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Case No. HP-2022-000016

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

Rolls Building
Fetter Lane
London, EC4A 1NL
16 January 2025

Before :

MR JUSTICE MELLOR

- -

Between :

PFIZER LIMITED **Claimant**

- and –

(1) GLAXOSMITHKLINE BIOLOGICALS S.A
(a company incorporated under the laws of Belgium)
(2) ID BIOMEDICAL CORPORATION OF QUEBEC
(a company incorporated under the laws of Quebec, Canada)

Defendants

MR. TOM MOODY-STUART KC and **MS. KATHERINE MOGGRIDGE** (instructed by **Marks & Clerk Law LLP**) appeared for the **Claimant**

DR. JUSTIN TURNER KC and **MR. THOMAS LUNT** (instructed by **Gowling WLG**) appeared for the **Defendant**.

Hearing date: 13th December 2024

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APPROVED JUDGMENT

This judgment was handed down remotely by circulation to the parties' representatives by email. It will also be released for publication on the National Archives and other websites. The date and time for hand-down is deemed to be Thursday 16 January 2025 at 10.30am.

THE HON MR JUSTICE MELLOR

Mr Justice Mellor:

1. I handed down my Main Judgment in this case on 7 October 2024: [2024] EWHC 2523 (Pat). This judgment deals with the issues argued at the Form of Order hearing on 13 December 2024. The issues were familiar: costs, interim payment, confidentiality and permission to appeal. Unfortunately, a very busy last week of term prevented me from completing this judgment until early in the new year.

Costs

2. The costs incurred in this case are very significant, and there is a very significant disparity between the costs incurred on each side. Pfizer's total costs are estimated at £6.312m, whereas GSK's are estimated at £3.67m. The disparity is primarily relevant to the amount of the interim payment, but it is also capable of affecting comparisons of the costs incurred on particular issues.

3. Fortunately, the issues narrowed so the battlelines at the hearing were arranged as follows, with both sides accepting that I should made an issues-based order:

    i) Pfizer were prepared to accept an overall deduction from their costs of 15% which was made up of:

        a) On Priority/Belgian law/Novelty, a deduction of 10% of Pfizer's costs.

        b) On the Abandoned Issues, a deduction of 5% (representing both a deduction of Pfizer's costs and a reverse payment of GSK's costs).

    ii) For their part, GSK contended for an overall deduction from Pfizer's costs of 38.75%, made up as follows:

        a) On Priority/Belgian law/Novelty, a deduction of 11% of Pfizer's costs and a reverse payment equal to 11% of Pfizer's costs.

        b) On the Abandoned Issues, a deduction of 5% (agreed and stated above).

        c) On AgrEvo obviousness and insufficiency, a deduction of 11.75%.

4. So the issues for decision related to:

    i) Whether Pfizer should pay GSK's costs of the Priority/Belgian law/Novelty issues and how that should be expressed as a further % deduction of Pfizer's costs.

    ii) Whether the AgrEvo obviousness and insufficiency issues were suitably circumscribed issues and whether they should give rise to a further deduction from Pfizer's costs. On that latter point, Pfizer contended that if any deduction was to be made, 11.75% was too high and any deduction should be lower.

Applicable Principles

5. The applicable principles were not in dispute and are well-known. I was reminded of my summary of the principles in *Lifestyle Equities v Berkshire Polo Club* [2023] EWHC 2923 (Ch) at [35], where I set out the three questions commonly addressed on costs in IP actions:

> (a) Who is the overall winner? There is then the assumption that the overall costs should be awarded to the winner.
>
> (b) Are there any suitably circumscribed issues which it is appropriate in the circumstances for the winner to be deprived of their costs of?
>
> (c) Is it appropriate to go further and award the losing party their costs of that issue from the winning party?

6. I was also reminded that I had recently applied this approach in *Sandoz v Biogen* [2024] EWHC 2911 (Pat), where I also referred to and relied upon the following at [5]-[7]:

> "5. At [39], I also referred to the following summary from *Pigot v Environment Agency* [2020] Costs LR 825 at [6]:
>
> > (1) The mere fact that the successful party was not successful on every issue does not, of itself, justify an issue-based cost order…
> >
> > (2) Such an order may be appropriate if there is a discrete or distinct issue, the raising of which caused additional costs to be incurred. Such an order may also be appropriate if the overall costs were materially increased by the unreasonable raising of one or more issues on which the successful party failed.
> >
> > (3) Where there is a discrete issue which caused additional costs to be incurred, if the issue was raised reasonably, the successful party is likely to be deprived of its costs of the issue. If the issue was raised unreasonably, the successful party is likely also to be ordered to pay the costs of the issue incurred by the unsuccessful party…
> >
> > (4) Where an issue based costs order is appropriate, the court should attempt to reflect it by ordering payment of a proportion of the receiving party's costs if that is practicable.
> >
> > (5) An issue based costs order should reflect the extent to which the costs were increased by the raising of the issue; costs which would have been incurred even if the

> issue had not been raised should be paid by the unsuccessful party.
>
> (6) Before making an issue-based costs order, it is important to stand back and ask whether, applying the principles set out in CPR r.44.2, it is in all the circumstances of the case the right result. The aim must always be to make an order that reflects the overall justice of the case.

6. Both sides reminded me of this passage from the judgment of as Birss J (as he then was) in *Unwired Planet v Huawei* [2016] EWHC 410 (Pat) at [5], on what amounts to a '*suitably circumscribed issue'*:

> "One issue is: what is a suitably circumscribed issue? Or in other words, at what level of generality or granularity is that matter to be decided? Plainly it will vary from case to case. Often in patent cases one kind of suitably circumscribed issue and appropriate level of granularity is taking things at the level of individual cited items of prior art, but that is not a hard and fast rule. It is possible for a suitably circumscribed issue to arise within a broader category. An example of this was the Court of Appeal in ConvaTec Technologies Inc v Smith & Nephew plc [2015] EWCA 803 (Civ). Here, instead of dealing with the costs at the level of the issue of infringement as a whole, the court made a special order relating to experiments which formed part of the infringement case."

7. Finally, Biogen drew attention to the wise words of Henry Carr J in *Hospira v Cubist* [2016] EWHC 2661 (Pat) on the meaning of the phrase 'suitably exceptional' which was used in some earlier formulations of the third question i.e. when it might be appropriate to award costs to be paid by the successful party. Henry Carr J explained:

> "'In my view, this apparent dichotomy may be resolved by a proper understanding of the phrase "suitably exceptional". It is intended to indicate that if the unsuccessful party succeeds on a particular issue, that is not, on its own, sufficient to award costs against the successful party. There must be something which makes it appropriate and just to order not only that the successful party does not recover his costs, but also that it should pay the costs of the relevant issue. On the other hand, it is not intended to imply that such awards of costs will be extremely rare. Where there is a discrete issue, which required substantial expenditure of costs, it may be just in all the circumstances to order payment of costs.'

7. I propose to apply these well-known principles.

Application to the facts

8. On the first question, unsurprisingly the parties were agreed that Pfizer was plainly the overall winner. The outstanding points arise under the third and second questions.

The Priority/Belgian law/Novelty issues

9. On the Priority/Belgian law/Novelty issues, I have no doubt that GSK should not have to bear their costs and that a further deduction from Pfizer's costs is appropriate. As is apparent from my Main Judgment, these issues were entirely separate. I addressed the Priority/Belgian Law issues from [554]-[598] and Novelty from [599]-[628]. GSK characterised the challenge to priority as the worst type of technical point – technical in the sense of without merit and plainly wrong. I am inclined to agree.

10. The remaining issue concerns the appropriate % deduction.

11. Despite the overall disparity in overall costs, on the Priority/Belgian law/Novelty issues, the costs estimated on each side were similar.

12. Pfizer's estimated total costs of these issues were £588k, or approximately 9.3% of their costs, which Mr Gilbert was prepared to round up to 10%. There was a debate whether those estimates included novelty or whether, as GSK contended, an additional 1% was to be added to cover novelty.

13. On GSK's side, Mr Inman's evidence was to the effect that GSK's costs can be ascertained with reasonable accuracy because a separate team worked on Priority and Belgian law. His estimate of GSK's total costs on these issues was £687,267, albeit it involved an estimate of counsel's fees based on a pro rata estimate of the total time spent on the issue which may have been a little high. That figure amounted to 18.7% of GSK's costs or 11% of Pfizer's costs.

14. Applying a suitably broad brush, I consider that the appropriate overall % deduction to Pfizer's costs is 20%.

AgrEvo, Insufficiency & Plausibility

15. The points which were run under this heading require some unpacking. To do that, I reminded myself of the way they were run in the Skeleton Arguments and the expert evidence (to the extent they were addressed at all).

16. AgrEvo and a part of the insufficiency arguments were run as a squeeze on 'stabilizes' and to 'keep GSK honest' on that point. Pfizer submitted that the squeeze did its job and also pointed out that even when arguing on permission to appeal, there were signs that GSK were attempting to resile on the meaning of 'stabilizes'.

17. However, Pfizer ran other discrete and standalone insufficiency/plausibility arguments – in particular the adjuvant point which I decided against Pfizer at [831], and the inability to tell whether an antigen was 'stabilized' within the meaning of the claim, which I rejected at [814].

18. Pfizer's primary position was that these issues were not suitably circumscribed, a point they say is confirmed by the fact that neither side was able to identify or separate out their costs under this heading. Pfizer say these issues are very difficult to separate out from the construction issue on 'stabilizes' or obviousness more generally, which, they say, is why their squeeze arguments did their job and contributed to their overall success at trial.

19. For GSK, Mr Inman initially estimated the costs relating to these issues incurred by GSK based on a paragraph counting exercise conducted on GSK's opening and closing skeletons as an average of approximately 12%. A similar analysis of Pfizer's opening and closing skeletons gave an average of 9.8% of Pfizer's costs. These figures led him to propose a deduction of 10% under this head.

20. In his reply statement, Mr Gilbert set out the results of an 'inclusive' paragraph counting exercise under this head from (a) the Judgment – 5.8%, (b) Pfizer's Skeletons – 11.75% and (c) GSK's Skeletons – 13.97%. Somewhat opportunistically, GSK then adopted the 11.75% figure, as set out in 3.ii)c) above.

21. Having considered the significance of these arguments and their likely costs burden, I concluded that the paragraph counting exercises based on the skeletons yielded figures which were too high. Furthermore, I do not believe that Pfizer should be deprived of all their costs of these issues, because I agree that some of them did successfully act as a squeeze on 'stabilizes' with relatively little cost consequence.

22. On the other hand, Pfizer did run issues under this head on which they lost which were not squeezes. In all the circumstances, I conclude that a further deduction of 5% of Pfizer's costs is appropriate.

23. Accordingly, the total deductions from Pfizer's overall costs amount to 30%. Standing back and considering the whole of this complex case in the round, this seems to be an appropriate level of deduction.

24. So the order for costs I make is that GSK must pay 70% of Pfizer's costs to be the subject of detailed assessment if not agreed.

Interim Payment

25. Pfizer's position was that they should be awarded an interim payment of 70% of their costs. By contrast, GSK argued that it was highly likely that Pfizer's costs would be assessed down heavily on any assessment. GSK proposed that the interim payment should be £1.863m. This appeared to be derived as follows:

    i) First, Pfizer's solicitors costs should be no more than GSK's, which meant that Pfizer's total costs should be treated as £4.346m.

    ii) Second, that GSK's suggested deduction of 38.75% should be applied to that figure, yielding £2.662m.

    iii) Third, 70% of that figure yields £1.863m.

26. The first step appeared to me to be arbitrary and unprincipled, since it involved a reduction of £2.37m in Pfizer's costs. As I understand matters, GSK's argument translates into a % interim payment of around 43% of GSK's (already reduced) starting point for Pfizer's costs or just under 30% of Pfizer's overall costs total.

27. I reject GSK's argument, although I do consider it is necessary to take account of the large disparity in the total costs incurred on each side. I propose to reflect that point by ordering the interim payment at 60% of Pfizer's costs entitlement.

28. So the interim payment is 60% of 70% of £6.312m, which I round to £2.65m. Since the holiday period has now passed, this sum must be paid within 14 days.

Confidentiality

29. As is often the case in trials of this nature, the alleged infringer (i.e. Pfizer) was obliged to disclose technical and commercially sensitive information to enable the claim to be tried. At the start of the trial I made the usual *pro tem* CPR31.22 Order to protect the information which Pfizer alleged to be confidential. Pfizer now seeks to make that Order permanent. GSK does not oppose.

30. The approach I have to apply was not in dispute – see the approach taken by the Court of Appeal in *Lilly Icos v Pfizer* [2002] 1 All E R 842.

31. Mr Gilbert addressed the relevant points in his sixth witness statement and produced, in an exhibit, a list of all documents which Pfizer contend should retain their confidential status. I am satisfied that those documents or parts should remain confidential and his list forms part of the Order I propose to make in this regard.

Permission to Appeal

32. In support of their application for permission to appeal, GSK filed draft Grounds of Appeal, comprising some 32 grounds extending over 7 pages, accompanied by a detailed Skeleton Argument of 70 paragraphs: in my view, a rather scatter-gun approach. The main points were developed in oral argument and these related to (i) the Skilled Team, (ii) their CGK, (iii) construction of 'polypeptide' and infringement of EP710 by equivalence and (iv) obviousness.

33. It is undoubtedly the case that my finding as to the composition of the Skilled Team underpinned the whole of the rest of the judgment, such that, if I erred on that issue, the whole Judgment would be undermined. However, even if I was correct as to composition of the Skilled Team, GSK still contended they could succeed on appeal.

34. In a similar way, my finding that the hotly disputed point D was CGK would, if it is wrong, undermine all my findings of obviousness.

35. As Pfizer pointed out, a number of the 'grounds' amounted to a contention that I should have dealt expressly in my judgment with certain points, yet on receipt of the draft Judgment, GSK did not make any request that I should deal explicitly

with those points, the following being by way of example: (a) the notes made of Dr Jardetsky's slide presentation and (b) my Arrow reasoning.

36. Furthermore, although a number of the grounds are expressed in terms that I was 'not entitled' to make the finding or conclusion in question, or that there was no basis for it, upon examination these appear to be quarrels with my assessment of the evidence.

37. Nonetheless, there are certain points raised by GSK in their application for permission to appeal which I believe I should address, not least in order to assist if, as seems likely, this goes further.

38. Although GSK addressed the CGK point first, it is logical to consider their criticisms in the following order.

Skilled Team.

39. Dr Turner submitted that the approach I took to identifying the relevant Skilled Team as set out in [51] was incorrect, even though I reached the same conclusion by addressing the *Illumina* questions at [57]-[69].

40. The point stressed in argument was that Yin was 'not a vaccinology paper and was not addressed to a vaccinologist'. That seems to me to be beside the point, for the reasons I explained in [51].

41. I do not believe the criticisms of my identification of the Skilled Team disclose a point which has a real prospect of success on appeal. My reasoning at [51] cannot be read in isolation, since, in one sense, it anticipated and relied on what I found later as to the composition of real teams in this area, when a structural issue was identified.

42. GSK also submit that there was an inconsistency between [66(ii)] and [224]. However, what I found in [224] was that Dr Taylor's experienced technician might well be able to follow the (quite detailed) instructions in [0018] of the Patent, but I went on to refer to the structural expertise necessary to assess how modifications of those types or combinations of them would be likely to affect the structure of the protein – i.e. expertise of the structural biology specialist and not of the experienced technician. This is important in the context of the Patent which (as I said in [784(ii)]) claims a seemingly minimal degree of stabilisation. In practice, a greater degree of stabilisation was required for a useful immunogen and vaccine, something which only the structural biology specialist member of the team would be able to design and assess. As I said in [337], 'the Skilled Team requires a person with the expertise to understand, model and if appropriate, exploit these structural differences' [illustrated in the Yin papers].

43. Furthermore, so far as implementation of the Patents is concerned, bearing in mind (a) the significance of the protein structures in the Patent and (b) the availability of people with structural expertise, I found it odd that Dr Taylor's Skilled Vaccinologist would not call such a person into the team.

44. The final point GSK made was that I erred in finding a structural specialist would be included because '*structural matters affect[ed] the antigen'* in [65], on the basis that was something the Patent disclosed for the first time. This point bleeds into GSK's criticisms of my findings on the disputed CGK, to which I now turn.

CGK

45. As indicated earlier, GSK's principal argument was that my conclusions on the disputed CGK, and point D in particular, were wrong. GSK contended I was not entitled to find point D (and related propositions) formed part of the CGK, submitting first, that there was no documentary evidence which was capable of supporting my findings, and second, that in so far as I made reference to documents, I misinterpreted their technical contents.

46. GSK's criticisms focussed on [381] of my Judgment, but it should be kept in mind that I had already discussed a number of aspects of Dr Taylor's evidence which went to CGK and demonstrated that persons in this field were interested in developing compounds capable of binding to the F protein so as to prevent or inhibit fusion – see [325], [330], the 'central passage' underlined in the quote in [359] and Dr Taylor's acceptance in the passage quoted in [360].

47. With those passages in mind, the references I set out in [381] provided additional support. However, GSK's criticised each of the citations I set out in [381] and I should explain them in a little more detail.

48. Before doing so, I keep two points in mind:

    i) First, that Point D combines and rests on some important foundations: (i) Dr Johnson's basic principle, as explained in further detail below; (ii) the CGK understanding that, at the priority date, the RSV F protein existed in a metastable prefusion conformation and a thermodynamically stable postfusion conformation and (iii) the RSV F protein found on the virion is considered to be in the prefusion conformation (see [390]).

    ii) Second, it is worth recording that it became apparent from Dr Turner's cross-examination and submissions that when he referred to the need for documentary evidence of these disputed CGK points, he was looking for the disputed points to be spelled out explicitly (i.e. in the terms expressed in Dr Johnson's evidence) in a document or documents. Whilst it is frequently the case that points which form part of the CGK are spelt out in documents, especially textbooks, this is not a universal requirement. There may be pieces of CGK which are well understood but are not explicitly stated in textbooks, often because they are basic and go without saying amongst those in the art.

49. The 'basic principle' I referred to in the first part of [381] derived in part from the 'principle' Dr Johnson mentioned in Point D itself, as supplemented in her Third Report, and in part from the answers she gave in cross-examination set out below. As she said in her Third Report: [in effect, Point D] 'was based on the principle that antibodies that bound to the prefusion form would prevent transition to the postfusion state and block fusion of the membranes, thereby blocking virus

infection.' Dr Johnson went on to refer to Professor Weissenhorn's evidence that 'this principle would also have been part of the CGK of the structural biologist'. As for her answers in cross-examination, I had in mind:

i) First, '..the general principle of fusion inhibiting antibodies and neutralising that form and the effectiveness of that response.' [T3/428$_{2\text{-}4}$]. Page 428 was also where Dr Johnson referred to other textbooks which would also discuss that 'basic principle', the titles of which were not correctly transcribed: the first of which was likely to be by Abbas (see Johnson 1, [53v]) and the second of which was Paul's 'Fundamental Immunology (Johnson 1, [53iv]), even though extracts from these were not produced.

ii) Second, at [T3/p438$_{6\text{-}11}$] '…and again a basic understanding of immunology, not RSV F specific, but just an antibody function for fusion proteins. If you do not have that prefusion, even if the epitope is expressed on both, if you do not have that ability to bind to the prefusion form, that means fusion is going to occur and you lose your protection.'

50. The passage I cited at [381(i)] is part of a longer extract from Fields Ch 41 which I summarised in [351]-[358] in the context of Dr Taylor's 'corrections'. This passage demonstrates that the differences between the prefusion and postfusion forms of the PIV5 F protein were being discussed and, as Dr Taylor accepted in the passage of cross examination cited in [357], the change in structure observed in PIV was likely to be reproduced in RSV F.

51. Furthermore, Dr Johnson cited this very passage in her Third Report at [58] in support of her evidence that the natural, mature or native form of RSV F was generally understood to be to the metastable prefusion conformation, a point I accepted at [380].

52. Although Dr Turner attacked this citation on the basis that it did not 'concern neutralising antibodies, or teach that the prefusion conformation was a target for neutralising antibodies', it was, as I stated in argument, one of the foundations for Point D.

53. Dr Turner made a particular attack on the passage I cited in [381(ii)]. However, it is important to be clear that I cited the *summary* of Sakurai 1999 expressed in Cane. Both in cross-examination and in his submissions, Dr Turner was keen to demonstrate that the Sakurai paper itself was not capable of supporting Points A, B or D since it described a theory that there are two forms of F protein – mature and immature forms. He submitted that the paper postulates that the immature forms of the F protein are released from infected cells to act as decoy antigens so that the immune response is directed away from the F protein – rather like chaff deployed by an aircraft. It is said I overlooked the teaching of the Sakurai paper itself. However, no-one ever suggested the Sakurai paper was CGK and I referred only to the *summary*, as expressed in Cane. In the context of the CGK understanding by the Priority Date of 'mature' and 'native' forms of the RSV F protein, my point was that this *summary* suggested to the Skilled Team the notion of highly neutralising antibodies recognising the mature i.e. prefusion form.

54. Whilst this may have been a misreading of what would be understood by the Skilled Team if they read the Sakurai paper itself, nonetheless Dr Taylor's evidence in cross-examination confirmed that this *summary* would have been known [T5/p794$_{18}$-795$_{2}$] and, slightly later at [T5/p797$_{19}$-798$_{6}$], that 'someone considering this at the priority date would think that the native form they were referring to here was in the prefusion conformation' (emphasis added). These were not passages which she sought to correct.

55. As to my third citation in [381(iii)], Dr Turner was keen to emphasise it was from a general chapter in Fields, not specifically on RSV – a point I was well aware of – but, more importantly, he submitted:

    i) The reference to the 'native' protein was not a reference to the prefusion conformation of the F antigen.

    ii) Instead he submitted the authors were drawing a distinction between inactivated virus particles in which the F protein will be denatured (i.e. non-native), on the one hand, and non-denatured protein on the other (i.e. native) and that, therefore the authors were not purporting to distinguish between the pre- and post-fusion conformations.

    iii) The reference was incapable of supporting Points A, B or D.

56. However, I read the extract from Fields differently in that each sentence deals with a different topic. As for the second sentence, those in the field were well aware of the disadvantage or possible danger of denatured F proteins from the formalin-inactivated RSV vaccine (in the CGK section at [172]-[176]). However, other than adverting to the difficulties created by denaturing in the second sentence, in my view, the first and third sentences are not concerned with denatured proteins at all. In the context of [381(iii)], [382] and [380], it is clear that I took the reference to 'native' protein in the third sentence to refer to the prefusion form. So Dr Turner's challenge involves a challenge to my finding of fact which I do not believe has any prospect of success.

57. Although Dr Turner's Skeleton Argument went on to submit that I failed to address Dr Taylor's evidence where she did not agree that points A, B and D were CGK, this submission seems to ignore all the concessions extracted from Dr Taylor in cross-examination. Reading my judgment as whole, it is clear I rejected this evidence from Dr Taylor.

58. I will briefly mention some other criticisms of my findings as to CGK.

59. First, my findings at [389]-[392]. The criticism appears to rest on the distinction between (a) whether RSV vaccinologists knew of the existence of the different conformations of the RSV F protein and (b) whether RSV vaccinologists were considering the different conformations in their approach to vaccine design. GSK submit that in this section I found the former but not the latter, but this argument ignores the significance of the 'basic principle' mentioned earlier.

60. Second, it is said I was 'not entitled' to find that the Skilled Team would, as a matter of CGK have regard to other viruses for the purposes of informing their

approach to vaccine design. This submission flies in the face of Dr Johnson's evidence (to which I referred at [393]) and Fields (see [396] et seq.)

61. For all these reasons, I do not consider GSK has a real prospect of success in their challenge to my CGK findings.

Construction – 'polypeptide'

62. GSK's first point was that I failed to construe the claims in the light of the specification. This argument rests on the notion that the specification contemplates embodiments in which amino acid sequences are linked by disulphide bonds, and these embodiments are described in the Patent as 'polypeptides'. However, as I found at [491], GSK's argument confuses what the Patents disclose with what they claim. I recognised the possible conflict, but concluded the claims are much more limited than the disclosure.

63. Overall, I concluded that the Patents own internal dictionary definition of 'polypeptide' in [0043] applied. GSK's second point was that I failed to appreciate that the definition 'does not require that monomers be joined only through amide bonds'. I find this a rather bizarre argument. The definition adopted the standard and accepted meaning of 'polypeptide'. If the patentee had intended to broaden the meaning beyond its standard meaning, in my view, it would have made this clear and would have had to make that clear.

Infringement by equivalence

64. GSK's first criticism concerned the relevant inventive concept which I adopted, but GSK's inventive concept ('the use of an RSV antigen, in which the prefusion conformation of the F protein is stabilised, as an immunogen') is plainly expressed at too high a level of generalisation since it omits any mention of particular features of the relevant claims, namely:

    i) for EP710, the structural features of (a) no furin cleavage site but (b) the inclusion of a trimerization domain on the C-terminal of the F_1 domain.

    ii) for EP258, the inclusion of a trimerization domain on the C-terminal of the F_1 domain that stabilizes the prefusion conformation.

65. GSK's second criticism was that I failed to apply properly the first *Actavis* question, but that criticism only applies, as I understand matters, on the basis of GSK's construction of polypeptide. Furthermore, this criticism does not engage with the finding I made that the 'way' was different because the degree of stabilisation achieved in Pfizer's RSVPreF was materially different, notwithstanding the presence of a trimerization domain.

66. GSK's third criticism is that, on Actavis question 3 on EP710, the structural features in the claim were insufficient to support my conclusion. This appears to be a somewhat indirect challenge to the findings I made on question 1, in [551]. The criticism is somewhat bizarre, bearing in mind the invention and the claim are all about and founded upon the particular structural features set out in the claim.

Inventive Step

67. GSK's first point is a criticism of my findings as to the way in which GSK's expert evidence was prepared. There is nothing in this, or the next few points (PIV vs RSV).

68. GSK's main point appears to be that it was necessary to take their posited 6 steps to arrive at the invention. Although, as GSK submit, I dismissed them as directed at a case of obviousness over the CGK (at [664]), nonetheless I addressed each of their 6 steps at [666]-[668] and [794]-[799], which are not addressed in GSK's grounds. Other points are repeats of their challenges to my CGK findings.

69. GSK's other points concern alleged misidentification of the differences between the cited art and the relevant claims of EP710, but all these appear to be trivial.

Secondary Evidence

70. GSK's Skeleton Argument contained a number of paragraphs on my analysis of the secondary evidence, but all of these seemed to quarrel with my weighing and assessment of the evidence, without revealing any error of principle.

Dr Taylor's evidence

71. Again, these points appear to be either quarrels with my assessment of the evidence or (re Calder) inaccurate. I expressly addressed Dr Taylor's reliance on Calder in making her corrections at [362] and the point I made there was that Dr Taylor appeared to be taking the unrealistic view that nothing of any materiality had happened between Calder in 2000 and the priority date in 2007.

Arrow

72. GSK's challenge concerned [840]-[843] where I considered whether the declaration would serve a useful purpose.

73. Their first allegation is that I failed to direct myself by reference to the dictum of Arnold J (as he then was) in *Generics v Yeda* [2017] EWHC 2629 (Pat) at [207]. However, it is clear that I had that very point in mind in [841] from the language I used.

74. The second allegation concerns my 'nebulous' reference to 'a number of concerns' raised by Mr Gilbert with the allegation that I made no explanation, assessment or clear acceptance or rejection of his concerns.

75. In this regard, it is relevant to note that although Mr Gilbert was cross-examined, his cross-examination related exclusively to Professor Jardetsky's evidence. He was not challenged at all on his evidence going to useful purpose. GSK did not address the topic of Arrow relief at all in their Closing Skeleton Argument. Their oral closing contained one sentence, referring me to page 63 of GSK's Opening, essentially the *Generics v Yeda* point.

76. In context, I consider it is clear that I was accepting Mr Gilbert's concerns (not least because they had not been challenged) and I considered them sufficient to

justify the Arrow relief I granted. In any event, in [842] I made reference to four particular concerns. I did not think it was necessary further to lengthen an already long judgment, nor did GSK request further explanation when they received the draft Judgment (some 10 days before it was handed down).

Overall conclusion

77. It will be apparent that for GSK to succeed on appeal on any one of infringement, validity or the Arrow relief, they would have to overcome a number of obstacles, including the rather fundamental obstacles relating to the Skilled Team and the CGK. Stepping back, I do not consider GSK have a real prospect of success on appeal, so I refuse permission to appeal.