



Neutral Citation Number: [2020] EWHC 2818 (Pat)

Case No: HP-2016-000037

**IN THE HIGH COURT OF JUSTICE**  
**BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES**  
**PATENTS COURT**  
**INTELLECTUAL PROPERTY LIST (ChD)**

Royal Courts of Justice  
Rolls Building, 7 Rolls Buildings  
Fetter Lane  
London EC4A 1NL

Date: 22/10/2020

**Before :**

**MR JUSTICE MANN**

**Between :**

**AMGEN INC..**

**Claimant**

**- and -**

- (1) SANOFI-AVENTIS GROUPE S.A.**
- (2) SANOFI-SYNTHELABO LIMITED**
- (3) AVENTIS PHARMA LIMITED**
- (4) SANOFI WINTHROP INDUSTRIE S.A.**
- (5) SANOFI-AVENTIS DEUTSCHLAND GMBH**
- (6) REGENERON PHARMACEUTICALS, INC.**

**Defendants**

**Michael Tappin QC and Stuart Baran (instructed by Osborne Clarke LLP) for the Claimant**  
**Hugo Cuddigan QC and William Duncan (instructed by Linklaters LLP) for the Defendants**

Hearing date: 21<sup>st</sup> October 2020

**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.

.....  
MR JUSTICE MANN

**Mr Justice Mann :**

1. This is an application by the defendants in this matter to lift an agreed stay provided for in a quasi-Tomlin order stamped on 8<sup>th</sup> February 2015. (I say “quasi-Tomlin order” because the form of order does not have a schedule annexed in the traditional manner. It relies on a separate schedule kept by the solicitors to the parties in what is becoming (in my experience at least) the modern fashion.) The defendants challenge the patent which is the subject of the proceedings on various bases which I do not need to set out here. The defendants were represented by Mr Cuddigan QC and the claimant by Mr Tappin QC.
2. This action is a patent action in which the claimant sues for infringement of their patent which seeks to protect pharmaceuticals which treat elevated cholesterol levels. I do not need to say more about it than that. There are opposition proceedings in the EPO which are still in process, and which were on foot at the time of the Tomlin order. In that context there was an application by the defendants to stay the English proceedings which was settled on the basis of a Tomlin order whose proper effect is now in issue on this application. The order itself provided fairly conventionally for a stay on the terms of a schedule kept by the parties (but not annexed), with liberty to apply to carry the terms into effect.
3. The schedule provided for the interaction between the EPO proceedings and various aspects of the English proceedings and contained a concession on infringement. Its terms are set out in the Schedule to this judgment. It is necessary to set out practically all the terms of the Schedule in order that the nature of the agreement can be appreciated. They are contained in the Schedule to this judgment. In summary, and in order assist the reading of the Schedule and to identify the significant provisions, it provided as follows.
4. Paragraph 1 provides for the agreed stay, but obviously is not the operative stay itself. That appeared in the agreed order. Paragraph 2 contains an “infringement bind” – the defendants agreed that they infringed the significant claims as granted, but reserved the right to dispute infringement if the claims were amended by the EPO.
5. Paragraphs 3 to 6 referred to (to use a neutral term for the moment) the lifting of the stay on the application of either party in the event of the Opposition Division or the Technical Board of Appeals (“TBA”) not reaching their decisions by certain dates. The defendants seek to invoke those provisions.

6. Paragraph 8 contains an important effect of there being no stay if the EPO final decision had not been reached by that lifting date. In that event the EPO findings would be binding on the defendants in this action. In substance, what the defendants now seek to achieve in this application is the lifting of the stay before the final EPO decision so that they are not bound. Whether they are entitled to that lifting is what is in issue in this application.
  
7. Paragraph 11 contains what Mr Cuddigan described as a “non-aggression pact”. “A one-sided non-aggression pact” would be a more accurate description because it provides that the defendants will not initiate invalidity proceedings in other jurisdictions before the EPO pronounced, unless the claimant started infringement proceedings, in which event an invalidity challenge would be allowed. Mr Cuddigan had a subsidiary argument based on paragraph 11c.
  
8. Thus the English action was stayed. The chronology of the EPO proceedings was as follows:

By 31<sup>st</sup> August 2018 the Opposition Division had not delivered its oral decision

30<sup>th</sup> November 2018 – Opposition Division oral decision given.

By 29<sup>th</sup> February 2020 the TBA had not delivered its oral decision.

24<sup>th</sup>–25<sup>th</sup> March 2020 – date scheduled for TBA hearing. However, on 13<sup>th</sup> March 2020 this was adjourned, and on 27<sup>th</sup> March it was rescheduled for 28<sup>th</sup>-29<sup>th</sup> October 2020.

9. Neither of the parties applied to lift the stay in accordance with the schedule until this application was made by the defendants on 9<sup>th</sup> October 2020. The defendants now apply to remove the stay pursuant to paragraph 5 of the schedule on the footing that the EPO Final Decision was not made by 29<sup>th</sup> February 2020. They so apply even though the Final Decision is likely to be fairly imminent, and they could have applied some time ago, either under paragraph 4 or paragraph 5.

## The arguments

10. The case of the defendants is simple. They say that the provisions and scheme of the schedule are clear. The defendants (like the claimant, if it wanted to) can apply to remove the stay and have it removed without demonstrating anything other than the fulfilment of the time provisions in the schedule. Since the EPO decision was not available by 29<sup>th</sup> February, the defendants can have the stay removed. If he had to, Mr Cuddigan made a case for the removal of the stay on the merits, but he said that that was not necessary on the true construction of the Tomlin order and schedule. He claimed that his clients were justified in waiting as long as they have, and until the EPO was about to pronounce, because that prevented a waste of costs in concurrent proceedings. I observe that his evidence did not give that as the actual reason why the application to remove the stay comes so long after the date in paragraph 5 (and even longer after the date in paragraph 4) and so close to the date of the EPO's decision.
11. Mr Cuddigan said that all that is in keeping with the scheme of the Schedule. As a matter of compromise, the agreement binds the defendants to accept they have infringed the patent (paragraph 2), come what may. It binds them to accept the EPO Final Decision, but only if the stay has not been lifted by the time it is delivered. That is what the agreement was. The stay was not just a case management stay reconciling the familiar tensions between proceedings in the English court and the EPO. It contained more substantive provisions and also contained the "non-aggression pact" in paragraph 11. The claimant has in fact started such proceedings in at least 3 European jurisdictions (that was not challenged), and Mr Cuddigan went so far as to submit that clause 11c also entitled his clients to revive their English revocation claim because these proceedings, like the new European ones, involved a claim to revoke a National Patent within the meaning of that sub-paragraph.
12. Mr Tappin, for the claimant, said that on its true construction the defendants were not entitled to have the stay removed simply on demonstrating the passage of time beyond the dates in paragraphs 4 and 5. They needed the intervention of the court, and the court could and should decide whether, on all relevant facts, the stay should be removed. The context of this Tomlin order was the defendants' application for a stay pending the EPO decision pursuant to the principles and practices appearing in *IPCOM v HTC* [2014] RPC 12. It is not uncommon in such applications for the applicant to have to bind itself to undertakings in order to render the stay fair – see eg *Danisco v Novozymes* [2011] EWHC 3288 (Pat). That was the sort of thing which was achieved in this case, without the court having to extract the aspects which the defendants bound themselves to.
13. Mr Tappin submitted that there was only one stay – the stay ordered by the court in the body of the order. The court had control over whether the stay was removed, and did not have to remove it if there was no good reason for it. The schedule did not

entitle the removal as of right; the schedule gave permission to apply (“shall be at liberty to apply”) but no more. The defendants still had to make a case, and they had not. They had not sought a removal stay for all this time, and there was no reason to remove it now, now that the EPO was about to pronounce. The party seeking a change to the status quo needed to provide good reasons for doing so. He relied on *SP v BH* [2020] 1 WLR 2175 at paragraph 20:

“20. So far as relevant to this appeal, the effect of a Tomlin order is that a claim is compromised on scheduled terms. Further proceedings in the claim are stayed except for the purposes of carrying those terms into effect. The effect of a stay is not equivalent to a discontinuance: the stay may be removed if “proper grounds” or “good cause” are shown (*Cooper v Williams* [1963] 2QB 567, 580, 582).”

14. There are no proper grounds here. What the defendants are indulging in is a “cynical attempt” to get the benefit of clause 8 (or rather, avoid the consequences of clause 8) when the EPO decision is nigh and there is no case management case for removing the stay when the parties have been waiting as long as they have (by agreement) for the EPO decision.

## Decision

15. The essence of this case lies in the true construction of paragraph 8, along with the related paragraphs 3 to 7. As emerges from the arguments above, the essential question is whether the defendants are entitled to have the stay removed simply by applying, or whether they have to go further and make a positive case on the facts. Putting it another way, does the liberty to apply to lift the stay mean “liberty to apply in which event all relevant factors pertinent to a stay, including case management factors will be considered”, or does it mean “entitled to have the stay lifted”?
16. It is clear to me that the latter is the case. The stay may have been agreed in order to give the EPO a chance to get to its various decisions but it was not an entirely case management stay (treating the normal interaction of English and EPO cases as being within that description) whose removal would have to be considered in a case management context. That is apparent from the consequences of the removal of the stay, as set out in paragraph 8. If the stay is not lifted by the time the EPO delivers its decision(s) then the defendants are bound by its decision(s) on the validity of the relevant claims. That is not a case management consequence; it is a substantive consequence in terms of the rights of the parties. The stay and its removal have to be considered in that light.

17. The defendants have agreed that they will be bound by the EPO decision(s) if they are delivered within a timeframe (which I was told was based on estimated hearing dates plus some further time). They are given the option of escaping that consequence by the removal of the stay. It makes little sense that their apparent option should be constrained by other factors in operation at the time (which are likely to be case management matters relating to the interaction between the two sets of proceedings). Being bound by the EPO decision(s) or not is not something which can have been intended to be weighed with the other factors which are relevant to stay applications. It is of a different order. That clearly points away from Mr Tappin's construction.
18. One can illustrate that point in this way. Suppose that an application is made by the defendants on 1<sup>st</sup> March 2020, immediately after the TBA "target" date has been missed. On a case management basis, seeking to balance the effect of the two sets of proceedings, the court would have to consider all sorts of familiar things. On Mr Tappin's case it would also have to consider the effect of paragraph 8, along with those other matters. But by what criteria does it judge the extent to which effect should be given to the agreed consequence of removal of the stay? It is a matter which has been agreed between the parties as being a consequence, and it seems to me that it would be impossible for the court to treat it as something which has to be weighed in the overall balance. It is not a factor of that nature; it is not discretionary. The only way in which it can realistically be given effect to is by allowing the defendants to remove the stay if they want it removed, without more.
19. I think by far the more sensible construction is that urged by Mr Cuddigan. His clients have already bound themselves in relation to infringement in paragraph 2. That still stands. They were willing to bind themselves in relation to the EPO decisions, but only if they were delivered within the specified timeframes. That is a serious consequence. They had the option of an escape after that. There are no other express constraints on the ability to escape. There is simply the time factor. No implied restraints are necessary to make the agreement work, and it makes sense without more.
20. The cited dictum from *SP v BH* does not assist Mr Tappin. The dictum describes the effect of a traditional Tomlin order and the circumstances in which a stay can be removed. If the parties have agreed the circumstances in which a stay should be removed, then those circumstances, if they exist, are "proper grounds" or "good cause". So it all turns on what the parties have agreed. In this case the cause or grounds have been agreed to be the end of a period within which the EPO has not reached its decisions. *SP v BH* does not mean that in every case the court should inevitably look beyond what was actually agreed by the parties as being a justification for lifting the stay.

21. In this analysis I have not ignored the fact that the stay can be removed on the application of the claimant too. The construction I prefer works in relation to the claimant as well (though this was not developed in argument). If the EPO decisions(s) are not reached in time the claimant can have the stay lifted, and it should be lifted. It will then have the benefit of the infringement bind in paragraph 2, but will lose the benefit of the validity bind in paragraph 8.
22. Mr Tappin made much of the delay in the defendants' application, and of the fact that they now make it close to the time when the TBA will opine. I do not think this point assists him. One of the features of having black line date limitations is that they operate in a clear way. Once a date passes, it passes, and unless there is a further limitation on the consequences then the stated consequences flow. There are no further limitations. The parties could have agreed further limitations, but they did not. Mr Tappin did not submit that the lapse of time has given rise to any sort of waiver.
23. These conclusions do not mean that a stay for case management reasons, or for some other reasons, cannot be brought into existence. The order itself recites that the parties have agreed to stay the claim "pursuant to the terms of the [scheduled] Agreement" and then provides for a stay "on the terms of the Agreement, except for the purpose of carrying the terms of the Agreement into effect", with a liberty to apply "for that purpose". So the schedule itself is free to govern the terms on which a party is entitled to have "the stay" removed. Paragraphs 4 to 8 all refer to applications to lift "the stay". That stay is the one agreed on by the parties, in the terms agreed by the parties. It is a self-contained stay with its own terms. Those terms provide for its removal and the consequences of the removal. If those terms are triggered to remove "the stay", it would then be open to the other party to seek a further stay on whatever basis seems to it to be appropriate – case management or otherwise. If the action still needs staying, it can be stayed. But the important thing is that "the stay" agreed on will have been removed, with the consequences that have been agreed on (here, the removal of the binding effect of the EPO decision). That produces a coherent regime which allows objectively desirable stays to be imposed but also gives effect to the terms of the agreed stay. It produces an appropriate distinction between arguments which justify the existence of a stay per se on the one hand, and the regime governing the removal of a stay with specified consequences on the other.
24. For those reasons, therefore, I do not consider that the defendants have to demonstrate anything other than a desire to have the stay removed. I shall make an order removing it.
25. That conclusion makes it unnecessary for me to consider Mr Cuddigan's objective reasons for the removal for the stay. They are a change of circumstance in the form of new evidence said to be evidence of insufficiency, and a change in the law in two Supreme Court cases. The argument in relation to those was not particularly

developed and I shall not seek to reach a conclusion on them. Similarly, it is not necessary to reach a view on Mr Cuddigan's alternative approach based on paragraph 11c and the commencement of foreign proceedings. His point has a textual attraction, but is not wholly comfortable. I shall say no more than that.

## **Conclusion**

26. In those circumstances I shall accede to the defendants' application and lift the stay.

## **Schedule – Schedule to the Tomlin Order**



**Amgen Inc. v Sanofi-Aventis Groupe S.A. and others (HP-2016-000037)**

**Confidential schedule to Tomlin Order**

The following sets out the terms of settlement of the Defendants' application to stay these proceedings dated 19 December 2016.

For the purpose of the terms set out below, the "**EPO Final Decision**" means, in relation to the oppositions now pending to the grant of European Patent No.2215124 (the "**EPO Oppositions**"), the final decision of the Opposition Division ("**OD**") or, in the event of an appeal, the final oral decision of the Technical Boards of Appeal ("**TBA**"). The latter includes a final oral decision by the TBA in respect of any issues remitted to the OD by the TBA that were previously not considered by the OD and were later appealed.

1. Subject as set out below, all proceedings in action no. HP-2016-000037 ("**the UK Action**") shall with immediate effect be stayed pending the EPO Final Decision;
2. In relation to the UK Action only, the Defendants will not dispute that the acts in relation to the "Praluent Products" which are set out in the Particulars of Infringement in the UK Action constitute acts infringing claims 1, 10, 11 and 19 to 23 of European Patent (UK) No. 2215124 as granted. In the event of the EPO Final Decision upholding the validity of such claims in an amended form, the Defendants are free to deny that the Praluent Products possess any new integers of the amended claims;
3. In the event of the EPO Final Decision maintaining any of claims 1, 10, 11 and 19-23 of European Patent No. 2215124 as granted, questions of relief in relation to the UK Action will proceed to be determined by the Court;
4. Each of the Claimant and the Defendants shall be at liberty to apply to lift the stay in the event of the OD not having made an oral decision by 31 August 2018;
5. Each of the Claimant and the Defendants shall be at liberty to apply to lift the stay in the event of the EPO Final Decision not having been made by 29 February 2020;
6. Each of the Claimant and the Defendants shall be at liberty to apply to lift the stay following the EPO Final Decision;
7. In the event of the stay being lifted pursuant to paragraphs 4, 5 or 6 above, paragraph 2 shall continue to apply;
8. Provided that the stay is not lifted prior to the EPO Final Decision (either pursuant to paragraphs 4 or 5 above or otherwise), the Defendants shall, in the event of the EPO Final Decision maintaining any of claims 1, 10, 11 and 19-23 of European Patent No. 2215124 (either as granted or in amended form), be bound by the EPO Final Decision in the UK Action in relation to the validity of claims 1, 10, 11 and 19-23 of European Patent (UK) No. 2215124;
9. ...

10. The Defendants (and their respective subsidiaries, their respective parent companies and direct or indirect subsidiaries of their respective parent companies and the respective successors of each of them (together "**Affiliates**")) will not adduce evidence of, nor otherwise use the fact that there has been, a stay of the UK Action (including the relief sought therein), in order to seek a stay of other actions (pending or future) in respect of the "Patent Family" in any country or jurisdiction or to argue against (or seek a stay of) any relief, including but not limited to preliminary or permanent injunctive relief, sought or obtained by Amgen in any other case (pending or future) relating to the Patent Family in any country or jurisdiction. The "**Patent Family**" means any granted or issued patent in any country that claims priority to, or benefit of, any of US Provisional Application No. 60/957,668, filed 23 August 2007, Provisional Application No. 61/008,965, filed on 23 December 2007, Provisional Application No. 61/010,630, filed on 9 January 2008, or Provisional Application No. 61/086,133, filed on 4 August 2008...
11.
  - a. Prior to the EPO Final Decision, the Defendants (or their respective Affiliates), will not institute any proceedings to invalidate or revoke any of the national patents of European Patent No. 2215124 (each a "**National Patent**"), nor collaborate with any third parties in respect of invalidity or revocation suits against such patents, except as set out in paragraphs 11(b) and 11(c);
  - b. In respect any infringement action served by the Claimant prior to the stay of the UK Action against the Defendants or their respective Affiliates, manufacturers, distributors, direct or indirect customers or end consumers of their products (together the "**Protected Entities**") based on a National Patent, the Defendants (and their respective Affiliates) shall be entitled to institute proceedings to invalidate or revoke (and collaborate with any third parties in respect of invalidity or revocation suits) against such asserted National Patent, whether by formal counterclaim or a separate claim (for example, in a separate court in jurisdictions that bifurcate);
  - c. If the Claimant, its Affiliates, or any of their respective assignees or any of their respective licensees in respect of any National Patent, initiate or serve any new infringement proceedings against the Protected Entities based on any National Patent, the Defendants (and their respective Affiliates), shall be entitled to institute proceedings to invalidate or revoke (and collaborate with any third parties in respect of invalidity or revocation suits) against any or all National Patents (including National Patents which have not been asserted against any of the Protected Entities);
12. The Claimant shall not, and shall if so requested procure undertakings from its relevant Affiliates and its and their respective licensees that they shall not, bring any new proceedings, pending the EPO Final Decision, against the Protected Entities, for infringement of the UK designation of any member of the Patent Family;
13. The Claimant will not object to:

- a. any application by any of the opponents in the EPO Oppositions to the EPO requesting acceleration of the EPO Oppositions (including acceleration of any appeals to, and/or referrals back to the OD by, the TBA); or
- b. any request by the Defendants that the Court write to the EPO to recommend acceleration of the EPO Oppositions (including acceleration of any appeals to, and/or referrals back to the OD by, the TBA),

provided that such applications or requests do not inform the EPO and/or the Court of any of the terms of this Agreement other than paragraph 1; and

14. The Claimant shall not assign or otherwise transfer the UK designation of any member of the Patent Family to any third parties other than subject to the terms of the undertaking in paragraph 12 and 13 above and this paragraph 14.