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Case No: HP 2015 000060

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 18/02/2016

Before:

MRS JUSTICE ROSE

- -

Between:

ELI LILLY AND COMPANY	**Claimant**
- and –	
JANSSEN SCIENCES IRELAND UC **(formerly Janssen Alzheimer Immunotherapy)**	**Defendant**

Mr Andrew Waugh QC and Dr Stuart Baran (instructed by Simmons & Simmons LLP) for the Claimant
Mr Daniel Alexander QC (instructed by Linklaters LLP) for the Defendant

Hearing date: 10 February 2016

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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MRS JUSTICE ROSE

Mrs Justice Rose:

1. The Defendant ('Janssen') has applied for an order that patent proceedings brought by the Claimant ('Eli Lilly') in this court should be stayed pending the decision of the European Patent Office on the validity of the divisional patent challenged in these proceedings. The claim brought by Eli Lilly in this court seeks to revoke the specified claims of Janssen's patent EP (UK) 2 305 282 and also seeks a declaration of non-infringement ('DNI') in respect of the Eli Lilly's product solanezumab. The claim form was issued on 2 December 2015 and Janssen's defence was served on 13 January 2016. Solanezumab is an antibody proposed to be used in the treatment of Alzheimer's disease.

2. The procedural history relating to the divisional patent and to the parent patent, EP 1 994 937 in the EPO and the English Patent Court is as follows. In 2011 Eli Lilly commenced a claim in this jurisdiction to revoke the UK parent patent and included in those proceedings a claim for a DNI in respect of solanezumab. The UK parent patent was held to be invalid in a judgment of Arnold J in June 2013: [2013] EWHC 1737 (Pat). His conclusions on the issues before him were:

    i) the parent patent was not invalid on the grounds of added matter;

    ii) claim 1 in the parent patent was novel and was not obvious;

    iii) the parent patent was however invalid on the ground of insufficiency;

    iv) if the parent patent were valid, Eli Lilly's product would infringe claims 1 and 5.

3. As to that point (iv), Eli Lilly had argued that it was implicit in the parent patent claim that in order to treat Alzheimer's disease, the antibody to amyloid beta had to raise an immune response. Since solanezumab does not work by prompting an immune response in the patient, Eli Lilly argued that it was not covered by the patent. Arnold J rejected that argument on the proper construction of the patent. Eli Lilly assert, however, that Arnold J accepted the evidence that solanezumab does not prompt an immune response in the patient. There is a dispute in the proceedings currently on foot in this jurisdiction as to whether the court determining issues arising on the divisional patent is bound by those findings of Arnold J in relation to the parent patent. Janssen lodged an appeal against Arnold J's judgment but withdrew the appeal before it was heard.

4. Also in June 2013 the EPO Opposition Division held that the European parent patent was invalid. That opposition had been brought by Lilly on three grounds, insufficiency, obviousness and lack of novelty. The Opposition Division determined that the patent was insufficient and did not consider the other two grounds. Janssen lodged an appeal against that decision in October 2013. The oral proceedings before the Technical Board of Appeal are scheduled to take place on 12 – 13 May 2016.

5. The divisional patent, the UK designation of which is at issue in these proceedings, was granted by the EPO shortly after the UK parent patent was held to be invalid in Arnold J's judgment. There has been opposition to it at the EPO

by Lilly and others. The oral proceedings of the Opposition Division in the opposition to the grant of the divisional patent are scheduled to take place on 22 – 23 June 2016. It is expected that the EPO will announce the result of the opposition immediately and give reasons after – that is the Opposition Division's usual practice though it is not guaranteed that it will follow that practice. The divisional and parent patents will expire in November 2018.

6. In July 2015 Lilly started proceedings in France seeking revocation of the French designations of both the parent and the divisional patents. Janssen has applied to stay those proceedings and Eli Lilly has resisted the grant of a stay. A decision of the French court is expected by the end of February.

7. The principles to be applied when the court is considering whether to stay proceedings are set out in *IPCom GmbH & Co KG v HTC Europe Co Ltd* [2013] EWCA Civ 1496 ('*IPCom*'). The leading judgment in that case was given by Floyd LJ. He described the history of guidance on stays in the earlier case of *Glaxo Group Ltd v Genentech Inc* [2008] EWCA Civ 23; [2008] FSR 18 ("the *Glaxo* guidance"). The *Glaxo* guidance was regarded as generally discouraging the grant of a stay. The Supreme Court, in the course of judgments given in *Virgin Atlantic Airways Ltd v Zodiac Seats UK Ltd* [2013] UKSC 46 ("*Virgin*") questioned the correctness of the *Glaxo* guidance. That guidance was revised by the Court of Appeal in *IPCom*. At paragraph 68 of his judgment in *IPCom*, Floyd LJ restated the approach that the court should adopt in these cases as follows:

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

8. Arnold J applied these factors in *Actavis Group PTC EHF v Pharmacia LLC* [2014] EWHC 2265 (Pat) ('*Actavis*'). That was a claim for revocation of a patent and it was accepted that the Actavis product would infringe the patent if the patent were valid. At the time the application for a stay came before Arnold J the deadline for opposition to the patent had expired only shortly before and two opponents, Actavis and an undisclosed undertaking, had lodged oppositions. There had as yet been no hearing date set in the Opposition Division. Arnold J considered the relative timing of the two sets of proceedings. It was common ground there that it was possible that English proceedings would be resolved within two years. There was a dispute about the length of time likely to be taken by the EPO proceedings which had only just got going. There was no real confidence that there would be acceleration of the proceedings either at first instance or on appeal, leading to considerable uncertainty. Even with acceleration, the EPO proceedings were likely to take three years and maybe more if the case was remitted by the Board of Appeal back to the Opposition Division. The consequence was that if the English proceedings were stayed and then revived once the oppositions had failed, the English proceedings might take 5 years.

9. As well as uncertainties as to timing, Arnold J considered issues of commercial certainty. Arnold J considered the nature of the undertakings offered by Pharmacia: see para 12 of his judgment. Pharmacia undertook first, to seek expedition of the EPO proceedings; secondly that it would not seek an injunction against Actavis and its customers until the determination of the EPO proceedings and thirdly they undertook only to seek damages at a rate of 1 per cent of net sales from the period from launch until the conclusion of the EPO proceedings. Pharmacia did not at that stage undertake not to injunct further sales of the product if it was successful before the EPO and it also reserved the right to seek normal damages or an account of profits for sales after that time. Actavis argued that an important factor weighing against the grant of a stay was that even with the undertakings offered, Actavis would be at risk of having its product taken off the market some years after it has started marketing it. Actavis was also concerned that by the time the matters were resolved, there might be other generic competitors on the market.

10. Finally, Arnold J noted that the wasted costs of the parallel proceedings would be significant and that the EPO costs would be a fraction of the costs of the English proceedings. His assessment was set out in paragraphs 30 and 31 of the judgment.

> "30. Assessment. In my view, the competing considerations are finely balanced. In the end, however, I have concluded that they favour the refusal of a stay. The key reason for

> this is that the EPO proceedings have only just begun. As explained above, although it is likely that the EPO proceedings will be expedited, this cannot be guaranteed. Even with expedition, it is likely that the EPO proceedings will take at least three years to resolve, and there is a risk that this will take significantly longer. By contrast, the English proceedings will be resolved in two years. Thus this is a case where the relative timings of the proceedings means that some commercial certainty is likely to be achieved in relation to the UK market at an earlier date in the case of English proceedings than in the EPO (IPCom 8 and 10). Pharmacia's undertakings go a considerable way to reducing the commercial uncertainty to Actavis in the UK if the English proceedings are stayed, but in my judgment not quite far enough. While they do largely eliminate the commercial uncertainty during the period of the stay, and indeed give Actavis the positive benefit of ensuring that it can get on the market during that period rather than having to rely upon a claim under a cross-undertaking in damages, the problem is that they do not address the uncertainty caused by the prospect that Actavis may be removed from the market by an injunction in, say, five years' time and may have to pay ordinary damages or account for its profits for the last two of those years. That uncertainty will inevitably have a chilling effect on Actavis' investment decisions.
>
> 31. I also consider that refusal of stay is also supported by the possibility that an English decision may promote a settlement (IPCom 9) and by the public interest in determining the validity of the Patent (IPCom 11). The risk of wasted costs is a factor that favours the grant of a stay, particularly given the disparity between those costs and the damages that would potentially be payable by Actavis during the period of the stay in accordance with Pharmacia's undertakings, but I agree with Actavis that this is outweighed by the commercial uncertainty (IPCom 12)."

11. Matters did not rest there. The judgment contains a post script that when the judgment was circulated to the parties in draft, Pharmacia gave further undertakings not to seek an injunction at all during the life of the patent and that they would only seek damages of 1 per cent of net sales in the UK during the life of the patent. There was then a further judgment delivered two weeks later ([2014] EWHC 2611 (Pat)) in which Arnold J reconsidered the matter. He reiterated that the competing factors were finely balanced, even though the EPO proceedings were likely to last substantially longer than the English court proceedings. He held that the new undertakings offered by Pharmacia did substantially eliminate the commercial uncertainty to which Actavis would be exposed. Actavis still opposed the stay on the basis of exportability of the Patent

Court's judgment. But Arnold J held that the new undertakings tipped the balance in favour of the grant of a stay.

12. The main issues arising from the application of the *IPCom* factors in this case are similar to those that arose in *Actavis* namely:

    i) What are the relative likely timings of the English and EPO proceedings?

    ii) Is Eli Lilly prejudiced by significant commercial uncertainty if the English proceedings are stayed and it has to wait for the EPO proceedings to be finalised?

    iii) Are the undertakings offered by Janssen sufficient to reduce the commercial uncertainty faced by Eli Lilly to an acceptable level if a stay is granted?

    iv) Do the other facts in *IPCom* as applied to the facts here point in favour or against the grant of a stay?

The timing of the English and EPO proceedings

13. Mr Alexander QC appearing for Janssen stresses that here the situation is very different from the situation in *Actavis* in that the EPO proceedings are well advanced in relation to both the parent and the divisional patent and are likely to be completed in good time and before any English proceedings could be concluded. As regards the parent patent, the Technical Board of Appeal hearing is scheduled for May 2016 pursuant to an order for expedition following a request from Eli Lilly itself. In their decision, the Board recorded that one reason put forward by Eli Lilly to accelerate the proceedings was that it had initiated parallel national revocation proceedings against the French parent patent. The Board agreed that accelerated appeal proceedings would not only avoid the duplication of the proceedings but would also save costs and resources for the courts and parties involved. The second reason was the legal uncertainty arising out of the suspensive effect of the decision under appeal. Eli Lilly had submitted that the uncertainty was blocking considerable financial investments and thus delaying the commercial implementation of the therapy under consideration. Janssen opposed acceleration on the basis that there were no parallel infringement or multi-jurisdictional national revocation proceedings and they denied that there was a commercial disadvantage for Eli Lilly given that there was as yet no marketing approval for the product.

14. The Board acceded to Lilly's request:

> "The board considers in the absence of information pointing to an imminent termination of the French revocation proceedings, that the appeal proceedings could be terminated earlier than the case pending before the French court amounting in a decision which would affect the patent for all its designated states including France. Accordingly, the legal certainty gained in accelerating the case before the board and the possible avoidance of double work and

> unnecessary costs for the parties and the courts involved outweighs the reasons against such an acceleration expressed by the appellant".

15. Mr Alexander points out that the EPO agreed to accelerate this appeal even though there were no infringement issues raised in the French proceedings.

16. The hearing before the Opposition Division as regards the divisional patent is scheduled for 22 and 23 June 2016. That date was fixed some time ago and is not the result of any particular expedition.

17. As to the likely course of these two sets of proceedings, there is conflicting evidence from the parties. Janssen submits that the fact that the Technical Board of Appeal was prepared to accelerate the appeal relating to the parent patent appeal shows that it is likely to grant expedition for the divisional patent proceedings too, if the party which is unsuccessful before the Opposition Division seeks to appeal to the Technical Board. Evidence on this point is provided for Janssen by Hugh Goodfellow, the partner in Carpmaels & Ransford LLP who has conduct on behalf of Janssen of the opposition proceedings to the divisional patent. His evidence is that if any appeal from the opposition proceedings is not accelerated, the final Technical Board of Appeal decision in relation to the divisional is unlikely to be given until mid-2019. If both Lilly and Janssen asked for acceleration of the appeal, the Board would be likely to accelerate it, given that they have agreed to accelerate the appeal in relation to the parent patent. The likely timeline for such an accelerated appeal assuming that the written decision of the Opposition Division was delivered in July – September 2016 would be for a hearing before the Board and an orally announced decision sometime between July and September 2017.

18. Mr Alexander contrasts this with the position in the English proceedings which are at their very early stages. Even assuming that a trial can take place here in autumn 2016 and judgment is given before the end of the Michaelmas term, it is very unlikely that an appeal to the Court of Appeal will be heard and resolved by July 2017 – September 2017. He submits that the overwhelming probability is that the EPO's proceedings will have run their course not only at first instance but perhaps even on appeal to the Technical Board, before the English court's first instance decision and certainly before the English Court of Appeal determines the matter.

19. Mr Waugh contests Janssen's timelines. Eli Lilly relied on evidence from Andrew Sheard who works with Eli Lilly's in-house patent attorneys in the two sets of EPO proceedings. He says that it cannot be assumed that an application for acceleration of the appeal against the Opposition Division findings in respect of the divisional patent will be successful given that there are four opponents besides Eli Lilly and the Board has a heavy workload. He considers that it is 'improbable' that oral proceedings will take place between July and September 2017 because hearings rarely take place over the holiday period. His estimate is that it is unlikely that an appeal hearing would be scheduled before October 2017 even if a request for acceleration were filed as soon as the appeal was lodged and was accepted quickly. Timetables can also be derailed if a party requests a

postponement of the listed date for personal reasons which he says 'in practice they not infrequently do'.

20. More importantly, Mr Waugh also referred to what he called "the spectre of remission" in the EPO proceedings and submits that this puts a torpedo through all of Janssen's timelines in the EPO. The EPO Opposition Division's decision on the parent patent dealt only with insufficiency and did not consider Eli Lilly's challenge to validity on the basis of obviousness and lack of novelty. If Janssen win in May on the parent patent, that will overturn the Opposition Division's findings on insufficiency but all the other issues may be remitted to the Opposition Division. In Carpmaels & Ransford's letter dated 3 December 2013 to the EPO in the appeal in respect of the parent patent they set out at length Janssen's main request that the patent be upheld with the claims of the main request that were considered by the Opposition Division. There are then six auxiliary requests put forward if the Board does not consider the claims of the main request to be allowable. On the final page the grounds of appeal state briefly "The OD did not consider novelty and inventive step. Accordingly, the Board should remit this case to the OD to consider these issues".

21. Eli Lilly asked the Technical Board of Appeal in April 2014 to consider all issues at the hearing of the appeal in May 2016 but it is not clear whether they have acceded to this request. Mr Waugh submits that they may well not do so, even though they have accelerated the appeal, because an appellate decision on issues that were not determined at first instance deprives the patentee of his entitlement to two tiers of consideration before the patent is invalidated.

22. Mr Alexander says that the question of remission is less significant than Eli Lilly state. The real area of dispute is over whether the invention is sufficiently described. If the appeal is dismissed then the question of remission will not arise since the patent will be invalid on grounds of insufficiency. But if the appeal is allowed, it is up to the opponents including Eli Lilly to decide whether they want to pursue their alternative grounds for invalidating the parent patent before the Opposition Division. He submits that they have the judgment of Arnold J holding that the parent patent did not fail on the other two grounds which were litigated in the English proceedings. Eli Lilly are arguing in the present proceedings that Janssen should be estopped from challenging Arnold J's findings in their favour in respect of the parent patent – they should therefore not rely on their ability to re-litigate those same points before the Opposition Board on a remission as a reason for refusing the stay.

23. On the question of timing I consider that the advanced stage of the EPO proceedings and the likelihood that any appeal from the decision on the divisional patent will be accelerated are factors that point in favour of a stay. This situation is different from the situation in *Actavis* where the EPO proceedings had only just started. It is true that the EPO proceedings may be driven off course by, for example, requests for postponement by the other opponents or by remission of further issues if Janssen's appeal is allowed in respect of the parent. But given that the English proceedings are at their early stages, it is likely that the EPO decision on validity even at the appellate level will be available before the result in the English proceedings.

24. I also bear in mind in relation to this factor Mr Alexander's point that Eli Lilly could have commenced the English proceedings challenging the divisional patent much earlier, as soon as it was granted in June 2013. Mr Waugh says that Eli Lilly were not sufficiently confident that the solanezumab product was worth fighting for because it was only in July 2015 that a pooling of the data from the clinical trials which had initially been considered unsuccessful showed on further analysis that there might be some slowing of cognitive impairment in patients with mild or moderate Alzheimer's disease. However I accept Mr Alexander's point that the press release from Eli Lilly in August 2012 indicates that that conclusion had been arrived at earlier than last year.

Potential duplication

25. The 12th factor listed in *IPCom* was the avoidance of wasted costs. Mr Alexander submits that if the English proceedings go ahead there will be a substantial trial. The draft directions agreed by the parties envisage a trial lasting 6 to 7 days of category five complexity with two experts on each side. Costs estimated on the basis of the parent patent trial were about £5 million in aggregate though they are likely to be less for this trial because some of the ground is already familiar.

26. On this point I agree with Eli Lilly's submissions that these sums are not significant in light of the sums of money at stake commercially for these parties. Eli Lilly have spent over $500 million developing this one product and Janssen's parent group spent about $700 million on developing their own product bapineuzumab before it was abandoned. If solanezumab is successful it is likely to be a 'blockbuster' drug earning many millions of pounds for many years ahead.

Commercial position and uncertainty for Eli Lilly

27. Janssen has offered undertakings set out in the draft order which they say are very similar to those offered in the *Actavis* case and address the alleged commercial uncertainties in the same way. Janssen undertake:

    i) to support any application by Eli Lilly to the Technical Board to accelerate any appeal from the decision of the Opposition Division in relation to the divisional patent;

    ii) Not to seek a preliminary or final injunction in the United Kingdom against the Claimant or its licensees or customers in respect of infringement of the patent for the duration of the patent and any supplementary protection certificate ('SPC') that may be granted;

    iii) If validity is upheld, not to seek damages other than on a reasonable royalty basis.

28. There are three factors on which Eli Lilly rely to argue that the degree of commercial uncertainty created by the grant of a stay is still, even with these undertakings, sufficient to override the default position of the grant of a stay. The first is the existence of the DNI claim in the English proceedings. If there is a finding of non-infringement by an English court then that is the end of the matter because Eli Lilly can launch solanezumab regardless of whether the Janssen

patents are valid or invalid. Mr Waugh argues that the reference in the fourth factor listed in *IPCom* to the need to remember that national courts exercise exclusive jurisdiction on infringement issues comes close to saying that the existence of a dispute about infringement is an overriding factor.

29. In the Particulars of Claim served in the present proceedings, Eli Lilly contend that the specification of the divisional patent is, so far as concerns the issues in this action, the same in all material respects as that of the parent patent so that the findings of Arnold J in relation to the parent create an issue estoppel to prevent insufficiency of the divisional patent being re-litigated. There then follows an averment that the solanezumab antibody does not fall within the scope of any claim of the divisional patent. They also rely on an estoppel as regards Arnold J's findings that solanezumab does not work by prompting an immune response. It was not suggested by Janssen that the issues as regards infringement were insubstantial if the English proceedings go ahead. I regard that as an important factor pointing against the grant of a stay, although I do not regard it as a trump card in Eli Lilly's hands.

30. The question whether solanezumab is covered by the claims of the divisional patent is important in this case not only because of the straightforward issue of whether the divisional patent is infringed or not. Mr Waugh's second point was the importance for Eli Lilly of knowing where they stand in relation to any future application by Janssen for a supplementary protection certificate.

31. As I mentioned earlier, both the parent and the divisional patent will expire in November 2018. It seems very unlikely that Janssen will have their own product on the market exploiting the patent by that date for the purpose of supporting an application for an SPC. But if there is a third party product which has a marketing authorisation and which is covered by any valid claim of a basic patent, then the case law indicates (although the point is not beyond doubt) that Janssen can rely on that third party marketing authorisation to support its application for an SPC. It may therefore be very much in Eli Lilly's advantage not to obtain an authorisation for solanezumab before the expiry of the Janssen patents. If the Janssen patents are invalid of course it will make no difference. But if one or both of the patents is valid and if Eli Lilly would be obliged to pay a royalty to Janssen for the solanezumab product, it is in their interests to launch only after the Janssen patents have expired rather than to launch earlier and risk assisting Janssen to acquire an SPC which will then mean that Eli Lilly has to pay royalties for another five years.

32. Mr Waugh therefore argues that it is imperative for Eli Lilly to know as soon as possible whether their product is covered by any valid claim of Janssen's patent. They want to know whether to lodge their dossier with the European Medicines Agency in the first quarter of 2017. If they submit the dossier then it is very difficult to apply the brakes to the EMA process and delay the grant of the authorisation. If they have a DNI from the English court soon, they can submit the dossier in early 2017 confident in the knowledge that even if the marketing authorisation is granted before November 2018, Janssen will not be able to rely on it to apply for an SPC. If they do not have a DNI by early 2017 and the EPO upholds the validity of the patent during the course of 2016, then they will not know whether they should still submit their dossier in early 2017 and risk Janssen

claiming an additional five years of royalties or wait so that the marketing authorisation will be granted only after the Janssen patents have expired.

33. Mr Alexander complains that this point about the timing of the submission of the dossier to the EMA and the risk of assisting Janssen with obtaining an SPC was not raised in Eli Lilly's evidence or on the pleading. However, it seems to me an important point that arises on the somewhat unusual facts of this case namely that (i) the patent in respect of which Eli Lilly is seeking a DNI is about to expire without the patent holder having a marketing authorisation in place on which to base an application for an SPC; (ii) if Eli Lilly's product is authorised before the expiry of the patent, Janssen are likely to apply for an SPC on the basis of Eli Lilly's authorisation; and (iii) Janssen also intend to seek a reasonable royalty on sales of Eli Lilly's product throughout the life of any SPC granted and are not able to say yet what that royalty would be.

34. I therefore regard this as an important factor to weigh in the balance going beyond the general factor arising from the existence of a DNI claim in the domestic proceedings.

35. Further, the uncertainty created by Janssen's potential reliance on Eli Lilly's product to apply for an SPC is compounded by the fact that Janssen cannot say what the reasonable royalty rate would be. Mr Waugh contrasts the undertakings offered here by Janssen with those offered by Pharmacia in *Actavis*. In the latter case, Pharmacia was able to say that it would claim damages at a rate of 1 per cent. In the present case it is not surprising that Janssen may be reluctant to put a figure on the royalty that they would seek. I recognise that there are many factors that would need to be considered when deciding what a reasonable royalty rate is. I accept however that the uncertainty for Eli Lilly not only as to the duration of any royalty payment but as to the amount is an unsatisfactory situation which is not resolved by the undertakings offered by Janssen. This is relevant to the eighth and ninth factors listed in *IPCom* namely that there is considerable value for Eli Lilly in knowing as soon as possible whether solanezumab would infringe Janssen's patents if valid and also whether Janssen is likely to be able to rely on solanezumab to apply for an SPC. Not knowing those things makes it difficult for Eli Lilly to decide when to start the process of obtaining an authorisation for solanezumab and makes the process of negotiating a cross-Europe settlement of the dispute between the two companies more difficult.

Other factors

36. Mr Waugh also argues that a stay would deprive Eli Lilly of an exportable judgment. He referred to the case of *TNS Group Holdings v Nielsen Media Research* [2009] EWHC 1160 (Pat) which held that it is legitimate for a claimant to seek to obtain an English judgment on the validity of the patent in the hope that this will lead to a settlement throughout Europe and that it is also legitimate to seek to rely on that judgment in the courts of other contracting states or the EPO if no settlement can be reached. A similar point is that a fully reasoned judgment of the English court considering validity and infringement together would provide an important tool for settlement of their Europe wide disputes. I consider this a neutral point given that there might, if the EPO proceedings conclude that neither patent is valid, be a binding ruling which resolves these disputes.

37. Finally Eli Lilly point to the public interest in dispelling uncertainty; the 11th factor listed in the *IPCom* guidance. I accept this factor is relevant in relation to a therapy which has the potential to be a blockbuster product for an intractable disease which affects so many people: Mr Waugh described a cure for Alzheimer's disease as the Holy Grail of pharmaceutical therapies. I do not consider this a weighty factor given that the undertakings offered by Janssen go some way to ensuring that the product does come to the market but it is also a factor pointing against the grant of the stay.

Conclusion

38. Balancing all the points I have considered as relevant in the light of *IPCom*, I have concluded that I should refuse the grant of the stay and allow the English proceedings to go ahead. It may be that the EPO proceedings do produce a clear determination in Eli Lilly's favour rendering the English proceedings redundant. There is a risk therefore that some costs in pursuing the English proceedings will be wasted between now and then. However there is a chance that even though the EPO proceedings are resolved before the English proceedings, they will not be determinative of all the issues between these parties. The infringement issues are important in this case as I have described and it is better that the English proceedings which are before the only forum in which the infringement issue can be decided continue. Neither party was attracted by the idea of the English proceedings splitting out infringement from invalidity in some way. I therefore dismiss Janssen's application for a stay.

39. I will give directions for the continued progress of the English proceedings.