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Claim no. LM-2019-000185

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
LONDON CIRCUIT COMMERCIAL COURT (KBD)

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

Date: 9 January 2024

Before:

MR ANDREW HOCHHAUSER KC

Sitting as a Deputy Judge of the High Court

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Between :

SciPharm S.a.r.l	**Claimant**
- and -	
Moorfields Eye Hospital NHS Foundation Trust	**Defendant**

- -

Mr Ali Reza Sinai (instructed by **BBS Law incorporating OGR Stock Denton LLP**) for the **Claimant**
Dr Andrew Lomas (instructed by **Clifford Chance LLP**) for the **Defendant**
Hearing dates: 27 and 28 April 2023

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Approved Judgment

I direct that pursuant to CPR PD 29A para 6.1 no official shorthand note shall be taken of this Judgement and that copies of this version as handed down may be treated as authentic.

This judgment was handed down by the judge remotely by circulation to the parties' representatives by email and release to Bailii. The date and time for hand-down is deemed to be 9 January 2024 at 12 noon.

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Mr Andrew Hochhauser KC:

Introduction

1. In a judgment handed down on 16 March 2023 (the "**First Judgment**"), I found that the Defendant was in breach of a pharmaceutical drug development agreement made on 20 December 2011 (the "**DA**"). I will use the same abbreviations in this judgment as appear in the First Judgment. I do not intend to set out here the background and history of this matter which is fully detailed in that judgment.

2. Suffice it to say that in the First Judgment I made the following findings:

   (1) the Defendant's obligation under the DA was not limited to a fill and finish function but required it to manufacture validation batches to be used as part of the Claimant's MAA [§102];

   (2) the Defendant did not complete the Development. In the absence of a continuing GMP licence, the Defendant did not complete the stability testing it was required to do. Due to the cessation of manufacturing, it did not complete all the batches, and further it was unable to complete the work required by the demands of the CTD [§116];

   (3) there was work outstanding pursuant to the Day 70 Report and the responses to many of the questions posed therein, which the Defendant was unable to carry out, notwithstanding their obligations under clauses 4.1 and 4.5 of the DA, not least because it had decided to close its facility, rather than seek to comply with GMP and reinstate its manufacturing licence [§120];

   (4) the Defendant's validation batches and data were, to the knowledge of the Defendant, used in the MAA as part of the Module 3 submission. That formed part of its obligations under clauses 4.1, 4.4 and 4.5 of the DA. Once, however, the Defendant's activities were suspended for breaches of GMP, they could not be used in the market authorisation process. In the Day 70 Report, AGES stated that the MHRA's statement of the Defendant's non-compliance with GMP was "*considered as a major objection*". Further work had to be done, which the Defendant was unable to carry out, and it could not make the changes which AGES required. These were breaches of the DA [§124];

   (5) the Module 3 dossier was prepared by the Defendant pursuant to its obligations under the DA and the additional work agreed on 11 March 2013, referred to at paragraph 33 of the First Judgment. It was capable of being used and was used in the MAA, but once the Defendant suspended manufacturing in December 2013 and

was unable to carry out aseptic filling and sterile terminalisation in accordance with GMP, their validation process and data could no longer be used. As stated at paragraph 124 of the First Judgment, further work had to be done, which the Defendant was unable to carry out, and it could not make the changes which AGES required. These were breaches of the DA, because the Defendant decided to close its manufacturing facility, rather than to comply with GMP and seek to reinstate its manufacturing licence [§132];

(6) in breach of the DA, the Defendant failed to complete the stability testing making it necessary for the Claimant to instruct Recipharm to complete the stability testing. This was a decision imposed upon them by the Defendant's inability to carry out such work [§140];

(7) it was necessary for the Claimant to purchase replacement API in order to submit new validation batches for the MAA, because the Defendant had lost its GMP licence [§143].

3. In the light of finding in the Claimant's favour on liability, it is therefore necessary to consider quantum. Once again, the Claimant was represented by Mr Ali Reza Sinai of Counsel and the Defendant was represented by Dr Andrew Lomas of Counsel. I am grateful to them for their helpful, detailed written and oral submissions.

4. Under paragraph 55 of the Amended Particulars of Claim, the Claimant claims the sum of €1,794,932. The loss is pleaded under five separate headings:

(A) Production and Validation

(i)	Technical transfer from Moorfields:	€66,645
(ii)	Cost of replacement API:	€1,162,786
(iii)	Testing of API:	€21,178
(iv)	Credit for API larger batch sizes:	-€354,104
(v)	Production and documentation:	€453,515
(vi)	Validation:	€82,800
Sub Total: Production and Validation:		€1,432,820

(B) Stability Study and Module 3

(i)	Stability Study:	€68,600
(ii)	Preparation of Module 3:	€12,000
Sub Total: Stability Study and Module 3:		€80,600

(C) Finalisation Stability Study

(i)	Stability Study Finalisation:	€22,500
(ii)	Delivery of samples to Recipharm:	€6,501
Sub Total: Finalisation Stability Study:		€29,001

(D) Emergency Drug Batch

(i)	Production Emergency Batch:	€59,056
(ii)	Cost for analysis and release:	€2,048
(iii)	Auditing Recipharm:	€5,515
(iv)	Transfer costs API and Batch:	€7,965
(v)	Credit for standard production costs (that Moorfields would have charged):	-€6,873
Sub Total: Emergency Drug Batch:		€67,711

(E) Claimant's Additional Expenses

(a)	Generic Submission	
	(i) Evaluation of CMO's/Tech Transfer/ Supervising/Production set up:	€134,400
	(ii) Prolongation of clock stop/Development and Module 3/Re-submission:	€28,800
(b)	Clinical Study	
	(i) Negotiations for continuing use of Clinical Trial Material from Moorfields:	€9,600
	(ii) Patients' safety; vial substitution/ relabelling/discontinuation of recruitment:	€12,000
Sub Total: Additional Expenses		€184,800
Total loss:		**€1,794,932**

5. These figures are supported by an amended Schedule of Loss which contains a breakdown of the amounts claimed by reference to specific invoices and working hours. In relation to the figure of €1,162,786, relating to the cost of replacement API claimed (see §145(A)(ii) of the First Judgment), there is additionally an Annex A, which contains a further breakdown of the relevant invoices, which were charged in US dollars, showing the US$/€ conversion rate at the material date. Ms Tan at paragraph 34 of her witness statement dated 22 February 2021, as amended, stated that there had been an error in Annex A and amended the figure claimed for wasted API, which had been over-calculated by 3.7g in relation to full sample testing. This resulted in a reduction of €18,087.73.

6. In my First Judgment I set out the principles on which the quantum should be calculated. At §172 of the First Judgment I found that the Claimant was entitled to be compensated for the loss that is directly attributed to the Defendant's failure or inability to complete its obligations under the DA. At the time the DA was entered into it was envisaged that the Defendant would be the manufacturer and the steps that had to be taken by the Defendant included performing the Development of Product and co-operating with the

Claimant to achieve marketing authorisation for the Product. The fact that both parties were taking a commercial risk in not having a Supply Agreement in place, does not prevent recovery of the costs incurred by the Claimant in being able to ensure the fulfilment of the Defendant's obligations under the DA by a third party, giving it the benefit of the bargain entered into. The losses incurred by the Claimant included the production of the emergency batches[1].

7. At §175 of the First Judgment, however, I accepted the Defendant's submission that in the absence of any obligation upon the Claimant to reimburse CompLex, a company which was at the material time not part of its group, or the employers of Ms Tan and Ms Schuller, for the work claimed as additional expenses under paragraph 55(E) of the Amended Particulars of Claim, the Claimant has suffered no loss and therefore is not entitled to recover anything in this regard. Similarly, the Claimant is not entitled to recover the costs of the Chirogate invoices paid by CompLex relating to the replacement API, as claimed in paragraph 55(A)(ii) of the Amended Particulars of Claim. This reduces the Claimant's claim by some €993,482 (once credit is given for larger batch sizes). The Claimant has since been refused permission to appeal my finding that those expenses paid by CompLex are irrecoverable.[2]

8. I invited the parties to make further submissions on the balance of the Claimant's claim, particularly since a number of the points made by the Defendant, set out at §157 of the First Judgment, had not been addressed by the Claimant.

9. I confess that I had not anticipated the ferocity of the dispute in relation to the balance of the Claimant's claim, which has been reduced by more than 50%. Despite the filing of post-judgment skeletons, the time set aside to deal with permission to appeal and quantum was insufficient, and it was clear that the parties wished to make further submissions. The Claimant also wished to adduce in evidence the second witness statement of Bianca Tan dated 28 April 2023 and its exhibit ("**Tan 2**"), correcting some of the figures and cross-references to invoices and on the same day the Claimant produced further amendments to the Schedule of Loss.

[1] See §174 of the First Judgment.
[2] I should add, however, that the Defendant has been granted permission to appeal my finding as to liability on the grounds of my interpretation of the DA. That appeal is pending.

10. As a result, on 28 April 2023, I made an Order which, amongst other things:
    (1) permitted the Claimant to rely upon Tan 2 and its exhibit, subject to bearing the costs thereof and paying the Defendant's costs of that part of the hearing dealing with the application to adduce it in evidence;
    (2) required the Defendant by 4pm on 9 May 2023 to set out its case by reference to the points made in its skeleton argument in tabular form, item by item, in relation to each of the contested items claimed in the Claimant's schedule contained in its "Outline Response and Working Table" served on 26 April 2023 from p9 entitled "Outline Testing" to the end of that document;
    (3) permitted the Claimant by 4pm on 16 May 2023 further to respond in a further section to its schedule to the points contained in the Defendant's response.
11. In the event, as well as the documentation referred to in the Order above, I received some supplementary submissions from the Defendant and correspondence from the parties. Helpfully, the Consolidated Schedule of Loss (the "**Consolidated Schedule**") lists 50 items and summarises the parties' position in relation to each of them, referring to the relevant documents. I have carefully considered all the material before me and make the following findings in relation to the items of loss now claimed by the Claimant.

My findings on quantum

12. After deducting the sums paid by CompLex, and before turning to the further recalculations and concessions made by the Claimant, on the basis of the Amended Schedule of Loss, the maximum sum recoverable by the Claimant is €801,450.
13. In the Consolidated Schedule which has been completed by both parties, at the outset the Defendant has made a number of "large points" at letters [B] [C] and [E] to [G][3]. I will consider each of these first, before turning to the individual items, which I will address in the light of my findings on the former.

[3] Point [D] relates to an individual item which I will consider when addressing those.

[B] The Defendant submits that the Claimant no longer claims €196,000 relating to invoice 6600236.

14. These appear within A(v) of paragraph 55 of the Amended Particulars of Claim under the heading "Production and documentation", which has a total of €453,515. Dr Lomas submits that Tan 2 does not cure the Claimant's change of position, nor does it address the points made at paragraphs 3-8 of the Defendant's Riposte dated 28 April 2023. It is the fifth iteration of the Claimant's case on quantum. The Defendant has not had the chance to cross-examine Ms Tan on the revised figures. The sum of €196,000 should therefore be deducted and the total amount remaining is therefore €605,450.

15. The Claimant's response to this is Tan 2 has now been admitted in evidence. At paragraph 5, she explains the errors in calculation and in some of the cross-references. The corrected extract of the Amended Schedule of Loss exhibited to Tan 2 refers to the correct invoices and that in fact increases the claim by €11,667. However, the Claimant is not seeking that additional sum but limits itself to the original claim of €453,515 for "Production and documentation." The invoices now relied upon have always been in the bundles. The Defendant has already cross-examined Ms Tan on her credibility, diligence, and the reliability of her invoice selection, including one of the invoices which was wrongly cross-referenced. There is no better evidence than the primary loss documents, such as invoices and the quotation agreeing liability for those costs, which are contemporaneous and produced by an independent third party. The invoices have the added benefit of containing a detailed narrative from Recipharm, explaining the basis of the charge and cross-referring to the paragraph number of its agreement with the Claimant.

Discussion and conclusion on [B]

16. At §7 of the First Judgment, when addressing the evidence of each of the witnesses, I stated:

> *"I formed the view that each of the witnesses was truthful, and was doing their best to assist the court, although as I indicate later, I found that the quantum claims to be over-inflated. As Dr Lomas fairly stated at paragraph 13 of his written closing submissions: "No criticism of their honesty is made. They answered questions fairly, and generally avoided adopting the role of advocate for the Claimant". It must be remembered however, the events in question took place many years ago and furthermore much of the evidence related to events after the DA had been entered into and was of no assistance to its construction."*

At §8 therein, I also referred to the well-known dicta of Leggatt J (as he then was) in the *Gestmin* case and in particular the passage at [22] of his judgment where he said the best approach was to *"base factual findings on inferences drawn from the documentary evidence and known probable facts*…"

I am not convinced that Dr Lomas has been materially prejudiced in not being able to cross-examine Ms Tan further. He has made extensive submissions on the material documents. Having been through the documents in the corrected Amended Schedule of Loss, I am not prepared simply to dismiss €196,000 of the Claimant's claim because there were errors which have now been recognised and corrected. Whilst it is true that no reliance is now placed on the earlier invoice 6600236, that is only part of the picture and instead there are other invoices and documents that are relied upon. I was taken through these by Mr Sinai on behalf of the Claimant, by reference to Tan 2 and its exhibit[4]. I am satisfied on the balance of probabilities that there is now evidence before the Court which justifies the sum of €196,000 claimed under the Production and documentation section in (A)(v) of the Amended Schedule of Loss.

[C] There are no invoices for €96,167 in relation to part of the claim for Production and documentation

17. I am concerned that in relation to items 23, 30 and 31 of the Consolidated Schedule, there are no invoices or any proof of payment by the Claimant of the sums claimed. Items 23 and 30 are referred to at paragraph 5(iv) and (vi) respectively of Tan 2. In those sub-paragraphs reliance is placed on other documents, in particular paragraph 3.4 of Recipharm Quotation 147201-A dated 2 April 2015 (the "**Quotation**"), and the Validation Report signed by both the Claimant and Recipharm on various dates in November 2016 (the "**Validation Report**"), which confirms that all 12 validation batches were manufactured. Mr Sinai deals with the absence of invoices in paragraphs 32-35 of his submissions entitled "Claimant's Response to Defendant's Submissions [B], [C], [E] & [F]." He relies on the fact that there was a detailed costing agreement between the Claimant and Recipharm and there is no reason to believe either that Recipharm would carry out the work for no payment, and no evidence that the Claimant has refused to pay the agreed costs. In my judgment that does not go far enough and in the absence

[4] Day 2, 28 April 2023 pp2-21.

of an invoice or proof of payment by the Claimant, I disallow those sums in all three items.

18. I would add that the fact it has taken the Claimant no less than five attempts to get the basis for their claim in order has undoubtedly added to the costs of this litigation, and that will be a matter that will have to be considered when determining the appropriate costs order. This goes beyond the costs provision made in paragraph 2 of my Order dated 28 April 2023. Insofar as there are other challenges to other items within the sum of €453,515, I will consider those when looking at them.

[E], [F] and [G] Of the remaining sums, the Defendant submits that the Claimant has offered no credit for manufacturing costs the Defendant would have charged (i.e., if not in breach) for larger batch sizes/additional batches not used for process validation. Best metric in this regard (i.e., for credit value in [E] above) is Recipharm 1 mg/ml batch, which was 37.5% smaller in volume than under DA (2L vs 3.2L, see paragraph 38 of Tan 1). Recipharm could therefore generate all relevant process validation for an MAA using ~2L per batch (confirmed by Moorfields smallest batches being 1.8L and 1.9L). Therefore, if the Court is minded to award all clinical trials now claimed, that should be a discount on the final amount of 37.5%.

19. The Claimant responds to these points as follows:

    (1) It is simply claiming the costs of having to redo the process validation. This is in accordance with §95 of the First Judgment, where I stated:

    > *"I accept Mr Sinai's submission that the Defendant was contracted to produce process validation, which was in accordance with GMP, and which could be used in its MAA. When the Defendant lost its GMP licence, the process validation that it created could no longer be used in the MAA and had to be redone."*

    (2) The points made by the Defendant about additional benefits or causes are irrelevant.

    (3) The points about a subsequent agreement have been dismissed by the Court.

20. The Claimant also draws attention to the following. As can be seen from paragraph 3.4 of the Quotation, 12 validation batches were manufactured under three "Campaigns". The descriptions of each Campaign make it clear that the 12 batches (three of each strength) were for the following strengths (and this is accepted in paragraph in 24(d) of the Defendant's submissions dated 24 April 2023):

Batch 1:	1 mg/ml	Campaign 1
Batch 2:	1 mg/ml	Campaign 1
Batch 3:	10 mg/ml	Campaign 1
Batch 4:	10 mg/ml	Campaign 1
Batch 5:	1 mg/ml	Campaign 2
Batch 6:	10 mg/ml	Campaign 2
Batch 7:	2.5 mg/ml	Campaign 3
Batch 8:	2.5 mg/ml	Campaign 3
Batch 9:	2.5 mg/ml	Campaign 3
Batch 10:	5 mg/ml	Campaign 3
Batch 11:	5 mg/ml	Campaign 3
Batch 12:	5 mg/ml	Campaign 3

Batches 1 to 4 were manufactured under Campaign 1.
Batches 5 and 6 were manufactured under Campaign 2.
Batches 7 to 12 were manufactured under Campaign 3.

21. The cost of manufacturing each batch is quoted under paragraph 3.4 of the Quotation as follows:

Campaign #	**Batch # manufactured**	**Strength of batch**	**Cost of batch (€) as per Quotation**
1	1	1 mg/ml	39,000
1	2	1 mg/ml	98,000/3 = 32,667
1	3	10 mg/ml	98,000/3 = 32,667
1	4	10 mg/ml	98,000/3 = 32,667
2	5	1 mg/ml	38,000
2	6	10 mg/ml	32,667
3	7	2.5 mg/ml	38,000
3	8	2.5 mg/ml	163,335/5 = 32,667
3	9	2.5 mg/ml	163,335/5 = 32,667
3	10	5 mg/ml	163,335/5 = 32,667
3	11	5 mg/ml	163,335/5 = 32,667
3	12	5 mg/ml	163,335/5 = 32,667

22. From the above, the cost of manufacturing each strength can be calculated as follows:

Batch #	**Strength**	**Total cost (€)**
1, 2 & 5	1 mg/ml	109,667
7, 8 & 9	2.5 mg/ml	103,334
10, 11 & 12	5 mg/ml	98,001
3, 4 & 6	10 mg/ml	98,001

23. The table under paragraph 38 of Tan 1 shows the differences in batch sizes manufactured by the Defendant compared with Recipharm which can be set out as follows:

Strength	**D's batch size**	**Recipharm batch size**	**Difference in volume manufactured**
1 mg/ml	3.2 litres	2 litres	(1.2 litres ***less***)
2.5 mg/ml	1.9 litres	2 litres	0.1 litre
5 mg/ml	1.8 litres	3.5 litres	1.7 litres
10 mg/ml	2.7 litres	3.5 litres	0.8 litre
	9.6 litres	11 litres	**1.4 litres** more manufactured in total volume across all strengths

24. The cost per litre for each strength manufactured by Recipharm, as well as the differences in costs when compared with the Defendant, can be calculated as follows:

Strength	**Total volume manufactured by Recipharm of the strength**	**Total cost (€)**	**Recipharm's cost of manufacturing per litre (€)**	**Difference in cost compared with volumes manufactured by D (€)**
1 mg/ml	2 litres	109,667	54,833.50	(65,800.20 ***less***)
2.5 mg/ml	2 litres	103,334	51,667	516.60
5 mg/ml	3.5 litres	98,001	28,000	47,600
10 mg/ml	3.5 litres	98,001	28,000	22,400
Global difference in costs				4,716.40

25. The Claimant submits that the following principles can be derived:

(1) Recipharm costs of manufacturing the 12 validation batches were not dependent on the volumes manufactured;

(2) This is apparent from the fact that overall, Recipharm quoted only €4,716.40 more than they would have charged had they manufactured the same overall volume that the Defendant did (i.e., manufactured 1.4 litres less of the Product);

(3) It is therefore simply wrong to approach the assessment of damages on the basis that Recipharm charged more to manufacture larger batch sizes compared with what they would have charged had they manufactured smaller batch sizes;

(4) The Claimant's primary submission is that on the state of the evidence, there is no need (and certainly no injustice to the Defendant given its decision not to lead any evidence in support of its submission) to discount the amounts claimed for manufacturing the 12 validation batches;

(5) Alternatively, if a discount were to be made, it should be the difference in amount which Recipharm would have charged had they manufactured the same batch volumes as the Defendant, which is equitable because it gives credit for the savings in costs made by the Claimant's corresponding decision to manufacture 1.2 litres less of the smallest (1 mg/ml) strength. This amounts to €4,716.60;

(6) The Defendant's submission that that C has offered no credit for the "*manufacturing costs D would have charged… for larger batch sizes*" applies the wrong approach. What the Defendant would have charged for larger batch sizes is irrelevant, as costs had gone up by the time the Claimant approached Recipharm. The issue is what Recipharm would have charged had they been instructed to manufacture the same volumes. The above deduction of €4,716.60 justly caters for that.

26. In relation to the Defendant's contention in [F] that the Claimant ought to have carried out a process using 2 litre batch sizes of each strength and that there should accordingly be a 37.5% reduction across all the process validation costs claimed, the Claimant makes the following submissions:

(1) A market authorisation applicant has to validate all the volumes that it intends to sell commercially, otherwise those volumes cannot be sold. The corresponding consequence is that other batch volumes cannot be sold either. This means that according to the Defendant, the Claimant should have limited itself to obtaining a licence to only manufacture two litre batch volumes of each strength. Other volumes could not be manufactured because the processes for manufacturing those volumes (including stability) would not have been validated;

(2) There is therefore no evidence or basis for the Defendant's submission in para [F] that the best metric is to adopt 2 litre batches for each strength;

(3) As can be seen from paragraph 3.4 of the Quotation, the other costs of process validation are constant. For example, release analysis is fixed at €7,560 per 4 batches and the cost of process validation is fixed at €19,800 per 4 batches. These costs are not linked to the batch volumes for logical reasons. They are the costs of documenting the data and releasing the results.

Discussion and conclusion on [E], [F] and [G]

27. Having been through the parties' respective submissions and the material documents, I am not convinced that the Claimant is doing more than seeking to recover the costs of redoing the process validation, which I have found that the Defendant was obliged to carry out. As I said at §97 of the First Judgment:

> *"in any event, it seems to me that whether or not the Development Plan would result in a successful outcome, does not impact on the issue on whether the Defendant's obligations under the DA related both to the manufacture of the drug for clinical trials, providing data create the IMP and the IMPD* ***and*** *the production of validation batches of the drug for the purposes of the MAA. As paragraph 20(v) of the Particulars of Claim accepts that obligation contained no promise that that Product could be successfully manufactured or that a MAL would be obtained."*

I do not regard the Claimant as being under an obligation to carry out a process using solely 2 litre batch sizes of each strength because of the limitations that would impose. Had it done so, other volumes could not be manufactured because the processes for manufacturing those volumes (including stability) would not have been validated. Such a limitation was not envisaged when the Defendant was performing its obligations under the DA and carrying out validity testing. In the circumstances, I do not accept the Defendant's submission that a 37.5% reduction is necessary. There should, however, be a reduction of €4,716.60 for the reasons set out in in paragraph 25(5) above.

The Consolidated Schedule

28. I will now go through each one of the Claimant's claims, item by item. I am not going reproduce all of the voluminous submissions made on behalf of the parties, but instead will briefly give the reasons for my conclusions.

(A) Production and validation

29. A(i) Technical transfer from Moorfields: The total sum claimed by the Claimant for this head of claim is €66,645. The amount conceded by the Defendant is €16,295.

30. I turn to each of the disputed items. First item 3 of the Consolidated Schedule relates to the claim for €3,220, being the cost of preparation of the technical/feasibility batch, which it is alleged by the Claimant was cancelled at the last second by Mr Strieder. This item was considered at some length at the hearing on 28 April 2023[5]. I do not accept that the Claimant has established that there is evidence of any cancellation by Dr Strieder, and I therefore disallow this sum.
31. At item 8 of the Consolidated Schedule, the sum of €18,500 is claimed for Analytical Methods Set Up. I disagree with the Defendant that this sum does not relate to a process validation cost. I accept the Claimant's submission that paragraph 3.3 of the Quotation is the cost of transferring and setting up the analytical method for product validation of the 12 validation batches. I allow this sum.
32. Item 9 of the Consolidated Schedule refers to the sum of €28,000 referred to in invoice 640593 "147201 -3.2 Analytical Method (DP method)". I reject the Defendant's submission that is unrelated to the Defendant's breach. I accept the Claimant's explanation in respect of the words "DP", that this relates to the "Drug Product" and the validation of the drug and is therefore recoverable.
33. The total awarded under '(A)(i) Technical transfer from Moorfields' is **€63,425**, being the sum of €66,645 claimed, less €3,220, disallowed under paragraph 30 above.
34. A(ii) has already been disallowed because the Claimant did not incur these costs.
35. A(iii) Testing of AP: The total sum claimed by the Claimants for this head of claim is €21,178. The amount conceded by the Defendant is €10,178.
36. I turn to each of the disputed items. In items 11 and 12 of the Consolidated Schedule there are two sums of €5,500, referred to in invoices 640581 and 640593 under the description "full analysis API". I accept the Claimant's submission that these are process validation costs and not clinical trials materials beyond those the Defendant contracted to manufacture. They are therefore recoverable.
37. The Claimant is therefore entitled to the sum claimed of **€21,178** under this head.
38. A(iv) is a credit sum, which falls away, given that the cost of replacement API under A(ii) has been disallowed.
39. A(v) Production and documentation: This has been considered earlier to an extent. The total sum claimed by the Claimants for this head of claim is €453,515. The amount conceded by the Defendant is €17,082.

[5] See the transcript for 28 April 2023 at pp36-40.

40. I have already addressed the removal of invoice 6600236 and the exhibit to Tan 2 at paragraph 16 above.

41. At items 15 and 16 of the Consolidated Schedule, the same points are taken about two sums, €14,000 and €19,500 as were taken in relation to item 9, referred to paragraph 32 above. For the same reason, I allow these sums.

42. Item 17 relates to invoice 640669 in relation to the sum of €7,560 for the release analysis of 4 batches for the EMEA stability study in accordance with paragraph 3.4 of the Quotation. I am satisfied that this is a process validation cost, which is recoverable, and no credit arises.

43. Similar considerations apply to item 18 which also relates to invoice 640696 in relation to the sum of €7,560 for the release analysis of 4 batches in relation to release analysis for CTM batches in September in accordance with paragraph 3.4 of the Quotation. I am satisfied that this is a process validation cost, which is recoverable, and no credit arises.

44. Item 19 claims €38,000 in relation to a batch manufacture. The Claimant's narrative in the Consolidated Schedule states that it relates to Batches 7 and 8 as per paragraph 3.4 of the Quotation. However, on looking at the relevant part of the Quotation, and invoice 147201, the figure appears to relate to Batch 7 alone. The Defendant accepts that only the sum of €2,847 should be allowed, on the basis set out at paragraph 47(d)(ii) of its Quantum Submissions, which appear to accept that this sum relates to samples taken for validation work. A complaint is made that the Claimant paid a premium for the manufacture, which was considerably higher than the Defendant would have charged, and no attempt has been made to give credit for sums that would have had to be paid to the Defendant for an equivalent batch size. This seems to me to ignore the fact that the work had to be redone from scratch as a matter of urgency and the Claimant had to pay Recipharm the prices they were charging. They were not spoilt for choice in finding an alternative manufacturer at short notice. The Development Agreement concluded with Recipharm was identical to the DA, requiring the same work to be done. I therefore allow the sum of €38,000.

45. Item 20 claims €38,000 in relation to Batch 8 and refers to paragraph 3.4 of the Quotation and invoice 147201. The difficulty I have with this is that, unlike Batch 7, there is no specific breakdown in the Quotation of the manufacture cost of Batch 8, which is described collectively with the manufacture of Batches 8-12 in the sum of €163,335. Invoice 147201, however, quantifies this as €38,000. Again, the Defendant accepts that only the sum of €2,847 should be allowed, on the basis set out at paragraph 47(d)(iii) of its Quantum Submissions, which appear to accept that this sum relates to samples taken for validation work. For the same reasoning set out in paragraph 44 above, I allow the sum of €38,000.

46. Item 21 claims €125,335, relating to the batch manufacture of Batches 9-12 inclusive. The Quotation refers to the sum of €163,335 for "*GMP manufacturing batch 8-12 (for EMEA stability study & PV: 2 x 2.5 mg/ml; for PV only: 1 x 2.5 mg/ml & 1x 5 mg/ml)*." …". If one deducts the figure of €38,000 in relation to Batch 8 – see paragraph 46 above, this leaves the balance of €125,335, which is the sum which is claimed in invoice 147201. Again, the Defendant accepts that only the sum of €11,388 should be allowed, on the basis set out at paragraph 47(e)(i) of its Quantum Submissions, which appear to accept that this sum relates to samples taken for validation work. The point is made that 1 mg/ml and 10 mg/ml samples have been added which marks a departure from campaign 3 of the Quotation and suggests that further work was undertaken that was beyond the scope of the Defendant's obligations under the DA. However, the sum that was charged is exactly that which appears in the Quotation. Subject to further clarification by the Claimant (and any response by the Defendant) on this point in relation to the 1 mg/ml and 10 mg/ml samples[6], for the same reasoning set out in paragraph 45 above, I am willing to allow the sum claimed of €125,335.

47. Item 22 relates to a release batch analysis for four batches in paragraph 3.4 of the Quotation in the sum of €7,560, contained in invoice 147201. The Defendant submits that there is an element of duplication with invoice 640969, which claims exactly the same sum for the same analysis. Although the Claimant states: "*There is no reason to believe that Recipharm would duplicate their charges or that the Claimant would pay duplicated costs*", on the face of it, that is what appears to have happened. I disallow this sum.

[6] When submitting a list of typographic clarifications, Dr Lomas sought also to address this issue. I will hear both parties on this limited point at the hearing of consequential matters referred to at paragraph 69 below.

48. I have addressed item 23, which is a claim for €32,667, at paragraph 17 above. In the absence of an invoice or proof of payment by the Claimant, I am not prepared to allow this item.

49. In relation to items 24 and 25, as Ms Tan explains at paragraph 5(i) of Tan 2, invoice 640581 is the correct invoice for the manufacturing costs of Batch 1 of Campaign 1 in the sum of €39,000 and of Batch 5 of Campaign 2 in the sum of €38,000, as the wording makes clear. I allow these sums.

50. Item 26 relates to invoice 640593, as Ms Tan explains at paragraph 5(ii) of Tan 2, this invoice is the correct invoice for the manufacturing costs of Batches 2, 3 and 4 of Campaign 1 in the sum of €98,000. I allow this sum.

51. The total sum awarded under A(v) Production and documentation is **€408,571.40**, being the sum claimed of €453,515 less €4,716.60 under paragraph 27 above, €7,560 under paragraph 47 above and €32,667 under paragraph 48 above, and subject to the clarification referred to in paragraph 46 above.

52. A(vi) Validation: The total sum claimed by the Claimant for this head of claim is €82,800. None of the items under this head are accepted by the Defendant.

53. Item 27 relates to invoice 640593 and concerns the cost of a process validation consultant "*as described in the email 25/5-2015*" in the sum of €23,400. It is submitted by the Defendant that this relates to an entirely new or a changed process. This was not put to the Claimant's witnesses. Paragraph 3.4 of the Quotation expressly states that additional costs will be incurred if "*an external consultant may be required to allow for the timely performance of the validation*". It is a legitimate part of the process validation cost.

54. Item 28 relates to invoice 6600164 and concerns the cost of a process validation of four batches in the sum of €19,800. Once again, it is submitted by the Defendant that this relates to an entirely new or a changed process. I do not accept this. Paragraph 3.4 of the Quotation states that the cost of "*process validation on total of four batches*" is €19,800. I allow this item.

55. Item 29 relates to invoice 6600164 and concerns the cost of a process validation of two batches in the sum of €9,900. These are in addition to the four batches referred to in paragraph 54 above. Paragraph 3.4 of the Quotation expressly provides for "*additional costs for process validation on additional batches TBD*", but no explanation has been provided by the Claimant as to why these additional costs were necessary. All that is said is that they amount to €4,950 per batch, but what was envisaged under process validation

section of the Quotation was that there would be a total of four batches. I disallow this item.

56. I have addressed item 30, which is a claim for €29,700, at paragraph 17 above. In the absence of an invoice or proof of payment by the Claimant, I am not prepared to allow this item. I also make the point that the claim is for process validation of further batches above the original four envisaged under process validation section of the Quotation. No explanation has been given as to why this was necessary.
57. I therefore award the sum of **€43,200** under A(vi) Validation.

(B) Stability Study and Module 3

58. A sum of €80,600 is claimed under this head. €12,000 is accepted, relating to item 33.
59. In relation to item 31, which is a claim for €33,800 for "*a quotation for stability study*". There is no invoice or proof of payment for the quotation for this. I have addressed this in paragraph 17 above. No mention is made of it in Tan 2. I disallow this item.
60. Item 32 relates to invoice 147201, claiming €34,800 for "*3.7 in-use stability*". This study was part of the Quotation. It was work undertaken to finalise the stability study which the Defendant commenced but did not complete. I do not accept the Defendant's submission that it relates to a different study. I allow this sum.
61. I therefore award the sum of **€46,800** under (B) Stability Study and Module 3, being €80,600 less €33,800 for item 31.

(C) Finalisation Stability Study

62. A sum of €29,001 is claimed under this head. €23,550, relating to item 34, part of item 35 and item 36, is conceded.
63. Item 35 relates to a continuation of the stability study of 17 batches. The Defendant submits that its obligation under the DA related only to 12 not 17 batches and therefore only 12/17ths of this cost should be allowed. Invoice 6600030 states that 17 batches were transferred by the Defendant to Recipharm for completion of the stability study.
64. I therefore award the full amount of **€29,001** under (C) Finalisation Stability Study.

(D) Emergency Drug Batch

65. The sum of €67,226, item 49 for €485, having been abandoned during the course of Day 2 of the hearing. €52,946, is conceded. Only the last item, item 50 is contested.

66. Item 50 relates to a credit relating to standard production costs *"(that Moorfield would have charged)*". It is an allowance proposed by the Claimant for the costs the Defendant would have charged or incurred to manufacture a further batch. The figure advanced of €6,873 is the Euro equivalent of £5,148, which is based on quotation P1105. As the Defendant points out there is no reference to £5,148 in the relevant section of that quotation under "Manufacture and Release Testing"[7]. Instead, the Defendant advances a figure of €21,153 on the basis that "*the emergency batch size is likely to be three times (or more) the volume of the batch size quoted by the Defendant*"[8] and the appropriate allowance for the Defendant's costs of manufacture is €21,153. The Claimant's response is the Defendant provided no evidence of what it would have charged for the manufacture of the emergency batch, and it is therefore speculative. It also assumes that the Claimant would have agreed to it in non-emergency circumstances. I agree that the Defendant's proposed figure is speculative, and, on that basis, I am not prepared to award it. However, I need to understand more clearly how the figure of €6,873 is arrived at, based on P1105. Clearly the Defendant is entitled to a credit in this regard.

67. I therefore award the sum of **€67,226** under (D) Emergency Drug Batch, subject to clarification in relation to the figure of £5,148 by reference to quotation P1105.

Conclusion

68. Having found that the Defendant is in breach of the DA and is liable to the Claimant in damages, I award the Claimant the following sums:

A)(i) Technical transfer from Moorfields	**€63,425**
(A)(iii) Testing of API	**€21,178**
A(v) Production and documentation	**€408,571.40**
(subject to further clarification in relation to item 2 in relation to the 1 mg/ml and 10 mg/ml samples – see paragraph 46 above)	
A(vi) Validation	**€43,200**
(B) Stability Study and Module 3	**€46,800**
(C) Finalisation Stability Study	**€29,001**
(D) Emergency Drug Batch	**€67,226**
(subject to clarification in relation to the figure of £5148 by reference to quotation P1105 – see paragraph 66 above).	

[7] Bundle 3, p134.
[8] Paragraph 38 of the Defendant's skeleton argument.

69. There will be hearing listed for two hours at a date convenient to the parties within the first three weeks of next term to determine all matters consequential to this judgment, including finalising quantum (having clarified the two matters referred to in paragraph 68 above), interest, costs and any application for permission to appeal.