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Case No: CL-2021-0000303

IN THE HIGH COURT OF JUSTICE
KING'S BENCH DIVISION
COMMERCIAL COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 6 March 2023

Before :

MISS JULIA DIAS KC
SITTING AS A DEPUTY HIGH COURT JUDGE

- -

Between :

ETEBOXAGU AB	**Claimant**
- and -	
CYCLE PHARMACEUTICALS LTD	**Defendant**

- -
- -

Mr N. G. Casey (instructed by **Mills & Co.**) for the **Claimant**
Mr Matthew Parker KC (instructed by **Goodwin Proctor (UK) LLP**) for the **Defendant**

Hearing dates: 6-8 February 2023

- -

Approved Judgment

I direct that no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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MISS JULIA DIAS KC

This judgment was handed down by the judge remotely by circulation to the parties' representatives by email and release to The National Archives. The date and time for hand-down is deemed to be Monday 06 March 2023 at 10:30am.

Julia Dias KC sitting as a Deputy High Court Judge:

INTRODUCTION

Background

1. Hereditary tyrosinaemia type 1 ("HT-1") is a genetic disorder which prevents the body from fully metabolising tyrosine and can potentially lead to severe liver disease. The majority of infants born with HT-1 do not survive their first year of life; if they do, they are condemned to endure a chronic lifetime condition. Thankfully, the disease is extremely rare.

2. Dr Staffan Strömberg is a chemist and chemical engineer by training who has worked for a number of pharmaceutical companies in drug research and development, including Swedish Orphan Biovitrum AB ("SOBI") where he was head of research and development between 2001 and 2002. While at SOBI, Dr Strömberg dealt with a drug called nitisinone which SOBI had patented under the brand name of Orfadin. Orfadin was the first approved nitisinone drug treatment for HT-1.

3. Mr James Harrison is the founding shareholder of the Defendant company and Group CEO of its parent company. He has worked in the biotechnology industry for a number of years and first met Dr Strömberg in about 2009.

4. In around 2010, Dr Strömberg conceived the idea of developing a generic alternative to Orfadin. He was aware that in the case of niche drugs larger pharmaceutical companies very often do not devote their efforts to developing generic alternatives because the patients are few in number and the opportunity for profit commensurately less. He was also aware that SOBI's patents on nitisinone were due to expire from about 2012.

5. Dr Strömberg approached Mr Harrison with his idea and together they set up a joint venture through the medium of a Swedish company, Rosedale Pharmaceuticals AB, which they owned and funded equally. The company was subsequently renamed Cycle Pharmaceuticals AB but, to avoid confusion with the Defendant, I shall refer to it as "Rosedale". The company was to work, not just on nitisinone, but also on other "orphan drugs", i.e., drugs which the original developer was no longer selling for whatever reason. In around 2011, Dr Strömberg accepted a full time post elsewhere and decided not to continue with the joint venture. Mr Harrison therefore sold his stake in Rosedale back to Dr Strömberg for SEK1 and the company was wound up.

6. Mr Harrison, however, did wish to continue with the project and incorporated the Defendant company, Cycle Pharmaceuticals Ltd ("Cycle"), in the UK on 2 February 2012 for that purpose. Mr Harrison himself provided materially all the funding for the company and was the majority (80%) shareholder. Dr Strömberg held 10% of the shares and the remainder were held by a Professor Thomas Schnitzer.

7. Cycle likewise worked on projects other than nitisinone, but it was agreed that Dr Strömberg should share in the fruits of any successful development specifically of a nitisinone product, not least since he had been the originator of the idea to develop a generic alternative. Mr Harrison also wanted to avoid Dr Strömberg taking his idea to another better resourced company.

The Original Agreement

8. After some discussion (including as to a possible profit-sharing arrangement), the parties agreed that Dr Strömberg should be paid a royalty, and an agreement to that effect was concluded in January 2013 (the "Original Agreement").

9. The key clauses of the Original Agreement are as follows:[1]

> *"5 Cycle shall pay a royalty to Strömberg of 25% of Relevant Revenues.*
>
> *6 Relevant Revenues shall be defined as Cycle revenues generated from the sale of the Product to treat HT-1 in any market globally.*
>
> *…*
>
> *8 Relevant Revenues shall be Cycle's gross income from the sale of the Product excluding VAT and transport costs. However, should Cycle outsource the selling of the Product to a distribution partner recognising the revenues from the sale of the Product and then sharing those revenues with Cycle, then the Relevant Revenues, for the purposes of this agreement, shall be the distribution partner's gross income from the sale of the Product excluding VAT and transport costs.*
>
> *9 No royalty shall be payable if the gross margin from the Relevant Revenues is negative. The gross margin shall deduct only Cycle's direct product development costs, and Cycle's costs directly related to the manufacturing and selling of the Product to treat HT-1. For the avoidance of doubt, no administrative or management salaries, or discretionally* [sic] *spending, shall be deducted from the gross margin.*
>
> *10 Once Relevant Revenues commence, Cycle shall prepare monthly management accounts of the Product including the calculation of Relevant Revenues…*
>
> *…*
>
> *13 Should a dispute arise regarding the calculation of Relevant Revenues (or gross margin) this matter will be referred to an independent accountant, whose opinion shall be binding on the parties…"*

10. At this stage of course the parties had no idea what course the development would take and whether any product which emerged would simply be a generic copycat of Orfadin, or whether a different branded drug might be developed, or indeed whether nitisinone might be used to treat other conditions. While they intended to market any product wherever there were patients to be found, they were also aware that their major market was likely to be in the United States.

The US pharmaceutical market

11. It was common ground that the US pharmaceutical market for specialist drugs such as nitisinone operates in a unique, and uniquely complicated, way. In essence:

[1] The paragraphs of the Original Agreement were not originally numbered, but the parties helpfully produced a numbered version and I gratefully adopt that numbering for ease of exposition.

i) Importation, storage and distribution of drugs in the United States requires a distribution licence. Distribution licences are managed at state level and can only be obtained by companies with a US presence. The requirements may vary from state to state. A UK pharmaceutical company without a US presence cannot therefore itself import and sell drugs into the United States but has to use an importer. Such importer could be a distributor in its own right which undertakes the marketing of the drug in return for a profit share of typically 30%-40%, or simply a third party logistics provider responsible only for the importation, onward sale and shipment of the product as directed by the pharmaceutical company, with the latter remaining responsible for any marketing and sale arrangements.

ii) Specialist drugs are not available at ordinary pharmacies. A pharmaceutical company supplying specialist drugs will therefore enter into an agreement with one or more specialty pharmacies for the supply of the drug to the pharmacy at a particular price. The pharmacy will then dispense the drug to patients with the necessary prescription.

iii) The price to be paid by the specialty pharmacy to the pharmaceutical company is based on the company's published Wholesale Acquisition Cost ("WAC").

iv) There is no equivalent of the NHS in the United States. Most citizens have private health insurance, although some assistance is provided to those without insurance by the government backed schemes, Medicare and Medicaid. The cost of drugs will therefore typically be covered by a patient's health insurance (or "Health Plan"), but only where the drug has been approved by the Health Plan. Approval is negotiated on behalf of Health Plans by pharmacy benefit managers ("PBM"s) who enter approved drugs on to a list known as a "formulary".

v) Inclusion on a formulary is a matter for negotiation between the pharmaceutical company and the individual PBMs acting on behalf of Health Plans. Negotiations depend on many factors, including the amount of competition, the effectiveness of the drug, its differences from any competitors and the price charged, and it is frequently necessary for the company to offer a rebate on the price of the drug in order for it to be included on the formulary. Where there are competing drugs on the market, a rebate is in practice a commercial necessity. The level of rebate will be affected by whether the drug in question is a generic copy or a branded product. A higher rebate may also be paid to secure exclusivity or a more favourable position or "tiering" on the formulary. Rebates are mandatorily required by law at a fixed rate in the case of the government backed schemes, Medicare and Medicaid.

vi) Any rebate is paid to the PBM on behalf of the Health Plan in respect of each supply of the drug. The amount of rebate paid is commercially sensitive information which is kept confidential and is not publicly available.

vii) Where a drug on a formulary list is dispensed by a specialty pharmacy, the relevant PBM acting on behalf of the Health Plan will reimburse the pharmacy for all or part (depending on the level of cover available under the particular plan) of the cost of the drug paid by the latter to the pharmaceutical company.

The precise amount reimbursed to the pharmacy by the PBM is a matter for confidential negotiation and is not made public.

viii) The balance of the price which is not covered by insurance is paid by the patient him/herself by way of "co-pay".

12. In the event (although this was obviously not known at the date of the Original Agreement), Cycle adopted the distribution model illustrated diagrammatically in the Appendix to this judgment. While this refers to one particular specialty pharmacy, Diplomat, the same model was adopted in other cases. Thus, Cycle entered into a distribution services agreement with a third party logistics provider, Cardinal Health Inc. ("Cardinal"), whereby Cardinal agreed to purchase the product from Cycle at WAC minus 2% and to supply it to specialty pharmacies as directed by Cycle and at a price controlled by Cycle. Cardinal then undertook the shipment and importation of the product into the United States and stored it until it was purchased by a specialty pharmacy. Import duty and shipping costs were charged back to Cycle, which also paid a fee to Cardinal for its services.

13. Separately, but in parallel, Cycle entered into:

i) A Master Services Agreement with Diplomat, a specialty pharmacy, pursuant to which Diplomat agreed to purchase the drug from Cardinal at WAC minus 2% (i.e., the same price at which Cardinal acquired the drug from Cycle). No money passed from Diplomat to Cycle, but Cycle agreed to pay Diplomat a service and data fee.

ii) Individual rebate or formulary agreements with PBMs, each of which was acting on behalf of one or more Health Plans. These agreements typically provided for Cycle to pay an average rebate of 23%-40% directly to the PBMs for the benefit of the Health Plans.

14. Diplomat conducted its own private negotiations with the PBMs regarding reimbursement for the cost of the drug.

The proposed amendment

15. In mid-2013, a concern arose as to what would happen if Cycle were to sell its development project to a third party. Dr Strömberg was concerned that he might not continue to receive royalty payments in that scenario, while Mr Harrison saw considerable benefit in being able to sell the project "free and clear" of any royalty rights.

16. The parties therefore embarked on discussions as to a separate agreement dealing with this possibility. During the course of these negotiations, Mr Harrison proposed an amendment to the definition of Relevant Revenues in the Original Agreement. I shall have occasion to return to this in more detail when considering the Claimant's estoppel case below, but suffice it at present to say that the amendment was not accepted by Dr Strömberg and that both parties understood the Original Agreement to continue in force as originally drafted.

The Amended Agreement

17. Thereafter, the previously amicable relationship between Dr Strömberg and Mr Harrison deteriorated and in June 2016 a dispute arose between them regarding the allegedly intentional disclosure of confidential information by Dr Strömberg to SOBI employees. Cycle claimed that the Original Agreement had been terminated as a result.

18. The details of this dispute do not matter for present purposes and it was settled in January 2018 following a mediation. As part of the overall settlement, certain amendments were agreed to the Original Agreement (the "Amended Agreement"), which included Dr Strömberg accepting a lower royalty of 5%. The clauses set out above (with the exception of paragraph 8) were all deleted and replaced by (so far as relevant) the following:

*"5.1 Subject to the provisions of clause 5.2, Cycle shall pay to Strömberg a annual royalty (a "**royalty**") equal to an amount of 5% of Relevant Revenues (as defined in clause 8 of this agreement);*

5.2 For the calendar year 2018 to the calendar year ending 2022 (inclusive) the parties agree that the royalty payable to Strömberg under clause 5.1 for such calendar years shall be a minimum amount of $250,000.

...

8 Relevant Revenues shall be Cycle's gross income from the sale of and/or generated by the Product excluding VAT and transport costs. However, should Cycle outsource the selling of the Product to a distribution partner recognising the revenues from the sale of and/or generated by the Product and then sharing those revenues with Cycle, then the Relevant Revenues, for the purposes of this agreement, shall be the distribution partner's gross income from the sale of and/or generated by the Product excluding VAT and transport costs. For the avoidance of doubt Relevant Revenues will include any consideration received by Cycle as a result of an agreement by Cycle not to sell the Product.

...

*10 Cycle shall in good faith and with reasonable care and in accordance with normal accounting practices prepare calculations of the Relevant Revenues for the preceding quarter in question (each of such calculations being the "**Quarterly Calculations**") and will send copies of these to Strömberg within a period of time not exceeding 30 days from the end of calendar quarter to which the Quarterly Calculation in question relates.*

...

*12.1 Cycle shall provide to Strömberg within a period of 14 days following the earlier of the date of filing of Cycle's annual audited accounts with Companies House or 30 September (the "**Certificate Date**") a certificate from Cycle's auditors certifying the aggregate Relevant Revenues for the preceding calendar year (the "**Certificate**").*

...

> *20 Strömberg may transfer or assign his rights under this agreement to a company controlled by Strömberg. For the purposes of this agreement, "**Control**" means the beneficial ownership of more than fifty per cert (50%) of the issued share capital of the company or the legal power to direct or cause* [sic] *the direction of the management of the company and "**Controls**" and "**Controlled**" will be interpreted accordingly."*

The assignment

19. In February 2018, pursuant to paragraph 20 of the Amended Agreement, Dr Strömberg assigned the benefit of the agreement to the Claimant, a Swedish company of which he is the sole owner and controller.

The present dispute

20. After some years, the nitisinone development project bore fruit and Cycle developed a new branded product called NITYR for which it obtained approval from the US Food and Drugs Agency in the summer of 2017. NITYR was not a generic copy of either Orfadin or any of the other nitisinone products then available. Rather it had certain differences which in fact made it rather more attractive. For example it was in tablet form and therefore more easily ingested by infants than the other products which were in capsule form. It was also stable at room temperature whereas Orfadin had to be kept refrigerated. As such it was approved by the FDA on the basis that it was bioequivalent to Orfadin but not therapeutically equivalent.

21. Despite having obtained FDA approval in 2017, however, sales of NITYR into the United States could not begin immediately pending the negotiation of formulary agreements with PBMs. Until at least one such agreement had been concluded, a "new-to-market" block was imposed on the product which prevented its being sold.

22. Cycle therefore engaged a US health consultancy, Ashfield Healthcare, to negotiate formulary agreements with PBMs on its behalf and these were concluded over the following months. The first prescription for NITYR was dispensed in March 2018.

23. It is not in dispute that there was considerable delay on Cycle's part after March 2018 in providing calculations and making royalty payments to Dr Strömberg/Eteboxagu. It is also fair to say that Cycle's approach to the calculation of royalties has been somewhat less than consistent. Indeed, the calculations have been drawn up on a variety of markedly differing bases over the years.

24. The principal bone of contention between the parties is whether the royalty which is undoubtedly payable under the Amended Agreement should be calculated before or after the deduction of the rebates paid by Cycle to PBMs in respect of US sales. Cycle has deducted rebates before calculating the royalty, whereas Dr Strömberg claims that this is not permitted on a true construction of paragraph 8 of the agreement and that there has been a significant underpayment to date as a result.

25. The present proceedings were accordingly commenced on 18 May 2021 by Eteboxagu as assignee effectively seeking to recoup the alleged underpayment.

THE ISSUES

26. The parties agreed that I should at this stage confine myself to the main issues of principle in the hope that this would provide sufficient guidance to enable them subsequently to reach agreement on the figures or at least minimise the scope of any remaining disputes.

27. Accordingly, this judgment addresses the following:

i) Construction:

a) The correct construction of "Relevant Revenues" in paragraph 8 of the royalty agreement and, specifically, whether or not rebates are to be deducted before the calculation of royalty;

b) Whether either Cardinal or Diplomat (or any other entity fulfilling the same role) is a "distribution partner" for the purposes of paragraph 8 of the royalty agreement;

ii) Estoppel: If rebates are to be deducted on the true construction of the agreement, is Cycle nonetheless estopped by convention from so contending as a consequence of the exchanges regarding the proposed amendment in the summer of 2013?

iii) Certification: What is Cycle's obligation in relation to certification under paragraph 12.1 of the Amended Agreement?

THE WITNESSES

28. I heard oral evidence from three witnesses, each of whom had also given a written statement.

i) Dr Strömberg gave evidence on behalf of the Claimant. He professed himself to be comfortable giving evidence in English and it was clear that he was more than capable of doing so. However, even making due allowance for the fact that it was not his native language, I found him defensive and argumentative as a witness – on many occasions unnecessarily so. I do not find that he was untruthful or dishonest but there were times when it seemed as if he regarded the act of giving evidence more as a battle between himself and Cycle's counsel, Mr Matthew Parker KC, in which his objective was to make life as difficult for the latter as possible. Concessions had to be almost dragged out of him (for example, the apparently uncontentious fact that health insurers would not contribute anything to the cost of a drug unless it appeared on a formulary list and the fact that most sales would be to patients who were covered by Health Plans) and it was unsurprising that counsel expressed some frustration as a result. I therefore treat his evidence with some caution although, in truth, very little of it was directly relevant to the issues which I have to decide.

29. Mr Harrison gave evidence on behalf of Cycle, as also did Dr Stephen Fuller, Cycle's Head of Regulatory Affairs and Head of Business Development from July 2013 to December 2020. Mr Harrison was a very cautious witness who was reluctant to answer any question until he had read any relevant document fully and placed it in

context. Nonetheless, he readily made concessions when satisfied that it was proper to do so.

30. In his witness statement, he had stated that he *"first learned about the way rebates work in the US pharmaceutical market in May 2013"* and that *"through this reading and dealings with other pharmaceutical companies as I sought to launch Cycle, I became aware that calculating royalties from net sales (once rebates were deducted) was industry standard"*. However, a few days before the start of the trial, the Claimant disclosed a draft business plan dated 17 October 2011, which contained a simplified explanation of how the rebate system worked. At the outset of his oral evidence, Mr Harrison stated that looking at this document had prompted him to recollect that he was starting to learn about the way the US pharmaceutical market worked as early as late 2011 and that he was continuing to do so thereafter, including finding out about how other companies accounted for rebates. He therefore wished to correct his written evidence accordingly.

31. On behalf of the Claimant, Mr Noel Casey strongly challenged Mr Harrison about this change of evidence and suggested that he had not in fact been concerned in 2011-2013 with the accounting treatment of rebates and that his professed recovered memory was one which had in fact developed over time for the purposes of advancing Cycle's arguments in this case.

32. I reject this suggestion. It is true that the business plan was a document originally prepared by Mr Harrison in 2011 but it was clear that he had genuinely forgotten all about it until it was disclosed by the Claimant. Given that the document expressly described the way in which rebates worked in the United States, it is obvious (and indeed not challenged by Mr Casey) that he must have acquired at least some knowledge of the rebate system well before May 2013 and I see no reason to doubt that his interest extended to the way in which other pharmaceutical companies handled rebates and that this is a topic he was equally interested in throughout the entire period from 2011 onwards.

33. All in all, I formed the view that Mr Harrison was a witness of truth who was trying to assist the court to the best of his recollection.

34. So far as concerns Dr Fuller, he was knowledgeable and straightforward and I had no hesitation in accepting his evidence in full.

35. I therefore turn to the issues for determination. I am grateful to both counsel for their clear and helpful submissions, both written and oral.

CONSTRUCTION

(1) Relevant Revenues

36. The first issue concerns the true construction of paragraph 8 of the royalty agreement and, in particular, the definition of Relevant Revenues.

The rival submissions

37. The submissions of the parties can broadly be summarised as follows:

38. The Claimant argued that:

i) Paragraph 8 contained a bespoke definition whereby Relevant Revenues were defined as constituting Cycle's *"gross income"*. On its plain and ordinary meaning, "gross" means "before any deduction": see the Chambers dictionary definition of "gross", which is: *"total, including everything, without deductions;… (of pay) before the deduction of income tax, National Insurance, superannuation and other voluntary deductions."* Accordingly, Mr Casey argued, "gross income" *prima facie* included rebates.

ii) This was supported by the express exclusion in paragraph 8 of VAT and transport costs. VAT was likewise included in the concept of "gross income" and an express exclusion was therefore required if it was not to count towards Dr Strömberg's royalty. This demonstrated unequivocally that other constituents of "gross income" like rebates were not to be deducted. So far as concerned the exclusion of transport costs, while recognising that these would never normally be regarded as "income", Mr Casey argued that their express exclusion showed that the parties had specifically addressed the deductions to be made from "gross income" and identified only these two.

iii) The grant of rebates was essentially a commercial decision for Cycle and in concluding the royalty agreement the parties intended to insulate Dr Strömberg from the consequences of any such commercial decisions. It was therefore entirely in accordance with that intention that rebates should be included in the calculating of royalties.

39. For Cycle, Mr Parker argued that:

i) The starting point was that royalties were calculated as a percentage of Relevant Revenues. "Revenues" are cash inflows. In this case, Relevant Revenues were defined as "gross income" with specified deductions. "Gross income" could therefore logically not be greater than Cycle's revenues.

ii) A rebate is simply a discount to what would otherwise be the purchase price. Cycle's income where a rebate is allowed is the discounted price. The surplus of the headline price over the discounted price is never paid and cannot therefore represent income.

iii) The issue in the present case arises only because of the peculiarities of the pharmaceutical market in the United States, whereby Cycle was paid for NITYR by the specialty pharmacy via the importer but simultaneously paid rebates on each sale pursuant to the formulary agreements to the PBMs acting on behalf of the Health Plans. It was the Health Plans who were the effective purchasers of the drug and who ultimately paid the lion's share of the cost by reimbursing the specialty pharmacy.

iv) In this situation, the effective income to Cycle from a particular sale of NITYR was WAC minus 2% less any rebate and this was the only economic benefit that it received from the sale.

v) Such a construction was consistent with the way in which Cycle was required to (and did in fact) account for rebates under the applicable accounting standards. Thus FRS 102 (which applied from the time that sales of NITYR commenced in March 2018) provided as follows:

> *"2.25 The definition of income encompasses both **revenue** and gains.*
>
> *(a) Revenue is income that arises in the course of the ordinary activities of an entity and is referred to by a variety of names including sales, fees, interest, dividends, royalties and rent…*
>
> ***Measurement of revenue***
>
> *23.3 An entity shall measure revenue at the fair value of the consideration received or receivable. The fair value of the consideration received or receivable takes into account the amount of any trade discounts, prompt settlement discounts and volume rebates allowed by the entity.*
>
> *23.4 An entity shall include in revenue only the gross inflows of economic benefits received and receivable by the entity on its own account. An entity shall exclude from revenue all amounts collected on behalf of third parties such as sales taxes, goods and services taxes and value added taxes."*

vi) In this case, the fair value of the consideration received by Cycle was the price paid by Cardinal/Diplomat less any rebate paid to the PBMs.

Applicable principles

40. The principles of construction have been exhaustively rehearsed in numerous cases and are very well known and further exposition by another judge at first instance will not add materially to anything except the length of this judgment. Suffice it to say that the parties were agreed that the task of the court was to determine on an objective basis what a reasonable person would have understood the parties to have meant by the language that they had used, taking into account such background knowledge as was either known or reasonably available to both of them at the date of the contract.

Factual Matrix

41. There was nonetheless some debate before me about the extent of the background information or factual matrix that I was entitled to take into account. At this point it should be noted that, although the Claimant's claim is advanced under the Amended Agreement, neither party suggested that the amendments had effected any change in the meaning of Relevant Revenues or "gross income" in the Original Agreement. It therefore seems to me that the only relevant factual matrix is that which pertained at the date of the Original Agreement, i.e., January 2013. In so far as Mr Parker appeared to come close to suggesting that, because there was no change in meaning between the Original Agreement and the Amended Agreement, I could therefore rely on the factual matrix at the date of the Amended Agreement to inform the construction of the Original Agreement, I reject that suggestion.

42. Cycle's pleaded case as to the relevant background at the date of the Original Agreement was set out in paragraphs 6 and 7 of its Re-Amended Defence and substantially reflected the description of the US pharmaceutical market set out in paragraph 11. above. It exhibited the diagram appended to this judgment as a model which would or would be very likely to apply to the sale of specialist drugs like NITYR in the United States.

43. With one qualification, the Claimant in its Re-Amended Reply admitted and averred that these were all matters known to or reasonably available to the parties at the date of conclusion of the Original Agreement. The qualification related to Cycle's plea that there were drugs on the market in the United States that were in competition with NITYR. As to this, it was admitted that there were two other drugs on the market which contained nitisinone but these were said not to be direct competitors since they were not therapeutically equivalent to NITYR. No admissions were made as to the fixed rebate allegedly payable under the Medicaid programme.[2]

44. In his closing submissions, Mr Casey set out the matters which he invited the court to take into account by way of relevant factual background. While not disputing most of them as facts, Mr Parker nonetheless objected on the basis that none of them had been pleaded. He referred to the Privy Council decision in *Hallman Holding Ltd v Webster,* [2016] UKPC 3 at [11] in support of the proposition that where a party wishes to rely on relevant background facts it must plead them. Beyond a bare statement to that effect, however, there is no further discussion of the proposition in the case.

45. I can see the importance of pleading a case on factual matrix where the relevant fact or circumstance, or its availability to the parties, is disputed. It seems to me rather more difficult to justify excluding relevant *undisputed* factual background simply on the grounds that it has not been pleaded - unless it is inadmissible for other reasons, for example because it relates to prior negotiations. I am therefore prepared to take into account undisputed background matters which in my judgment would have been considered relevant by the hypothetical reasonable observer at the date of the contract. In truth, however, the matters relied upon by Mr Casey added little to the matters pleaded by Cycle.

The accountancy context

46. There was further debate before me as to the extent to which the "accountancy context" was relevant to the question of construction. In the end, however, this seemed to me to be a red herring.

47. It was common ground that while the term "revenue" has a recognised meaning as an accountancy term, the concept "gross income" does not. Mr Casey argued that neither Dr Strömberg nor Mr Harrison was an accountant and that there was accordingly no reason to suppose that either of them had any accountancy context in mind when negotiating the agreement. Mr Parker on the other hand pointed to the obligation to prepare management accounts (paragraph 10) and the provision for reference to an independent accountant in the event of a dispute as to the calculation of Relevant Revenues, as well as the reference to "gross margin" in paragraph 9 which was also a

[2] Cycle's plea that the "true price" of drugs supplied in the United States was the cost paid by the specialty pharmacy less any rebate was also denied, although in truth that is a matter of submission rather than factual matrix.

recognised accountancy term. In his submission, these references suggested that the accountancy context was relevant. He also drew attention to the requirement in paragraph 10 of the Amended Agreement to prepare the royalty calculations in accordance with *"normal accounting practices"*. For the reason given in paragraph 41., however, I reject the submission that the provisions of the Amended Agreement can be relied upon in construing the meaning of the Original Agreement.

48. Mr Casey's response was that none of these provisions required the court to construe paragraph 8 according to accountancy concepts in any event, since none of them was actually directed at the meaning of the definition in paragraph 8. As a matter of construction he is right about that. Moreover, even if I had been inclined to apply accountancy meanings to the terms used in the agreement, it still would not help me with the meaning of "gross income", which is not an accountancy term of art.

49. That said, it is legitimate in my view to regard the parties as having been objectively unlikely to have intended to adopt a definition of Relevant Revenues which was materially inconsistent with the way in which a company like Cycle would be required to prepare its accounts. To that extent, I regard the accountancy treatment of rebates as a legitimate sense check such that an intention to proceed on a basis inconsistent with normal accounting standards would require to be clearly and unambiguously manifested.

50. Finally, I should dispose of a point relied on by Mr Casey in argument based on the manner in which the royalty calculations were initially prepared by Cycle's Head of Accounting, Ms Nicola Giles. Mr Casey made much forensic hay of this point in his cross-examination of Mr Harrison, as he was perfectly entitled to do, but I leave it entirely out of account so far as concerns any question of construction. As I said during the course of submissions, I cannot see that anything said, done or thought by Ms Giles in 2018 can possibly be relevant to the construction of the Original Agreement some five years previously. I likewise ignore the subjective views of Dr Strömberg and Mr Harrison, although these are of course very relevant to the question of estoppel below.

Conclusions on "gross income"

51. In my judgment, Mr Parker is correct in saying that paragraph 8 starts from the point that royalties are to be calculated on revenues, i.e., on monies that are received by Cycle. Irrespective of any accountancy meaning, all businessmen would understand the word "revenue" to represent an inflow of money, not a cost or a payment out. This, it seems to me, necessarily informs the meaning of the term "gross income" since, having provided that the Relevant Revenues for the purposes of calculating royalties are to be "gross income", it would be very odd if "gross income" were to be construed as meaning something which would not be regarded as revenue at all. Clearly this is not conceptually impossible. For example, the agreement could have provided that Relevant Revenues were to be 200% of the cost of sales. However, it would be unusual to say the least and to my mind would require very clear wording indeed.

52. The provisions of paragraph 6 are also relevant in this context. While the paragraph as a whole is directed at the geographical scope of the agreement, it nonetheless emphasises that Relevant Revenues are revenues generated from sales of the product.

53. That being the case, there is to my mind unanswerable force in the proposition that where a seller allows a rebate to a customer, its revenue or income is the amount which is actually paid, in other words the price net of rebate. By way of example during argument I posited the example of selling a dog for £800 after allowing a 20% rebate or discount off the list price of £1000. Mr Casey argued that the seller's gross income in that case was nonetheless £1000, albeit the net income was only £800. However, it seemed to me that this submission flew in the face of reality. No doubt it can plausibly be said that the gross price in the example is £1000 and the net price £800, but that is to use different concepts. So far as income is concerned, there is only one income flow and that is the payment of £800 by the customer to the seller. I do not see that the position is any different if the rebate applied in the particular invoice is a volume rebate calculated by reference to a number of previous sales.

54. Is the situation nonetheless different where, because of the way the market works in the United States, the relevant cash flows go round in a circle between multiple parties rather than the rebate being directly set off against the price as between buyer and seller? In principle, I do not see why it should be different. There is no difference in substance and the overall economic reality for Cycle is exactly the same. As Dr Strömberg put it in his witness statement, a rebate is a discount on the price charged to the patient, but given to the insurance companies or their PBMs. It is of course ultimately the Health Plans which pay most of the cost of the drug, and because a rebate is allowed in relation to each sale, the cash inflow to Cycle is effectively only the surplus over the amount of the rebate. On any view the relevant transactions are all linked as shown in the Appendix and it therefore seems to me appropriate to treat them compendiously.

55. As for Mr Casey's submission that the express deduction of VAT and transport costs in paragraph 8 was an indication that rebates were not to be deducted, there were a number of problems with this.

i) First, the argument does not even get off the ground unless it is accepted that rebates are properly to be regarded as part of "gross income" in the first place.

ii) Secondly, it is by no means clear to me that VAT would normally be regarded as revenue or income. VAT is very different from income tax in this respect, being effectively collected on behalf of a third party, the Government. As such it comes in already earmarked as VAT and goes out again, still earmarked as VAT, without affecting the company's bottom line. Income tax, by contrast, goes only one way - out. It cannot be identified in any meaningful sense until it is paid and it is calculated on monies which the company has earned in other ways. As such, it is perfectly proper to describe a company's gross income as being its income received before payment of income tax, but I have serious doubts as to whether any businessman or woman would consider VAT to be part of their revenue or income. Indeed, Mr Casey's submission to the contrary sat somewhat uncomfortably with his own client's evidence that *"VAT charged was not revenue at all."*

iii) If so, then the express exclusion of VAT in paragraph 8 can only have been clarificatory and does not necessarily say anything about what other amounts might or might not fall to be included in "gross income".

iv) Thirdly, even if Dr Strömberg and I am both wrong about that, Mr Casey's argument smacked more than a little of trying to have his cake and eat it. On his case, the express exclusion of VAT was necessary because it would otherwise have been included in "gross income", whereas the express exclusion of transport costs was simply indicative of something which (as he accepted) could never have been regarded as income (being a cost, not a revenue item), but which the parties wanted to exclude anyway. Where express deductions are made for different items, one of which would (on the Claimant's case) and one of which would not otherwise be included in "gross income", it does not seem to me that anything useful can be spelled out of the deductions themselves as to what "gross income" was intended to mean.

56. Mr Casey further complained that Cycle was unable to articulate on its case what, if any, difference there was between gross income and net income. However, I do not see any necessary incoherence here. As Mr Casey himself argued, "gross" simply means the total income without any deductions (unless otherwise specified). Income tax is an obvious example of something which would be deducted from gross income in order to arrive at a figure for net income.

57. Finally, Mr Casey argued that the intention of the parties was to insulate Dr Strömberg from the consequences of commercial decisions taken by Cycle and that rebates were a matter of commercial discretion. However, I am unable to accept either premise of this submission.

58. First, I reject the suggestion that the objective intention of the parties when concluding the Original Agreement was to insulate Dr Strömberg from commercial decisions taken by Mr Harrison and Cycle. The submission, as it seemed to me, was in large part based on the fact that the parties had initially discussed a profit sharing arrangement which they abandoned in favour of a royalty agreement. The correspondence disclosed that one of the reasons why both men saw problems with a profit sharing arrangement was the difficulty in apportioning fixed costs between the nitisinone project and any other projects that Cycle might undertake.

59. However, not only is this all inadmissible on the basis that it concerns prior negotiations, but the conclusion does not follow from the premise. Just because there were understandable difficulties in apportionment of fixed costs, does not mean that the parties necessarily intended Dr Strömberg's royalty to be unaffected at all by any other commercial decisions taken by Cycle. As Mr Harrison pointed out, even under the royalty agreement, there were plenty of other commercial decisions which were capable of affecting the calculation of royalty, not least of which was the setting of the drug price in the first place.

60. Secondly, I am quite satisfied that the payment of rebates in the context of the US pharmaceutical market was a matter of commercial necessity, not simply one of discretion. Indeed the evidence to this effect was overwhelming:

i) It was common ground that payment of rebates was a commercial necessity at least where there were already competing drugs on the market. There was a debate in the evidence as to whether it was necessary to pay a rebate in the case of a pure generic copycat drug. Dr Strömberg said that it was not and that the rebate could be nil in these circumstances. Dr Fuller, on the other hand,

said that while that might be the case with a high volume, low cost drug like aspirin, it was not true for high cost, specialist, life-or-death drugs like NITYR where inclusion on a formulary was the only way in practice to achieve sales.

ii) Be that as it may, at the date of the Original Agreement, no-one knew what product would eventually emerge. It must therefore have been contemplated that rebates would have to be paid at least if Cycle came up (as in fact it did) with a branded product where competing products were already available.

iii) Dr Strömberg accepted in his written evidence that the objective of the project was to develop an alternative to Orfadin, and in his oral evidence that the drug was intended to compete with and possibly complement Orfadin. Whether or not NITYR was an exact replica, therefore, Orfadin was always going to be a competitor product, and NITYR was always going to be competing with it, either directly or indirectly.

iv) With rare diseases, the cost of drugs is always going to be very high because the market is so small. The prospect of selling such high cost drugs in the United States otherwise than to Health Plans via a formulary list was therefore vanishingly small. Dr Fuller accepted that NITYR could in theory have been marketed directly to potential patients but in practice he said it would never happen. Even Dr Strömberg in his witness statement averred that *"Patients will usually not buy a drug which the insurance company will not cover."* In his oral evidence he conceded that most patients purchasing NITYR would be covered by a Health Plan and he could not give any examples of when they might not be. He also accepted that the Health Plan would not cover any part of the cost of NITYR unless it was included on the relevant formulary.

v) The unchallenged evidence of Dr Fuller was that a fixed 23.1% rebate was mandatory in the case of the government backed Medicare and Medicaid programmes.

vi) Mr Casey suggested that a higher rebate might have been expected to result in a lower co-pay contribution for the patient thus making the drug more attractive to them and that it could therefore properly be regarded as a marketing tool. I do not accept this. The amount of co-pay that a patient would be required to make would depend entirely on the level of cover available under the applicable Health Plan and it would be completely speculative as to how the size of rebate might affect this.[3]

61. I therefore reject the submission that the payment of rebates was a discretionary marketing cost. On the contrary, it is clear to me that it was effectively an obligatory discount which Cycle was required to pay to the ultimate funder (the Health Plan via its PBM) on the purchase price of the drug.

[3] As explained by Dr Fuller in his oral evidence and clarified by Cycle's solicitors during the course of the trial, Cycle cover the costs of any co-pay for NITYR in order to be competitive with SOBI which does the same for Orfadin, although this was obviously not something which would have been in contemplation at the date of the Original Agreement. Cycle has sought to deduct its contribution to co-pay in its calculation of royalties but, to date, only from Q1/22 onwards. The Claimant has reserved its position as to the legitimacy of these deduction which it is agreed is a question for another day.

62. The fact that in certain circumstances, payment of a higher rebate might secure a higher tier on a formulary seems to me irrelevant. The size of the rebate is driven by numerous factors: the price of the drug, its effectiveness, the size of the market, whether there are competitors and so on. In any event, at the date of conclusion of the Original Agreement, the parties cannot have known what rebate agreements would be negotiated if and when any drug was successfully developed, not least because they had no idea what would eventually emerge from the development process. Indeed, Mr Harrison had not even seen a rebate agreement at that date. In any event, Mr Casey disavowed any suggestion that a distinction was to be drawn between that part of a rebate which was necessary in order to get on a formulary list at all and any incremental rebate which may be paid to secure a preferential position on the list.

63. In summary, both parties were well aware at the date of the Original Agreement of the way in which drugs were marketed in the United States and that rebates were inevitable if Cycle was to develop a branded drug (as it eventually did). I am therefore satisfied that the objective intention of reasonable commercial men in the situation of the parties would have been to regard Cycle's "gross income" as its effective income from the product which, in the case of sales in the United States, was the price after deduction of rebates.

64. A further important factor supporting this conclusion is the fact that Dr Strömberg's royalty was payable on Relevant Revenues received from sales of the product globally. However, rebates were only payable in respect of US sales because of the idiosyncrasies of the US pharmaceutical market. The parties must therefore have appreciated that the headline price in the United States would, or at the very least might, have to be increased in order to accommodate the payment of rebates.[4] In those circumstances, I do not consider that the parties could objectively have intended that royalties should be calculated on such an artificially inflated basis without also taking into account the corresponding rebates which would inevitably have to be allowed.

65. I have reached my conclusions thus far without reference to any particular accountancy context. However, as indicated above, I believe the accounting treatment of rebates provides a valuable sense check since it would be surprising if paragraph 8 required Cycle to calculate royalties on a basis that was inconsistent with the way in which it was obliged to account for them. Moreover, as Dr Strömberg accepted, the applicable accounting standards at the date of the Original Agreement were materials that were reasonably available to both parties had they chosen to consult them.

66. I was referred by Mr Parker to the provisions of FRS 102 which applied from March 2013. This states in paragraphs 23.3 and 23.4 that revenue is to be measured by reference to the *"fair value of the consideration received"* taking into account *"the amount of any trade discounts ... and volume rebates"*. Moreover, revenue should only include the *"gross inflows of economic benefits received and receivable"* while excluding sums collected on behalf of third parties such as VAT. I queried with the parties what the applicable standards were in January 2013 and in post-hearing submissions they agreed that the applicable UK GAAP standard at that date was FRS 5 (as previously amended). Cycle also referred to the corresponding international

[4] In fact, although this would not have been known at the time, the unchallenged evidence of Dr Fuller was that cost of NITYR in the United States was around US$25,000 for 60 x 10 mg tablets, compared to around $1,000 or less in the Middle East.

standard, IAS 18, but I agree with the Claimant that this has no relevance to Cycle as a UK company.

67. FRS 5 provides as follows:

"G1 This Application Note deals with revenue recognition from the supply of goods or services by a seller to its customers. It sets out basic principles of revenue recognition which should be applied in all cases.

G7 Revenue should be measured at the fair value of the right to consideration. …this will normally be the price specified in the contractual arrangement, net of discounts, value added tax and similar sales taxes."

68. In so far as Cycle purported to make submissions as to how these provisions would have been understood at the time, I ignore them on the basis that this is a matter of expert evidence which should, if it was to be relied upon, have been pleaded and proved in the normal way. Nonetheless, looking at the plain wording of FRS 5, it does not seem to me that its effect is materially different from that of FRS 102 and I proceed on that basis. In particular, I see no distinction in principle between a discount and a rebate in the context of determining the fair value of the *"right to consideration"* which in turn seems to me to be no different from *"consideration received or receivable"*.

69. In the event, therefore, the construction which in my view is correct is entirely consistent with the provisions of both FRS 5 and FRS 102 and therefore (unsurprisingly) also with the way in which rebates were treated in Cycle's accounts.[5]

70. Although neither party referred to it expressly, I also note paragraph 23.8 of FRS 102 which provides as follows:

"An entity usually applies the revenue recognition criteria in this section separately to each transaction. However, an entity applies the recognition criteria to the separately identifiable components of a single transaction when necessary to reflect the substance of the transaction. For example, an entity applies the recognition criteria to the separately identifiable components of a single transaction when the selling price of a product includes an identifiable amount for subsequent servicing. Conversely, an entity applies the recognition criteria to two or more transactions together when they are linked in such a way that the commercial effect cannot be understood without reference to the series of transactions as a whole. For example, an entity applies the recognition criteria to two or more transactions together when it sells goods and, at the same time, enters into a separate agreement to repurchase the goods at a later date, thus negating the substantive effect of the transaction."

71. This entirely supports the conclusion which I had in any event reached independently that it is appropriate to regard the various transactions depicted in the Appendix as a compendious package for the purpose of assessing Cycle's income.

[5] Mr Casey argued that Cycle's accounts in fact pointed to a different distinction between gross sales (which included VAT, rebates and discounts) and net sales (which deducted them). That may be so, but since "sales" are not necessarily the same as "income", I do not see where the argument takes him.

72. In my judgment the fair value of the consideration and economic benefit received by Cycle from a particular sale of NITYR is accordingly the price paid by Diplomat (via Cardinal) minus the rebate paid to the PBM on behalf of the relevant Health Plan.

73. It follows that rebates are properly to be deducted in arriving at Cycle's "gross income" for the purposes of paragraph 8 of the Original Agreement, and so also of paragraph 8 of the Amended Agreement.

(2) Distribution Partners

74. The issue here is whether either or both of Cardinal and Diplomat (or any other entities performing similar roles) is to be regarded as a "distribution partner" for the purpose of taking its income into account in calculating royalties under paragraph 8 of the Original Agreement.

75. I can deal with this shortly since in my view there can be no serious argument but that the income of a "distribution partner" is only to be taken into account where:

i) Sale of the product is outsourced to a "distribution partner";

ii) The "distribution partner" recognises the revenues from the sale of the product; and

iii) The "distribution partner" shares those revenues with Cycle.

76. The evidence on this point was all one way. It was set out in some detail in Dr Fuller's witness statement and was not seriously challenged in cross-examination. Given the eligibility requirements for obtaining a distribution licence in the United States as described in paragraph i) above, it was impractical for a small company like Cycle which was only selling a very specialist product to a very limited market, to distribute its own products in the United States. Cycle therefore engaged Cardinal and Diplomat pursuant to the arrangements described in paragraphs 12. and 13. above. However, it carried out its own selling and marketing in the sense that it was Cycle who negotiated agreements directly with specialty pharmacies like Diplomat, and Cycle which negotiated its own formulary agreements through Ashfield Healthcare.

77. Dr Fuller explained that Cycle had considered engaging a US partner to manage all the import, supply, marketing and negotiation with PBMs. However, entities undertaking a role of this nature would only operate on a profit share of typically 20%-40% which made no commercial sense for Cycle given the very limited market for NITYR. As he said in oral evidence, in order to be an economic proposition *"it would have to be a lot of sales, especially for such a small-volume drug in 50 different states."* In fact Cycle measured its US sales in the hundreds.

78. In these circumstances, I find that neither Cardinal nor Diplomat was a "distribution partner" for the purposes of the royalty agreement, substantially for the reasons advanced by Mr Parker.

i) Cardinal was not a "distribution partner" because:

a) It was not a "partner" in any meaningful sense. It was not responsible, or even sharing responsibility, for the selling or marketing of the

product but merely provided importation, storage and distribution services and onsold to specialty pharmacies as directed by Cycle in return for a fee. Cycle concluded its own agreements with the specialty pharmacies and PBMs.

b) Cardinal made no profit from selling the product and shared no revenues with Cycle, but simply passed on the price received from Diplomat in full. In other words, it was in Mr Parker's words simply a *"stopping point along the supply chain"*.

ii) Diplomat was not a "distribution partner" because:

a) The selling of the product was not outsourced to Diplomat and there was no joint endeavour in relation to sales. Cycle simply sold NITYR to Diplomat for supply to its own customers.

b) Diplomat did not recognise any revenues which were shared with Cycle. It retained in full the price paid to it by the PBMs as well as any co-pay and Cycle was not entitled to know how much that was.

79. The submission that Cardinal and/or Diplomat was a "distribution partner" was not pursued by Mr Casey with great vigour. All that really remained of the point in the end was a faint suggestion that because it was theoretically possible for Cycle to have set up its own US presence to import and distribute NITYR, this was a commercial decision which should not be allowed to impact on Dr Strömberg's entitlement to royalty, which should therefore be calculated on the basis of the gross income of Cardinal and/or Diplomat. However, even if it were correct (contrary to my findings) that as a matter of construction of the Original Agreement Dr Strömberg was entitled to be insulated from the consequences of Cycle's commercial decisions, that does not begin to entitle me to find that Cardinal and Diplomat were "distribution partners" when on the clear wording of the contract they were not.

ESTOPPEL BY CONVENTION

80. My conclusion that on the true construction of paragraph 8 of the Original and Amended Agreements, rebates were to be deducted before calculation of royalty makes it necessary for me to address the Claimant's case that Cycle was nonetheless estopped by convention from so contending by virtue of the exchanges which took place between Mr Harrison and Dr Strömberg in the summer of 2013 regarding a proposed amendment to the Original Agreement.

81. The applicable legal principles were not in dispute and can be derived from the judgment of Briggs J in *HMRC v Benchdollar Ltd,* [2009] EWHC 1310 (Ch.); [2010] 1 All ER 174 at [52] as approved with one qualification by Lord Burrows JSC in *Tinkler v HMRC,* [2021] UKSC 39; [2022] AC 886 at [45] and [49]:

i) There must be an assumption of fact or law which is made by both parties;

ii) It is not sufficient that the assumption is merely understood between the parties in the same way. It must be expressly shared between them in the sense

that there are words or conduct crossing the line from which the requisite sharing can objectively be inferred;

iii) The party alleged to be estopped (D) must have assumed some element of responsibility for the expression of the common assumption in the sense of conveying to the other party (C) an understanding that D intended C to rely on it;

iv) C must have relied upon the common assumption and not merely upon his or her own independent view of the matter;

v) The reliance must have been in connection with some subsequent mutual dealing between the parties;

vi) Some detriment must have been suffered by C or some benefit conferred on D so as to make it unjust or unconscionable to permit the latter to assert the true position.

82. The first three of these requirements were glossed by Lord Burrows in *Tinkler* at [51]-[52] where he explained that C must *know* that D shares the common assumption and must be strengthened or influenced in its reliance on the assumption by that knowledge. Further, D must objectively intend or expect that that will be the effect on C of its conduct crossing the line, so that one can properly say that it has assumed some element of responsibility for C's reliance on the common assumption.

83. Mr Parker also referred to the decision of Peter Macdonald Eggers QC in *Geoquip Marine Operations AG v Tower Resources Cameroon SA,* [2022] EWHC 531 (Comm) and, in particular, his analysis of whether the common assumption had to be clear and unambiguous and, if so, whether this was simply a matter of objective interpretation.

84. It is unnecessary for me to address this interesting debate because I am satisfied that the estoppel case fails at the first hurdle of establishing a common assumption subjectively held by both parties.

85. The amendment proposed by Mr Harrison was in the following terms:

"Relevant Revenues shall be Cycle's gross amount invoiced~~income~~ from the sale of the Product excluding VAT and transport costs, and reduced by the following amounts (if not previously deducted from the amount invoiced):

(a) amounts actually allowed as trade, selling commissions, volume or quantity discounts, including early pay cash discounts;

(b) amounts repaid or credited by reason of defects, recalls, accrued or actual returns, rebates and allowances of goods or because of retroactive price reductions specifically identifiable to [nitisinone];

(c) rebates and administrative fees paid to medical health care organisations in line with approved contract terms; and

(d) rebates resulting from direct or indirect government (of an agency thereof) rebate programs or chargeback programs;

However, should Cycle outsource the selling of the Product to a distribution partner with the distribution partner recognising the revenues form the sale of the Product and then sharing those revenues with Cycle, then the Relevant Revenues, for the purposes of this agreement, shall be the distribution partner's gross amount invoiced~~income~~ from the sale of the Product with the same exclusions and reductions applying as per the immediately preceding paragraph.~~excluding VAT and transport costs.~~"

86. Mr Casey submitted that, in proposing this amendment, Mr Harrison must necessarily have subjectively accepted that rebates were not deductible under the existing wording and that he needed the amendment in order to make sure that they would be. This was denied by Mr Harrison who maintained that he had always believed that rebates were to be deducted, but that later in 2013 he had been given a draft clause by Cycle's solicitors in relation to another transaction which seemed to him to capture the position as he understood it rather better. He therefore suggested to Dr Strömberg that they replace the existing wording with the new clause but said that that as far as rebates were concerned, he regarded it as purely clarificatory.

87. I have referred in paragraphs 29.-33. above to Mr Harrison's correction to his evidence as regards his knowledge of the US market and of the way in which other companies accounted for rebates.

88. It is, of course, Mr Harrison's subjective views in the summer of 2013 which are relevant for the purposes of the alleged estoppel and I am quite satisfied that at least by then, his subjective understanding was that rebates fell to be deducted before the calculation of any royalties. In this connection, I note that:

i) The case in estoppel only arises on the hypothesis that rebates are to be deducted on the true construction of paragraph 8. If that is the case as a matter of the objective interpretation of the contract, it is by no means implausible that it was also Mr Harrison's subjective belief;

ii) The substance of what Mr Harrison said he understood by "gross income" was what was shown in the draft business plan dated 28 June 2013 as "net sales". It is therefore noteworthy that when he proposed the amendment to Dr Strömberg on 15 July 2013, he said:

"Also pasted here is the definition of net sales that SJ Berwin provided to us for use in the Sandoz/Roxane contracts. I would be grateful if we could add these items into the net sales definition in our nitisinone contract."

Since paragraph 8 did not refer to "net sales" but to "gross income", this only makes sense if Mr Harrison did indeed believe that the two were synonymous.

iii) Mr Harrison could not recall precisely when he first received the clause from SJ Berwin, but he was cross-examined on the basis that it was around the time that he was preparing the draft business plan dated 28 June 2013. If so, then he plainly could not have proposed the particular wording any earlier and I see no

reason to doubt his evidence that he put it forward when he did because he and Dr Strömberg were in any event negotiating an amendment to their agreement around that time for the reasons referred to in (iv) below. The proposal of the wording is therefore not in itself inconsistent with an existing subjective belief that rebates fell to be deducted.

iv) Mr Harrison was cross-examined vigorously on the basis that (as he agreed) he would not have proposed an amendment for no reason. However, the reason negotiations were taking place at all in the summer of 2013 was because of the need to reach agreement – described by Mr Harrison as a "free and clear" agreement – as to what was to happen in the event that Cycle sold the project to a third party. Mr Harrison said, and I accept, that he wanted the free and clear agreement concluded quickly as he was anxious to raise finance for Cycle from other sources and thought that this would assist him. But as appears from a later email sent by Mr Harrison's business partner, Bill Robinson, to Dr Strömberg, the latter had been anything but co-operative to the extent that Mr Robinson felt impelled to express his frustration and irritation at the length of time it had taken to reach agreement.

v) In those circumstances, I do not find it at all implausible that when Dr Strömberg rejected the amendment, Mr Harrison kept his eyes firmly on the main prize and, since he thought that rebates were deductible in any event, decided not to push the matter for risk of jeopardising finalisation of the free and clear agreement. In truth, dropping the amendment is far more consistent with a subjective belief that rebates were already deductible under the existing wording than with the converse. If Mr Harrison had genuinely believed that rebates were not deductible, and that this was a matter of importance, it seems to me far more likely that he would have persisted with the amendment. I therefore accept his evidence that he did not abandon the amendment because he in fact understood and accepted Dr Strömberg's view that rebates were not to be deducted.

89. Mr Casey realistically accepted that unless he could establish that Mr Harrison subjectively believed that deduction of rebates was not permitted under the Original Agreement, his argument did not get off the ground. I can therefore deal with the other ingredients of estoppel by convention relatively briefly.

90. First, the amendment proposed was quite different from the existing wording. It did not simply seek to add a further list of deductions from "gross income". Instead, it adopted a completely different starting point of "gross amount invoiced" and I accept Mr Parker's submission that it is not necessarily self-evident that either VAT or rebates would be deducted from "gross amount invoiced" without express wording. The wording also proposed some deductions which on no view featured in the Original Agreement, such as administrative fees and credits for defective goods. It is therefore perhaps understandable that it was rejected out of hand by Dr Strömberg. But the proposal of an entirely new definition with a completely different starting point cannot without more amount to a representation as to what Mr Harrison subjectively believed the unamended wording to mean. I am therefore not satisfied that there was any conduct or representation crossing the line which suggested that Mr Harrison subjectively thought that rebates were not to be deducted.

91. Secondly, Dr Strömberg's evidence in cross examination was that *"I can't read what he was thinking in these words that he has changed to. But I am convinced that he wanted to change the agreement we had in place… If he, in this document, is telling me what he means by the old agreement, no. The answer is no."* If Dr Strömberg did not know what Mr Harrison's subjective interpretation of the Original Agreement was, he can hardly have relied on it. Mr Casey attempted to retrieve some of this ground in re-examination but it was unconvincing.

92. Thirdly, I am not persuaded that Dr Strömberg ever made clear to Mr Harrison his own position on the deductibility of rebates under the Original Agreement. Even accepting that he subjectively thought they were not deductible, I cannot be satisfied to the requisite standard (the burden of proof being on the Claimant in this respect) that he ever articulated this to Mr Harrison. So far as the documents go, he simply returned a version of the free and clear agreement omitting all reference to the proposed amendment.

93. It is true that Dr Strömberg gave evidence, both written and oral, to the effect that there had been an intervening telephone conversation in which he had stated that he did not agree to the amendment and would only accept the deduction of VAT and transport costs as per the original wording. Mr Harrison could not recall any such conversation, although he could not go so far as to say positively that one did not take place. The contemporaneous documentary exchanges do not point either way.

94. But even if a conversation did take place, the primary focus was likely to have been the free and clear agreement and the proposed amendment would have been very much subsidiary to that. Moreover, given that the new wording appeared to propose all sorts of new deductions, it is not implausible that Dr Strömberg, as he said in his witness statement, *"told Mr Harrison that I would not agree to a change in the definition of "Relevant Revenues". I told him that I would agree only to the deduction of VAT and transport costs."* However, that is to say no more than that Dr Strömberg wanted to maintain the Original Agreement and Mr Harrison would not have had any reason to infer from that alone anything at all about Dr Strömberg's views as to the deductibility of rebates under the unamended wording.

95. In those circumstances, I cannot discern that Mr Harrison assumed any element of responsibility in the sense of conveying an understanding that he intended Dr Strömberg to rely on a subjective assumption which, as I have found, he did not hold himself and which he did not appreciate was held by Dr Strömberg.

96. Fourthly, I am also sceptical as to whether Dr Strömberg relied on any supposed conventional understanding when agreeing the Amended Agreement some 4½ years later as part of the settlement of an entirely different dispute. In particular, it is not clear to me that (to the extent that he thought about it at all), Dr Strömberg was relying on a *conventional* understanding rather than on the mere fact that the Original Agreement has not been superseded and his own subjective view of what it meant. However, since the estoppel argument fails anyway, it is unnecessary to make any finding on this point.

97. Mr Casey also referred me to the decision of Geoffrey Vos MR in the recent case of *ABN Amro Bank NV v Royal & Sun Alliance Insurance plc,* [2021] EWCA Civ 1789, [2022] 1 WLR 1773 at [78] and [87] in relation to estoppel by acquiescence. He did

not press this very hard as an alternative case, but in so far as he did, it must fail on the grounds that in order to establish an estoppel by acquiescence *ABN Amro* establishes that the party estopped must know what it is he is acquiescing to. As I have held in paragraphs 92.-94. above, I am not satisfied that Mr Harrison did know what Dr Strömberg's views were on the deductibility of rebates under the Original Agreement.

98. It follows that I can deal very briefly with a further point regarding the assignment by Dr Strömberg to the Claimant. Cycle denied that Eteboxagu was entitled in its capacity as assignee to rely on any estoppel established as between itself and Dr Strömberg. No authority was cited in support of that proposition and Mr Parker contented himself with the submission that it would be very odd if an entirely new party could take advantage of a conventional understanding reached between two completely different parties. Mr Casey's riposte was that Exteboxagu could hardly be described as a completely new party, being owned and controlled by Dr Strömberg and, as such, squarely within the category of entities to which the Amended Agreement expressly permitted an assignment. He therefore submitted that it would be even more odd if Eteboxagu could *not* take advantage of the estoppel.

99. As to the law, Mr Casey relied on *PW & Co. v Milton Gate Investments Ltd,* [2003] EWHC 1994 (Ch.); [2004] Ch. 142 as establishing that an estoppel by convention will generally bind assignees. This is a case which was decided in the very specific context of landlord and tenant, although I accept that the assumption of Neuberger J (as he then was) appears to have been that assignees in general would be both bound by and entitled to the benefit of an estoppel by convention.

100. I have to say that Cycle's position was unattractive and technical in the extreme. Nonetheless, it seems to me that this is a very difficult area on which I would ideally have required much more detailed submission. As the point does not arise in the light of my findings, I say no more about it.

CERTIFICATION

101. The obligation to certify Relevant Revenues on which the Claimant relies is contained in paragraph 12.1 of the Amended Agreement set out above. It is therefore the construction of that agreement with which I am concerned. By the date at which it was concluded, namely January 2018, the relationship between the parties had deteriorated and Dr Strömberg had been removed from playing any further part in the project. It seems to me that this is part of the relevant factual matrix against which the Amended Agreement was concluded and I find that the objective intention of the certification clause was accordingly to provide him with independent third party confirmation that the figures on which his royalty was based were accurate.

102. It is common ground that no certificate has been provided to date. Cycle's auditors, PwC, have apparently stated that they are not prepared to issue a certificate to the Claimant unless it signs a letter of engagement which contains a wide-ranging disclaimer, such as to undermine the worth of the certificate almost entirely.

103. The Claimant and Dr Strömberg are not clients of PwC. It is therefore unsurprising that PwC would want to limit their liability and there was no evidence before me to

suggest that the letter of engagement put forward by PwC was anything other than standard in the profession.

104. However, the question for me is the nature of the obligation undertaken by Cycle. Mr Casey submits that it is an unambiguous and unqualified obligation to provide a certificate of the aggregate Relevant Revenues for the preceding calendar year and that it is up to Cycle how it sets about providing this. If it causes difficulty, that is too bad; Cycle should have thought about that before undertaking the obligation.

105. For his part, Mr Parker submits that the parties could not objectively have intended Cycle to do something which is impossible. But this begs the question as to whether provision of a certificate is in fact impossible. The immediate problem appears to have arisen because PwC have assumed or been instructed that they have to provide a certificate directly to the Claimant and/or Dr Strömberg. However, there is nothing in paragraph 12.1 which requires this and certainly nothing which obliges either Dr Strömberg or the Claimant to enter into a letter of engagement with Cycle's auditors as a pre-condition of a certificate being provided.

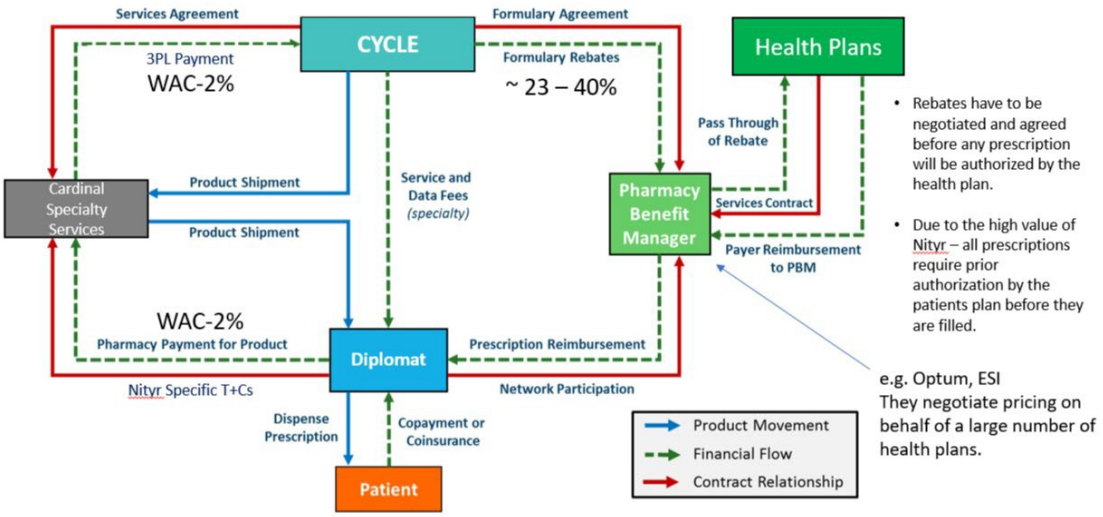
106. In fact, paragraph 12.1 is entirely at large as to the nature and form of the certificate to be provided. The only obligatory requirement is that it certifies the calculation of Relevant Revenues and, by extrapolation from amended paragraph 10, that these have been prepared in accordance with normal accounting standards. I therefore see no reason why the relevant certificate cannot be provided to Cycle rather than directly to the Claimant or Dr Strömberg, thereby avoiding the need for a letter of engagement.

107. It is, of course, true that PwC know full well the purpose for which the certificate is required and might demand reassurance from Cycle that they will not face liability as a result of the certificate being provided to the Claimant. Most likely, that reassurance would take the form of an indemnity, but if that is the necessary precondition of obtaining a certificate, then so be it. It may be commercially unpalatable for Cycle to provide such an indemnity, but it is the author of its own misfortune in this respect. It could easily have consulted its auditors before agreeing to the obligation in paragraph 12.1 and if it failed to do so, it only has itself to blame.

108. I therefore agree with Mr Casey that Cycle's obligation under paragraph 12.1 is unqualified. However, provided the certificate certifies what it is required to certify there is no constraint on the nature or form in which it is to be provided and this is a matter which Cycle is free to negotiate with its auditors.

109. So far as the Claimant is concerned, in my judgment its obligations under paragraph 12.1 go no further than an implied duty not unreasonably to withhold co-operation should it be the case that Eteboxagu's co-operation is essential for the provision of a certificate: see *Mackay v Dick* (1881), 6 App. Cas. 251.

110. I will defer consideration of any question of breach and loss until the parties have had an opportunity to consider their respective positions in the light of this judgment. All issues of quantum and interest in relation to the principal claim are likewise reserved for further determination if they cannot be agreed.


Services Agreement
CYCLE
Formulary Agreement
Health Plans
3PL Payment
WAC-2%
Formulary Rebates
~ 23 – 40%
Pass Through of Rebate
Cardinal Specialty Services
Product Shipment
Service and Data Fees (specialty)
Pharmacy Benefit Manager
Services Contract
Product Shipment
Payer Reimbursement to PBM
WAC-2%
Pharmacy Payment for Product
Diplomat
Prescription Reimbursement
Nityr Specific T+Cs
Network Participation
Dispense Prescription
Copayment or Coinsurance
Patient
Product Movement
Financial Flow
Contract Relationship
• Rebates have to be negotiated and agreed before any prescription will be authorized by the health plan.
• Due to the high value of Nityr – all prescriptions require prior authorization by the patients plan before they are filled.
e.g. Optum, ESI
They negotiate pricing on behalf of a large number of health plans.