Neutral Citation Number: [2018] EWHC 3425 (Ch)

Case No: HP-2018-000012

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

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

Date: 30/11/2018

Before:

MR. JUSTICE HENRY CARR

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Between:

MERCK SHARP & DOHME LIMITED	**Claimant/Part 20 Defendant**
- and –	
GLAXOSMITHKLINE BIOLOGICALS S.A.	**Defendant/Part 20 Claimant**

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MR. THOMAS HINCHLIFFE QC and **MR. STUART BARAN** (instructed by **Hogan Lovells international LLP**) appeared on behalf of the **Claimant/Part 20 Defendant.**

MR. TOM MOODY-STUART QC (instructed by **Powell Gilbert LLP)** appeared on behalf of the **Defendant/Part 20 Claimant.**

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Approved Judgment

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MR JUSTICE HENRY CARR:

Timing issues

1. The first issue I have to resolve on this CMC is the relative timing between the PPD and the identification of claims said to be independently valid.

2. The general field to which the patents relate is vaccines against *streptococcus pneumoniae*. Such vaccines work, in part, because they comprise antigens that will be present on the surface of bacteria in an infection. The patient's immune system detects these antigens and builds up an immune response so that it is ready to fight in the event of an actual infection by that bacterium. The vaccines of interest in the present case comprise polysaccharides, which are sugar derivative molecules, that would be on the bacterial surface. They are conjugated (chemically joined) to a suitable carrier protein. The patents relate to the chemistry of that conjugation process.

3. This claim has been brought by the well known company Merck Sharp & Dohme Limited, (MSD) against GlaxoSmithKline Biologicals SA (GSK); the purpose of the action being to clear the way of the patents prior to launch by Merck of its own multivalent conjugated pneumococcal vaccine product.

4. Merck or members of the Merck Group have sought to invalidate or oppose the equivalents of the patents in a number of jurisdictions including Japan, Canada, USA, EPO (in respect of one of the patents in suit), Germany and the Netherlands. Therefore, it is a major piece of international litigation with considerable commercial value.

5. MSD contends that GSK should nominate which claims in the patents are said to be independently valid before MSD provides a product and process description (PPD) in respect of its proposed V114 product, so that the PPD can then focus on the claims actually in dispute. GSK wishes to wait until it has received the PPD before committing on independent validity. Currently, GSK has identified across the two patents 22 claims which are said to be independently valid.

6. Mr. Hinchliffe, who appears on behalf of MSD, has pointed out that certain of the claims might well require a considerable amount of searching through documents in order for MSD to adequately address whether they have been infringed in the PPD because it is quite possible that these measurements have not yet been taken. The purpose of the PPD is of course to avoid the cost of such an exercise. Whilst Mr. Moody-Stuart, appearing on behalf of GSK, points out that there is no evidence to support that proposition, I have no reason to doubt what Mr. Hinchliffe says.

7. On the other hand, I have considerable sympathy for Mr. Moody-Stuart's point that it is very difficult to commit, without knowing the details of the process alleged to infringe, as to which claims are definitely going to be asserted to be independently valid. In my view, the fair result is to require GSK to use its best endeavours further to narrow the list of independently valid claims on which it relies prior to the PPD but with liberty for GSK to apply, once the PPD has been served, to alter or amend that list.

8. It also seems to me, given what I have heard, that it may be that this is a case where, in the end, a PPD is not the most efficient way of finding out the necessary information to decide on infringement. It may be, particularly if there is a dispute about the adequacy of the PPD, that an inspection of the process, with an opportunity to take certain measurements and samples, will cut through what may otherwise be a long dispute with several trips to court.

Judgment on disclosure order

9. This is a relatively simple issue. MSD has, in my view quite properly, indicated that since the court has allowed GSK's amendment to introduce an infringement counterclaim, it is considering pleading a prior use defence in response. GSK seeks a disclosure order in relation to that defence, if pleaded. MSD contends that this is not the time for such an order. If it pleads a prior use defence, then when it has done so – and when the parties determine what is actually in dispute in relation to such a defence – the parties should determine the scope of the disclosure then and it is hoped that the parties may be able to agree this. The form of the order proposed by GSK is that in the event that the Part 20 defendant's defence to its counterclaim, served under paragraph 2 of the proposed order, includes an alleged prior use defence, the Part 20 defendant shall on or before 26th April make and serve on the Part 20 claimant a list in accordance with form N265 of the documents in their control relating to the alleged prior use defence. If the Part 20 claimant wishes to inspect such documents that are in the Part 20 defendant's control, it shall give notice in writing if it wishes to do so and such an inspection shall be allowed at all reasonable times, upon reasonable notice. In summary, it is an order for standard disclosure with the no doubt laudable aim of avoiding a further trip to court.

10. On this issue, I agree with MSD. I think that until the prior use defence has been pleaded, it is not appropriate to order standard disclosure. It may be that disclosure will be more focused and specific to particular categories once the nature of the section 64 defence is pleaded and what is in issue has been clarified.

11. On the other hand, I do not think it is appropriate to leave 42 days, as is currently planned, for MSD to make its mind up about the section 64 defence and I propose to order that within 28 days MSD shoud make a decision on this point and inform GSK accordingly.

12. I should also add that section 64 defences are notoriously disclosure heavy, because they commonly involve an investigation as to what happened internally within the organisation which pleads that defence over a considerable period of time. Therefore, it may well be, when this case comes back to court, that a wide disclosure order be made.

Judgment on confidentiality agreements

13. I shall now give judgment upon two disputes concerning the content of confidentiality agreements that have otherwise been agreed between the parties. The disputes concern, first of all, whether the requirement to sign confidentiality undertakings should extend to barristers and solicitors and support staff, such as secretaries and paralegals acting for GSK. MSD says that it should.

14. The second dispute is whether the receivers of the confidential information should be restrained from using that information in connection with the drafting or amending of any patent applications or patents for the purposes of the UK proceedings.

15. As to the first question, Mr. Hinchliffe referred me to the well-known fact that it is common in patent cases for the parties to need to exchange commercially sensitive confidential information. This is true in the present case. MSD's information about its plans in relation to its V114 product and the process by which it is made are said to be highly confidential. The confidentiality, at least for the purposes of the hearing before me today, is not in dispute. It is agreed that the directions should include an order that information deemed confidential by one or both parties shall only be exchanged in accordance with the terms of the confidentiality agreement, included at annex 1 to the order for directions.

16. Mr. Hinchliffe's case is that there are several useful purposes of confidentiality undertakings, including making absolutely clear, both to the proprietor of the information and the receiver, what is said to be confidential and what acts in relation to it are or are not permitted. Secondly, acting as a reminder to busy professionals that they must take care in relation to that information and, thirdly, providing properly for appropriate recourse in the event of a breach, however it may arise.

17. I was referred to the familiar authorities which explain the balance that needs to be drawn between, on the one hand, protection of the claimant's confidential information and, on the other hand, to ensure that the interest of the defendant in defending the action are not prejudiced by lack of access to the relevant information. In particular, I was referred to the cases of *Warner-Lambert v Glaxo* [1975] RPC 354, *Roussel Uclaf v ICI* [1990] RPC 45 and as a part of a judgment cited by Daniel Alexander QC in *Magnesium Elektron Ltd v Neo Chemicals and Oxides (Europe) Ltd* (No. 2), [2017] EWHC 2957, *Lilly v ICOS* (No. 2), [2002] EWCA Civ 2. I have all these principles in mind when drawing the balance that I consider needs to be arrived at.

18. MSD explains that its request is not motivated by any suspicion in relation to any persons acting for GSK in this case. The request for GSK's representatives to sign up to confidentiality undertakings does not comprise any suggestion that they cannot be trusted. They accept that professional qualifications carry ethical responsibilities but they point out that mistakes can happen including mistakes by barristers and solicitors.

19. MSD are particularly concerned about GSK's position that persons who do not have any professional obligations, such as support staff, paralegals and secretaries should have access to MSD's confidential information without having to provide undertakings. It also points out that matters of appearance are important in this context. It is important that the confidentiality of MSD's information is not merely respected but seen to be respected. Mr. Hinchliffe explained that from the perception of his clients, if a mistake did happen without a signed confidentiality undertaking, that would be perceived as particularly unfair.

20. Essentially MSD's case is that asking GSK's representatives all to sign up to such an obligation is beneficial, because it emphasises the importance of the information, crystallises the obligation and gives MSD reasonable comfort that the obligations will be adhered to.

21. Mr. Hinchliffe also referred to the fact that in proceedings in Belgium in a case between *GlaxoSmithKline Biologicals v Sanofi*, GSK itself proffered similar requests for undertakings, which were agreed to by Sanofi and then inadvertently breached. I have to say I got very little out of that case. It appears that, for reasons known to the parties, GSK asked for very wide undertakings which were accepted by Sanofi, and they failed to prevent a breach.

22. Turning then to GSK's answer. It say's that it objects to all individuals in the confidentiality club signing undertakings before they have access to any information. GSK is happy for its in-house legal representatives and experts to sign the undertakings but contends that it is not necessary and disproportionate for individuals solicitors, counsel and support staff to sign such undertakings.

23. Each case depends on its own facts. In the present case, I am influenced by the fact that Dr. Gilbert explains on behalf of Powell Gilbert that MSD's proposal would a very significant administrative burden on GSK's legal team as all trainee solicitors, paralegals and support staff who, from time to time, may be involved in litigation are required to sign up to the undertakings. Over the course of litigation, she explains that it is entirely to be expected that there will be changes in such personnel and she regards the proposal as entirely unworkable. If it were left there, then I would have concerns that MSD's information was being inadequately protected. However, pursuant to paragraph 10 of the proposed confidentiality regime, which paragraph is agreed, Powell Gilbert have accepted an express obligation to take all reasonable steps to ensure that all of the individuals subject to the confidentiality regime comply with their obligation under the terms of the agreement.

24. It seems to me more desirable that Powell Gilbert, as opposed to individuals such as secretaries, should take responsibility so that, in the event of a breach, Powell Gilbert is potentially liable rather than those individuals. I have no doubt Powell Gilbert, in those circumstances, will be very careful to draw attention to all of the individuals concerned as to the importance of complying with their obligations.

25. Indeed, it seems to me at least *prima facie* that the effect of this clause is that Powell Gilbert are accepting a duty of care owed by them to MSD the breach of which might enable MSD to sue Powell Gilbert in tort for negligence. Therefore, I have no doubt that proper measures will be taken to ensure that no breach occurs.

26. In all the circumstances I consider that the regime offered by Powell Gilbert is satisfactory to protect all the interests concerned. I will not require counsel, solicitors or support staff acting on behalf of GSK to sign those undertakings.

27. That brings me to the second issue between the parties, which concerns the use that can be made of confidential information for the purposes of these proceedings.

28. MSD's case is that amendments to the claims, in the context of this action, may be proffered to attempt to cure the patents' invalidity. The need for an amendment to a patent arises out of the invalidity arguments raised. Amendments are put forward to narrow the claims of the patent so that certain prior art no longer anticipates the patent or renders it obvious. Alternatively, amendments may be put forward to deal with added matter or insufficiency attacks.

29. MSD's case is that the need for amendment is unrelated to infringement. It is not for a patentee continually to re-craft its claim during litigation using its knowledge of the other party's highly confidential acts or plans with the aim of capturing such acts or plans as infringements. So amendment and the infringement counterclaim, according to MSD, are distinct and unrelated.

30. Furthermore, MSD contends it is clear from *Warner-Lambert* that the purpose of compelling disclosure of the alleged infringing process is put forward so that the patentee may formulate its infringement case, not so that it can reformulate the intellectual property rights on which it is based.

31. The way forward suggested by MSD is to incorporate an obligation that those who receive the confidential information for the purposes of infringement action should not be the same people as those formulating the amendments for validity purposes.

32. GSK is content to be subject to a confidentiality agreement that mirrors the provisions of CPR 31.22(1) but objects to the inclusion in paragraph 4(c) of MSD's draft of an obligation requires GSK and its legal team not at any time to use the information in connection with the drafting or amending of claims of any patent application or patents, including the patents in suit and any other patent, which may become subject to the proceedings, in each case including the UK and all other designated States.

33. Dr. Gilbert points out that MSD's proposal places a very significant fetter on GSK's ability to conduct the proceedings and is inconsistent with the general position under the CPR. The PPD is provided in lieu of disclosure and as such is subject to the same express limitations on use afforded by CPR 31.22(1). That rule provides:

> "(1) A party to whom a document has been disclosed may use the document only for the purpose of the proceedings in which it is disclosed, except where – (a) the document has been read to or by the court, or referred to, at a hearing which has been held in public; (b) the court gives permission; or (c) the party who disclosed the document and the person to whom the document belongs agree."

34. It is correct that a party is generally free to use disclosure documents for the purposes of proceedings in which they are disclosed. Indeed, Mr. Moody-Stuart pointed out that in the *Warner-Lambert* case itself the party receiving the confidential information was free to use it for the purposes of the proceedings in which it had been disclosed.

35. In the present case, the parties are agreed, as is normal, that the issues of infringement and validity are so closely linked that they should be heard together in the same proceedings. MSD consented to the counterclaim being brought.

36. Mr. Moody-Stuart suggests that MSD's proposal restricts GSK from using the PPD to consider amendments, which it may in due course consider appropriate in light of the issues in the invalidity case.

37. There is no doubt that "proceedings" in Rule 31.22 encompass a claim and a counterclaim. Furthermore, Dr. Gilbert points out that it would be procedurally unworkable to require disclosure given in respect of a claim to be excluded from use in a counterclaim. The issues of infringement and validity of patents are closely

linked, giving rise to potential squeeze arguments, and it is routine for parties to amend patents to preserve validity whilst maintaining a case on infringement.

38. GSK states that MSD's position would have the effect of limiting permitted use significantly from that provided for under the rules, with the effect of preventing GSK's (but not MSD's) legal advisers – both solicitors and barristers – and experts from being allowed to represent GSK on both infringement and validity aspects of the proceedings, if an amendment is made. This, it is said, will undo all of the procedural savings, which make the agreed infringement counterclaim the most proportionate way forward.

39. Stepping back from this dispute, it seems to me that, subject to the statutory limitations on amendment, namely an amendment cannot add subject matter compared with the application and cannot extend the scope of protection of the claim, it is perfectly proper and indeed common when formulating an amendment to cure potential invalidity to take account of the consequences for infringement. Indeed in an infringement claim, it would be very surprising if this was not done. It is also very common to involve leading and junior counsel in discussions about the form of amendment, which, according to MSD's proposal, would not be allowed to happen if those representatives were to present the case in court.

40. I have reached the firm view that GSK should not be restrained in any way from the use to which it puts this information in the UK proceedings beyond that which is provided for by our rules.

41. I accept Dr. Gilbert's evidence as to the particular difficulties this would cause, difficulties which would not affect MSD's conduct of the case and, therefore, would lead to an inequality in the way in which the parties could be represented.

42. Therefore, I reach the conclusion that MSD's proposal in this regard should not be accepted.

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