphs 9-12 of his affidavit, he sets out an explanation for Eli Lilly's decision to proceed first in the London Patents Court. He maintains that it should hardly be a matter for criticism that Eli Lilly brought its first attack in a "*familiar common law jurisdiction offering a specialist patent court, as well as the full range of common law evidential tools, in the hope of successfully challenging the patent at issue with the reasonable expectation of prompting a general resolution of the matter, if successful*". Unsurprisingly, Mr. Smith highlights that the proceedings in London were successful in that they prompted the deletion of all of the claims at issue in those proceedings. He expresses disappointment that the outcome "*did not provoke a more general resolution"* (by which I understand him to mean a worldwide or at least Europe wide resolution).

64. In paragraph 17 of his affidavit, Mr. Smith stresses that, contrary to the suggestion made by Dr. Stansfield in his second affidavit (which I have sought to summarise in paragraph 62 above), the issue of how or where to manufacture batches of the active pharmaceutical ingredient for the purpose of Phase III trials is not, in fact, relevant to Eli Lilly's case that it will suffer prejudice as a consequence of the grant of a stay. In paragraph 18, Mr. Smith reiterates that Eli Lilly needs to prepare a commercial manufacturing facility capable of producing active pharmaceutical ingredient for global supply in time for launch. While he does not say that everything has to be decided in 2019, he says that investment decisions need to be made as early as 2019. He also says – and this is potentially important – that the capital investments required to prepare for commercial manufacture at such a scale are "*in no way equivalent to the costs involved in producing Phase III batches*". Mr. Smith maintains that the capital investments required are "*much more substantial*" than the cost of bringing or defending the revocation proceedings. In the course of the hearing before me, counsel for Eli Lilly suggested that this averment is not refuted by Dr. Stansfield in his third affidavit sworn on 18 June, 2018. In my view, counsel for Eli Lilly is correct in so suggesting. It should also be noted that (as recorded in paragraph 78 below) further detail is provided by Mr. Smith in his third affidavit (to which Eisai did not respond).

65. Mr. Smith also reiterates that it is standard commercial practice for Eli Lilly to commence its preparations for and to make the necessary investment decisions with regard to commercial manufacture of a new medicine several years in advance of any anticipated launch date so that all regulatory requirements together with Eli Lilly's own standards for quality and compliance are met in time for launch. Mr. Smith explains that by taking this approach, Eli Lilly provides for contingencies which may arise in areas such as sourcing, technology transfer, registration and stability studies, process validation and engagement with regulatory authorities. These averments are not directly addressed by Dr. Stansfield in his third affidavit. Instead, Dr. Stansfield suggests that any capital investment before the emergence of positive Phase II data is inherently risky, and he suggests that it is "*reasonable to suppose*" that if major capital investment is required for the manufacture of this specific compound, it would ordinarily be deferred until after the Phase II study has been completed. He also suggests that it would not be surprising if a company developing a product staggered manufacturing investment until there were signs that the Phase III trial would be successful. I deal in more detail below with Dr. Stansfield's third affidavit. However, I would observe at this stage that, given that Eisai is itself part of a pharmaceutical manufacturing group, one would expect that if the preparatory steps (and the timing of those steps) suggested by Mr. Smith were wholly outside the experience of pharmaceutical companies, this would have been very clearly stated by Dr. Stansfield.

66. While Mr. Smith accepts that there is no guarantee that Eli Lilly's compound will succeed in trials or be authorised for supply, he stresses that, in the event that the treatment is authorised for supply, it has the potential to be of real significance to patients with this disease. He also expresses the view in paragraph 22 of his affidavit that the risk of delaying the supply of a potential treatment for Alzheimer's disease could not be regarded as an acceptable outcome from a procedural application brought by Eisai "*where, moreover, they assert no specific prejudice (other than costs …) to them*". I do not, however, believe that it is altogether fair to suggest that the only prejudice alleged by Eisai is costs. Eisai also draw attention not just to financial cost, but to the very real risk that court resources may be wasted if the patent is either revoked in its entirety or amended in form during the course of the proceedings at the EPO.

67. With regard to the duration of the process at the EPO, Mr. Smith clarifies that, in his previous affidavit, he was not suggesting that the possibility of the proceedings being referred back to the Opposition Division by TBA was "*certain*". He says that he is personally aware of one case in the EPO (Appeal No. T0449/13) where the patent in question had been upheld at first instance on the main request claims. Seven auxiliary requests had been submitted. These were not assessed by the Opposition Division at first instance. An expedited hearing was granted for the appeal before TBA and the oral hearing was held in less than 12 months. However, in the course of the oral hearing, TBA decided to remit the proceedings back to the Opposition Division to consider the auxiliary requests. The Opposition Division revoked the patent and an appeal against this decision (No. T0449/15) was dismissed. He says that it took more than two years after the initial appeal decision for the decision to revoke the patent to become final.

68. With regard to the concern expressed by Dr. Stansfield that discovery and expert reports in the present case may have to be "*revisited*" in the event that the patent is amended at the EPO, Mr. Smith, in paragraph 33 of his affidavit, says that in light of the nature of the patent, the nature of the objections to it, and in particular the nature of the eleven auxiliary requests (all of which represent a narrowing of the form of the patent), the issues to be resolved in these proceedings if the patent is upheld in amended form will comprise essentially the same issues, narrowed somewhat, as distinct from different or additional issues. Mr. Smith accepts that there is a potential of added matter challenges to arise, but he suggests that this would be unlikely to require any discovery or additional expert evidence. Counsel for Eli Lilly has drawn attention to the fact that when Dr. Stansfield came to swear a replying affidavit (Dr. Stansfield's third affidavit), he does not address this point (as to the narrowing of the claims) by Mr. Smith. This is potentially of some significance in the context of the concern expressed by Eisai about wasted costs and potential waste of court resources if the patent is amended at some stage during the course of the ongoing proceedings at the EPO. This is an issue that I consider in more detail below.

69. In relation to the point made by Dr. Stansfield that any decision by the High Court in these proceedings may be appealed to the Court of Appeal and in certain circumstances to the Supreme Court, Mr. Smith says in paragraph 38 of his affidavit that a first instance decision from the court would "*generate a great degree of commercial certainty for Lilly …".* In my view, having regard to the decision of the Supreme Court in *Hay v. O'Grady* [1992] 1 IR 210, there is some substance to this point at least insofar as findings of primary fact are concerned. The findings of primary fact made in the High Court may therefore provide a concrete basis on which decisions could thereafter be made.

70. In turn, Mr. Smith's second affidavit provoked a response from Dr. Stansfield. In his third affidavit, Dr. Stansfield reiterates the

points previously made by him that commercial production by Eli Lilly is a very long way off, and he maintains that one should have regard to the stages that Eli Lilly will inevitably have to go through before Eli Lilly will ever reach the point of having a product available for sale in the market. Dr. Stansfield also makes the other points recorded by me at paragraph 65 above. He further suggests that Mr. Smith has not provided any detail regarding the nature and cost of the intended investment at Kinsale or an explanation as to why this investment is required in respect of an established facility at which other active pharmaceutical ingredients are already made. This is an issue subsequently addressed by Mr. Smith in his third affidavit (as summarised in paragraph 78 below).

71. In this affidavit, Dr. Stansfield also highlights that Eli Lilly has abandoned the Phase II clinical trial in respect of its monotherapy. He also says that the most advanced trial that Eli Lilly currently has in progress is the Phase II combination therapy which will not complete until December 2020. According to Dr. Stansfield, this points to a delay of over 18 months in Eli Lilly's programme with "*a consequent further pushing back of any need for capital manufacturing expenditure".*

72. Dr. Stansfield also focuses on certain statistics published by TBA which he suggests show that the phenomenon of remittal back to the Opposition Division from TBA is "*rare*". He says that in 2016, 12.4% of opposition cases were the subject of a remittal, and that this dropped to 11.4% of cases in 2017. I am not sure that I would regard a 1 in 8 or a 1 in 9 rate as "*rare*".

73. At this point, although not addressed by Dr. Stansfield in his affidavit, it might be noted that the statistics from TBA provide potentially useful evidence in relation to the outcome of *inter partes* cases before the EPO. These statistics (which were exhibited by Dr. Stansfield) are to be found in the annual report of TBA for 2017. At p 15 of the 2017 report, the statistics show that in 2016, 39.3% of cases resulted in a dismissal of the appeal. The equivalent figure in 2017 was 42.8%.

74. The statistics also show not only the number of appeals that were successful in whole or in part in each of 2016 and 2017, but they also provide useful detail as to the range of outcomes which emerge from appeals.

75. In 2016, 60.7% of appeals were stated to be successful in whole or in part. In 2017, the figure was slightly less, namely 58.2%. However, not all successful appeals result in revocation of the patent. In 2016, 20.5% of cases resulted in revocation, while in 2017, the figure was slightly higher at 22.1%. In addition, as Dr. Stansfield says, 12.4% of appeals in 2016 resulted in "*resumption of opposition proceedings*" (in other words, these were remitted back to the Opposition Division). As noted above, the figure for 2017 was 11.4%.

76. In only a very small number of cases was the patent maintained in its original form. The figure for 2016 was 4%. In 2017, it was even less – at 2.8%. These figures are significantly outnumbered by appeals where the patent was maintained but in an amended form. The number of cases falling into this category in 2016 amounted to 23.8%. In 2017, the figure was 21.8%. It must, of course, be borne in mind that all of these figures are simply statistics. They cannot be used in any real way to predict the outcome of Eli Lilly's appeal to TBA. Nonetheless, they are helpful in identifying the range of outcomes that can emerge from appeals to TBA.

77. The exchange of affidavits culminated in one further affidavit from Mr. Smith. His third affidavit was made on 29 June, 2018. In the hearing before me, counsel for Eli Lilly suggested that what is said by Mr. Smith in paragraph 3 of his affidavit encapsulates Eli Lilly's position in relation to prejudice in the event that a stay is granted. In paragraph 3, Mr. Smith says:-

> *"Dr. Stansfield continues to treat Lilly's commercial imperative in this case – namely to obtain certainty as soon as it may do as to the patent position in the jurisdiction in which it proposes to manufacture – as merely being a question of assessing the preparatory steps that can be put off for a number of years, with a view to weighing the expense of what has to be done now as opposed to later against the cost of the proceedings. Leaving aside the difficulty of taking that approach …and leaving aside the fact that Lilly clearly must follow its own procedures and protocols in this regard and not what Dr. Stansfield may feel is sufficient, the point that I wish to make is that if Lilly is not actively engaged in the process of managing the commercial risk by pursuing a definitive answer in the State as to the validity or otherwise of the Patent as soon as it may have it (which it will not be if a stay of these proceedings is granted having regard to the non-binding effect of a finding of validity at the EPO) various preparatory steps may be delayed with potential knock-on effects on the ultimate supply of what will be a very important treatment for Alzheimer's disease (if it completes clinical trials successfully) and the decision to manufacture in the State may even have to be reviewed".*

78. In paragraph 5 of his affidavit, Mr. Smith says that Eli Lilly must take its own approach to preparations for manufacture. Mr. Smith emphasises that Dr. Stansfield has not addressed the risk management point raised by him in his previous affidavits in relation to the protocols and procedures operated by Eli Lilly. Mr. Smith explains again that the concern of Eli Lilly in relation to its investment decisions is to minimise risk to ultimate manufacture – i.e. the concern is not in relation to the cost of manufacture of trial batches. In paragraph 6 of his affidavit, Mr. Smith draws attention to the type of preparations that he says Eli Lilly will have to pursue (such as the sourcing of raw materials, technology transfer, the obtaining of regulatory clearance) that must be followed through in order not to disrupt or delay manufacture. He says that even where established facilities for the manufacture of active pharmaceutical ingredients exist (such as clearly exist in Kinsale), significant capital investments are typically required in order to manufacture a new medicine in a compliant fashion on a commercial scale. He estimates that the typical capital costs of modifying existing equipment or adding new equipment to a facility so that a new small molecule can be manufactured on a commercial scale is typically in the region of €5 million-€10 million, and can exceed that. He also says that, in addition, further investments must be made in training employees to operate equipment. While this evidence is at a somewhat general level, it nonetheless provides some answer to the criticism made by Dr. Stansfield in paragraph 4 of his third affidavit (which I have noted in paragraph 70 above. It should also be noted that there has been no attempt by Eisai to controvert what is said in this paragraph.

79. In paragraph 8 of his affidavit, Mr. Smith says that cost to a pharmaceutical manufacturer of any substantial delay in the launch of a new preventative or curative treatment (in an area where no such treatment is yet available) would "*typically significantly outweigh the likely costs of these proceedings and the likely cost of capital investment at ….Kinsale ….combined".*

80. Mr. Smith does not contradict Dr. Stansfield's averments in relation to the monotherapy trials. However, Mr. Smith says that Eli Lilly's position as regards manufacturing in Ireland has not in any way changed as a consequence of this, and he says that his previous evidence on affidavit was always predicated on Eli Lilly's focus on a combination therapy. Mr. Smith says that there is nothing in Dr. Stansfield's affidavit which in any way impacts upon the timeframe for making investment decisions in relation to preparations for manufacture.

81. I should make clear that the affidavits on both sides also address other issues. For example, there is a debate between the parties in relation to proceedings in Norway where the Norwegian Court of First Instance has granted a similar application by Eisai for a stay of the proceedings. That application has been appealed by Eli Lilly. I do not consider it necessary in this judgment to consider the position in Norway. It is clear from the affidavits before the court that there was never any suggestion of an intention on the part

of Eli Lilly to manufacture the product in Norway. Moreover, I know nothing at all about the principles that are applied under Norwegian law in relation to an application for a stay of this kind. Nor do I know anything about Norwegian patent law. I do not believe that any useful purpose would be served by spending time on events in Norway. I also bear in mind the point made in paragraph 13 of the *IPCo*m guidance (which seems to me to be equally valid on both sides of the Irish sea) that the hearing of an application for a stay should not become a mini trial. There is a limit to the extent to which the court can usefully analyse the myriad of arguments ventilated on both sides in this case.

The proposal made by Eli Lilly

82. Before proceeding further, I should record at this point a proposal that was made on behalf of Eli Lilly during the course of the hearing which took place before me. In the course of the first day of the hearing of Eisai's application for a stay, counsel for Eli Lilly intimated that his clients would be prepared to seek an accelerated hearing of the appeal to TBA, and that they would be prepared to agree to a stay on the hearing of the revocation proceedings in Ireland on the basis that, in the meantime, discovery and all of the other pre-trial steps would be completed in Ireland. A formal written proposal was issued by the solicitors for Eli Lilly to the solicitors for Eisai later that evening. However, the proposal was not received in time to enable the legal team for Eisai to take instructions in relation to it. On the second day of the hearing, the terms of the proposal were opened to the court. Insofar as relevant, the proposal was in the following terms:-

> *"….in an effort to move matters forward as pragmatically as possible, our client proposes as follows:*
>
> *1. That the hearing of your client's stay application be adjourned for a period of 12 months to a fixed date in July* [2019].
>
> *2. The parties shall expeditiously advance the pre-trial steps in these proceedings (including discovery and the preparation and exchange of witness statements) in the period prior to the adjourned date.*
>
> *3. Our client would forthwith (and in any event within a period of 10 days) request that the relevant Board of Appeal of the EPO accelerate the processing of its appeal of the decision of the Opposition Division in respect of the Patent.*
>
> *4. That, should the Board of Appeal grant accelerated processing and subject to the Board of Appeal reaching a decision on the appeal by 1 November, 2019, no hearing of the substantive trial in these proceedings would take place pending that decision.*
>
> *5. That, should the Board of Appeal refuse to grant accelerated processing, each party would have liberty to re-enter the stay application prior to the adjourned date".*

83. Although counsel for Eisai was not in a position to obtain instructions in relation to this proposal, he nonetheless made it clear in his closing submissions that the proposal was unacceptable. Counsel for Eisai submitted that there was a huge burden facing the parties in preparing these proceedings for trial. He emphasised that the discovery sought in these proceedings went significantly beyond what had been agreed in London in respect of the English proceedings. He also emphasised that experts will have to be engaged and reports will have to be drawn up. Not only will appropriate experts have to be identified, but there will be a "*tremendous amount of time*" spent in terms of identifying relevant documentation for the experts and preparing that documentation for submission to experts. This is against a background where, as noted above, there are four quite separate areas of expertise required in this case. It should also be noted that a not insignificant number of the documents to be discovered are in Japanese, and therefore, these documents (which are likely to be highly technical in nature) will have to be translated into English. In a letter dated 16 April, 2018 from Whitney Moore (the solicitors for Eisai) to William Fry (acting on behalf of Eli Lilly), it was stated that, outside of its central compound database, Eisai holds a significant volume of documentation in Japanese including more than 100 laboratory notebooks in relation to chemistry alone.

84. In addition, counsel for Eisai strongly made the point that the proposal made by Eli Lilly undermines what is said by Mr. Smith in his affidavits about the need for commercial certainty by 2019. Counsel drew attention to the recognition inherent in the proposal described in paragraph 82 above, that there would be no trial in Ireland until 2020 at the earliest. In the words of counsel for Eisai:-

> *"So, that proposal in itself evidences that, in fact, here you can manage with investment decisions being made as soon as possible and not in 2019. So, 2020 at the earliest but it would seem as soon as possible is the new 2019, even though last week it was all 2019 or bust on the part of Lilly".*

Weighing the competing contentions of the parties

85. As noted in paragraph 52 above, I must assess whether Eli Lilly has advanced good reasons as to why a stay should not be granted. I must then weigh those reasons against what McCracken J. in Ireland and Aldous L.J. and Laddie J. in England considered was the desirability of imposing a stay, together with the other factors identified by Eisai. As a first step, it seems to me to be helpful to consider what is the likely duration of proceedings before the EPO.

The likely duration of proceedings before the EPO

86. In the course of his submissions, Mr. Newman S.C., counsel for Eisai, has said that, on the evidence before the court, an accelerated hearing before TBA is likely to take place within 12 months from the date TBA agrees to expedite the appeals. This has not been contested by Eli Lilly. Mr. Ferriter S.C. said that Eli Lilly was not disputing Dr. Zilli's evidence that an accelerated hearing before TBA would "*hopefully ….get ….on within a period of 12 months*". This is not as long as the likely duration of the EPO proceedings in *Merck*. It will be recalled that in *Merck*, McCracken J. recorded that the likely length of time it would take for appeals at the EPO to be heard was in the region of 3-4 years.

87. However, counsel for Eli Lilly, emphasised the length of time that may potentially elapse before proceedings are concluded at the EPO in the event that TBA decides to remit the matter to the Opposition Division.

88. Counsel for Eli Lilly stressed that there were a number of possible outcomes before the EPO. Based on a combination of the submissions of counsel and on the figures available from TBA (as set out in paragraphs 72-76 above), I believe the following scenarios are possible:-

> (a) having regard to the figures available from TBA for 2016 and 2017, counsel drew attention to the fact that statistically speaking, in approximately 1 in 8 or 1 in 9 cases, TBA has remitted the matter back to the Opposition Division.

Counsel suggested that remittal is more likely in practice in cases where there are (as here) auxiliary requests. Based on the statistics, it was suggested by Mr. Ferriter that it was "*not at all inconceivable*" that TBA will remit matters back to the Opposition Division, in which case it was suggested that there could be a delay of between 18-24 months before the Opposition Division would complete its assessment of the auxiliary request the subject of the remittal. In this context, I was reminded that the opposition proceedings here commenced in May 2016, and it was January 2018 when there was a hearing, which in turn was followed by a written decision in February 2018. On this scenario, it could be 12 months before a hearing takes place at TBA (having regard to Dr. Zillies' evidence). In the event of a remittal back to the Opposition Division, this could incur a further period of 19 months or so, following which there could be a further appeal to TBA which, assuming an accelerated hearing would be granted, would take a further 12 months thereafter. On the basis of this scenario, there could be a period of three years seven months before a final decision would emerge from the EPO;

(b) the next point to bear in mind is that, as noted above, the final decision by the EPO would not result in finality of the issues in these proceedings unless the EPO decided to revoke the patent. Eli Lilly has made it clear that it would still wish to proceed with revocation proceedings in Ireland if the patent is upheld. Thus, one could still have a scenario where, even after a further period of three years and seven months before the EPO (if the scenario outlined at (a) were to ensue), it would be 14-15 months thereafter before a trial of such revocation proceedings takes place in Ireland (on the basis of the time estimate outlined in paragraph 8 above);

(c) the next possible scenario is that TBA upholds the opposition in full and declares the Patent to be invalid. That would mean that proceedings before the EPO would conclude in a little more than 12 months' time. Based on the figures for 2016 and 2017 (recorded in paragraph 75 above), there would appear to be a 1 in 5 statistical prospect that this would occur. In such a scenario, it would not be necessary to proceed with the Irish proceedings;

(d) the next possible scenario is that TBA may uphold the patent in its entirety at the end of the likely 12 month period. However, again, based on the statistics which have been published for 2016 and 2017, it would appear that the maintenance of the patent as granted occurs in only a tiny minority of cases. As noted above, only 4% of cases in 2016 resulted in this outcome, while the figure for 2017 was 2.8%. However, to this must be added those cases where the patent is maintained in an amended form. Again, as noted above, this accounted for 23.8% of cases in 2016, and 21.8% of cases in 2017. In both of these cases, based on the evidence given by Mr. Smith, the proceedings in Ireland would resume relatively quickly.

The balance of justice

89. Counsel for Eli Lilly sought to suggest that it was only in a minority of cases that the outcome of the proceedings before the EPO would determine the matter in a way that would make the Irish proceedings unnecessary. As noted in paragraph 88(c) above, there would appear to be a 1 in 5 chance (based purely on statistical information for 2016 and 2017) that this would occur. Thus, save in the event that the patent is revoked, there will in all likelihood be a trial in Ireland. Counsel stressed that in all other cases, Eli Lilly will be proceeding with its revocation proceedings in Ireland, and, as outlined in paragraph 88(a) above, he maintained that there was also an appreciable risk that even with an accelerated hearing before TBA, the proceedings at the EPO might not be concluded within the 12 month timeline suggested by Eisai. Against this background, counsel argued that it made sense to permit the Irish proceedings to proceed, and that the only prejudice which Eisai had identified was the actual legal costs that would be incurred in the event that the revocation proceedings are not stayed.

90. However, it has to be acknowledged, in my view, that wasted costs (particularly in terms of court resources) is a significant part of the rationale underlying the approach which the courts take that the grant of a stay should be the default position. It is obviously desirable that wasted costs should be avoided. This is particularly so in an Irish context where it is not uncommon to find that there is an insufficient number of judges available to deal with the sheer number of cases in court lists. For example, in the present term, the President of the High Court was left in a position where he had no alternative but to adjourn cases pending in the Non-Jury List in the second half of July due to an insufficient number of judges. In the Chancery and Non-Jury Lists, it is also not uncommon for parties to find on any given day that their case cannot proceed because of the lack of judges. While this should not happen in the Commercial List, it would be very unsatisfactory, in an Irish context, if court time were to be devoted to the hearing of a case based on one version of a patent if there were a risk that the form of the patent might be amended, or a risk that the patent itself might be revoked by a decision taken at the EPO – especially where there is a reasonable prospect that such a decision might be given within a period of 12 months. While I accept that, on the basis of the figures for 2016 and 2017, there may only be a 1 in 5 chance that the decision of the EPO will result in a revocation of the patent (thus making the continuation of the Irish proceedings unnecessary), there is still a significant percentage of cases where, on appeal, the patent is amended by TBA. Taken together, the statistics available for 2016 and 2017 (summarised in paragraphs 75-76 above) suggest that there is something above a 40% chance that a patent will either be revoked or amended by TBA. In my view, that is a significant chance that cannot be ignored in circumstances where court resources in this jurisdiction are, frankly, already over-stretched. This seems to me to be consistent with the concern expressed by MacMenamin J in the Supreme Court in *Tracey v Burton* [2016] IESC 16 at pp 20-22 and by Twomey J in *Nutrimedical v Nualtra* [2017] IEHC 253 at p 20. While I appreciate that the factual and legal contexts of those cases are quite different to this case, the underlying concern appears to me to be equally applicable here.

91. I also appreciate that in *IPCom*, Floyd L.J. appeared to play down the role which wasted costs should play. As summarised in paragraph 46 above, Floyd L.J. suggested that while a court should seek to arrange matters to avoid wasted costs, the court should recognise that, unless stays are to become mandatory, the risk of wasted costs will be outweighed in some cases by other factors. One of the factors identified by Floyd L.J. was that costs would not necessarily be wasted if the steps in the national proceedings can produce some commercial certainty or promote settlement. I do not disagree with these observations by Floyd L.J., but in an Irish context, and against the background described in paragraph 90 above, I am of the view that the concern expressed by Lord Sumption in paragraph 38 of his judgment (quoted in paragraph 41 above) has a particular resonance in an Irish context. In a jurisdiction where court resources are limited, a waste of those resources would, in truth, do little credit to our procedures. Accordingly, there is, in my view, a strong presumption in favour of a stay on the hearing of these proceedings where, in the absence of such a stay, the court could embark upon a hearing of revocation proceedings in respect of a patent which might either be revoked by the EPO or where it could be amended. This is especially so in the present case where there is at least a prospect that a final decision will emerge from the EPO within 12 months from now.

92. In circumstances where there is a prospect that within a further period of 12 months, the proceedings before the EPO could potentially be resolved completely, I can see no plausible basis on which it could be said that a trial should proceed in Ireland in the meantime or in parallel with the hearing at TBA. Against the backdrop of the 2016 and 2017 statistics (which, as noted above, show at least a 40% chance of either a revocation or an amendment of the patent), the potential waste of court resources would, in my

view, outweigh the commercial considerations put forward by Eli Lilly. I do not wish to suggest that in all cases, concern about waste of court resources will outweigh commercial considerations. However, in the present case, it is clear from the proposal made by Eli Lilly (as set out in paragraph 82 above) that it can, in fact, live with no substantive trial in these proceedings before November, 2019. In my view, counsel for Eisai is correct in suggesting that, in light of the proposal made by Eli Lilly, the case previously made by Mr. Smith in the affidavits sworn by him on behalf of Eli Lilly - that Eli Lilly effectively required a first instance hearing in 2019 - falls away. By making a proposal that no hearing of the substantive trial in these proceedings should take place in the event that TBA reaches a decision on the EPO appeal by 1 November, 2019, Eli Lilly is effectively conceding that there will not be a trial in Ireland in 2019. Having regard to that concession, the commercial considerations outlined in Mr. Smith's affidavit will not be irreparably undermined if a trial does not take place until after November 2019. Accordingly, there is no good reason that would justify the court devoting its scarce resources to a lengthy trial of these proceedings in advance of the expected TBA decision in November 2019.

93. In these circumstances, it would make no sense not to stay a hearing of the Irish proceedings at least until November 2019. However, the application by Eisai is not simply for a stay on the holding of a trial in Ireland. Eisai wishes to obtain a stay that would prevent any steps being taken in the Irish proceedings pending the determination of the opposition proceedings at the EPO. In my view, it is therefore necessary to consider where the balance of justice lies in relation to a stay which would have the effect of preventing any steps being taken in the Irish proceedings.

94. In this context, Eisai raises very similar issues in relation to wasted costs. Eisai argues that it would make no sense that the costs of discovery should be incurred or that the costs and inconvenience of engaging experts and undertaking experiments should not be incurred in circumstances where those costs will have been wasted if, for example, TBA either revokes the patent or decides that the form of the patent should be amended in any substantial way. Eisai also argues that, in such an eventuality, there would be a significant waste of court resources since the court would have spent time in, for example, hearing and determining the applications for discovery on both sides, and possibly also hearing applications in relation to the nature of the experiments to be conducted.

95. In my view, these are significant issues which continue to support the proposition that the starting premise must continue to be that a stay should be granted on all steps in these proceedings unless there are strong reasons to the contrary.

96. Against the risk of wasted costs on Eisai's side (and, to an extent, the risk of wasted resources on the part of the court), there is on Eli Lilly's side all of the concerns expressed by Mr. Smith in his affidavits in relation to obtaining commercial certainty as soon as possible so that Eli Lilly can make what are described as essential commercial decisions in relation to the capital investments required to prepare the manufacturing facility at Kinsale for manufacture of a new compound here. As explained by Mr. Smith in his affidavit, Eli Lilly will need to make investment decisions as to whether to proceed with preparations for the expansion of its existing manufacturing plant, the sourcing of raw materials, technology transfer and the obtaining of the necessary regulatory clearance for the expanded manufacturing facility for the making of this new compound. Mr. Smith has explained that if these steps are delayed, this will have a potential knock-on effect on the ultimate supply of what could potentially be a very important treatment for Alzheimer's disease (in the event that clinical trials are successful and a marketing authorisation is obtained). In this context, I must bear in mind that there is, on the basis of the figures from the TBA (as summarised in paragraph 76 above) a greater than 1 in 5 prospect that the validity of the patent will be upheld either in its original or some amended form. In such circumstances, these proceedings will continue. If, in the meantime, there is a stay on all steps in these proceedings, more than a year will be lost before the expected decision by TBA in November, 2019.

97. Eisai has, of course, sought to question Mr. Smith's evidence in a number of ways. As already mentioned, it has suggested that the case for urgency now made by Eli Lilly is inconsistent with the speed at which it has progressed proceedings in Ireland (particularly when compared to the way in which proceedings were taken in London 17 months previously). Eisai has also called into question the need for any of these decisions to be made at this stage in circumstances where the launch date for any new manufactured compound would be some time in 2025 or 2026. Eisai has also criticised the way in which Eli Lilly did not reveal to the court (until after Eisai had brought it to the court's attention) that the monotherapy clinical trials had been abandoned, and, of course, Eisai has strongly argued that the very fact that clinical trials are still underway means that there is a significant risk that Eli Lilly will not succeed in developing a compound that will be safe and efficacious for Alzheimer patients.

98. Counsel for Eisai drew attention to the language used in the affidavit of Laura Scott sworn on 1 November, 2017 grounding Eli Lilly's application for entry of these proceedings into the Commercial Court List in which she had merely said that Eli Lilly "*is considering whether*" to manufacture its product in Ireland. Counsel contrasted what was said by Ms. Scott in November 2017 with the position now adopted by Mr. Smith (some months later) in the context of the present application for a stay - suggesting that a definite decision had been made to manufacture in Ireland. Counsel also reiterated that there was a fundamental contradiction at the heart of Eli Lilly's position in circumstances where it had not (at least prior to the proposal described in paragraph 82) given any indication that it intended to expedite its own appeal before TBA.

99. Counsel also placed significant emphasis upon the risk not only that the patent might be revoked by the EPO, but that it might be amended. This is the point that was made in strong terms by Dr. Stansfield in his second affidavit (as summarised in paragraph 59 above).

100. Counsel for Eisai has also drawn attention to the approach taken by McCracken J. in *Merck* where, notwithstanding that the petitioner in that case had a manufacturing plant in Ireland, that was not sufficient to persuade the court that a stay should not be granted. Counsel for Eisai argued that in *Merck*, the petitioner had a "*live commercial interest*" which was much more immediate, real and present than the hope expressed by Eli Lilly to commence manufacture at some "*far distant date*" in the future. He suggested that the horizon for the launch of the manufactured product by Eli Lilly is "*just too distant*" to justify a refusal of the stay in this case. He also stressed that, in the absence of a stay, a final decision will not emerge in the Irish proceedings potentially until all avenues of appeal have been exhausted from a first instance decision of this court. At the time of the hearing of this application on 4 and 5 July, 2018, I was informed that the Court of Appeal is currently fixing hearing dates in 2020 for appeals which are now ready for hearing.

101. It should also be recalled that, as recorded at paragraph 62 above, Dr Stansfield has suggested that there is nothing to prevent Eli Lilly from manufacturing trial batches of its compound pending the determination of the proceedings and that, in circumstances where a launch is some years away, this should be sufficient for Eli Lilly's purposes. As noted in paragraphs 65 and 70 above, he has also sought to call into question Eli Lilly's need to make commercial investment decisions as early as Mr Smith has suggested.

102. These are weighty arguments put forward by Eisai. However, there are a number of substantial competing considerations on the other side of the equation which seem to me to be important and which, taken together, seem to me to tilt the balance against the grant of a stay on all steps, namely:-

(a) in the first place, while Dr. Stansfield has sought to throw cold water on the evidence put forward by Eli Lilly that necessary investment decisions with regard to commercial manufacture of a new medicine must be taken several years in advance of any anticipated launch, the evidence given by Mr. Smith in his second affidavit (as summarised in paragraphs 64 and 65 above) was not directly addressed by Dr. Stansfield in his third affidavit in response. I am very conscious that Eisai is, like Eli Lilly, part of a substantial pharmaceutical group. If Mr. Smith's evidence was without foundation in the pharmaceutical world, Eisai was peculiarly in a position to provide evidence to the court to undermine or robustly controvert what was said by Mr. Smith about the need for investment decisions to be made at an early stage. Instead, the evidence given by Dr. Stansfield in his third affidavit merely suggested that any capital investment before the emergence of positive Phase II data is "*inherently risky*" and he somewhat faintly suggested that it was "*reasonable to suppose*" that if major capital investment is required, it would ordinarily be deferred until after the Phase II study had been completed and there were signs that the Phase III trials would be successful. Given the vehemence with which other statements were made by Dr. Stansfield elsewhere in his affidavits before the court, it is curious, to say the least, that Dr. Stansfield was so reticent in his third affidavit. More importantly, on the basis of the affidavit evidence before the court, I do not believe that what has been said by Dr Stansfield has undermined the evidence given by Mr Smith about the need for Eli Lilly to make investment decisions at an early stage in relation to planning for an expansion of its existing manufacturing facilities to enable it to be ready for the earliest possible launch of its new compound in the event that all trials are successful and a marketing authorisation is obtained.;

(b) secondly, in circumstances where Mr. Smith's evidence (about the need for investment decisions to be made at an early stage) has not been seriously undermined, I must bear in mind that if the remaining interlocutory steps are not taken in these proceedings, those investment decisions could be put in jeopardy if, for example, TBA in 12 months' time decides to uphold the validity of the patent (whether in its original or amended form) or if it decides to remit the matter back to the Opposition Division. If the remaining interlocutory steps in these proceedings were to be taken only at that stage, there would be a further delay of more than one year before any hearing could take place of these proceedings. Having regard to the evidence before the court, that is likely to have serious repercussions for Eli Lilly in making the necessary investment decisions to enable it to be in a position to launch a new compound as early as possible;

(c) thirdly, it seems to me to be of very great importance that we are dealing here with a potential treatment for Alzheimer's disease. While there is no guarantee at all that the compounds currently under development and subject to testing by Eli Lilly will result in the successful launch of a treatment for Alzheimer's disease, there is, in my view, a strong public interest in ensuring that the risk of any delay in supply of a potential treatment for such a devastating disease should be minimised to the extent that it is reasonably possible to do so;

(d) fourthly, with regard to Eisai's argument based on *Merck*, it seems to me that there is a significant difference between the *Merck* case and the present case. In *Merck*, the petitioner had the benefit of an undertaking that no infringement proceedings would be taken by the patentee against it pending the determination of the proceedings before the EPO. This removed any commercial uncertainty for the duration of the stay. Thus, the undertaking neutralised the concern expressed by the petitioner in that case;

(e) in contrast to the present case, it also has to be acknowledged that in *Merck*, there is nothing in the judgment of McCracken J. to suggest that the pharmaceutical in question was of a potentially ground-breaking nature in the treatment of a disease which causes so much discomfort and unhappiness as Alzheimer's;

(f) I also appreciate that a first instance decision in this court may well be appealed. The thrust of Eisai's argument in this context is that it is unreal to think that Eli Lilly will be in a position to make commercial decisions of the kind proposed by it until the outcome of any appeal to the Court of Appeal (which will be several years after the High Court hearing). However, having regard to *Hay v O'Grady* [1992] 1 IR 210, it seems to me that a first instance determination will be of significant benefit to Eli Lilly in achieving certainty in that the findings of primary fact made at that hearing by the High Court will not, in all likelihood, be capable of being set aside. The legal advisors to Eli Lilly will therefore be in a position to provide reasonably workable advice to Eli Lilly at that point as to the prospects of the High Court decision being upheld or overturned on appeal. In my view, there is therefore a significant degree of certainty that can be achieved;

(g) I have not lost sight of the argument made by Eisai that discovery may have to be revisited and that experiments may have to be re-worked. This is an issue which I deal with in more detail below. However, I must balance that risk against the commercial risk for Eli Lilly if it is prevented from getting this case into a state of readiness between now and the date of decision by TBA. In light of the fact that TBA may well uphold the patent (either in its original form or in some amended form), there is a significant prospect that in November 2019, Eli Lilly will wish to proceed with the revocation proceedings in Ireland. If, in the meantime, Eli Lilly has been prevented from proceeding with the remaining interlocutory steps in these proceedings, it will then be facing into a period of more than a year before a trial could take place;

(h) I have also not lost sight of the risk that the Phase II and Phase III trials may fail. That is an ever present risk in the development of new therapies but it seems to me that this consideration is outweighed by the very substantial public interest in securing the earliest possible date for the launch of a potential new treatment for this destructive and desolating disease. While there is no guarantee that the treatment will be a success, there is at least a chance that it will and, in my view, that tilts the scales significantly against a stay of all steps in these proceedings.

103. Of course, I must bear in mind that substantial costs may be wasted by Eisai in dealing with discovery, the appointment of experts, the carrying out of experiments and any other pre-trial steps. These costs may be entirely wasted if the proceedings before the EPO result in revocation of the patent, and they may be wasted in part if the form of the patent is amended. However, I am conscious that (as set out at paragraph 62 above) these costs have been estimated by Dr. Stansfield to be less than €2 million. In this context, Dr. Stansfield's figure of "*around €2 million*" appears to have included the cost of a 4-6 week hearing. On that basis, it seems to me that the costs of discovery and the other costs to be incurred in preparation for a trial must be less than €2 million.

104. I am of the view that the considerations outlined in paragraph 102 above significantly outweigh Eisai's concerns about legal costs. Moreover, if, in due course, Eisai can demonstrate that costs have been entirely wasted as a consequence of steps being taken in these proceedings in advance of any decision by the EPO, Eisai would, in my opinion, have a basis for seeking to recover those costs against Eli Lilly in due course. While it would be entirely wrong to pre-judge the outcome of any such application, Eli Lilly might well find it difficult to successfully resist any such application if made, and if it is clear that costs were needlessly incurred having regard to the ultimate decision taken in the EPO proceedings.

105. Even more importantly, it seems to me that the costs of up to €2 million that may be incurred on the part of Eisai must be

weighed against the uncompensatable losses that may be suffered by Eli Lilly if it is delayed in the launch of a potential treatment for Alzheimer's disease in the event that it ultimately succeeds in revoking the patent either here or before the EPO. I have to bear in mind that in an application for a stay of this kind, there is no requirement that the applicant for the stay should provide an undertaking as to damages. In short, there is no "come back" for Eli Lilly in the event that it establishes that the patent is invalid and it successfully develops a treatment for Alzheimer's disease but is delayed in the launch of its new treatment by the existence of a patent which is subsequently found to be invalid.

106. I am, of course, conscious that it is not only the costs which Eisai may incur that should be weighed in the balance. In addition, I must have regard to the potential waste of court resources if, for example, the court spends time in dealing with discovery or other interlocutory issues and the patent is subsequently revoked at the EPO, or its form is amended. I acknowledge that there may be some court time spent on discovery and other issues. However, the potential waste of court resources in dealing with such issues seems to me to be of a markedly smaller scale than the court time that would need to be devoted to a trial which both sides agree could last 4-6 weeks, and which it seems to me could last even longer.

107. Moreover, it seems to me to be unlikely that court resources would be entirely wasted in dealing with these issues if all that happens at the EPO is that the form of the patent is amended. In this context, it is significant that, as noted in paragraph 68 above, Dr. Stansfield did not challenge Mr. Smith's averment in paragraph 33 of his second affidavit that, if the form of the patent is amended, it is likely to result in a narrowing of its form. In particular, Dr. Stansfield did not controvert Mr. Smith's averment that each of the eleven auxiliary requests represent a narrowing of the form of the patent. While at first sight, it might appear that eleven auxiliary requests might result in a myriad of potentially different forms of the patent, this is not, in fact, the position. As counsel for Eisai explained on the second day of the hearing, the reason why there are eleven auxiliary requests is that, at the EPO, one has to put in a different document to reflect each potential permutation. As Mr. Newman said:-

> *"So, in fact, you can have only a couple of substantive different points to be made, and yet it comes out as being a considerable number of auxiliary requests because you have got to put in every permutation.*

So the emphasis on that I think is misplaced".

108. If the form of the patent is narrowed, then I find it difficult to see that, for example, it would be necessary, in the event of an amendment of the patent, to re-revisit discovery. It may well be the case that some parts of the documents to be discovered would no longer be directly relevant, but it would seem to be improbable that it would be necessary to undertake new discovery. To that extent, it seems to me that the costs of carrying out discovery would not be entirely wasted save in cases where the EPO proceedings result in a revocation of the patent.

109. Furthermore, in so far a court resources are concerned, it seems to me that the amount of time that would be spent by the court on discovery and other interlocutory matters would be relatively small such that the concern about the waste of court resources is not so acute in the case of the interlocutory steps under discussion here. In addition, it seems to me that any concern about the waste of such court resources (limited though it would be) is outweighed by the public interest in ensuring that, insofar as possible, any delay in the launch of a potentially life changing treatment (such as a treatment for Alzheimer's disease would be) should be minimised.

110. In all of the circumstances, it seems to me that it is appropriate that the steps necessary to allow this case to go forward for hearing should not be stayed. While it seems to me that a stay should be imposed on a trial (at least up to November 2019), I believe that there are very good reasons why the stay should not apply to the further steps that have to be taken in these proceedings in order to put them in a state of readiness for trial.

111. It seems to me that the stay on the trial should continue until 30 November, 2019 in the hope that by then, a decision of TBA will be available. If that decision upholds the validity of the patent in its current or some amended form, then there would be no reason why a date should not be fixed for the hearing of these proceedings at that point. If, on the other hand, TBA decides to revoke the patent, then I appreciate that the costs that have been incurred in the intervening period will have been wasted. Nonetheless, for the reasons outlined above, the balance of justice appears to me to justify this.

112. If, on the other hand, TBA decides to refer the matter back to the Opposition Division, this may well justify the stay on the trial being lifted. However, at this stage, it would be premature to make any order to that effect. That would be a matter for debate at that stage, but it seems to me that it would not require a lengthy hearing of the kind devoted to the present motion.

The Orders to be made

113. In light of the considerations outlined in paragraphs 89 to 110 above, it seems to me that there is very good reason in the present case why a stay should not be imposed on anything other than the trial in this case. The order of the court will therefore be to stay the fixing of a trial date of these proceedings until after 30 November, 2019 and to refuse a stay on discovery, the carrying out of experiments or the other interlocutory steps that will require to be taken in order to put these proceedings in a state of readiness for trial.

114. Subject to the orders set out in paragraph 113 above, the application for a stay should be adjourned to the Commercial List for mention to Monday, 2 December, 2019.

115. In so far as costs are concerned, I will hear the parties on a date to be agreed in October 2018 in relation to costs but I believe it is appropriate to indicate that, subject to hearing the parties, it strikes me that the proper order to be made, in circumstances where both parties have succeeded in part, is to make the costs of the motion to date costs in the cause.

The motions for discovery

116. As noted above the motions for discovery brought by the parties were listed for mention before me. These should now be adjourned to the Commercial List for mention on Monday, 8 October, 2018 for the purposes of fixing a date for hearing. However, I am firmly of the view that, in the meantime, every effort should be made by the parties to try to reach agreement in relation to discovery to the greatest extent possible. With that in mind, a meeting should take place between the parties' legal representatives (either face to face or by telephone conference) in advance of 8 October with a view to attempting to reach agreement on discovery.

Denis McDonald