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Case No: HP-2024-000020

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

The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: Thursday, 6th June 2024

Before:

MR. JUSTICE MEADE

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Between:

SAMSUNG BIOEPIS UK LIMITED	**Claimant**
- and -	
ALEXION PHARMACEUTICALS, INC. **(a company incorporated under the laws of the State of Delaware, USA**	**Defendant**

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MR. JAMES WHYTE (instructed by **Simmons & Simmons LLP**) for the **Claimant**
MR. DAVID IVISON (instructed by **Freshfields Bruckhaus Deringer LLP**) for the **Defendant**
MS. KATHERINE MOGGRIDGE (instructed by **Osborne Clarke LLP**) for **Amgen**

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Approved Judgment

Transcript of the Stenograph Notes of Marten Walsh Cherer Ltd.,
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MR. JUSTICE MEADE:

1. This is an application for expedition of infringement and revocation proceedings which relate to a European Patent (UK) in the name of Alexion Pharmaceuticals, which I will just refer to as the "Patent." There are a number of actions within these proceedings. In particular, there is an infringement action by Alexion against Samsung Bioepis ("Samsung"); that is an action number that ends 021 and a revocation action by Samsung which ends 020. Both of those proceedings were begun on the same day, the day of grant of the Patent, which is 1st May this year. Also a defendant to the infringement action is Amgen, which is separately represented and to which I will come in a moment.

2. The application, as I have said, is by Samsung for expedition of the trial. Mr. Whyte appears for Samsung today, seeking expedition for the trial to take place as early as December this year, but otherwise for such lesser degree of expedition as I might be willing to grant. Mr. Ivison appears for Alexion to resist the application and Ms. Moggridge appears for Amgen, which takes a neutral stance on the application, neither actively supporting it nor resisting it, but Amgen do say that they intend to co-operate with Samsung, and vice versa, in relation to the conduct of the proceedings going forwards.

3. There are also proceedings in the UPC where an application for an interim injunction is to be heard in the near future and where proceedings on the merits are intended to take place next year and probably, according to the evidence I have, in the second or third quarter of next year.

4. The litigation is about an antibody drug called eculizumab, which is used in the treatment of a number of rare diseases. The details are not specifically important but two of the indications that the drug is used for are called "PNH" and "aHUS". Alexion has marketed eculizumab under the name Soliris for many years. Samsung and Amgen now have biosimilars and it is that that has led to litigation between the parties.

5. Alexion has had product protection for eculizumab for many years and it is a major feature of the positions taken by Samsung and Amgen, that it cannot be right that the Patent can give Alexion refreshed rights over the antibody for which it has already had protection. I decline to get into the details of this today. I understand, of course, that it is a major part of the narrative of Samsung and Amgen, but neither submits that it is a matter that is capable of summary judgment and it is, therefore, an issue ultimately for trial, along with the various other attacks on the Patent to which I will come, and it forms part of the basis of a file wrapper estoppel plea made by Amgen concerning events and statements which took place in the course of prosecution and opposition in the EPO.

6. The law on expedition has been considered in a number of cases familiar now in the Patents Court and there is little dispute about it before me today. The key authority is the well-known decision of the Court of Appeal in *WL Gore & Associates v Geox* [2008] EWCA Civ 622 which has been reviewed on a number of occasions including by Mellor J in *Abbott v Dexcom* [2021] EWHC 2245 and by me in cases including *Teva v Janssen* [2021] EWHC 1922 (Pat).

7. The four key headings from *Gore* are: (1) whether the applicants have shown good reason for expedition; (2) whether the expedition would interfere with the good administration of justice; (3) whether expedition would cause prejudice to the party; and (4) whether there are any other special factors.

8. A point which sometimes comes up in these cases concerns whether the first stage of the test is a threshold or not. That was considered by the Court of Appeal in a case called *Petter v EMC* [2015] EWCA Civ 480 which I considered in the recent decision which I gave in *DISH v Aylo* [2024] EWHC 1310 (Pat) which was only reported very recently if at all and which as a result had not come to the attention of the parties today, and where I held that it was necessary for the applicant for expedition to cross a threshold and show some objectively ascertainable urgency before the other factors fall to be considered. I accept the submission by Mr. Ivison that that is a degree of urgency is a discrete matter that has to be considered and that listing is not simply an exercise in triage, weighing up all the factors applicable to each case as it comes in.

9. At the same time, in *Teva v Janssen,* to which I have referred already at paragraph 6, I said that the matters which fall to be considered in relation to expedition lie on a sliding scale and I adhere to that. I do not think it is inconsistent with what the Court of Appeal said in *Petter* or indeed what I said in *DISH v Aylo*. Sometimes there is a high degree of need for a really major degree of expedition and sometimes less. But once an objective need for urgency has been shown, then the factors fall to be assessed in an analogue and not binary way.

10. Mr. Ivison also submitted that there are cases where there is a specific cliff edge sort of date, like a product launch or expiry of some relevant intellectual property right, and that if a case for expedition is not based around getting to trial before that sort of event, then it must be very dubious whether expedition is required at all.

11. I reject that in the stark terms in which it was put. Certainly there are cases, as Mr. Whyte for Samsung accepted, where there is a very discrete date and if a trial does not take place before that date there is no point in expediting it at all. But if a case does not fall within that sort of category there can still, in my view, be an adequate need for expedition if, for example, there is a continuing harm accruing over time which can reasonably be thought possible to bring to an end by having a trial and obtaining a decision.

12. In the present case, what Samsung says – and I bear in mind that it is Samsung's burden to satisfy me that there should be expedition – is that the market for eculizumab is a small one in which the relevant decision makers have a good knowledge of what is going on, not just in the UK, but abroad, and that steps taken by Alexion to bring its patent rights to the attention of national authorities and individual prescribers will have inhibited them, or may inhibit them, from choosing Samsung's biosimilar product because those people will be concerned that if they switch to Samsung's product and then Alexion prevails in litigation, they would have the undesirable task of switching their patients back, which it is said by Samsung, with the support of evidence from Mr. Parker of Simmons and Simmons, Samsung's solicitors, is not as easy to do as it would be with small molecule drugs. Samsung's position, therefore, is that there is going to be a continuing chilling effect of the existence of this litigation in the minds of decision-makers and prescribers.

13. Alexion's response to that is that whilst it has contacted the NHS and indeed individual clinicians in Germany, those events have taken place and are now in the past and it has no intention of contacting prescribers in this country. I add by way of parenthesis that there are only a very small number of centres, I was told there are two in the case of PNH, in the UK where patients with these conditions are treated.

14. My attention was also drawn to two letters sent to the NHS by Alexion, drawing the NHS's attention to the existence of Alexion's patent rights, which are said by Alexion in its skeleton and in the evidence of Dr. Stothers of Freshfields to be "unremarkable". Certainly they met with a robust response from the NHS, which has gone on to consider tenders by Samsung and by Amgen, which mean that it is now possible for both of those companies to sell their biosimilar products in the UK. I will have to return to consider in a moment whether that gives rise to a sufficient need for expedition.

15. The other factual matters that I need to consider in connection with the application are these: first of all, the UPC proceedings. I have given the rough timetable for those already. There will be no injunction gap in the UPC proceedings, or at least none is alleged, but Samsung do say that if Alexion is able to get an interim injunction in the UPC which, of course, will be resisted, then that will emphasise what it says is the chilling effect in the UK to which I have already referred. Samsung also says that it would be desirable to obtain a decision from this court in advance of the UPC decision on the merits in Q2 or Q3 next year.

16. Those points are somewhat undermined by two things: one is the state of the authorities in the UK which say that trying to get a decision ahead of foreign proceedings in itself cannot found a desire for expedition but only support an application for expedition which is already supported by a commercial need for certainty; and, secondly, the absence of the injunction gap, which means that, unlike a bifurcated system where a UK decision may have additional utility, the UPC will be able to consider all the matters together, and so says Mr. Ivison on behalf of Alexion.

17. A further category of factual matters to which I need to have regard in making my decision is what is involved in the trial. I have been given an estimate for the duration of the trial of nine days, which consists of: three days of cross-examination; two days of closing submissions; a day and a half of pre-reading; half a day of oral opening and two days of time for the parties to write their closing submissions. It has also been submitted to me by Mr. Whyte, and not contradicted by Mr. Ivison, that this is a one-expert case, which is consistent with what I have read.

18. Samsung and Amgen have put their pleadings in at different times because, as I have said already, Samsung started a revocation action and therefore their Grounds of Invalidity went in at the very beginning, whereas Amgen's have only gone in overnight (last night) because they constitute Amgen's defence to the infringement action that Alexion began.

19. The pleadings are extensive and complicated. A large number of citations are relied on for obviousness and multiple citations are relied on for novelty, although Amgen is the only party attacking the Patent relying on lack of novelty. There is some degree of mismatch in the pleadings over the prior art, with certain matters being relied on by Samsung that are not relied on by Amgen and, to a more limited extent,

matters relied on by Amgen that are not relied on by Samsung. I do not intend to pick through the detail and anyway, in the time available for this application, I have not been shown the prior art and have to proceed, to some extent, on impression.

20. Samsung does not explicitly, at the moment at least anyway, plead either file wrapper estoppel or, as Amgen does, abuse of process arising from events during prosecution in the EPO, but it has raised the same factual matters in introductory sections to its pleading and it will now have to consider and decide whether it falls in behind Amgen and raises these as discrete legal arguments.

21. I was addressed in relation to priority as well, but Mr. Whyte points out that priority has been conceded by Alexion and insufficiency, where Mr. Whyte explained (for reasons I need not go into, but which I accept) that the insufficiencies are run by way of a squeeze seeking to deploy statements made by Alexion in the course of prosecution.

22. At this early stage, clearly Samsung and Amgen have not yet co-operated to bring their pleadings into line. Each of their counsel at this hearing have submitted to me that they have the intention to do that and they have confirmed more concretely that although they will not necessarily agree to have the same counsel at trial, they do agree that it will not be the case that leading counsel for the two of them will make submissions at trial on the same topic, which is useful and which I accept. At the moment, they say that they intend to seek to share an expert but have not been able to get that as far as identifying one, which is understandable.

23. I am not persuaded there is anything in the pleadings which show that Samsung and Amgen are currently taking inconsistent positions on technical matters, so I expect that sharing an expert ought to be possible.

24. Although the case is, in its pleadings, of a high level of intricacy and complexity, my overall conclusion is that the thrust of Samsung and Amgen's respective positions are very close to each other. Although there are prior art pleadings in particular where each is running points that the other is not, my expectation is reasonably high that they will be able to fall into line with some discussion. And quite apart from their statement that they intend to seek to do that, one's experience is that it is in their interests to do so and that enlightened self-interest will lead them in that direction anyway.

25. I also bear in mind that the relatively high degree of intricacy and indeed technical complexity is exactly the reason why this one patent trial is estimated to take nine court days at trial and in itself, it seems to me, it does not militate against expedition if expedition were otherwise justified.

26. The other important part of the factual picture on the procedural side is the position of Alexion. Alexion has explained that its advisers have availability issues over the period under discussion. I was provided with a helpful chart of those issues with the evidence of Dr. Stothers of Freshfields.

27. The issues up until the end of calendar year 2024 are all to do with counsel. Those fall away because, owing to the state of the lists, even if I thought expedition was otherwise justified there is no question of bringing this trial on before the end of the

calendar year 2024 anyway. So the matters of availability covered in Dr. Stothers's table which are potentially significant, and certainly said by Mr. Ivison to be significant, are matters in calendar year 2025, when there is a trial in Canadian proceedings between Alexion and an Amgen entity from mid-January to mid-February, a trial in a case called *Dyson v Shark Ninja* between late January and early February where Dr. Stothers is the lead partner; a case spanning a fortnight in mid-late March in *Generics v AstraZeneca* where Dr. Stothers is again the lead partner; and then another trial in Canadian proceedings between Alexion and a Samsung entity, which is not until June and really therefore does not bear on my decision.

28. Those are the broad categories of fact that I have to consider and I therefore turn to the *Gore* factors to do that.

29. The first factor which, as I have said already, must be regarded as a threshold factor, is whether there is objective need for some degree of urgency. In my view this can only be found, if it is to be found at all, in the commercial situation surrounding communication of Alexion's asserted rights to national authorities and prescribers. There can never be certainty in these situations and all the court can bring to bear is common sense and experience in the context of evidence which is almost necessarily and almost always incomplete because neither litigant knows exactly what the other is doing or how the market operates.

30. Nonetheless, I think it is fairly obvious from the manner in which Alexion wrote to the NHS and its behaviour in Germany in relation to public authorities and in relation to writing to prescribers, that it was Alexion's desire to use the existence of its asserted rights under the Patent to negatively impact the suppliers of biosimilars in the form of Samsung and perhaps Amgen too, although of course Amgen are not supporting this application. Mr. Ivison did not provide any other explanation for Alexion's course of conduct. I also accept, as supported by common sense, the evidence of Mr. Parker that in this small and highly specialised world, what happens in Germany will come to the attention of the relevant people in the UK and vice versa. For these biosimilar products I also accept, as supported by Mr. Parker's evidence, as sensible, that clinicians may be inhibited from switching to a biosimilar if they are concerned that as a result of litigation, they will have to switch their patients back in due course.

31. I accept as having some force Alexion's point that whatever their intention may have been in writing to the NHS, it did not work, but I find that an unsatisfying submission in its broad scope and I think it amounts to saying that having attempted to create a bad smell around Samsung's products, Alexion can now brush it off because customers have become accustomed to holding their noses. I think it is obvious what Alexion's intention was. I think it is reasonably to be inferred that it may well be having a continuing effect and I therefore accept that there is at least some degree of need for expedition to address that situation, if it can be accommodated consistently with the other *Gore* factors.

32. So I conclude that Samsung has cleared the first hurdle and shown some good reason for expedition. I accept Mr. Ivison's point that it is not a “cliff edge” case and I agree, therefore, that it does not *per se* merit the greatest degree of expedition and, in any

event, the earliest date that Samsung seek cannot be accommodated for reasons I have given.

33. Factors two and three tend to go together. They concern good administration of justice and prejudice to the parties, which tends to engage the court's ability to entertain a trial in the time sought, plus its impact on other litigants on the one hand, and on the other hand, the ability of parties to accommodate the expedited trial.

34. As I have said already, the Patents Court, without severe disruption, could not accommodate a trial of this length this calendar year and anyway I suspect that that would be a very tight squeeze to be ready in time. From about the middle of February 2025 onwards, although the Patents Court has some trials listed, they are not on the whole category 4 or category 5 trials and therefore the ability of the Patents Court to accommodate an expedited trial without inconveniencing other litigants who have already got their place in the queue is there.

35. I consider that although, as I have said, the case is an intricate one, it ought not to be problematic to have it ready for trial in that sort of timeframe. Both sides have known the shape of this litigation for quite some time, as evidenced by the immediate starting of proceedings on the first day of the Patent's grant, and both sides have been gearing up for proceedings in the UPC, where, as its case law is starting to show, there is an intense focus on the concrete objective merits of the claim at the interim stage.

36. I also expect with a reasonable degree of confidence that the amount of prior art pleaded will come down to manageable levels both because of the assurances given to me by Samsung and Amgen, and because experience tells one that that is just what always happens.

37. In addition to the points about the pleadings that I have already mentioned, I was also directed to the fact that Amgen in particular has kept open the possibility of search-based disclosure. As far as I can tell, the only conceivable place where that could arise is on the file wrapper estoppel point. As I said in the course of argument, experience shows that those do not in fact really ever involve factual evidence from the patentee, but rather consideration of objective statements made in public documents. It was confirmed to me by counsel for Amgen that it does not in fact actively intend to seek search-based disclosure on those points which at the moment are matters that it has pleaded, and reserves only the right to do so if something pleaded or said by Alexion triggers that need, which seems to me to be unlikely.

38. So it seems to me that this is, albeit at the higher range of intricacy and technical complexity, a normal patent action with file wrapper estoppel added on in a context where both sides have already had a very good amount of time to get ready and I conclude that there is no difficulty from the point of view of getting the case ready for it to come on some time from mid-February onwards.

39. A point was made that conceivably Samsung could have started an *Arrow* declaration quite a bit earlier than these proceedings. I acknowledge that as a theoretical possibility but even had it done so, it could only have put in play some modest part of the sweep of issues which now form part of this case. I do not think it would be fair to attribute any blame to Samsung in not having followed that course, and I think it is

a backward-looking point about blame and not a forward-looking point about practicalities anyway.

40. I also have to bear in mind the points about availability urged on me by Alexion, which I have touched on already, but if, as I have found already, there is some objective need for expedition, then I think the matters urged on me by Alexion in relation to Dr. Stothers's availability cannot reasonably overcome that. It is a matter for advisers and their clients to have these sorts of things in mind, but the decisions about resources that were taken – and I criticise them in no way – mean that there were always going to be periods when Dr. Stothers was busy with two matters at once. Even had the trial been put in May 2025, for example, which is the time which Alexion says it would accommodate, there would still quite clearly have been times when Dr. Stothers was going to have to work on multiple cases at once, for example, when the evidence was being put together.

41. I think that in the right case, availability of a key solicitor could be just as important as the availability of counsel, but the matters put before me on this application do not rise to anywhere near that level and so, whilst I understand the reasons that have been put forward and they are no doubt genuinely put forward, I do not think they attract any real weight in the circumstances of this case.

42. So I would be willing to direct expedition for the reasons given which revolve really about the need for commercial certainty as regards the UK market. The UPC proceedings are a secondary consideration in my view, both on the facts of this case and as the authorities indicate, but they provide some modest support for my decision. It may be that the UPC, if there is a trial, let us say, in the summer of next year when a decision has come from the UK, would be assisted by it, but it cannot be a major factor because, in the absence of an injunction gap, the UPC would be able to make its own decision with regard to all the issues anyway.

43. So I draw some support for my decision from the UPC proceedings, but they are not necessary to it and my decision primarily is based on the situation within the UK.

44. So I will direct that this trial should be expedited to be heard at a time no earlier than mid-February 2025. That does not mean it will be in February because there will be some need for Listing to work out the best time having regard to the available resources in the Patents Court, but it could be as early as then if that is appropriate, and I will indicate that earlier is better than later.

45. So that is my conclusion. I will expedite the trial for the nine days indicated to a time no earlier than mid-February 2025.

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