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Case No: HP-2022-000027

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: Wednesday, 25th September 2024

Before:

MR. JUSTICE MEADE

Between:

Claimants

(1) PFIZER INC.
(2) BIONTECH SE

and

MODERNATX, INC.

Defendant

Claim No. HP-2022-000022

Between:

Claimant

MODERNATX, INC. - and -(1) PFIZER LIMITED (2) PFIZER MANUFACTURING BELGIUM NV (3) PFIZER INC. (4) BIONTECH MANUFACTURING GMBH (5) BIONTECH SE

Defendants

MR. ANDREW WAUGH KC and MR. STUART BARAN and MS. KATHERINE MOGGRIDGE (instructed by Freshfields Bruckhaus Deringer LLP) for Moderna MR. TOM MITCHESON KC (instructed by Taylor Wessing LLP) and MR. MICHAEL CONWAY (instructed by Powell Gilbert LLP) for Pfizer/BioNTech

Approved Judgment

Transcript of the Stenograph Notes of Marten Walsh Cherer Ltd., 2nd Floor, Quality House, 6-9 Quality Court, Chancery Lane, London WC2A 1HP. Telephone No: 020 7067 2900. DX 410 LDE Email: <u>info@martenwalshcherer.com</u> Web: www.martenwalshcherer.com

MR. JUSTICE MEADE:

- 1. I have to now deal with the individual issues on EP 565 where there is an argument that Pfizer should either not have its costs or pay Moderna's costs. Each issue involved seems to me to be sufficiently discrete that I ought to consider whether to deprive Pfizer/BioNTech of their costs or go further and consider whether there is a sufficient reason for the costs to be paid to Moderna.
- 2. The first issue is WO 340 obviousness and I am quite satisfied from my familiarity with the case that it was a direct, proportionate and an appropriate response by Pfizer/BioNTech to Moderna's very late change of position on priority to drop the argument. I therefore make no deduction from Pfizer's costs for that.
- 3. Next, insufficiency/plausibility: this is a relatively difficult one because, first, certainly there was a shepherding squeeze which ought to have been the occasion of only a modest amount of costs. Secondly, there were a large number of detailed scientific points levelled against the disclosure of the patent by Professor Dougan, which were unsound, as I found in my judgment and I think probably ought not to have been made at all and probably did occasion some real costs. Thirdly, there is a squeeze against priority, it is said. I find it plausible there was such a squeeze, but I do not really have visibility of it because of the fact that priority was dropped, which is a situation that Moderna brought about.
- 4. This is, therefore, actually an issue and a squeeze with a number of sub-elements to it, but overall I think justice is best reflected by not making an award in Pfizer/BioNTech's favour, but also not making any order that they have to pay Moderna's costs
- 5. Next is Pardi. In my view, it ought to have become clear to Pfizer earlier than it did that Pardi was extremely unlikely to add anything to the successful attack. That does not mean that it was wrong to maintain it at an earlier stage because I do accept that it came at matters from a different angle and it might have been an important piece of prior art in different scenarios. Again, I think the fair order is to make no order in Pfizer/BioNTech's favour, but also not to require it to pay Moderna's costs.
- 6. Finally, there is WO 674 novelty. I am very clear in my own mind that this was a direct squeeze against added matter and largely a successful one as well and therefore I make no deduction; Pfizer/BioNTech should have the costs of WO 674 novelty.

(For continuation of proceedings: please see separate transcript)

- 7. I now have to deal with the issues on '949 where Pfizer/BioNTech contends that it should have its costs or at least that Moderna should not have its costs on some individual issues, it being accepted, which is obviously correct, that Moderna is the overall winner.
- 8. The first issue is the conditional claim amendments where focus is directed by Mr. Baran to a sum of £15,500 spent by BioNTech. In my view, putting forward a claim amendment is a significant step in any litigation and BioNTech was fully entitled to take its own independent view. That was bound to cost at least a modest amount of

money and I am not surprised at the amount that it cost and, therefore, BioNTech shall have its costs in addition to Pfizer.

- 9. Secondly, the evidence of Professor Bryant, an immunologist, where a rather complex situation arose: the CMC order permitted the parties to call an immunologist and, as it turned out, Pfizer/BioNTech were not planning to call one on '949, but they did nominate Professor Dougan, who did, indeed, in the end give immunology evidence on '565. But that did not enable Moderna to understand that he would not be doing so on '949, so Moderna was taking matters forwards in a state where it could not know for sure what Pfizer's intentions were, but it did in due course put in a report from Dr. Bryant which said that an immunologist would not in fact be part of the skilled team, but went on to explain certain immunology matters which would be known to them if they were.
- 10. Mr. Baran reminds me that a somewhat similar situation arose in *Teva v Grünenthal* over the question of an expert being put in in reply only and makes the point that in the Netherlands, Pfizer was running a point based on immunology evidence. I have to say that, with the wisdom of hindsight and this is more a point for future guidance than something that conditions my decision on costs in this case it would have been better if Moderna had written to Pfizer to clarify its intentions. That is probably the better course if a party is considering putting in an expert report where its primary contention is that expert would not be part of the skilled team at all, and it ought to be expected of the other party receiving a letter like that to respond constructively. But that did not happen in this case and Dr. Bryant's evidence went in. What is sought by Pfizer and BioNTech is not only that Moderna not have its costs of Dr. Bryant's evidence, but that they should be paid their costs of considering it.
- 11. Against the somewhat unclear situation that faced Moderna, I do not think it was sufficiently unreasonable or wrong or out-of-the-ordinary to put in Dr. Bryant's evidence as a precaution and I therefore am not going to order that Moderna should pay the costs to Pfizer and BioNTech of considering that evidence.
- 12. Next, familiarity with the RNA Modification Database: Mr. Baran's main point against the award of costs to Pfizer and BioNTech, it not being argued that Moderna should have its costs, is that this was a micro-issue or a sub-sub-issue. I do not accept that submission. It looks, on the face of the judgment, like it was because the point was surrendered by Moderna after the oral evidence. But it was a point that was fought out quite significantly and although, in the way that my judgment ultimately unfolded, it may not have been critical, it could have been very important. I think it was entirely justified for Pfizer and BioNTech to contest it and contest it hard. Furthermore, I take into account that the reason why the point had to be pulled was because of documents associating Professor Rosenecker with the RNA Modification Database which, in my view, should have been appreciated earlier.
- 13. I do not think this was a sub-issue or a micro-issue; I think it was a distinct issue. Had it not been for the fact that Moderna gave up on the point, there would have been a section in the judgment albeit probably quite a short one specifically dealing with the point.

- 14. Taking account of the fact that I therefore reject Mr. Baran's main submission that it was a sub-issue, but also of the way in which the point went wrong for Moderna, I think this is an appropriate case for the opposing parties to be awarded their costs.
- 15. Finally, secondary evidence: again, it is not accepted that this was a separate point, but in my view it very clearly was. I had to write a section in the judgment about it and it involved quite complicated issues of the way matters evolved in the art and which team in the art knew of which other teams' work and so on and so forth.
- 16. It is not to be encouraged to bring secondary evidence into a case where it is unlikely to help and my ultimate decision in the judgment was that the argument failed because it was not even possible to know which groups saw the prior art some of them certainly did not and the timing did not permit a conclusion about when they would have published. There were also what I referred to as the usual uncertainties about other reasons why they might not have pursued the patented approach. I think it was, or at least ought to have been, relatively obvious to Moderna that the secondary evidence argument was very unlikely to succeed and was not proportionate and for that reason I award Pfizer and BioNTech their costs of that issue too.
- 17. Mr. Baran, again, suggested that the percentages of costs attributed to the issue were too high, but this again was a relatively complicated and fact-intensive dispute. I am not surprised by the amount spent on it by Pfizer and BioNTech and I accept Mr. Mitcheson's submission that the £45,000 spent by BioNTech in addition to the £145,000 spent by Pfizer is not duplicative but reflects the fact that in the very busy time immediately before trial, some aspects of this task were, as it were, sub-contracted by Pfizer to the Powell Gilbert/BioNTech team and, therefore, I award those costs to Pfizer and BioNTech.
- MR. BARAN: I think we might need one further input from you, unless I am mistaken. On the RNA Modification Database we need to know the size of the percentage deduction because my learned friend contends for 5% of Pfizer's costs and 1% of BioNTech and I contended those were too high and it should be limited to the 77K, which was 1.9%. I think we need to know what percentage ----
- MR. JUSTICE MEADE: Where does the 77 and 1.9 come from?
- MR. BARAN: If my Lord recalls, I said 145K was too much and that came from the paragraph-counting approach, that is 0.7% in Moderna's evidence and 1.7 of Pfizer's as a yardstick, so it should be something on that ----
- MR. JUSTICE MEADE: Thank you very much, Mr. Baran.
- 18. I reject that submission as well. I think it is not at all surprising that is significant amount of work went into that and I do not think a paragraph-counting exercise reflects the amount of work that is likely to have gone into it.

(For continuation of proceedings: please see separate transcript)

19. I now need to deal with the rate of interest – should it be 1% or 2% above base rate? The authorities are not consistent on the question of the rate but, in my view, the decision of Males J in *Kitcatt*, which draws on a previous judgment of Flaux J (as he

then was), contains a concrete and more general statement of principle than the other cases from which individual rates can be taken and I accept Mr. Mitcheson's submission about the difference between individual claimants and the rates at which they can borrow and well-off corporate parties, as explaining why 2% was awarded by Males J.

20. I have to say that in my own experience, 1% above base rate is what I have generally ordered when the point has arisen, albeit, I should make it clear, without having had the degree of argument that I have had today, so I will opt for 1% above base rate.

(For continuation of proceedings: please see separate transcript)

- 21. I hear what Mr. Mitcheson says, but I think the situation on '949 is entirely straightforward and I am going to make the usual order at the 1% above base rate, the reasons for the rate being what I dealt with a short while ago.
- 22. Mr. Mitcheson is entirely free to argue that parity should apply to '565 in some way, but I do not think there is any reason to leave '949 hanging. I think it was up to Pfizer/BioNTech to identify that they wanted to defer that for three months if they had thought of that, but they did not.
- 23. So I am going to make what I regard as the standard order on '949.

(For continuation of proceedings: please see separate transcript)

- 24. Mr. Baran seeks an interim payment of 70% on the basis that that is standard. It is certainly common but there are a number of distinguishing features to this case. First of all, Moderna's total is very, very close to the combined total of Pfizer and BioNTech together, Moderna having made the decision to sue two separate undertakings in the same action. Secondly, for reasons I have touched on earlier today, I find the amount of money spent on infringement surprising and quite liable to be reduced in due course. Thirdly, although I am not in a position really to go into it today, I find both the rate and the number of hours put into the case by Professor Rosenecker really very out-of-the-ordinary and I do not have confidence that that is not symptomatic of a similar approach in other aspects of the case.
- 25. All of these things lead me to conclude that I should be cautious in the amount of the interim payment awarded and I settle on 50%, as Mr. Mitcheson contends for. It is not necessary to my decision and I do not draw on what happened in the Pledge case, where apparently 50% was agreed. I do not know why that was or what drove it but, in any event, for all the other reasons I have given, 50% is the proportion that I shall opt for.

(For continuation of proceedings: please see separate transcript)

- 26. I am going to give permission to appeal on '949. The primary reason is that the novelty argument turns on the construction of the prior art and the law of individualised disclosure and pointers.
- 27. I am considerably more dubious about the obviousness appeal and if it were that alone, I might well refuse permission to appeal. But it is impractical to give permission on one ground and refuse it on another when it is the very same piece of prior art in play.

- 28. So, I give permission to appeal on '949 and I make it clear that the reason for my doing so is because I think without implying that I think I was wrong, I do not think I was there must be a realistic prospect that the Court of Appeal could take a different view for the reasons I have given already and with the further consideration that, as Mr. Mitcheson says, the Dutch court reached a different conclusion, albeit perhaps on different evidence.
- 29. So, I give permission to appeal on '949 on the basis there is a realistic prospect of success and I have not yet taken into account the argument which remains to be had potentially on '565 about some other compelling reason.

(For continuation of proceedings: please see separate transcript)

- 30. I am now asked to deal with the question of permission to appeal on '565. There are three limbs to this. Paragraphs 1-4 in the draft grounds deal with obviousness, paragraph 5 deals with added matter and then, separately, I have to deal with a submission by Moderna that even if I conclude that there is no reasonable prospect of success on the appeal, I should give permission for some other compelling reason.
- 31. In my view, the appeal on obviousness has no reasonable prospect of success and I agree with Mr. Mitcheson that paragraphs 1-4 of the draft grounds are simply an effort to re-argue the case. I think that is true of all of them, but it became ever more clear in the course of argument to me that this is a very fact-based proposed appeal. It seeks to take the odd word here and there in my judgment and subject it to a degree of scrutiny that is unrealistic and designed to conceal the fact that this is looking at all of the facts all over again.
- 32. For example, it is said that I was not entitled to find that Dr. Ulmer and Dr. Sola were inherently exceptionally cautious. I fail to understand that. I heard their evidence over an extensive time, looking at many documents and many contemporaneous publications and I think it is hopeless to try to persuade the Court of Appeal that I was not able to calibrate the degree of caution characteristic of those two scientists.
- 33. Similarly, a point is made about two particular words that Professor Dougan used, "expect" and "could". I was faced with the task of assessing his evidence as a whole, which I did, including its shortcomings, and I specifically dealt with the question of his use of the word "expect".
- 34. By way of another example, focus is placed on the fact that I used the words "reason for optimism" in paragraph 717 of my judgment. I did not attribute the very word "optimism" to either of the witnesses, as is clear from the fact that the word does not appear in quotes in that paragraph of my judgment. I was just expressing an overall view about the perspective of those witnesses having calibrated myself to the fact that they were cautious people.
- 35. Then it is said that I missed out a particular section of about half a page from Professor Sola's evidence, at 1388-1389, my having mentioned specifically pages 1389-1390 in paragraph 717 of my judgment.
- 36. I took a couple of instances in that part of my judgment, as I think is clear from the judgment itself, from Dr. Sola's evidence to illustrate support for her having thought

that there were some reasons to think that there might be success. In my view, it is hopeless to argue that there was not such support at pages 1389-1390. It may be true, I will express no opinion, that page 1388 might have been more supportive of Moderna's case, but I think it is a hopeless argument to say that the judge has to list out every single page and paragraph that might have supported the losing party's case. My task was to identify adequate material, and the primary material, that I thought supported my conclusion and I think it is evident from the judgment that that is what I did.

- 37. It is also said that I did not have in mind that, ultimately, what was important was success as a vaccine. I think that is also hopeless. The wrap-up in paragraph 732 of my judgment refers to very good prospect of an effective vaccine. All of the preceding paragraphs, including the ones that we have looked at already, were about vaccines and I therefore think there is nothing in that point.
- 38. It is unnecessary for me to comment on added matter. That might have been more promising in terms of permission to appeal, but as Mr. Waugh accepts, Moderna would have to succeed on obviousness and on added matter to overturn my judgment and since there is no chance, in my view, of succeeding on obviousness, added matter is not relevant.
- 39. The second basis for seeking permission to appeal is that there is some other compelling reason and what is relied on is the importance of the case and the large amount of money at stake; I am referred by Moderna to the decision of Arnold J (as he then was) in the *Idenix* case, where having said that he would give permission to appeal because he thought some points did have a prospect of success, he went on to say that he would have given permission for some other compelling reason, namely the importance of the case and the use being made of the judgment in other jurisdictions.
- 40. His statement about there being a compelling reason is secondary and I think, strictly speaking, probably obiter, but it does give some support for the fact that there is a possibility for a judge (sitting at first instance) to find that there is a compelling reason, based on the importance of the case and the potential use of the judgment in other jurisdictions.
- 41. I do not read Arnold J as having said that in every important case where a judgment might be used in other jurisdictions, there must necessarily be a compelling reason. If that were good enough, then permission would be given in many cases in the Patents Court where the judge was otherwise inclined to refuse it.
- 42. My attention was also drawn to the decision of Cockerill J in *Deutsche Bank*, where she gave permission to appeal on the basis of some other compelling reason, even having found that the appeal had no prospects of success, because she was confident that if she did not do so, the Court of Appeal would.
- 43. She also made the point, which I think is the significant one of principle, that normally considerations of giving permission to appeal for some other compelling reason are best left with the Court of Appeal. I think that is a valid point that simply was not on the mind of Arnold J when he dealt with *Idenix*. If I refuse permission on that ground, it would be open to Moderna to go to the Court of Appeal and ask them.

- 44. In my view, the amounts of money involved in this case are very significant, but they are not as colossal as may first appear because the time over which damages are payable is not that extensive, given the Pledge context, and this is only a decision about the UK as a jurisdiction and obviously geographically no more extensive than that. Despite the context of the pandemic being one of exceptional importance, in terms of global health and the global economy, that does not mean that this particular trial had the same degree of significance. In my view, at the end of the day, it is a fairly straightforward decision and a fairly normal decision about obviousness where I have been able to reach a clear conclusion.
- 45. It is particularly prayed in aid by Moderna that the EPO might be influenced by my judgment. It is possible that they might but they may very well also make their own decision on obviousness, given that they will have, no doubt, different evidence and different arguments, so I attach little importance to that. I am also not at all satisfied that if I refuse permission on this basis, there will not be time for the Court of Appeal to think about that and, if it were to give permission, to render its judgment in time for the EPO.
- 46. For all those reasons, I decline to give permission to appeal on the basis of some other compelling reason. I do not think there is a compelling reason but, in any event, I think it is best that those decisions be left to the Court of Appeal where possible. I do not disagree with the decision that Arnold J made in *Idenix*. As I have said already, that was no doubt justified, as he said, by there being the existence of some argument with a prospect of success. But, as I have also said, I do not think it is a decision that in every important case where there is the possibility for the use of a judgment in other jurisdictions, there is necessarily a compelling reason.
- 47. So I refuse permission to appeal on '565, but Moderna is, of course, free to ask the Court of Appeal, both on the basis of their being a reasonable prospect of success and some other compelling reason.