Neutral Citation Number: [2023] EWHC 1523 (Comm)

Case No: CL-2021-302

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

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

Date: 11/08/2023

Date hand down hearing fixed 20/06/2023

Before :

HIS HONOUR JUDGE PELLING KC
SITTING AS A JUDGE OF THE HIGH COURT

- -

Between :

EXELOGEN INC	**Claimant**
- and –	
THE UNIVERSITY OF BIRMINGHAM	**Defendant**

- -
- -

Stephen Hackett (instructed by **Griffin Law**) for the **Claimant**
Anna Edwards-Stuart (instructed by **Pinsent Masons LLP**) for the **Defendant**

Hearing dates: 12-15 and 19-21 June 2023

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

This judgment was handed down by the Judge remotely by Teams, circulation to the parties' representatives by email and release to The National Archives. The date and time for hand-down is deemed to be 9:55 on Friday 11TH August 2023.

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HIS HONOUR JUDGE PELLING KC SITTING AS A JUDGE OF THE HIGH COURT

HH Judge Pelling KC:

Introduction

1. This is the trial of a claim by the claimant for (a) damages for an admitted breach of contract; (b) damages for breach of an alleged but disputed duty of confidence; (c) a remedy for alleged but disputed unjust enrichment and/or damages in respect of two causes of action in which it is alleged the defendant is vicariously liable for the acts and omissions of one of its employees, Professor Alexandra Sinclair, who is Professor of Neurology and Head of the Metabolic Neurology Research Group at the defendant.

2. In relation to the breach of contract claim, the defendant admits breach but denies causation and disputes that quantum should be calculated in the manner contended for by the claimant.

3. The breach of confidence claim added nothing since it is not alleged by the claimant that it can recover by way of damages for breach of confidence more than it is entitled to recover as damages for the admitted breach of contract. Unsurprisingly therefore, it was abandoned at the start of the trial. The unjust enrichment claim was abandoned too although later in the first day of the trial. That claim was correctly abandoned for the short reasons given following my summary below of the relevant background facts. An understanding of those facts is required before why it was appropriate for the claimant to abandon its unjust enrichment claim can be understood.

4. The vicarious liability claims were (i) a claim that Professor Sinclair procured a breach of the defendant's contract with the claimant that is the subject of the breach of contract claim and (ii) an alleged unlawful means conspiracy. Neither of these claims has been made against Professor Sinclair personally, who is not a party to (though she is a witness in) these proceedings. The first of the vicarious liability claims added nothing to the claim against the defendant for damages for its admitted breach of contract and the second was disputed on the basis the defendant is not vicariously liable in respect of the alleged participation of Professor Sinclair in the alleged conspiracy. In any event this claim too adds nothing in the sense that it will not enable the claimant to recover more than is recoverable for breach of contract. Equally unsurprisingly therefore, these claims too were abandoned at the start of the trial. It is an unfortunate feature of this case that such allegations should have been made against Professor Sinclair in a way that prevented her from defending herself. I record therefore that the effect of the withdrawal of the vicarious liability claims is that the allegations made against Professor Sinclair are accepted by the claimant to be without foundation.

5. In those circumstances, this trial is limited to the determination of the causation and quantum issues that arise in relation to the claimant's admitted breach of contract. The scheme of this judgment is therefore (a) to set out the relevant background and terms of the relevant agreement between the parties and summarise who gave evidence at the trial; (b) to explain why the unjust enrichment claim was correctly abandoned; (c) to determine the causation issues that arises and (d) to determine the amount, if any, that the claimant is entitled to recover as damages for breach of contract.

Factual Background and the Agreement between the Parties.

6. The dispute between the parties arises out of a contract between the claimant and defendant concerning the commercialisation of research by Professor Sinclair into the use of a drug called Exenatide for the treatment of idiopathic intracranial hypertension ("IIH"), which is the subject of various patent and other intellectual property rights held by the defendant.

7. IIH is a medical condition involving increased pressure on the brain caused by the cerebrospinal fluid that surrounds it. If left untreated it can cause blindness. Currently there is no licenced medical treatment available. Exenatide is marketed in an immediate release formulation to be administered by sub cutaneous injection by Amylin under the brand name Byetta. It is or will shortly be out of patent protection. Currently it is licenced only for the treatment of an unrelated condition. The technical reasons why and how Professor Sinclair identified Exenatide as a potential treatment for IIH are scientifically interesting but essentially irrelevant to the issues that arise in this litigation and so I don't propose to take up time describing it.

8. In the result however, in August 2015, the defendant applied for and obtained patents in relation to the new method of treatment in numerous European countries, the United States of America and Japan and in September 2015, Professor Sinclair applied on behalf of the defendant for orphan drug designation from the European Medicines Agency, which was awarded in March 2016, and in March 2016 from the US Food and Drug Administration, which was awarded in May 2017. Orphan drug designation is concerned with the re-purposing of existing medicaments and is a means by which a period of market exclusivity can be obtained for use of the drug for the identified repurpose. These steps were the platform from which commercial exploitation by the defendant could be launched. The patent and orphan drug designation provides time limited protection to the right holder and its assignees or licencees. It follows that the more time that passes between the date when the rights are registered and the date when the rights holder or its licencees or assignee can obtain regulatory approval for use and start to exploit the rights commercially, the less time there will be in which such an assignee or licensee can exploit the exclusivity conferred by the IP rights to recover its development costs and make monopoly enhanced profits from such commercial exploitation. These factors are fundamental and were well known to both the claimant and defendant at all material times down to the execution of the original agreement between the parties and thereafter. The contrary is not and could not be suggested.

9. It is common ground that in order to bring a pharmaceutical product to market various pre-licencing clinical trials and regulatory steps have to be completed including (a) a Phase 1 trial to demonstrate safety; (b) a Phase 2 trial, which consists of a proof of concept trial and then a clinical trial on a relatively small cohort of patients to demonstrate both efficacy and safety; (c) a Phase 3 clinical trial, which is again concerned with efficacy and safety but utilising a much larger cohort of patients and a final phase concerned with obtaining regulatory approvals. Only after completion of each of these stages can commercial exploitation of the product commence.

10. The proof of concept element to Phase 2 can be achieved at a relatively modest cost but the remaining clinical trial element of Phase 2 is expensive. The Phase 3 clinical trial is much more expensive to conduct than the Phase 2 clinical trial segment. Phase 1 was

not necessary because Exenatide had already been licenced for use in humans, although the evidence suggests that Phase 1 might be required if the compound being used, or its dose or the method of administering it, was altered. If a Phase 1 exercise was required then it would have extended by many months the delay between the date when the defendant obtained its rights protection and the date when the product could be released to the market. However, that aside, Phases 2 and 3 had to be completed if Exenatide was to be licenced for the treatment of IIH. None of this is disputed.

11. By March 2017, the defendant and Professor Sinclair were ready to embark on Phase 2. However, the defendant was not able to fund that activity itself. Various attempts to interest joint venture partners failed until 9 March 2017, when the defendant entered into an agreement with Biodome Partners LLP ("Biodome"), an US registered entity controlled by Mr Artin Asadourian, under which Biodome was granted an exclusive right until 30 September 2017 to initiate negotiations for the grant to it by the defendant of an exclusive licence of the patent and orphan drug designation rights that had been acquired by the defendant. In consideration of the grant of that option, Biodome was to seek funding to "*catalyse*" the agreement of such a licence. All parties fully understood that the grant of a licence by the defendant was dependant on a variety of factors, of which the most important was the identification of an investor or investors willing to support the product through its Phase 2 and subsequent stages of development. No one suggests that a licence would have been granted unless funding or an investor willing to fund to that level had been obtained by Biodome. Neither funding nor an investor had been obtained by the date when the initial agreement was due to expire, which, in consequence, was varied by extending the period of exclusivity twice down to 31 March 2018. I refer below to the initial agreement as extended as the "original agreement".

12. In early 2018, Biodome raised sufficient funding to allow the formation of the claimant as a special purpose vehicle and it was incorporated (under the laws of the State of Delaware in the United States of America) in March 2018. Mr Asadourian had also introduced Professor Sinclair to Mr George Barnett, an "*angel*" investor with a background in pharmaceuticals. On formation of the claimant, Mr Asadourian and Mr Barnett became its directors, Mr Barnett became its Chief Executive Officer and Professor Sinclair its Chief Scientific Officer. Professor Sinclair joined the board of the claimant in July 2018. For reasons that I explain below, Biodome was an entity called an "*incubator*" in the language of the US based pharmaceutical industry. For reasons I explain below, the claimant was formed rather earlier in the process of development than might normally be expected.

13. On 16 April 2018, the claimant, Biodome and the defendant entered into the agreement at the heart of this dispute. It novated the previous agreements between the defendant and Biodome by replacing the latter with the claimant and further defined the obligations of the parties for the future ("novation agreement"). The novation agreement preserved the terms of the original agreement between the defendant and Biodome and the parties to the novation agreement agreed that the original agreement together with the novation agreement constituted the entire agreement between them with any conflict in their respective terms being resolved in favour of the terms set out in the novation agreement. I refer to the original agreement and its novation together hereafter as the "*Agreement*".

14. Substantively the parties to the novation agreement agreed that:

> "…
>
> 5) [Biodome] shall be removed as a Party to the Original Agreement from the date of this Third Amendment and shall be replaced by [the claimant] and [the claimant] shall take over the obligations and liabilities of [Biodome] as well as receiving the benefits currently accruing to [Biodome] from the Original Agreement; and
>
> 6) In consideration of the execution and delivery ·by the [defendant] of this Agreement, [the claimant] shall pay a non-refundable fee ("Option Fee") of US twenty thousand dollars (US$20,000) to the [defendant] within 30·days of the [the Agreement] effective date. This fee shall be used for funding the [defendant's] research being carried out by Dr. Alex Sinclair in the IIH-ICP trial to obtain human proof of concept data and the terms and conditions governing the use of these monies shall be agreed between the [defendant] and [claimant] in a further written agreement … "

The terms of the Option were varied by clause 7 of the novation agreement to the following:

> "Subject to the terms of this Agreement, [the claimant] shall have as an exclusive option period ("Option Period") until: (i) June 30, 2019 or; (ii) 30 days after the Completion and Data delivery of the first in human proof of concept study currently underway for treating patients with IIH, whichever is later, to notify the University of its desire to initiate negotiations for the Exclusive License ("Option Notice"). Upon receipt of the Option Notice within the Option Period, the Parties shall enter into negotiations for the Exclusive License. If the Exclusive License is not consummated by the date that is ninety (90) days after the date of the Option Notice ("Negotiation Period"), or any extension thereof as mutually agreed upon by the Parties in writing, the [defendant] shall have no further obligation whatsoever to [the claimant] with respect to the Patent Rights, and the University may freely dispose of the Patent Rights as it sees fit in its own discretion. [The claimant] has the exclusive right to extend the Option Period by twelve (12) additional months by paying the University a non-refundable US twenty five thousand dollar (US$25,000) fee within the Option Period:" [Emphasis supplied]

As is apparent therefore, the Option Period would not come to an end until 30 days after completion of the phase 2 testing. It is common ground that such testing had not completed by the date of breach. At trial, the claimant made clear that it did not take the point concerning the maximum length of the option contained in the novation agreement and was content to accept that the mutual intention of the parties was that it would last until 30 June 2019 unless extended to 30 June 2020 by the claimant by paying the US$25,000 fee referred to in the option clause. I proceed on that basis. Even

on this basis, as is common ground, the defendant breached the Agreement in November 2018, when it, acting by Professor Sinclair but with the knowledge of the defendant, opened up discussions with another entity concerning the development and marketing of the product.

15. It is at this point that the parties' factual cases deviate. The claimant maintains that in August 2018, Messrs Asadourian and Barnett, and Professor Sinclair, attended a pitch meeting with a company called Electrocore Incorporated ("Electrocore"). The claimant's case is that Electrocore intended to (or at any rate there was a realistic prospect that it would) make an investment into the claimant sufficient to enable the phase 2 and phase 3 stages to be completed but that it did not wish to do so until early 2019. It is also the claimant's case that Messrs Asadourian and Barnett were themselves willing to finance the phase 2 stage up to a sum of US$250,000 if necessary. It is common ground that whilst this would have been sufficient to fund the proof of concept element of the phase 2 clinical trials, it would not have funded the completion of those trials, which would cost between US$1.5-2.5m. The claimant maintains that Professor Sinclair disengaged thereafter. Although Messrs Asadourian and Barnett maintain that they would have themselves invested the money necessary to complete the Phase 2 testing (or at any rate the proof of concept element), they did not in the event do so and do not suggest they informed Professor Sinclair at any stage that such was their intention.

16. The defendant's case is that Electrocore did not at any stage commit to, or otherwise indicate, that it would be willing to consider, providing any investment in the claimant either in early 2019 or otherwise and any delay beyond November 2018 would have progressively adversely impacted the commercial exploitability of the defendant's rights for the reasons explained earlier – the longer Phase 2 was delayed, the longer it would be before Phase 3 could be commenced or completed and therefore the less time that was protected by the defendant's intellectual property rights and therefore the less likely that the claimant would be able to exploit those rights or sub licence another to do so. The defendant's case and the evidence of its witnesses (which on this point I accept) was that the primary concern of the defendant throughout was to make Professor Sinclair's treatment available to the sufferers of IIH. Its concern was that unless there was a reasonable opportunity available to a commercial partner to exploit the treatment commercially on an exclusive basis, that would simply not happen because pharmaceutical companies would not take on the development risk associated with a new treatment without the comfort of being able to exploit the product on an exclusive basis for a period sufficient to enable it to recover its costs of development and make profits thereafter. This is why the defendant would not simply release its intellectual property to the public domain. In that event no one would be able to obtain the exclusivity necessary to enable development costs to be recovered or a satisfactory profit made.

17. The defendant maintains that by November 2018, the claimant had failed to raise funds necessary to complete phase 2 – something that Mr Barnett acknowledged in an email to Professor Sinclair of 7 November 2018 in these terms:

> "Alex, thank you for making the time to meet with Artin and myself today. I heard your frustration and disappointment that,

> despite more than a year of efforts, we have not raised sufficient funding yet to advance your research …"

The assessment of the defendant and Professor Sinclair was that with no funding having been obtained, Phase 2 testing could not be completed and unless Phase 2 could be completed there was no prospect of Phase 3 commencing or progress in bringing the treatment to market being made.

18. Whilst the defendant may be correct in that assessment, in the absence of a contractual termination mechanism, they nevertheless remained bound by the Agreement and the option contained in it unless and until either the claimant repudiated it and the defendant accepted that repudiation or the Agreement was discharged by agreement. The defendant does not allege that the claimant repudiated the Agreement, much less that it purported to accept any such repudiation. Thus, whilst the defendant maintains that it had no choice but to breach the Agreement, the defendant nonetheless became a contract breaker by so acting.

19. On or about 21 September 2018, Professor Sinclair had been introduced to Dr Loveridge, who controlled, or at any rate acted on behalf of Warambi SARL, a French registered pharmaceutical company. Dr Loveridge proposed that he manage bringing Exenatide to the market using funding to be raised by an initial public offering to take place in Australia on behalf of an Australian registered public company called Invex Therapeutics Pty Limited ("Invex"). His evidence was and I accept that he was only prepared to do so if the defendant agreed to assign its intellectual property rights to Invex, conditionally on it being able to raise the capital necessary to enable development of the treatment to be completed.

20. On 5 October 2018, Professor Sinclair requested the claimant acting by Mr Barnett to waive the option conferred on it by the Agreement. That was refused initially and not thereafter agreed. On 6 November 2018, the defendant purported to serve notice of termination of the Agreement alleging breach of the agreement by virtue of non-payment of the Option Fee. The defendant admits that the Termination Notice was not effective to terminate the Agreement or in any event it did not want to rely on it.

21. The Invex IPO was fully subscribed (raising Aus$12m) and in March 2019, the defendant assigned its patent rights to Invex, which has trademarked Exenatide as a drug for the treatment of IIH using the name "*Presendin*". Currently, it is preparing for the commencement of the Phase 3 trials. The defendant admits, as I have said, that it breached the Agreement by entering into negotiations with Dr Loveridge that resulted in the assignment of its patents rights to Invex in March 2019.

The Unjust Enrichment Claim

22. In my judgment the unjust enrichment claim had no prospect of success and was rightly abandoned. The basis on which this cause of action was advanced is summarised in the claimant's opening written submissions as being that the defendant had the benefit of Messrs Asadourian and Barnett's expertise, for which there was a failure of consideration in that the claimant was not given the benefit of the agreed exclusive option period. In my judgment this is unsustainable in the circumstances of this case. Unjust enrichment (or the old common law cause of action of *quantum meruit*) is generally only available either where there is no valid or subsisting contract between

the parties or the contract is subject to an express or implied term that entitles the claimant to payment of a reasonable sum for services provided - see Benedetti v Sawiris [2013] UKSC 50 per Lord Clarke JSC at [9] & [10].

23. In this case (a) there was a contract between the parties; (b) it did not contain an express term entitling the claimant to a reasonable or any sum for the services of Messrs Asadourian and Barnett or any other services to be provided by the claimant; and (c) it is not alleged there was an implied term of the Agreement to that effect and could not be, applying conventional English law principles - see Marks and Spencer Plc v. BNP Paribas Securities Services Trust Co (Jersey) Limited [2015] UKSC 72; [2016] AC 742 as applied in Ali v. Petroleum Company of Trinidad and Tobago [2017] UKPC 2; [2017] ICR 531 and countless first instance decisions since then. The original agreement granted the claimant an option, which was expanded as set out in the April 2018 novation agreement reproduced above, in consideration of what is set out as being the consideration in the original agreement, the effect of which was preserved by the terms of the novation agreement. That consideration was agreed in the following terms and was never varied:

> "Consideration. In consideration of the execution and delivery by the [defendant] of this Agreement, [Biodome] shall invest time and resources in pursuing all reasonable sources of funding, partnering and business structures to catalyze a license deal for the Patent Rights"

24. In any event the unjust enrichment cause of action depends on demonstrating that the defendant has been enriched at the expense of the claimant. Where services are provided in circumstances where it is understood that they will be paid for but there is no agreement to that effect or there is an agreement that they will be paid for by payment of a reasonable sum, it is not difficult to see how that condition would be satisfied. However, in a case like this, it is not and could not be alleged that any benefit has been conferred on the defendant by the activities of the claimant and in any event any such disenable benefit as was provided as consideration for the execution and delivery of the Agreement by the defendant.

The Trial

The trial took place between 12-15 and 19-21 June 2023. I heard evidence of fact:

(i) On behalf of the claimant from:

a) Mr Asadourian, the co-founder of Biodome, who with Mr Barnett incorporated the claimant;

b) Mr Barnett; and

c) Mr Francis Amato, at the material time the CEO of Electrocore;

ii) On behalf of the defendant from:

a) Dr Jonathan Watkins, the Head of Intellectual Property Services at the University of Birmingham, an employee of University of Birmingham

> Enterprise Ltd, a wholly owned subsidiary of the University which exploits IP in research from the University and the person who was responsible on behalf of the defendant for the contractual arrangements with Biodome and the claimant;
>
> b) Professor Sinclair; and
>
> c) Dr Loveridge.

25. The parties obtained permission from Robin Knowles J at the CMC to adduce expert evidence in relation to three issues namely:

> "10.1. The net profits that would have been made by the Claimant if it had brought the product to market as described at paragraph 50.1 of the Amended Particulars of Claim;
>
> 10.2. the value of the Option Right (as defined at paragraph 19 of the Amended Particulars of Claim); and
>
> 10.3. the hourly rate that the Claimant's services would have commanded on the open market."

The issue referred to in paragraph 10.3 of Robin Knowles J's order related to the unjust enrichment claim, which as I have explained has been withdrawn, and the third alternative way in which the damages claim for breach of contract was pleaded in paragraph 50.3 of the amended Particulars of Claim. However, that alternative was not persisted with at trial either. Paragraphs 10.1 and 10.2 of the CMC Order reflect the alternative ways in which the claimant maintained at trial that damages were to be assessed in the circumstances of this case.

26. I heard expert evidence adduced by the claimant from Dr Walton, the co-founder of what is now PharmaVentures Limited, a consultancy that provides patent licensing and related advisory services to the global biotech and pharmaceutical industries including the valuation of pre-clinical and clinical stage products, product portfolios and companies. The defendant adduced expert evidence from Ms Roula Harfouche FCA, a Partner of HKA Global Ltd, who has extensive experience in valuing companies and businesses including biotech companies and the assessment of losses suffered from the loss of opportunities to launch new pharmaceutical and healthcare products, or existing products in new markets.

27. As will be apparent from the outline summary of the issues that arise set out above, these claims are concerned with events that took place in excess of 5 years ago. Inevitably this has an impact on the reliability of recollection of the witnesses of fact who gave evidence. In those circumstances, I have tested the oral evidence of each of the witnesses of fact, wherever possible, against such contemporary documentation as there is, admitted and inconvertible facts and inherent probabilities. This is an entirely conventional approach – see Onassis and Calogeropoulos v. Vergottis [1968] 2 Lloyds Rep 403 at 407 and 413. It is of course necessary to consider all of the evidence – see Kogan v. Martin [2019] EWCA Civ 164 per Floyd LJ at paragraphs 88-89. There is however nothing either in this authority or the requirement to consider all of the evidence that prevents the evaluation of oral evidence using the techniques I have

referred to. In my judgment, the use of such techniques is all the more appropriate having regard to the passage of time since the events with which this case is concerned – see Gestmin SGPS SA v. Credit Suisse (UK) Limited [2013] EWHC 3560 (Comm) per Leggatt J (as he then was) at paragraphs 15-22.

The Principles Applicable to the Breach of Contract Claim

28. The primary way in which the claim for damages for breach of contract is advanced is as a loss of a profit earning opportunity. For these purposes, the claimant alleges that:

    i) But for the admitted breach of contract, " … *the Claimant would have been able to negotiate for an exclusive licence of the Patent Rights to bring the product to market. Preliminary meetings with investors had been successful, and once the Trial had concluded the Claimant would have been able to obtain investment, meaning that negotiations for a licence of the Patent Rights would have been highly likely to succeed* …". – see paragraph 49 of the amended Particulars of Claim; and

    ii) As a result of the breach, " … *the Claimant lost the opportunity to bring the drug to market and profit from its sales. The Claimant would have achieved this with the benefit of the Patents by making the drug market ready by completing clinical development and gaining market approvals from regulatory agencies in all major markets, manufacturing the drug either by Contract Manufacturing Organisation (CMO) or directly, and then selling the manufactured drug either by Contract Sales Organisation (CSO) or directly*." – see paragraph 50.1 of the amended Particulars of Claim.

    The claimant alleges on this basis that it is entitled to recover by way of damages, " … *the net profit that it would have made by bringing the drug to market in this way … subject to an adjustment for loss of chance to reflect the possibility that the Claimant would not have been able to conclude a successful deal with the Defendant for the licensing of the Patents* …" which adjustment the claimant alleges " … *ought to be modest* …" since, if the defendant had honoured the Agreement, " *… the Claimant could have raised the requisite funds (which the Claimant intends to prove it would have done) then there is no reason why the Defendant would not have concluded a deal to licence the Patents to the Claimant*..." – see paragraph 50.1 of the amended Particulars of Claim. I refer to this claim as the "*Lost Opportunity Claim*" below.

29. The alternative basis on which damages were claimed is pleaded in paragraph 50.2 of the amended Particulars of Claim in these terms:

> "Alternatively, the Claimant was deprived of the Option Right, which (given that it was at the time of the 1 August 2018 valuation the Claimant's only asset) was valued at US$7.5m. The Claimant accordingly seeks that sum in damages or the Sterling equivalent as the court may find. "

    That claim has not been made out for the reasons that I explain in detail at paragraph 64 and following, where I address this point in its relevant factual context. The same valuation was relied on by the claimant to support its case as to the quantification of its loss of opportunity claim. As I explain below it did not assist on that issue either. As I

also explain below, on the facts of this case there is no material distinction to be drawn between the way the claim is pleaded respectively in paragraph 50.1 and 50.2, other than by reference to the alleged US$7.5m valuation. If the claim under paragraph 50.1 fails, the claim under paragraph 50.2 cannot succeed other than by reference to the alleged US$7.5m valuation.

The Lost Opportunity Claim

30. The principles that apply to lost opportunity claims are common ground between the parties and are well known and established. In summary:

> "... the plaintiff must prove as a matter of causation that he has a real or substantial chance as opposed to a speculative one. If he succeeds in doing so, the evaluation of the chance is part of the assessment of the quantum of damage, the range lying somewhere between something that just qualifies as real or substantial on the one hand and near certainty on the other. I do not think that it is helpful to seek to lay down in percentage terms what the lower and upper ends of the bracket should be."

see Allied Maples v. Simmons and Simmons [1995] 1 WLR 1602 per Stuart-Smith LJ at 1614. This approach has been consistently followed ever since – see Gregg v Scott [2005] UKHL 2 and Perry v. Raleys Solicitors [2019] UKSC5; [2020] AC 352 per Lord Briggs at [21]. As Stuart-Smith LJ's summary makes clear, the chance is to be ignored if it is merely speculative - a point emphasised by the Supreme Court in Gregg v Scott (ibid.) *per* Lord Nicholls at [17].

31. In the context of this case therefore, it is agreed between the parties that there are three issues that must be resolved being:

    i) Whether the claimant's alleged loss of the opportunity to take Exenatide to market and profit from its sales is real or substantial rather than being merely speculative (the "*Substantiality Issue*");

    ii) Whether the defendant's admitted breach of contract has caused the claimant to lose that chance (the "*Causation Issue*"); and

    iii) The value to be attributed to that lost chance (the "*Valuation Issue*").

    If the answer to (i) is negative then the other issues do not arise. If the answer to (i) is affirmative but the answer to (ii) negative then (iii) does not arise and (iii) only arises if the answers to both (i) and (ii) are affirmative.

The Substantiality Issue

32. The defendant's case is that the claimant is able to demonstrate a no better than speculative loss of opportunity to take Exenatide to market and profit from its sales primarily because, as at the date of the breach, there was a no more than speculative prospect of the claimant raising sufficient funds to complete the Phase 2 clinical trials whether from Electrocore or at all.

33. Further the defendant submits that it would be fully entitled to decline to grant an exclusive licence when negotiating with the claimant in good faith unless it could be satisfied that by so doing it would achieve its objective in getting the drug to market so that patients suffering from IIH could be treated and the defendant get its fair share of any revenues generated. That would require the claimant to have obtained the necessary funding described earlier or an investor willing to apply such funding. As I have said, without such funding there was no question of the defendant granting the claimant a licence. In addition, it would require both a commercialisation plan and a forecast of sales but neither could be prepared without funding or an investor willing to provide it. The defendant submits that the claimant could not comply with any of these requirements in November 2018 because it did not have funding nor a commercially exploitable product nor a commercialisation plan or any reliable financial forecasts. The defendant submits therefore that it would be fully entitled to refuse and would have refused to grant the claimant an exclusive licence in these circumstances. Furthermore, it submits that there was a no more than fanciful prospect of the claimant obtaining funding or an investor prior to the end date the claimant has conceded should be adopted.

Funding Generated to 6 November 2018

34. The claimant had failed to generate any funding down to 6 November 2018 (as Mr Barnett acknowledged in his email to Professor Sinclair quoted in paragraph 17 above) and in my judgment it has not shown it had any realistic prospect of generating any funding either down to 30 June 2019 or 30 June 2020, being the two dates when the claimant accepts the option would have come to an end. Without such funding in my judgment there was no realistic prospect of the defendant granting the claimant an exclusive licence of its IP rights. This is obvious and is the reason why, for example, the claimant had not served notice to commence negotiations for the grant of a licence under the option at any stage down to 7 November 2018 or at all.

35. Phase 2 could not be completed, and the Phase 3 clinical trials could not be begun until funding had been obtained. The evidence as set out in Mr Barnett's documentation suggests about US$346,000 would be required to complete the proof of concept element of the Phase 2 trials – see trial Bundle, page 5722. In practice the longer the delay in commencing and completing phase 2, the longer the delay to the commencement of the Phase 3 clinical trials and, therefore, the shorter the period of exclusivity provided by the defendant's patents available for the purposes of commercial exploitation. The attractiveness of the offer from the perspective of a commercial funder reduced almost linearly with the reduction in the period of exclusivity available. This meant that the prospect of obtaining funding or an investor eroded over time in a similar fashion. In my judgment, this problem was made much worse because the medication that the treatment relied on was available generically and the only basis which exclusivity could be maintained against use of generically available drugs was price. This too was a disincentive so far as inward investing was concerned.

36. Mr Asadourian maintains that in the 2-year period ending in November 2018, he had spent more than 2000 hours working on the project. Mr Barnett claims to have spent more than 3000 hours on the project in the 18-month period ending in November 2018. Each were experienced pharmaceutical industry professionals whose main attraction from the point of view of the defendant was their ability to open doors to those who

might be able to provide funding. Despite that apparent effort, no funding of any sort sufficient to fund even the phase 2 trials had been obtained down to the date when the defendant breached its contract with the claimant. This is highly material to an assessment of what was likely to happen in the period down to 30 June 2019 or 2020 if the option was extended.

The Falahat Loan

37. The claimant maintains that US$50,000 had been raised by way of a loan from a Mr Falahat. Mr Falahat did not give evidence. The only evidence of this loan referred to in the course of the trial was a Promissory Note dated 8 January 2018 signed by Mr Asadourian. It records a promise by Biodome to pay that sum to the order of Mr Falahat on or after 8 January 2021. There was no evidence that any part of the sum loaned was passed to or expended by the claimant. There was no evidence referred to at the trial that the loan had been novated to the claimant.

38. However, after the trial had been completed I was sent a copy of a document entitled "*Convertible Promissory Note*" ("CPN"). This document was not included in the trial bundle and was not the subject of any cross examination so any conclusions I reach in relation to it must necessarily be tentative. It is dated 1 June 2018 and describes the "*Principal Amount of Note"* as being "*$51,079.90"*. Although it does not say so, an explanation may be that this is the principal amount referred to in the Promissory Note together with interest that had accumulated down to the date when the CPN was signed. However. There is no direct evidence this is so.

39. The loan obligation referred to in the CPN was an obligation to repay the principal together with interest at 6% per annum upon request not before 1 June 2021 unless the loan was converted in accordance with clause 2, which provides:

> "**Conversion upon a Qualified Financing**. In the event that Company issues and sells shares of its equity securities (the "Equity Securities") to investors (the "Investors") on or before the Maturity Date in an equity financing with total proceeds to the Company of not less than $2,000,000 (excluding the conversion of the Notes or other indebtedness) (a "Qualified Financing"), then the outstanding principal balance of this Note and any unpaid accrued interest shall automatically convert in whole without any further action by Holder into such Equity Securities sold in the Qualified Financing at a conversion price equal to the price paid per share for Equity Securities by the Investors in the Qualified Financing multiplied by 0.80. The issuance of Equity Securities pursuant to the conversion of this Note shall be upon and subject to the same terms and conditions applicable to the Equity Securities sold in the Qualified Financing. "

Clause 1(c) of the CPN provides that the CPN " … *is issued as complete satisfaction for the cancellation of the January 8, 2018 Promissory Note issued to the Holder by Biodome Partners, LLC.*" It is difficult to know what to make of this document in the circumstances. On balance however, I conclude that the claimant has not proved that

the sum referred to in the CPN was ever received by the claimant. I reach that conclusion for the following reasons.

40. Firstly, Professor Sinclair's evidence was that she was never told about the receipt by the claimant of this sum. I accept this evidence, as I accept all Professor Sinclair's evidence. There is no rational reason why Mr Asadourian or Mr Barnett would not have informed Professor Sinclair of the receipt of the money if it had in fact been received. This is particularly so given the break down in the relationship due to the failure to raise funding that developed following the final meeting with Electrocore in August 2018. It is also inconsistent with the contemporaneous email to Professor Sinclair from Mr Barnett referred to earlier and the internal notes I refer to below, in which Mr Barnett acknowledges that no funding had been raised.

41. Secondly the only document produced by the claimant that is relied on as supporting the receipt of this sum is a spread sheet produced by Mr Barnett that contains a reference to *"$40,000 first angels*". Mr Barnett maintained that this was referring to the sum lent by Mr Falahat. I am not satisfied that is so for the following reasons.

42. Firstly, the sum referred to is US$40,000 not either the US$50,000 referred to in the Promissory Note or the US$51,079.90 referred to in the CPN. Mr Barnett suggested that the reference to US$40,000 was an error and should have been to US$50,000. I reject this evidence. Firstly, if the CPN is the governing instrument then the reference should have been to US$51,079.90 not to US$50,000. Mr Barnett made no mention of the sum referred to in the CPN. This provides further support for my tentative conclusion that the CPN never became operative or at any rate the sum referred to it was not received by the claimant. Secondly, on the face of the document, the phase "*first angels*" is to be read in context with the phase "*next angels*" in the subsequent rows in the spread sheet. In that context these rows indicate planned use of funds assuming receipts from investment angels and was not intended to record actual receipts. Thirdly, had it been intended to record receipt of the loan then somewhere in the spread sheet provision should have been made for its repayment but there is none as far as I can see. This point applies whether US$50,000 had been loaned to the claimant under the Promissory Note or US$51,079.90 had been loaned to the claimant under the CPN. I say that because until conversion in accordance with clause 2, the CPN was a promissory note in respect of a loan repayable on demand after 1 June 2021.

43. Secondly, Mr Barnett was cross examined about these issues - see T2/15-16. He asserted that the phrase "*Funds Received*" at the head of the left-hand column of his spread sheet referred to all the sums that followed – see T2/15/11-15. I reject that evidence. If that was right then it would apply to all the sums listed elsewhere in that column that on any view had not been received (respectively US$250,000, US$175,000 and US$2m). That phrase applies to the only sum that had been received – the US$45,000 invested by Messrs Asadourian and Barnett – as is apparent from the fact that it appears in the row that relates exclusively to that payment.

44. Thirdly, although Mr Barnett maintained that the reference to $40,000 was an error – see T2/15/24-16/1 - I do not accept that to be so as I have said. Had a sum as precisely defined as US$51,079.90 been received it is inherently improbable that sum would have been mistakenly mis-stated in a spread sheet of this importance. It would have to be accounted for in the books of the company. In any event it does not explain the other

points already considered – the failure to inform Professor Sinclair of the receipt at any stage including in particular when she was complaining in the Autumn of 2018 about the fact that nothing had been raised and the failure to record it as a debt that would require repayment or would so unless converted.

45. All these factors together lead me to conclude that the claimant has failed to prove the loan it relies on. Either the sum was received by Biodome but not passed on to the claimant or was not received at all. It was not received by the claimant. Had it been it would have been entirely straightforward for the claimant to produce its accounts showing the receipt or a bank statement showing the receipt but it has not done so.

46. Even if all this is wrong and in fact the claimant did receive US$51,079.90 from Mr Falahat (or his corporate vehicle) it does not take the issues that arise in this claim anywhere. It does not demonstrate that the claimant had a realistic prospect of raising the finance needed within a reasonable time of 6 November 2018. Rather it emphasises the failure to raise anything like the sums required by that date notwithstanding the apparent time and effort deployed to do so and the inherent improbability of it doing so in the future.

Future Funding prospects

47. The suggestion by the claimant that there was a real, as opposed to a speculative, prospect of the claimant raising sufficient funds to complete the Phase 2 clinical trials depends on three points. Firstly the claimant contends that as at 6 November 2018, there was at least a realistic prospect of raising the sums necessary to complete Phase 2 from Electrocore by way of equity investment into the claimant. Secondly, the claimant contends that there was a realistic prospect of raising the necessary finance in the same way by attending the JP Morgan Conference in early 2019 – an annual industry networking conference where those seeking investment for pharmaceutical and allied projects can compete for such investment on a speculative basis by pitching the projects to those willing to consider funding. Thirdly, Messrs Asadourian and Barnett were ready willing and able to invest between them the sum of US$250,000.

48. *Context*

It will be necessary for me to consider each of these propositions in some detail. However, it is necessary first to set the context in which each of these alleged opportunities needs to be considered. First, for the reasons set out above, no funding at all had been raised in the period down to 6 November 2018. It necessarily follows that neither Mr Asadourian nor Mr Barnett had been able to persuade their many contacts in the pharmaceutical industry to invest certainly to the level required or probably at all.

49. Secondly, the product into which investors were being asked to invest substantial sums was problematical because it depended on use of a drug that was available generically and did not depend on a novel or IP protected means of delivery.

50. Thirdly, the exclusivity period protected by the defendant's IP rights was finite in length and getting shorter so that the longer that elapsed before Phase 2 could be commenced and completed, Phase 3 could be started and completed and regulatory approvals obtained, the less attractive the offer became because any investor was left with a

reducing period of exclusivity in which to recover its costs and make a profit – a point accepted by Mr Hackett on behalf of the claimant in the course of his closing submissions at T4/21/2-16.

51. Fourthly, there was no commercialisation plan or detailed financial projections available which served only to emphasise the difficulties associated with the project that were apparent from its nature, the salient elements of which I have set out above. The absence of such materials would have made obtaining third party funding difficult and as I explain below would have been a major disincentive to the defendant granting a licence had the claimant served notice to commence negotiations.

52. Finally, the level of investment needed just to complete the Phase 2 trials must be remembered. It was common ground it would cost US$269,000 to complete the proof of concept sub-stage of the Phase 2 trials. It would cost substantially more to complete the phase 2 clinical trials. Various sums were mentioned by Messrs Asadourian and Barnett in the course of their evidence in a range of between US$1.5m to US$2.5m. It was suggested that to complete Phase 3 and obtain regulatory approval would cost between US$12.5m and US$17.5m.

53. *Electrocore*

The possibility of investment by Electrocore too must be viewed in its correct context. Firstly, Electrocore is a US registered and domiciled company that manufactures and sells (or in 2018 manufactured and sold) a single electrical medical device called Gammacore – a device that prevents or relieves headache by electrical stimulation. At no material time had the company either manufactured or sold medicinal drugs. In June 2018, it had participated in a US$90m Initial Public Offering in order to finance its expansion into other specific projects identified in the prospectus. Against that background, Mr Asadourian's evidence was that having approached Electrocore, " … *we were making good traction, we were getting good feedback and ultimately had very, very positive engagement with Electrocore in August 2018 which would have been for significant funds, not just 250,000 …"*. In the end however, no offer was forthcoming. The claimant's case however is that there was a more than realistic prospect of an investment offer being made sometime in 2019.

54. The claimant called Mr Amato as a witness. He was the CEO of Electrocore until October 2019. During that period his evidence is and I accept that he had " … *complete oversight of the entire business operations of the company and was involved in the consideration and process of all investments that the company undertook*." There were a series of meetings between officers of Electrocore and Messrs Asadourian and Barnett concerning the product. The final meeting was in August 2018. It is at that point that Mr Amato's evidence given orally deviates from what he stated in his witness statement. In his statement he had said:

> "We took the initial position to the board, however as a consequence of the recent IPO the board took the decision that their institutional investors would not want to engage in any large investment so soon after the IPO. Specifically, we had pitched our institutional investors on the basis of the treatment for which we already had FDA approval. Having obtained

> US$90,000,000 from an initial public offering on the strength of that pitch less than two months before, we did not think it was appropriate to start deploying that money so quickly on a different drug. We therefore resolved not to make any investment before the New Year and informed Exelogen accordingly." [Emphasis supplied]

He added at paragraph 12 of his statement that:

> "Electrocore had substantial available capital from the initial public offering to enter into a licensing deal and it was very likely that we would have agreed to provide significant investment in early 2019. However as a consequence of the breakdown of the relationship between Exelogen and the University of Birmingham we were unable to proceed." [Emphasis supplied]

55. In cross examination this evidence altered materially. Having referred to the August 2018 meeting, he then said:

> "A … we'd raised $90 million for the purposes of commercialising our own product, and if we were to in-licence anything, we wouldn't suggest to the board that we would spend nearly 15% of what we raised in …"

Non Electrocore products. He was then asked about the presentation to the Electrocore board, as to which he said:

> "A. I didn't feel that there was enough support from the board members as we had -- including JP Errico and others, as we had conversations. Before going forward to the board meeting, I had a discussion with our chairman at the time, Carrie Cox, and generally folks thought that we should wait until 2019.
>
> Q. Fine. So in fact you didn't even get to make a proposal to the board, the ...?
>
> A. We made the proposal to the individual board members about it.
>
> Q. I see. Informally.
>
> A. Yes.
>
> Q. Okay. I just thought that there was a meeting and kind of agenda item number 20 was "Proposed ..."?
>
> A. I don't have board minutes where we had a discussion around that.
>
> JUDGE PELLING: Was it on the agenda of the board or not?

> A. It was not on the agenda at the board meeting --"

The long and the short of it is and I find that there was insufficient support for the project amongst the members of the board of Electrocore to justify Mr Amato even placing it on the agenda for consideration by the board of Electrocore. As he added a little later in his cross examination, paragraph 11 of his statement was inaccurate to the extent that it implied there was a formal consideration by the board to invest in 2019. As he said all they had was a "*... general discussion about it ...*" and he accepted that when he said in paragraph 12 of his statement that "*it was very likely that we would have agreed to provide significant investment in early 2019*", it would be fair to analyse the position as being "*maybe, maybe not*" – see T1/160/14-22.

56. In my judgment on this evidence there was a no better than speculative prospect of Electrocore investing in the claimant because (a) it had raised US$90m for investment in its own products; (b) for obvious reasons, it did not wish to invest in anything that required the sort of sums required by the claimant on projects that were not specifically identified in its IPO prospectus and (c) investment in the claimant did not command sufficient support even to justify it being put to the board formally. Had there been sufficient interest, it is more likely it would have been listed for formal consideration and a resolution passed as to what was to be done with the opportunity – if only fixing the future date by which it would next be considered by the Board.

57. In my judgment that view of the appetite of Electrocore's Board for investment in the claimant is supported by Mr Barnett's email to Mr Errico, a director of and major shareholder in Electrocore on 6 September 2018, in which he stated:

> "JP, greetings. We understand that Electrocore is not in a position currently to work with us on our next milestones. You and I spoke about your separate angel group (CV), and the possibility of continuing the dialogue in that capacity.
>
> Have you had a chance to review the patent application attached below, and discuss with your colleagues?"

There are a number of points that emerge from this email. Firstly, Mr Barnett recognises that there is no present prospect of receiving investment from Electrocore. Secondly, there is no mention at all of the possibility of this being revisited by Electrocore much less revisited in early 2019. Thirdly, had there been any encouragement given to him by Mr Errico that Electrocore would invest in the near future to the levels discussed earlier (or otherwise) then in my judgment the email, would have been in very different terms. It would have referred to the possibility (if this is what had been offered) of formal future consideration of investment and would have either confirmed when that was to take place if a date or date range had been indicated by Electrocore or would have attempted to procure agreement, or at least an indication, of when that further consideration would take place. What it would not have referred to was to the possibility of investment by Mr Errico's " … *separate angel group (CV), and the possibility of continuing the dialogue in that capacity*…"

58. More importantly however, the email is consistent with Mr Errico having raised the possibility of investment by his separate (i.e. separate from Electrocore) angel group. Had there been any real possibility of Electrocore investing in the near future, it is close

to inconceivable that Mr Errico would have mentioned the alternative possibility, even in passing. It is common ground that Mr Errico was a seasoned executive director, shareholder and investor in the pharmaceutical industry. To my mind it is entirely unreal to suppose that such a person would not have been alive to the duties he owed to Electrocore as a director of a public company or the willingness of shareholders in public companies registered in the United States to take action against those who breach their duties as directors of public companies. It is plain that investment by Mr Errico in the claimant using Mr Errico's " … *separate angel group…"* would be (and I consider it probable would have been understood by Mr Errico to be) a breach of the fiduciary duty he owed to Electrocore as long as Electrocore retained a real but delayed interest in considering investment in the claimant.

59. Although it was suggested on behalf of the claimant that Mr Errico's comment was made in passing, it is one apparently picked up by Mr Barnett. Whether it was mentioned in passing by Mr Errico or not, by mentioning it in his email Mr Barnett was implicitly recognising that there was no real possibility of Electrocore wanting to invest and is inconsistent with the notion that there was a real prospect at the date of the email that Electrocore would enter into negotiations in the future.

60. Mr Barnett's emails to Mr Asadourian and his discussions with and emails to Professor Sinclair at this time are also inconsistent with him thinking there was a real prospect of Electrocore investing in the future. I have mentioned the relevant part of the 6 November email to Professor Sinclair earlier. I need mention only two other examples.

61. The first is an email from Mr Barnett to Mr Asadourian of 5 October 2018, where he reported a conversation with Professor Sinclair in which he described her as being " … *very concerned by the lack of progress in raising funds for the IIH Pressure trial and other Exelogen needs…"* Had there been any real prospect of Electrocore reconsidering its position, Mr Barnett would have been saying so to Professor Sinclair in the clearest terms and would have been reporting to Mr Asadourian that he had done so. This email in my judgment is entirely consistent with the views I expressed earlier concerning the reality of the situation.

62. Finally, in Mr Barnett's own notes of his conversation with Professor Sinclair on 6 November 2018 confirm the reality of the situation. In that note, Mr Barnett records:

> "Position - me - sources drying up in the US / lines of inquiry
>
> - AlexS now anxious, experience w/ Electrocore; risky, wants to complete the trial, don't know where, want the University's help + University won't help with the option agreement - internal grant, attract other investors"

The real points are that emerge from this note are (a) Professor Sinclair's despair at the lack of progress, which would not have been expressed in this way if she had been told or otherwise understood there was any prospect of investment by Electrocore in the near future; (b) the absence of any comfort being provided by Mr Barnett as to the availability of investment leads and (c) his positive assertion that investment leads in the US were drying up and (d) there being no mention of the possibility of investment by Electrocore in the future, which would have appeared in this note and would have

arisen in the conversation with Professor Sinclair had it existed. This note is entirely consistent with Professor Sinclair's oral evidence (which as I have said I accept) that:

> "I did ask George a number of times. George, I believe, was really trying in earnest to find new options and we had very candid conversations. I remember him talking to me about he didn't have immediate options of where to go or future options about where to go."

63. Professor Sinclair's evidence was that at no stage was she told by either Mr Barnett or Mr Asadourian that there was a prospect that Electrocore would invest in the claimant in the near future or at all. I accept this evidence not least because it is entirely consistent with the material referred to above. If there had been any realistic prospect of investment in the future by Electrocore then there is no doubt at all that either Mr Barnett or Mr Asadourian or both of them would have been saying so. The reality was as described by Professor Sinclair in her evidence: " … *after this call (with Mr Barnett) in the time afterwards, there was no recommendation of other pitches that we could do or other tangible leads and I really felt that we had got to the end of the line . There was no suggestion of where to go next* …" She added (consistently with what is reflected in Mr Barnett's note referred to above) that:

> "Obviously we had had many people to talk to in the early days and it had got less and less and less and less, and this had been building for about five months, this Electrocore pitch, and we did it, and they categorically turned us down, and I think we've explored that already, and then there was nobody else on the table. So I did feel very despondent, yes."

64. *The US$7.5m Electrocore "Pre Money" Valuation*

Finally, I should say something about Electrocore's "pre-money" valuation of the claimant. It might have been but was not I think in the end argued that the effect of this alleged valuation was one that would have lifted the claimant's chances of attracting an investment from Electrocore. The basis for this point is a signed statement apparently dated 1 August 2018 signed by Mr Duhart, which was in these terms:

> "On August 15, 2018, as a senior officer of Electrocore Inc, l Dan Duhart attended a critical investment meeting between Senior Management of Exelogen Inc and Electrocore. During this confidential meeting, attended by Exelogen senior management as well as Alexandra Sinclair, Exelogen was valued, on a pre-money basis, at USD 7.5 million. This valuation was based on our assessment of the business case, market opportunity and development status presented Exelogen management as well as the exclusive global option owned by Exelogen for the rights to license the exenatide IP from the University of (sic) Burmingham."

65. As noted earlier, this was the basis of the alternative claim to damages pleaded in paragraph 50.2 of the amended Particulars of Claim and as a basis for concluding that

there was a real prospect that Electrocore would invest substantial sums in the future. I do not accept that is so for the reasons that follow.

66. The difficulty about placing any reliance on this document for either purpose is that it does not purport to value the claimant scientifically but more importantly makes clear that the premise on which the valuation is based is that the claimant has an exclusive global option to a licence of the defendant's IP rights whereas of course it does not have and never had such a right. It only had a right to enter into negotiations for a licence. On the pleadings this was described as being an error – see paragraph 11 of the Reply, where it is pleaded that:

> "Paragraph 43 is noted, however notwithstanding what is said on the document (in error) the valuation was indeed conducted on the basis of the right the Claimant had under the Option Agreement (i.e. a right to negotiate)."

67. Mr Amato's evidence on this issue did not assist the claimant. He told me in the course of his re examination that the valuation was arrived at on the basis that the claimant had an exclusive licence agreement – see T1/162/5-163/6. The key point remains that the claimant did not have such a licence or an option to take up such a licence but only a right (providing it triggered the option by notice) to negotiate for a licence.

68. In those circumstances, I reject the notion that this constitutes evidence from which I can conclude that the claimant is entitled to recover the sum of US$7.5m as alleged in paragraph 50.2 of the amended Particulars of Claim. I reject the submission that I should infer there was a real prospect of an investment by Electrocore in the sums required to complete Phase 2, Phase 3 and the post Phase 3 regulatory steps firstly because the assumption on which it was prepared does not reflect the reality, secondly, there is no material that demonstrates how this figure was arrived at other than on the basis of the false assumption identified but more particularly because this valuation was arrived at before the August meeting, following which it became clear that Electrocore had no appetite to invest in the claimant and because in any event this apparent valuation has to be weighed in the round with all the other material I have considered in arriving at a conclusion as to whether the claimant has proved a more than speculative chance that Electrocore would invest in the claimant. For the reasons explained above, viewing this material in the round, I consider a no better than speculative chance has been demonstrated.

69. *Personal Investment by Messrs Asadourian and Barnett*

I turn next to the suggestion that Messrs Asadourian and Barnett were ready willing and able to invest between them the sum of US$250,000. I reject this suggestion as untrue. Had this been the position then it would have been mentioned at some stage and certainly by the Autumn of 2018 when it was clear that so far as Professor Sinclair was concerned, the possibility of attracting third party investment had disappeared and her despondency resulting from that was known to at least Mr Barnett and was reported by him to Mr Asadourian. That this was so is unsurprising – given the absence of third party interest that Messrs Asadourian and Barnett had been able to generate and the level of expenditure that was necessary before there could be any expectation of a profit being made, it would have been commercially absurd for either to have invested at this

level given the real risk that no further progress could be made. Professor Sinclair was not told by either that they intended to invest to this level because in truth they had no such intention, at any rate otherwise than as part of a wider investment group. My conclusions on this issue are factors that affect the credibility of each as witnesses whose evidence I could safely rely on.

70. *The JP Morgan Conference*

The final possibility concerns the JP Morgan conference. Although the defendant submits that Messrs Asadourian and Barnett's enthusiasm for this route as a source of funding is inconsistent with a belief on their part that Electrocore would invest in the claimant, in my judgment the one does not follow from the other. As long as an investment had not become legally binding, it obviously made sense to seek other investment opportunities.

71. That said, in my judgment resorting to the JP Morgan conference was a sign of desperation when viewed together with the material I have considered above. There was no realistic reason to suppose attending the conference would result in investment at the level required. The conference was an annual event. Professor Sinclair described it in her oral evidence as a networking event. I am satisfied that in large part that is what it was. However, I accept too that it was an opportunity to pitch projects to investors on a speculative and competitive basis. I accept Professor Sinclair's description of the process in her evidence:

> "… you would line up investor meetings at sort of 20 or 15-minute intervals, or 30-minute intervals throughout the day in a hotel room, or something like that, and you would try and book into all of those slots different people to come and talk to you. So you would get a high throughput, but we'd already explored the book of all the investors that Artin and George had access to for 18 months. There were 608 rows of investors that they had explored relationships with on the Excel spreadsheet where they kept track of everything.
>
> JUDGE PELLING: And am I understanding correctly that the value of the link with Artin and George was that they brought to the table, as it were, a black book full of contacts which got you through the relevant front door. Whereas, or am I oversimplifying, when you go to the JP Morgan conference you are in a pack with a whole load of other people all doing the same thing to the same pitch recipients?
>
> A. You've described it quite correctly."

72. The key point made by Professor Sinclair in relation to this issue is that it did not involve any reliance by Messrs Asadourian and Barnett on their established relationships to raise investment. The whole point behind the defendant establishing a relationship with Mr Asadourian at the outset was to take advantage of his contacts within the pharmaceutical industry, principally in the United States, to generate investment. As Professor Sinclair said a little later in her oral evidence, the JP Morgan Conference was an opportunity to seek investment from " … *unsolicited relationships*

that you haven't built with people that aren't necessarily interested in your space …[s]o the chances of success are far diminished …" There is no evidence that by attending the JP Morgan conference Messrs Asadourian and Barnett would have generated any more success by pitching in this way to investors attending the 2019 Conference than if the defendant and Professor Sinclair had attended and had themselves pitched to investors willing to listen. Mr Barnett accepted that Mr Asadourian had attended the 2017 conference and Mr Barnett had attended the 2018 Conference without generating any investment. Having regard to the totality of the evidence about the Conference, I accept as accurate Professor Sinclair's statement in the course of her oral evidence that "… *(i)t was a very last-ditch attempt …*" with no realistic prospect of success.

The Defendant's Requirements

73. The Substantiality Issue is concerned with whether the claimant's opportunity to take Exenatide to market and profit from its sales was real or substantial. Its ability to do so depends on whether there was a realistic prospect of the defendant granting it an exclusive licence by no later than 30 June 2020. This depends on an analysis of the objectives of the defendant and its expectations from a potential licensee. This issue must be judged against the background fact that at no stage had the claimant sought to serve a notice to commence negotiations under the option. In my judgment their reason for this was obvious – unless and until it had obtained the funding necessary to enable the product to be brought to market. There was no prospect at all, and Messrs Asadourian and Barnett knew full well that there was no prospect, of the defendant granting the claimant a licence for the obvious reason that the defendant's purpose was to ensure the product got to market in order to be available to treat patients and there was no real prospect that the claimant could do that without obtaining the necessary investment.

74. As to the likely approach of the defendant if such a notice was ever served, the evidence of Dr Watkins is critical. Dr Watkins was a witness of truth and candour and I am confident I can rely on his evidence. Nonetheless, where I have been able to do so, I have tested what he says using the methods identified earlier.

75. In summary Dr Watkins evidence relevant to the issue I am now considering was and I accept and find that:

    i. The defendant did not and does not carry on commercial activity other than with commercial partners because to do otherwise would be contrary to its charitable status;

    ii. Granting options to such partners to negotiate for a licence was and is standard practice for the defendant;

    iii. That practice is adopted by the defendant because it enables the defendant to judge whether the option holder had the knowledge and resources to implement any licence that may be granted to it;

    iv. That at the point when a party in the position of the claimant triggers negotiations, the defendant would expect the proposed licensee to produce:

> " a commercialisation plan, and in that a forecast of sales, and also an offer for what the licence terms might be. In that commercialisation plan we would expect to see … what the clinical trials might be, when they might happen, what the time lines might be, when you might get to market authorisation, is there intention to out license or try and turn into a pharma company themselves. It would be everything about it …" The defendant's objective was to see that the technologies that are developed by its researches get to the point where they " … *do some good in the world, in this case that patients for IIH and other indications were to get treated ... and if that were to happen, the [defendant] would get its fair share of any revenues that were generated* …"

v. In the context with which this case is concerned, a delay in the product being commercialised would diminish the possibility of it getting to market and treating patients because the commercial partner would have a shorter exclusivity period in which to earn the revenues necessary to cover development costs and make a profit higher than would be possible from marketing the product without IP protection; and

vi. A major driver of the terms of the licence is likely to be the third party investor into a company such as the claimant because the investor is likely only to be prepared to invest if the licence being offered is on terms acceptable to it.

76. The key point in summary is that the purpose of granting an option is specifically to enable the defendant to reach a judgment on whether the proposed licensee has the knowledge and resources to get the product to market (whether by manufacturing and marketing the product itself or sub or under licencing an entity able to do so). In this case, the defendant would be expecting the claimant to raise the funding necessary to complete the Phase 2 clinical trials and that it had available to it either the resources or a partner with the resources sufficient to enable the Phase 3 clinical trial and the subsequent regulatory steps necessary to bring the product to market primarily so that patients could be treated.

77. On this analysis it is manifest that the claimant had no realistic prospect of so doing. It had not generated any investment at all aside from the US$45,000 Messrs Asadourian and Barnett had invested at the outset and (on its case, which I have rejected) a further US$50,000 alternatively US$51,079.90 allegedly lent to the claimant. I accept that a major investor would not invest other than conditionally into the claimant but would wish to participate in any negotiations triggered by the claimant under the option and conclude whether to invest once the terms of the licence had been agreed, again conditionally.

78. The real problem is that there was no such investor available to the claimant. All those known to Messrs Asadourian and Barnett had been tried and had passed. There was of course the speculative possibility that an investor might turn up but that cannot be characterised as a real or substantial chance. Why that may be is in part a matter of

speculation. However, it is likely to include that no prototype formulation or method of delivery had been identified, which prevented the commencement or completion of the proof of concept part of the Phase 2 trials. At least one investor had given feedback to the effect that because the drug was generic, a different formulation and/or system of delivery was required in order to strengthen IP protection and, therefore, attractiveness of the offer to the investing market. This feedback has added significance because it was being produced in late March 2018. Not only did it express concerns about the strength of the IP rights to hold off competition, but it concluded but the financial model was unsatisfactory. Mr Asadourian accepted in cross examination by reference to this criticism that at this stage "*the business plan was not mature …*".

79. It was of significance that in this feedback, Messrs Asadourian and Barnett were described as being "*… two incubator executives …"*. This is a US Pharmaceutical industry expression. I asked Mr Asadourian to explain what it meant – his explanation was that:

> "A. So Biodome Partners is an incubator. This is prior to the founding of Exelogen, which was the operational company. Biodome Partners is what we use to go out there and do these initial investor engagements, to generate this kind of feedback and refine the business case as we go forward.
>
> …
>
> And so we do present Biodome Partners as an incubator and not the operational company. The operational company came with Exelogen. And that's where the funding would go to bring in the full business team."

The reality appears to be therefore that, at this stage, at least the project had not passed the incubator stage even though the claimant had been registered and started to trade. The fundamental problems identified in this feedback continued with the presentation to Electrocore, where the product was still the generic (non-IP protected) drug and with no mention of any novel delivery mechanisms capable of IP protection. These were serious weaknesses that were almost bound to concern investors. The point that matters for present purposes is that without an investor, there was no real prospect of persuading the defendant that it ought to grant a licence to the claimant. As Dr Watkins recognised in his evidence, most investors would expect to be involved in the licence negotiations because whether and at what level an investor would be prepared to invest would depend on the terms of the licence as well as the other commercial factors I have mentioned.

80. On the material available I conclude that a major obstacle to obtaining the real interest of an investor arose from the commercial undesirability of going to market with a generic drug without any distinguishing (and IP protected) elements. It was this that prevented the development of a viable commercialisation plan and without that, not merely would the defendant not wish to grant a licence but an investor would be unlikely to want to get involved either. A difficulty is that until issues concerning drug refinement, dosing and delivery had been resolved it was not even possible to say with

certainty whether a Phase 1 trial would be required. If that was required then significant delay would result. This was bound to be considered problematic by an investor.

81. In reality, in the two years during which Mr Asadourian had been involved, there had been no significant progress. At the outset Professor Sinclair had started her proof of concept Phase 2 trial using a generic version of the drug and had sought patent and orphan drug protection on that basis. Nothing technical had changed by November 2018. The proof of concept trial was still on going, the Phase 2 clinical trials had not been commenced, no funding had been obtained, no additional IP protection had been sought because no steps had been taken to work on the drug dose, composition or delivery issues and therefore doubts remained as whether or to what extent Phase 1 trials might be required. Unless and until these issues were resolved it was highly improbable that a commercialisation plan or financial projections could be prepared or an investor could be attracted and for those reasons there was no real prospect of the claimant being granted a licence by the defendant. Until a decision has been reached on the cost of making the active ingredient (which will depend on whether the generic product is to be used and if not what the development and manufacturing costs of the new product will be) and all other associated costs including but not limited to the cost of developing and manufacturing the delivery system, it is simply not possible to provide financial statements that are anything other than high level broad estimates. That is what the claimant by Messrs Asadourian and Barnett provided. That would not come anywhere near satisfying a rational investor and in consequence the defendant.

82. In my judgment for these reasons, the claimant's alleged loss of the opportunity to take Exenatide to market and profit from its sales was at best merely speculative. As I have explained, paragraph 50.2 is pleaded exclusively by reference to the US$7.5m "*pre money*" valuation apparently arrived at for the claimant. For the reasons explained above, a claim to damages based on that valuation must fail. No other alternative basis for advancing the claim under paragraph 50.2 has been pleaded. In any event I see no real distinction between paragraph 50.1 and 50.2 other than the inclusion within that paragraph of the reference to the alleged US$7.5m valuation. In truth if the claim under paragraph 50.1 cannot succeed then the claim under paragraph 50.2 cannot either. Each is premised on the loss of the option. Even if there is a conceptual distinction between the two ways the claim is put, it is a distinction without a difference on the facts of this case. If (as I have concluded) there was a no better than speculative chance of the claimant raising the necessary investment by no later than 30 June 2020, then the option had no value.

The Causation Issue

83. The defendant has admitted that it has breached the Agreement by depriving the claimant of the chance of negotiating the grant to it of a licence of the defendant's relevant IP rights. The claimant is entitled to recover damages for the loss proved to have been caused by that admitted breach. In my judgment plainly on the findings I have made so far the claimant has not proved that the loss it alleges has been caused by the breach. There was no prospect whatsoever of the defendant granting a licence unless and until the claimant had obtained the funding necessary to bring the treatment to market, whether directly or by entering into an arrangement with a funding partner. For the reasons I have given already, there was no or no more than a speculative chance of the claimant obtaining such funding. It follows that the claimant has failed to prove the

loss it asserts was caused by the admitted breach of contract. It follows that this claim fails at that point.

The Valuation Issue

84. Given the conclusions that I have reached so far, strictly it is not necessary for me to carry out the valuation exercise. Inevitably any assessment of the value of the opportunity will be counter factual and *obiter* and any assessment of the percentage of the nominal full value of the opportunity lost will be inconsistent with the conclusions that I have reached so far.

85. In those circumstances, my preferred option would have been simply to leave these issues unresolved as ones that it was not necessary for me to resolve in light of the finding made so far. However, with some hesitation, I have decided to set out my conclusions on these issues. However, it should clearly be understood that what I set out below does not have any impact on the conclusions reached above and should not be read as having or as having been intended to have any impact on those conclusions, which are those that are dispositive of this claim.

86. There is a fundamental difference of view between the two experts as to how the valuation exercise should be approached in the circumstances. Dr Walton's opinion is that the correct method of valuation involves using a Discounted Cash Flow ("DCF") method incorporating an adjustment to reflect clinical and regulatory risks inherent in the development of pharmaceutical drugs. This technique involves identifying future revenues, future development, manufacturing, marketing and other costs and arriving at an estimated Net Present Value ("NPV") of the profit before tax that would be made during an assumed period of commercial exploitation by discounting back from the date the costs would be incurred or revenues received to the date when damages are to be assessed. There is a dispute as what date should be adopted. The general rule in English law is that damages are to be assessed at the date of breach[1] although the court has long had the power to depart from the general rule where it would work injustice[2]

87. If this exercise is done correctly it involves looking at different heads of costs and when they will be incurred as well as what revenues are likely to be earned and when. Potentially different discounts have to be applied for different metrics within that exercise. Where the risks of earning the revenues are immaterial then the discounting that is applied is only that necessary to arrive at the net present value in financial terms of a cost to be incurred or a revenue to be received in the future. Inevitably that involves making assumptions to enable calculations to be carried out such as the effect of inflation and the cost of money as a component of the discounting process.

88. In addition, where there is a substantial risk that the revenues will not be earned, that too must be taken into account in arriving at a net present value. That is an important consideration in a case such as this for the reasons identified by Dr Walton in paragraph 35 of his report:

> "35. Risk is an important factor to consider in DCF calculations as about 90% of all drugs entering clinical trials fail. Even a drug

[1] See Chitty on Contract, 34th Ed. Vol 1 paragraph 29-105 and footnote 583.
[2] See above and footnote 585.

> that has completed all its clinical trials and has been submitted for regulatory approval still carries the risk of rejection by the regulatory bodies who may consider the clinical data submitted to be insufficient. A drug at Phase I of its clinical development therefore carries a far heavier burden of risk. It might fail to show safety in its Phase I trial(s), then, even if it is shown to be safe, it might fail to demonstrate efficacy in its Phase II trials, and, if it does succeed, it could thereafter fail to confirm those safety and efficacy features in a much larger Phase III trial. Each of these trials carries a different, probability of success and a risk adjusted DCF will use these differing probabilities to generate a risk adjusted Net Present Value, also known as an Expected Net Present Value or eNPV."

Dr Walton considers that these factors (the need to discount to reflect present value of cost and revenues to be incurred or received in the future and the risk of product development failure) are to be taken into account by a combined discount rate of 12.5% alternatively 15%. These have been arrived by taking a Weighted Average Cost of Capital ("WACC") of 7% and adding either 5.5% or 8% for additional risk factors. Having arrived at a net profit figure being revenues to be received less costs to be incurred to arrive at an "*expected NPV*", Dr Walton then applies a further discount to reflect the acquisition by the claimant of the funding necessary to meet costs to incurred. Had the model involved borrowing this would have been the assumed cost of borrowing the sums necessary to fund such expenditure. However the model does not involve borrowing but involves inward equity investment. Dr Walton considers this must be taken into account by applying a deduction to reflect this factor. I have some doubt about this as a technique because of the obvious differences between equity and debt funding with debt funding creating a cost that will be reflected on the balance sheet of the borrower whereas equity funding impacts existing shareholders by diluting their interest but does not impact the company balance sheet. However, both parties were insistent that this was the appropriate course to adopt and I do so to the extent that it is necessary. Subject to that point and otherwise making the assumptions that he identifies in his report, Dr Walton arrives at a lost net profit figure "*at market ready stage"* which he presents in tabular form as:

A	eNPV of Exenatide IIH orphan drug at market ready (2026)	US$	349,094,101	to	US$	435,767,681	**100%**
B	Value assigned to future commercial partner	US$	174,547,051	to	US$	217,883,840	**50%**
C	Value retained by UoBirmingham (cost of license terms)	US$	69,818,820	to	US$	87,153,536	**20%**
D	Value assigned to Exelogen* = (A-[B+C])	US$	104,728,230	to	US$	130,730,304	**30%**
E	Equity dilution of 50%		50%			50%	
	Claimant's Lost Net Profit	**US$**	**52,364,115**	**to**	**US$**	**65,365,152**	**15%**

89. Ms Harfouche considers this to be entirely mistaken. Her evidence is not that expected NPV modelling is inappropriate in principle but that it is inappropriate to apply it in this case because, on the facts available, it cannot give a reliable estimate of the net present value of the profits that will be made in the future measured at the date of

breach. Her position is therefore that this methodology should not be used at all in the circumstances of this case but if it is to be used then various fundamental mistakes have been made by Dr Walton in the way he has estimated the net present value of the profits that have been lost. She has carried out a calculation which attempts to correct these supposed errors. For the reasons set out below, I consider that the NPV approach is in principle correct and that subject to the corrections made by Ms Harfouche (other than one) it enables me to make an assessment of the sum lost or put another way the value of the option lost.

90. In paragraph 3.8 of her report, Ms Harfouche identifies various steps that would have to be taken before revenues could be earned and, therefore, profits made. These include:

> "…
>
> c) completing the Phase II trial and reaching positive results that justify seeking to proceed to the Phase III trial;
>
> d) securing patent protection for Exenatide for the treatment of IIH;
>
> e) securing the financing required to complete the Phase III trial;
>
> f) successfully completing the Phase III trial;
>
> g) successfully registering and obtaining marketing approval for the Product;
>
> h) establishing the required production, distribution and marketing capabilities or successfully negotiating agreements with a third party producer and a third party marketing agent; and
>
> i) successfully marketing the Product to healthcare providers and other purchasing authorities such that the sales volume and price are sufficiently high for Exelogen to generate a profit."

Ms Harfouche's opinion is that:

> "The probabilities of steps 3.8c) to 3.8i) above could not be estimated with any degree of reliability as at the Date of Breach. They are each a function of many factors. This is not just limited to the efficacy and safety of the Product and the potential profits it could generate, but also to the competence of Exelogen in successfully negotiating with a number of parties."

She adds that:

> "the potential use of Exenatide for the treatment of IIH was at such an early stage that, even assuming that the Product could be brought to market, the key inputs into the assessment of future

> profits (market size, penetration, price, costs and so on) could not reliably be estimated."

91. This is consistent with the position adopted by Invex in its IPO prospectus which it will be recalled was offered to the market for the purpose of raising finance to enable Exenatide to be trialled and if successful sold commercially for the treatment of IIH. However in its prospectus Invex declined to forecast future earnings because any " … *forecast or projection information would contain such a broad range of potential outcomes and possibilities that it is not possible to prepare a reliable best estimate forecast or projection on a reasonable basis.*". This is a relevant consideration because at that stage Invex were no further forward than the claimant had been in relation to the development of the product. Ms Harfouche's opinion was that because the future net profits were so difficult to estimate with any reliability, " … *it is also very difficult to reliably estimate a discount rate that properly reflects such a high degree of uncertainty*."

92. As I have said Ms Harfouche considers that in any event various errors have been made by Dr Walton in how he has applied his own chosen methodology and assumptions. It is to this last mentioned issue I now turn.

93. The fundamental point that Ms Harfouche makes is that any discounting back to arrive at a net present value should be discounting back to the date of breach not some randomly selected future date. In principle (and subject to the award of interest on any judgment, which I am not concerned with at this Stage) I agree with this approach since it reflects the general position as a matter of law – see footnotes 1 and 2 above.

94. Dr Walton assumes that the product would be market ready in 2026 – see the table reproduced above – and forecasts profits forward from 2026 to 2037 and then discounts them by 4.5 years (to the date of his report) to 15.5 years and then applies a further discount to take account of the effect of attracting inward equity investment mentioned earlier.

95. Ms Harfouche makes the point that if the assumed market ready date is correct and date on which damages are to be calculated is the date of breach in November 2018, then the discount range should be 8-19 years. In principle I consider this approach to be correct. No good reason has been identified for departing from the general rule. It is sometimes necessary to do so in order to take account of something that has happened so that certainty can replace an assumption to ensure greater fairness in the assessment. However here nothing of relevance changed between the date of the breach in November 2018 and the date of Dr Walton's report other than the Invex IPO had been completed and it had commenced development work. That is immaterial for present purposes because it was not a model that the claimant ever considered. It was a model that involved raising funds by an IPO then taking an assignment of the defendants IP rights. In those circumstances there is no reason or justification for departing from the general rule.

96. The 2026 date chosen by Dr Walton comes from information published by Invex in July 2022. Whilst it might be argued that a date earlier than 2026 should be adopted if the start point is treated as being November 2018, there is no reliable basis so doing. I treat 2026 as the start date that is agreed between the experts.

97. Ms Harfouche further criticises Dr Walton because (a) he has assumed that it is certain that the product could be brought to market at the date of his valuation (the date of his report) whereas manifestly that was not the case. Broadly she considers that in order to arrive at a net present value of profits it is necessary to adjust the figures at various stages to reflect the risk of the project failing at the various development stages that are yet to be concluded. This last figure has been arrived at by multiplying the chances of successfully completing Phase 2 (70%) and Phase 3 (67%) to give a cumulative probability of 47% and then multiplying that by 81% to reflect the probability of completing the subsequent regulatory steps to arrive at a cumulative probability of 38%. Again, I do not understand this to be in dispute as a matter of principle. I do not accept that it is appropriate to assess damages at the later date adopted by Dr Walton on the basis he relies on namely that by then Phase 2 had been completed. True it is that stage had been completed but by Invex. This case is concerned with the calculation of the loss suffered by the claimant and involves assessing the prospects of it (or an investor or partner if one could be found). That does not involve looking at what Invex achieved (using a business model that was materially different from that which the claimant proposed using) but what the claimant would have achieved and they are two very different things. For those reasons I prefer the approach adopted by Ms Harfouche.

98. Finally, Ms Harfouche criticises Dr Walton because he does not deduct any costs that would be incurred prior to the point at which the product was brought to market. In relation to this point, it was submitted by the claimant that this was taken care of by line E in the table reproduced above. I do not accept this is so. As I have explained this adjustment is applied by Dr Walton because he considers some allowance needs to be made for the equivalent of the cost of borrowing to fund development costs. However, that is not a sufficient deduction as a consideration of the analogy provided by debt financing shows. If notionally £100 is borrowed and then expended it is necessary to take account of (a) the cost of borrowing the £100 and (b) the fact that the borrower no longer has the £100 because it has been expended. Thus, in principle, I accept that if the premise of a "*dilution*" adjustment is correct – that is that it is necessary to reflect the notional cost of acquiring the money necessary to fund pre-market expenditure – then it is also necessary to provide for the fact that the sums raised by inward investment have been expended in development and other pre-ready for market costs. To ignore this factor is in my view mistaken.

99. The defendant submits that the table reproduced above has been produced on a "*completely false basis"* and should be rejected. There are a number of "*big picture"* reasons why I agree with that submission.

100. Firstly, as I have said the estimate Dr Walton has arrived at assumed a probability of success of 100%. That is wrong as I have said and cannot survive his own evidence that success in the final three stages of development is cumulatively only 38%.

101. Although I take the view (as does Ms Harfouche – see paragraph 2.5 of her report and her oral evidence at T3/145/15-22) that the impact of the chance of the claimant raising the required funding (what Ms Harfouche identifies in her report as "A%") and successfully negotiating a licence agreement with the defendant (what Ms Harfouche identifies in her report as "B%") are matters for me rather than being a question for expert evidence, I accept that before that exercise can be carried out it is necessary first to arrive at a net present value for future profit and then discount that figure down in

the manner described by Ms Harfouche in order to arrive at the figure to which I must then apply an assessment of the chance of the claimant raising the required funding and successfully negotiating a licence agreement with the defendant. That is so because the project was only part way through Phase 2 at the date of breach so none of the risk posed by that phase and those that followed had been resolved.

102. I agree with Ms Edwards-Stuart when she says that Dr Walton assumed a probability of success of 100% because he was proceeding on the basis of paragraph 50.1 of the Particulars of Claim as it was originally pleaded rather than the amended version. As originally pleaded, the claim had been advanced on the basis of an assertion that the claimant had " *... lost the opportunity to license the market-ready drug to a manufacturer. Accordingly the Claimant is entitled to and claims the profit that it would have made on granting such a licence* …". If this was right then it would be inappropriate to de-value the NPV figure by the probability reductions imposed by Ms Harfouche. However this formulation was simply wrong and was replaced on amendment with the assertion that the claimant had " … *lost the opportunity to bring the drug to market and profit from its sales. The Claimant would have achieved this with the benefit of the Patents by making the drug market ready by completing clinical development and gaining market approvals from regulatory agencies in all major markets, manufacturing the drug either by Contract Manufacturing Organisation (CMO) or directly, and then selling the manufactured drug either by Contract Sales Organisation (CSO) or directly*." This engages directly the requirement to make the probability adjustments for the risk of failure at each of Phases 2, 3 and the regulatory approval stage made by Ms Harfouche.

103. Secondly, as I have explained already, I accept that erroneously Dr Walton has left development costs out of account.

104. Thirdly, Dr Walton has discounted for a much shorter period than is justified in my judgment. He has discounted back to the date of his report. As I have said, in my judgment in order to arrive at the correct measure of damages it is necessary to discount back to the date of the admitted breach (November 2018). True it is that on this basis the claimant could say it has been kept out of its money (assuming any was due by way of damages on this basis) between then and judgment but that will be corrected to the extent it arises by an award of interest in the usual way. It may be that this exercise would result in the interest balancing the element of discounting back to the date of breach but to ascertain that requires the calculation to be carried out.

105. The point put to Ms Harfouche at T3/168/24, that the valuation methodology used by Dr Walton was pretty standard in the industry is not to the point. Ms Harfouche has not ever suggested that the methodology is a wrong approach - only that in her opinion it is wrong to use it in this case because the paucity of information available means that a lot of reliance has to be placed on assumptions or figures sourced from other places produced in other contexts, which makes the outcome unreliable because as Dr Walton acknowledge in the course of his oral evidence "*rubbish in equals rubbish out*". As Ms Harfouche put in her oral evidence, " … *the data we have is the only data available. So in my view it is not a reliable approach in the context of the way we're doing it*."

106. All that said, at paragraph 2.4 – 2.5 of her report, Ms Harfouche reviewed Dr Walton's assessments in case I concluded (contrary to her evidence) that in principle he was

correct to approach the question in the way he had. Ms Harfouche's evidence at paragraph 2.4-25 of her report (as updated by the Joint Statement) was as follows:

> "**The value of the Option Right based on the Net Profits as at the Date of Breach**
>
> 2.4 Despite my view that it is not possible reliably to estimate the Net Profits, to assist the Court, I have reviewed and corrected Dr Walton's valuations of the Net Profits and the Option Right based on the Net Profits, which are unreliable, significantly overstated, and unsafe to use. I arrive at an expected NPV, as at the Date of Breach, of the share of the original shareholders of Exelogen in the Net Profits that Exelogen may have earned in the But For Scenario of USD [1.1] million.
>
> 2.5 To arrive at an estimate of the loss suffered by Exelogen as a result of the breach, i.e. of Exelogen being deprived of the Option Right, the Court will need to multiply my illustrative value of USD [1.1] million by A%: the chance of Exelogen raising sufficient funding to complete the IIH Pressure Trial, and B%: the chance of Exelogen successfully negotiating a licence with the University."

She explained how she had arrived at her calculation taking account of the omissions from Dr Walton's assessment referred to above in her oral evidence at T3/146/9-21 in these terms:

> "A. It's the expected NPV of the company in total, or a share of it anyway. So you have the net cash outflows for the development costs in years 2019 up to, I think, 2022, 2023. I'll have to look at my model. And then you have the net cash inflows that come in post-launch from 2026 onwards, and it's the present value of all these cash flows. And it also takes into account the probability of success of going through to phase 2, to phase 3, to registration, to launch. Which is cumulatively the 38% that Dr Walton has used and I have not changed.
>
> Q. That is the expected NPV at what date?
>
> A. So it is as at the date of breach in terms of timing.
>
> …
>
> Q. So it's the same approach as to the option right, is it?
>
> A. Exactly."

Ms Harfouche set out the result of her calculations (subject to her qualifications concerning reliability) in the DCF spreadsheet attached to her report, which takes account of the various points made above apart from what she called A% and B%. She reduced the net totals at the various stages to a short table.

Total for the Product	Commercial partner(s)	The University	Exelogen (fully funded)	Original shareholders of Exelogen
100%	**50%**	**20%**	**30%**	**8%**
(6,753,488)	(3,376,744)	(1,350,698)	(2,026,046)	(552,652)
(14,111,972)	(7,055,986)	(2,822,394)	(4,233,592)	(1,154,813)
(15,730,315)	(7,865,158)	(3,146,063)	(4,719,095)	(1,287,245)
12,851,313	6,425,656	2,570,263	3,855,394	**1,051,650**

The bottom line gives the total outturn to the end of sales. The left hand column bottom figure gives the adjusted total loss of profit that would have been earned from commercialisation of the product at the various stages of its development (reading from the top Phase 2, Phase 3, Post Phase 3 regulatory approvals and finally period of sale) applying the discounts for the risk of failure at each stage referred to above.

107. On this basis there would be a total net profit before tax received from sales of the product at net present value of US$12.85m. However, the underlying assumption is that in order to commercialise the product it would be necessary to licence a commercial partner and equally it would be necessary for the claimant to pay the defendant for its exclusive licence. It follows therefore that there must be deducted from the total net revenues of US$12.85m an assumed sum that would go to the commercial partner sub or under licenced by the claimant (US$6,425,656) and the sum that would be paid by the claimant to the defendant as consideration for its exclusive licence (US$2,570,262), which leaves the claimant receiving the NPV of the total net profit figure (US$12.85m) less the sum of US$6,425,656 and US$2,570,262, which gives the figure of US$3,855,394. Whilst the figures Ms Harfouche adopts involve making assumptions, I agree in principle with this approach and with the assumptions that she has made and in principle find that the NPV of the sum lost by the claimant on the assumption set out in paragraph 50.1 of the amended Particulars of Claim should be approached in this manner.

108. Where I part company from Ms Harfouche is at the final stage of her calculation where she reduces the NPV figure to US$1,051,650. I do not agree that it is appropriate to further reduce the US$3,855,394 figure to reflect the interest of the original shareholders. This case is concerned with the loss suffered by the claimant not its shareholders. How any profit made by the claimant should be split between shareholders is immaterial.

109. Whilst I have some sympathy with Ms Harfouche's absence of reliability point, when assessing damages it is inevitable that some assumptions will have to be made with the court being obliged to do the best it can with what material is available. Doing the best I can with the limited material available, and preferring Ms Harfouche's evidence in all respects on the issue I am now considering, other than in relation to her reduction of the NPV figure to US$1,051,650, I conclude that I should estimate the net profits that would have been made by the claimant assessed at the date of the breach (before taking account of what Ms Harfouche calls A% and B%) would have been US$3.85m rounded in order to recognise that this is very far from a precise science.

110. The final issue that I would have had to determine in the counter factual event that I had concluded that the defendant's breach of contract had caused the claimant had been

deprived of a real or substantial chance of obtaining an exclusive licence from the defendant is to arrive at a discount that reflects the risks that Mr Harfouche characterises as A% and B%.

111. All of the factors that I have referred to as leading me to the conclusion I reached on the substantiality issue would be relevant to an assessment of the overall probability of the claimant obtaining a licence from the defendant. Also relevant to that assessment is that in the result the only model by which the product could be progressed to market is the IPO and assignment of IP Rights model that was used by Invex and never at any stage suggested by or on behalf of the claimant. Had I been satisfied that the claimant had established a substantial as opposed to a no more than fanciful chance of obtaining a licence from the defendant, I would have assessed the probability of the claimant succeeding in obtaining a licence from the claimant at no more than 20%. I calculate this sum at US$771,078.80, which I round down to US$771,000.

Conclusion

112. This claim is dismissed on the ground that the claimant has failed to establish that the admitted breach of contract has deprived the claimant of anything more than a speculative chance that it would have been able to obtain a licence from the defendant under the Agreement. If that is wrong, I would have assessed damages at US$771,000.