Neutral Citation Number: [2021] EWHC 1712 (Comm)

Claim No: CL-2019-000719

IN THE HIGH COURT OF JUSTICE

BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES

COMMERCIAL COURT (QBD)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 23/06/2021

Before:

SIR ROSS CRANSTON
Sitting as a Judge of the High Court

- -

Between:

JAMP PHARMA CORPORATION	**Claimant**
- and -	
UNICHEM LABORATORIES LIMITED	**Defendant**

- -
- -

GUY MORPUSS QC and DAVID LOWE (instructed by **Macfarlanes LLP**) for the **Claimant**
ANDREW THOMAS (instructed by **Armstrong Teasdale Limited**) for the **Defendant**

Hearing dates: 4, 5, 6, 10 May 2021

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Approved Judgment

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Covid-19 Protocol: This judgment was handed down by the judge remotely by circulation to the parties' representatives by email and release to Bailii. The date and time for hand-down is deemed to be 23 June 2021 at 10:30 am.

SIR ROSS CRANSTON:

INTRODUCTION

1. The main issue in this case is whether the claimant, Jamp Pharma Corporation ("Jamp"), entered a legally binding agreement for Unichem Laboratories Limited ("Unichem") to supply it with Tizanidine, a muscle relaxant drug, for the Canadian market. Jamp is a company incorporated in Canada, where it manufactures and distributes pharmaceutical products. Unichem is an Indian pharmaceutical company, which develops and manufactures a range of pharmaceutical products and licenses their sale and distribution worldwide.

2. The parties had entered an agreement in early 2019 under which Unichem supplied another drug to Jamp, Alfuzosin, as the Canadian distributor. That agreement contemplated the supply of additional products. Jamp's case is that in April/May 2019 Jamp and Unichem reached a legally binding agreement for the supply of Tizanidine as well as Alfuzosin. It was not an agreement "subject to contract". Unichem's case is that a legally binding agreement was conditional upon the terms being set out in a formal addendum signed by both parties. The parties negotiated an addendum, which was reduced to writing, but Unichem never signed it.

3. During the trial I heard evidence remotely because of the Covid pandemic. For Jamp there was evidence from Mr Sukhad Juneja, vice-president of portfolio management & scientific affairs, and Ms Sophie Jacques, director of marketing and communications, both based in Canada. For Unichem there was evidence from Mr Santosh Mahil, chief commercial and international business development officer, and Ms Pragati Shetty, the associate general manager, international business, both based in India. These four factual witnesses all gave credible evidence and tried to assist the court. On the whole their evidence was consistent with that given by the others. It transpired that the differences between them were on relatively minor matters which were not central to the issues in the case which needed resolution.

4. There was also expert evidence from Dr Andrew Tepperman, for Jamp, and Professor W. Kilgallon (the industry expert) and Mr Gordon Hodgen (the accounting expert) for Unichem. The experts were called in relation to the quantum of damages for breach should there be a binding contract between Jamp and Unichem as Jamp asserted. Both experts tried to assist the court, although there were limitations in the evidence of both Dr Tepperman and Professor Kilgallon since their expertise did not extend to all the matters in issue.

BACKGROUND FACTS

The Agreement

5. The background to the dealings between the parties over Tizanidine was the contract entitled "Product Dossier, Supply and Distribution Agreement" ("the Agreement"), entered in early 2019 after a period of many months' negotiation. Its recitals stated that the parties wished to enter it, among other matters, (i) to have through Jamp what were referred to in the Agreement as the "Products" approved by Health Canada, the government agency responsible for marketing approvals for pharmaceuticals in that country; (ii) to provide for the manufacture and supply of the Products by Unichem to

Jamp; and (iii) to authorize Jamp to distribute the Products in Canada on an exclusive basis.

6. Article 1 of the Agreement covered the provision of a product dossier to Jamp, in return for a fee, and for its responsibility for obtaining the marketing approvals from Health Canada. Article 1.1 conferred on Jamp the exclusive right to register, manufacture, market, distribute and sell the Products in Canada. Article 1.9 of the Agreement stated:

> "1.9 Products: For the purposes of the agreement, Products shall initially mean the products set forth in Annexure 1. Thereafter, the Parties may by mutual consent expressed in writing add any product to Annexure 1."

7. Annexure 1 to the Agreement identified only one product, Alfuzosin. It was to be supplied in tablets of 10mg strength, a pack size of 100, and a batch size of 700,000. The purchase price was CAD $4.00 per unit, and the fee payable on approval was CAD $50,000.

8. By article 2.1 the Agreement was to be effective from 18 December 2018 and was to continue on a product-by-product basis for ten years from the date on which Jamp received notification of compliance from Health Canada approving a drug for sale on the Canadian market.

9. Article 3 dealt with the supply, packaging and delivery of the products. Articles 3.1 and 3.2 dealt with the exclusive purchase and supply of the products in Canada. Article 3.2 read:

> "3.2 Exclusive Supply of Products in Canada: Unichem shall not during the Initial Term and any Subsequent Term directly or indirectly sell, either by itself or through other Persons, the Products for resale in Canada, or licence or otherwise grant rights in the Product Dossiers with a view to sale of any Products in Canada. …".

10. Article 3.7 covered storing and shipment, article 3.10 making Unichem's delivery obligation ex works. The purchase price was laid down in article 4.1 and Annexure 1. It was to remain fixed during the initial period for a product.

11. The Agreement contained an entire agreement clause (article 11.8). Article 11.9 stated, in part:

> "11.9 Amendment/Waiver/Remedies: This Agreement may not be amended, nor any provision waived, except by written instrument."

12. Article 11.12 laid down the laws of England and Wales as the governing law and conferred exclusive jurisdiction for disputes on the courts of London.

13. The Agreement was signed by Mr Louis Pilon, president and CEO of Jamp, on 28 January 2019, and there were two signatories for Unichem, Mr Mahil and Mr Dilip Kunkolienkar, on 20 February 2019.

Negotiations for Tizanidine

14. The Agreement covered only one product, Alfuzosin. In the course of the negotiation of the Agreement, included in an email from Unichem of 31 August 2018 was "the offer for the below interested products". The email set out details in tabular form for Meloxicam, Memantine and Tizanidine. As regards Tizanidine the details were strength 4mg, batch size 1.5 million, pack size (in bottles) of 150 or 1000, with a purchase price of CAD $6.00 or CAD $32.80, and with a dossier fee of CAD $100,000, payable 25% upon signing of the agreement, 25% upon filing of the marketing authorization application, and 50% upon approval.

15. Around six months later, on 15 March 2019, following the signature of the Agreement, Mr Nishank Gohel, a business development manager at Jamp working under Mr Juneja's supervision, emailed Ms Shetty of Unichem that Jamp had had Tizanidine tablets in its wish list earlier and had received Unichem's proposal for the "project". The email continued that the project had been on hold, but Jamp was now ready to move ahead, so accordingly "kindly note our counter offer for the project as below". There followed the details in the same tabular form as in the Unichem email the previous year, labelled "Unichem's offer", with "Jamp's offer" added as follows: "Counter offer, (CAD) $2.6 for pack of 100 [and] licensing fees CAD $70,000". The email concluded: "Request you to review and let us have your feedback to proceed further with Amendment and conclude."

16. Unichem's response was in an email from Ms Shetty dated 27 March 2019, called "our revised offer". Details were for the same strength, but with a pack size (bottle) of 100 tablets, at a transfer price CAD $3.20, and a licensing fee of CAD $100,000. The milestones for the payment of that licensing fee were

> "25% Upon signing off an addendum",

50% upon filing of an abbreviated new drug submission ("ANDS") with Health Canada, and 25% upon approval of the ANDS. The email concluded that Unichem looked forward to receiving "the draft addendum to proceed in this project".

17. Jamp replied the same day, 27 March 2019, thanking Unichem for "your counter offer", stating that it would evaluate it and revert within the week for finalization.

18. An internal email within Jamp dated 27 March 2019 contained evidence of Jamp's inhouse evaluation for Tizanidine. It set out a snapshot of calculations in what was called within the organisation a "Green table". Overall, with the lowest available price charged by AA Pharma, another Canadian pharmaceutical company distributing Tizanidine in Canada, Jamp would make a gross margin of 90.45 percent inclusive of freight costs. The Green table calculations assumed a lack of competitors. It contained a transfer price per tablet of CAD $0.0352, a dossier price of CAD $100,000 and a lowest available price (in the province of Quebec) of CAD $0.386.

19. The Green table contained forecast sales of 702,451 tablets in year 1; 936,575 in year 2; and 1,130,759 in year 3. In his first witness statement Mr Juneja stated that these represented 7, 10 and 12 percent of the market over the first three years. It was common ground at the hearing that these forecasts actually represented 15, 20, and 25 percent of the market over that period. In making that correction in his second witness

statement, Mr Juneja explained that Jamp used standard market share estimates, for example 3, 5, and 7 percent; 5, 10, and 15 percent; or 7, 10 and 12 percent per annum depending on the product. He assumed that the higher figures of 15, 20, and 25 percent were used because Tizanidine was a single source product.

Emails of 10 and 15 April 2019

20. On 10 April 2019 Mr Gohel of Jamp emailed Unichem that it had evaluated the offer and was "fine with the commercials for the project". However, since a different milestone model had been agreed in the case of Alfuzosin and it had compromised on some points, Jamp

> "would like to retain the same structure that we signed as a standard draft and proceed further with only signing of Addendum towards the current agreement for new products."

The email concluded:

> "Kindly confirm and based on your feedback, I shall be sharing the Addendum copy for you to review and conclude."

21. Five days later, on 15 April 2019, Unichem through Ms Shetty replied, thanking Jamp for its confirmation of the Tizanidine offer, and confirming the rest of the terms as being the same as with Alfuzosin. She requested that Jamp should "share the addendum accordingly".

22. On 17 April 2019 Jamp emailed that it would share the addendum very shortly.

The draft Tizanidine Addendum

23. The first draft of the "First Amendment to the Dossier, Supply and Distribution Agreement (Added Product: Tizanidine)", as it was described, and which I simply call the Addendum in this judgment, was "dated as of May ____, 2019". It began with the following recitals:

> "Whereas section 13.9 [this was a typographical error; the parties agreed it should have been 11.9] of the License and Supply Agreement provides that it may not be amended except by written instrument;
>
> Whereas section 1.9 of the License and Supply Agreement provides that Products initially mean the products set forth in Annexure 1 to the License and Supply Agreement. Thereafter, the Parties may by mutual consent add any product to Annexure 1;
>
> Whereas the Parties desire to execute this first amendment to the License and Supply Agreement (the 'First Amendment') in order to add the product Tizanidine tablets (the 'New Product') as a Product, and to make certain other amendments as a result thereof."

24. Clause 2 of the draft was entitled "New Product". Clause 2.1 provided that the New Product was added as a product to the Agreement, as set forth in Schedule A, as of the date of the First Amendment. By clause 2.2 all other terms in Schedule A applied to

the New Product only. Schedule A stated the product as Tizanidine, of strength, 4mg; pack size, 100 tablets; pack type, bottle; purchase price, CAD $3.2; and Dossier Purchase Fee upon approval, CAD $100,000. The Schedule added that the Canadian brand reference was AA Pharma Product; DIN: 02259893.

25. Clause 3 was headed "Interpretation". Clause 3.3 read that the Addendum would:

> "supersede all promises, agreements, conditions or understandings, whether oral or written, between the Parties with respect to the subject matter hereof".

26. Clause 3.4 read that, except as provided, no subsequent alteration, amendment, change or addition to the Agreement as amended hereunder should be binding unless expressly provided in an instrument duly executed by the parties.

27. Clause 3.5 provided:

> "This First Amendment may be executed in any number of counterparts and each of such counterparts shall for all purposes constitute one agreement binding on each of the Parties, notwithstanding each of the Parties is not a signatory to the same counterpart, provided that each such Party has signed at least one counterpart".

28. Clause 3.7 added: "This First Amendment shall become effective from the date set forth above".

29. Following clause 3 there was text to the effect that the document was being executed by the parties' duly authorized representatives. There was then provision for signatures, one on behalf of each party.

Emails of 9 and 12 May 2019 and later events in May

30. On 9 May 2019 Mr Gohel of Jamp sent Unichem what he described as "the addendum for Tizanidine" as an attachment to an email. He added:

> "Kindly review and if OK, we shall initiate the signature and send a partially executed copies (sic) to you. Feel free to approach, in case there are some comments on the draft."

31. In an email to Jamp of 12 May 2019, Ms Shetty of Unichem stated that the Addendum was acceptable but said that she had added two signatories for Unichem. (What she had done was to add an additional signatory box, as well as the names of the two signatories who would be required to sign the Addendum on Unichem's behalf.) Ms Shetty continued that she was on leave during the week, but "can you please proceed and send us partially executed copies for our signature".

32. There was no draft attached to the email, but on 18 May 2019 Ms Shetty sent the draft, with an added space for a second signature to be provided on behalf of Unichem, as well as the names of the two signatories who would be signing on its behalf, Mr Mahil and Mr Kunkolienka, the same signatories to the Agreement of early 2019.

33. In an email of 20 May 2019 Mr Gohel of Jamp responded that the Addendum would be signed. There was an internal email within Jamp the same day in relation to arranging the chief executive, Louis Pilon, to sign it.

34. Meanwhile, Jamp was making arrangements in anticipation of a contract going ahead. On 17 May there was an internal email from its acting general manager for clinical development as regards the bio-equivalence study which would need to be conducted for Health Canada approval. The email noted the class to which Tizanidine belonged and the need to plan it with a 2-WC design. It stated that the "tentative" cost was CAD $80,00 and 120 units would be needed for the study.

35. In late May 2019 Jamp made arrangements to purchase 4 packs of 100 tablets each of Tizanidine for the purposes of conducting the bioequivalence study. The cost was CAD $36.86 per pack, CAD $147.44 in total. Jamp also passed on information to Unichem so that it could obtain an import licence for the tablets. There was an internal email within Jamp of 1 June 2019 about this and the need to assign a regulatory lead within the company for the project to proceed. The email added: "We would intimate you as soon as the agreement for this project is signed".

36. In fact, Unichem was negotiating with another Canadian company, Mint Pharmaceuticals Inc ("Mint") based in Ontario, for the sale and distribution of generic pharmaceuticals in Canada. In his evidence, Mr Juneja said that he was very surprised when he finally learnt that Unichem had signed a contract with Mint in relation to Tizanidine. In his evidence Mr Mahil suggested that Mr Juneja would have known that he was talking to Mint but accepted that he did not tell Mr Juneja specifically about his discussions with Mint regarding Tizanidine. In my view none of this evidence is inconsistent, especially against the background of Mr Mahil's visit to Canada in June.

The June meetings

37. There was a meeting between representatives of Jamp and Unichem in Mumbai on 4 June 2019, and in Montreal the following day.

38. Ms Shetty of Unichem was the only person attending the Mumbai meeting who gave evidence at the hearing. In her witness statement she said that she had told the Jamp representatives, Mr Gohel and Ms Stuti Dave, that discussions concerning the proposed addition of Tizanidine to the Agreement were "on hold". When cross-examined she said that she "did not mention about the addendum of contract". To my mind these two statements are not inconsistent. Ms Shetty could well have referred to the proposed addition of Tizanidine to the Jamp-Unichem Agreement without specific mention of the Addendum. Moreover, it seems to me that Ms Shetty's reference in her witness statement to the addition of Tizanidine to the Agreement was a construct for the purposes of explanation in her formal witness statement, and her failure to use that phrase in a Unichem internal email dated 4 June 2019 to Mr Mahil about the day's meeting goes nowhere.

39. If it matters, I also accept Ms Shetty's evidence that what she said to the Jamp representatives was that Tizanidine was on hold not, as the Jamp representatives recorded in their minutes of the meeting, that there were "technical issues" impeding progress. In the internal email dated 4 June 2019 to Mr Mahil about the meeting, Ms

Shetty stated that as regards Tizanidine she had told the Jamp representatives that it would go slowly as there were internal discussions going on, she would obtain clarity from management shortly, and until then the discussions were on hold. There is no reference to technical issues. It seems to me more likely that the "on hold" language used in that email, sent only a little while after the meeting occurred, represents the phraseology Ms Shetty used with the Unichem representatives.

40. Nonetheless, I accept Mr Morpuss QC's submission that the documents are consistent with Unichem's evident desire not to tell Jamp that it was seeking to do a deal with Mint. In cross-examination Mr Mahil accepted that he had told Ms Shetty to be careful what she said to Jamp because he did not want them to know that Jamp was about to do a deal with Mint. That is the obvious explanation to Ms Shetty's "on hold" explanation to Jamp's Mr Gohel and Ms Stuti.

41. The meeting the following day in Montreal, 5 June 2019, was between Mr Mahil of Unichem and Mr Juneja of Jamp. In their evidence both said that it was a pleasant meeting, over a number of hours, including lunch, during which they discussed social as well as business matters. In cross examination, Mr Mahil said that Mr Juneja had asked why he, Mr Mahil, did not sign the Addendum, since he was a signatory, and he had replied that Unichem was talking to other people as well. In his witness statement Mr Mahil said that, during the visit, he had told Mr Juneja that the Addendum needed to be signed by Unichem if it were to be binding.

42. Mr Morpuss challenged this. That had not been mentioned in Unichem's defence - where it was only said that Mr Mahil told Mr Juneja that he would go back to India and think about it - and if Mr Mahil had said it, it would have rung alarm bells with Mr Juneja. Even if I did not accept Mr Mahil's evidence, which I do, I accept Mr Thomas's submission that Mr Mahil said nothing during the visit to suggest that the Addendum would not need to be counter-signed by Unichem. Indeed, my conclusion on the evidence is that both Mr Mahil and Mr Juneja accepted that a binding contract was conditional on signature of the Addendum by both parties.

43. It is common ground that Mr Juneja gave Mr Mahil a copy of the Tizanidine Addendum during the 5 June 2019 visit, which had been signed by Jamp's chief executive, Mr Pilon. Mr Juneja's evidence was that Mr Gohel had reminded him to hand over the Addendum at the meeting. Mr Mahil did not counter-sign it but took it away with him. Mr Juneja accepted in both his witness evidence and during cross-examination that he was aware at the meeting on 5 June 2019 that during his Canadian trip Mr Mahil was visiting rival pharmaceutical companies. Mr Mahil's unchallenged evidence was that it was standard practice in the industry for a company like Unichem to seek out the best fit of partners in a market such as the Canadian market. In the course of negotiations with a potential partner, Unichem did not tell other partners that they might be negotiating elsewhere as well.

44. Against this background it must have been evident to Mr Juneja that Mr Mahil did not regard the Tizanidine deal as completed. There was plenty of time during the visit, but Mr Mahil did not sign the Addendum, even as a gesture since Unichem's requirement was that there would be two signatories on its part. (In fact the draft Addendum which Mr Juneja gave him did not include the additional signature box or signatory names added by Ms Shetty in the draft she had returned earlier.)

45. Mr Juneja's position was made plain just over a week later, on 13 June 2019, when the appointment of a regulatory lead for Tizandine was raised internally within Jamp. Mr Juneja sent an internal email to Mr Gohel:

> "We need to have a counter signed copy [of the Addendum]."

Mint's contract with Unichem

46. As indicated Unichem had been negotiating with Mint as regards generic pharmaceuticals for the Canadian market. It entered a contract with Mint as regards Tizanidine on around 16 July 2019.

47. Jamp became aware of this as a result of Mr Gohel of Jamp emailing Mr Mahil on 22 July 2019, recalling that it had been a long time since the early June meeting, and seeking feedback on what was set out in the email. Under the heading "In-Nego [in-negotiation] products" there were six pharmaceuticals listed in Mr Gohel's email, including Tizanidine, with the remark: "Please comment, whether we are going ahead for this project or not." In the section "Signed project" the only pharmaceutical listed was Alfuzosin, with the comment that a quote for stability studies had been received of USD $51,000. In concluding the email Mr Gohel requested Unichem to "to review all the proposals and lets (sic) finalize quickly." In unchallenged evidence Mr Juneja said that the use of the phrase "in nego" reflected only that there was no signed agreement.

48. On 23 July 2019 Mr Mahil replied that Unichem had signed Tizanidine with Jamp's competitor with much higher prices and a license fee as in Unichem's expectation. With Mint Unichem had also signed Lamotrigine. Unichem had signed only one product with Jamp so far but, the email continued, was finding difficulties since it was not getting support from Jamp's team as a partner.

49. Mr Juneja then sent a WhatsApp message to Mr Mahil on 23 July 2019that he was surprised with the email. Could they speak over the telephone when Mr Mahil had time? Mr Juneja followed with an email stating that he was deeply disappointed with Mr Mahil's email. As regards Tizanidine, it read, Unichem was going back on what had been mutually agreed. It was already "agreed and finalised and partly signed by Jamp"; Unichem should not have offered and discussed the product with a competitor; and Unichem was not acting in good faith. At 22:52 on 23 July 2019 Mr Juneja sent another WhatsApp message about speaking on the telephone. Mr Mahil replied "Sure". In his evidence Mr Mahil explained that he had been travelling from Mumbai to Shanghai but by that time had arrived so could answer. There was then a conversation between 22:58 and 23:15. Whether the conversation assuaged Mr Juneja's disappointment, and whether the expression in his email to Mr Mahil was for internal Jamp consumption, have no relevance to these proceedings.

THE CONTRACT ISSUE

50. The issue between the parties was whether the emails in April and/or May 2019 constituted a binding agreement. Both Jamp and Unichem accepted that there was an offer of terms in relation to the supply of Tizanidine and an acceptance of those terms. However, the issue between them was whether there was conditionality in the way

acceptance could be made or the intention to create legal relations demonstrated. In other words, was the agreement in effect "subject to contract".

51. Both sides accepted that the matter was to be determined objectively as a matter of construction of the relevant emails. Jamp's case was that objectively construed the emails of 10 and 15 April 2019 constituted a binding agreement about Tizanidine without more, but that if needs be reference could also be made to the May emails as containing a binding agreement. Unichem contended that the matter was conditional on the signature of the Addendum by both parties, which never occurred. It bolstered its case by reference to communications and events subsequent to the April and May emails as confirming the parties' objective intention that there would be no binding agreement until the draft Addendum had been agreed and signed by both parties.

Legal principles

52. Although there were some differences between the parties as to how subsequent events could be used to determine whether a contract is in existence, there was a great deal of agreement on the legal principles applicable in the case. There are four bodies of relevant legal principle.

53. First, an offer may be conditioned on its acceptance being expressed or communicated in a prescribed way and, in those circumstances, it can generally be accepted only in that way: *Chitty on Contracts*, 33rd ed, paragraphs 2-064 to 2-068. It is a matter of construction whether an offer requires an acceptance to be expressed or communicated in a specified way. Merely because the agreement envisages a signature by both parties, and leaves space for those signatures, does not of itself constitute a prescribed mode of acceptance: *Maple Leaf Macro Volatility Master Fund v Rouvroy* [2009] EWCA Civ 1334; [2010] 2 All ER (Comm) 788, [16], per Longmore LJ.

54. Secondly, whether parties intend to create legal relations and there is a binding contract is conditional not upon their subjective state of mind but upon a consideration of what was communicated between them by words or conduct, and whether that leads objectively to a conclusion that they intended to create legal relations and had agreed upon all the terms which they objectively regarded or the law required as essential for legally binding relations: *RTS Flexible Systems Ltd v Molkerei Alois Muller GmbH & Co KG* [2010] UKSC 14, [2010] 1 WLR 753, [45], per Lord Clarke. In *Barbudev v Eurocom Cable Management Bulgaria* [2012] EWCA Civ 548, Aikens LJ acknowledged *RTS Flexible Systems* as the leading case on the intention to create legal relations, although he cautioned that in a commercial contract the onus of demonstrating that there was a lack of intention to create legal relations lay on the party asserting it and that it was a heavy one: [30].

55. One common way of negating contractual intention, commonly used in real property transactions, is to insert a specific "subject to contract" clause in the agreement. In these circumstances whether the parties are contractually bound is normally conditional on a formal contract being approved, even when there is no uncertainty as to the terms of the agreement: *Chitty on Contracts*, 33rd ed, paragraphs 2-127, 2-172. That a draft agreement has been produced, envisaging signatures by both parties, does not of itself make their agreement subject to contract.

56. In the *RTS Flexible Systems* case the agreement was neither one for the sale of land nor one which was expressly "subject to contract". It was a draft contract for the design and installation of two production lines in a factory. Clause 48 provided that the proposed contract "may be executed in any number of counterparts provided that it shall not become effective until each party has executed a counterpart and exchanged it with the other." That was treated as equivalent to a subject to contract clause. Lord Clarke said that, given that no formal contract was signed or exchanged, unless and until the parties agreed to vary or waive clause 48 the contract would not become binding or effective: [65]. However, in the circumstance of that case, and consistently he said with commercial sense, "[t]he clear inference is that the parties had agreed to waive the subject to contract clause, viz clause 48": [86].

57. The third body of legal principle concerns the well-known principles for the interpretation of documents contained in authorities such as *Investors Compensation Scheme Ltd v West Bromwich Building Society* [1998] 1 WLR 896 and *Arnold v Britton* [2015] UKSC 36, [2015] AC 1619. In brief, the inquiry in construing a contract concerns what the parties using the words they have against the relevant background would reasonably have been understood to mean. As regards determining contractual intention and whether a particular mode of acceptance had been prescribed, Longmore LJ said in *Maple Leaf Macro Volatility Master Fund v Rouvroy* [2009] EWCA Civ 1334, [2010] 2 All ER (Comm) that the entire course of correspondence had to be considered: [17].

58. Fourthly, as I put it in the Court of Appeal in *Reveille Independent LLC v Anotech International (UK) Ltd* [2016] EWCA Civ 443, drawing on a passage in *Chitty on Contracts*, 32nd ed, 2015, para 13-129, "the subsequent conduct of the parties is admissible to prove the existence of a contract, and its terms, although not as an aid to its interpretation": [41]. Elias and Underhill LJJ agreed. To similar effect is the recent decision of Coulson LJ in *Farrar v Rylatt* [2019] EWCA Civ 1864, who held that the fact that while the project was up and running one party had made repeated attempts to have a profit sharing agreement drawn up was one of the factors for concluding that there was no binding agreement in place: [84]. There is further support for the principle in Christopher Clarke J's judgment in *MSM Consulting Ltd v Tanzania* [2009] EWHC 121 (QB), 123 Con LR 154, where he considered that the subsequent dispatch of a new set of terms was difficult to reconcile with the acceptance of the earlier terms: [113].

59. Nothing in *Percy v Suffields Ltd* [1916] 2 Ch 187, which Mr Morpuss highlighted, casts doubt on considering the parties' correspondence and conduct subsequent to an agreement about its terms to determine the existence of a binding contract. In that case Lord Cozens-Hardy MR said that once a definite offer had been made and accepted without qualification, and it appeared that at that point the correspondence of offer and acceptance contained all the terms agreed on between the parties, the contract could not be affected by subsequent negotiation. "When once it is shewn that there is a complete contract", he said, "further negotiations between the parties cannot, without the consent of both, get rid of the contract already arrived at": at 192. I accept Mr Thomas's submission that Lord Cozens-Hardy MR's remarks were based on there being a definite offer, accepted without qualification, and a completed contract; that is not the position where the subsequent correspondence and conduct is

being used to illuminate whether there is a binding contract through an unqualified acceptance.

10/15 April 2019 emails

60. Mr Morpuss contended that there was nothing in the language of the 10/15 April 2019 emails to indicate any conditionality as with a subject to contract clause. The 10 April 2019 email contained an offer which was accepted in Unichem's 15 April 2019 email. At that point there was nothing further to agree, and a contract came into existence, albeit that the parties intended it to be formalised in a signed addendum, which would "accord" with the agreement already reached. The 10 and 15 April 2019 emails were the "mutual consent expressed in writing" required by article 1.9 of the Agreement to add Tizanidine.

61. In my view, when construed objectively, the chain of emails leading to and including the emails of 10 and 15 April proceeded on the basis that for a binding agreement to come into existence between Unichem and Jamp as regards Tizanidine, the parties had to conclude and sign the formal Addendum to the Agreement. In other words, those emails contain "words which according to their natural construction import[ed] a condition", per Parker J in *Von Hatzfeld-Wildenburg v Alexander* [1912] 1 Ch 284, 288-289. To put it another way, the words the parties used in those emails were not simply an expression of their desire as to the way the transaction they had already agreed would be manifest. To the contrary, objectively construed the words meant that the signature of the Addendum was a condition to any binding agreement between the parties on Tizanidine coming into effect.

62. It is convenient to begin with Mr Gohel's "counter-offer" email of 15 March 2019, which culminated in those of 10 and 15 April 2019. There was the reference in the email to an "amendment" and to proceeding with an "Amendment and conclude". In other words, the email anticipated that a deal regarding Tizanidine would be effected on concluding an amendment to the Agreement. Article 11.9 provided, of course, that any amendment would be by written instrument. Whether intentionally or not, the route Mr Gohel chose to enter for the deal about Tizanidine was something more than a simple exchange of emails which would have satisfied article 1.9 or even the formality of the signature of a document.

63. This amendment route was pursued by Ms Shetty when she sent her "revised offer" email of 27 March 2019, with its first milestone payment of CAD $25,000 "upon signing off an addendum", and the email's conclusion that Unichem looked forward to receiving "the draft addendum to proceed in this project". Again there is language demonstrating that the agreement in relation to Tizanidine becoming binding was conditional on the signature of an addendum.

64. Then there were the crucial emails in April. In the first of the emails, on 10 April 2019, Mr Gohel stated that Jamp agreed to the commercial terms for Tizanidine, but that it wanted to retain the same structure as with the Agreement. He added that Jamp would like to "proceed further with only signing of Addendum towards the current agreement for new products". He requested confirmation and stated that "based on your feedback, I shall be sharing the Addendum copy for you to review and conclude."

65. In Mr Morpuss's submission, the "review and conclude" phrase in the 10 April 2019 email was not Mr Gohel inviting a renegotiation of the terms that had been agreed. If Unichem agreed to the milestone payments proposed by Jamp, what Mr Gohel was to produce was an addendum that reflected the terms agreed.

66. To my mind Mr Thomas is correct in his submission that objectively the 10 April 2019 email demonstrated that Jamp intended for the terms of the new agreement in relation to Tizanidine to be set out in a formal "Addendum" (with a capital "A") to the Agreement, that the Addendum was to be signed, and that the offer contained in the email (for offer it was) was conditional on the conclusion in this way of the signed Addendum referred to. As Mr Gohel put it in the email, Jamp would "proceed further with only signing of Addendum". It was the language of requirement or condition; it is not permissive language or language simply expressing a desire to record an agreement in writing. That construction is reinforced in the context of the Agreement which, as we know, contained provisions for a written instrument for any amendment.

67. Ms Shetty's email of 15 April, responding to Mr Gohel's email five days earlier, demonstrated the same objective intention. In the email she confirmed that the terms should be those for Alfuzosin, adding, significantly: "Please share addendum accordingly". Mr Morpuss contended that the word "accordingly" indicated that Unichem was not expecting Jamp to come up with new terms in the addendum but was expecting to receive a document which accorded with what had been agreed and putting that agreement into more formal terms.

68. In my view, Unichem in this email demonstrated its objective intention for the terms of the agreement in relation to Tizanidine to be set out in an addendum, and that "accordingly" the addendum would also need to be signed by the parties to be effective as with the Agreement itself. An objective reading of these emails as a whole, and in context, demonstrates, in my view, that any agreement was conditional on the Addendum being signed by both sides if there was to be a binding contract between them about Tizanidine.

May emails and the Addendum

69. Mr Morpuss's primary case was that agreement had been reached in the April emails. He submitted that in the 9 May 2019 email Mr Gohel was not offering an opportunity to renegotiate the agreement already reached but was asking Ms Shetty if the Addendum accorded with the April agreement. Mr Morpuss's secondary case was that if agreement had not been reached in April 2019, consistently with article 1.9 of the Agreement, it was reached in the May exchanges, when from 12 May 2019 all substantive terms were agreed.

70. In my view the key point is that in stating that the Addendum was acceptable, Ms Shetty's reply email of 12 May 2019 was making clear that, as with the Agreement, there needed to be two signatories from Unichem. In the context of the email chain, which began on 15 March, she was reiterating the point that for an agreement to be effective the Addendum needed to be signed, and signed along the same lines as with the Agreement, with two signatures from Unichem to be effective.

71. In my view, the May emails are part of a picture where Jamp and Unichem premised what they said and did on the basis that there would be a written addendum to the

Agreement, setting out their respective contractual obligations regarding Tizanidine, which needed to be signed by both sides if it were to be binding. Consistently with *Reveille Independent LLC v Anotech International (UK) Ltd* [2016] EWCA Civ 443 and the other authorities cited earlier in this judgment, and with what Longmore LJ said in *Maple Leaf Macro Volatility Master Fund v Rouvroy* [2009] EWCA Civ 1334, [2010] 2 All ER (Comm) about considering the entire course of correspondence, these are matters relevant to confirming, in this case, the objective intention of the parties at the time of their emails in April.

72. Then there is the Addendum. Mr Thomas placed emphasis on the fact that, in accepting the terms in the draft Addendum in her 12 May email, Ms Shetty was accepting the formality requirements in clause 3.5 (execution by at least one person from each side). He submitted that clause 3.5 of the Addendum was equivalent to a "subject to contract" provision.

73. It is clear from *RTS Flexible Systems Ltd v Molkerei Alois Muller GmbH & Co KG* [2010] UKSC 14, [2010] 1 WLR 753 that there is no requirement for the phrase "subject to contract" to be used to indicate that an agreement shall not be binding until there is a formally signed contract. However, clause 48 in that case provided expressly that the agreement was not to become effective until each party had executed a counterparty and the counterparts had been exchanged. By contrast clause 3.5 is concerned with the mechanics of signing and does not contain any conditionality.

74. In my view, however, the Addendum as a whole and in context indicated that Tizanidine would not be added as a Product to the Agreement until it had been executed by both parties. Thus, it was described as the First Amendment to the Agreement and, as set out earlier in the judgment, the first recital referred to article 11.9 of the Agreement which provided that it might not be amended except by "written instrument". To my mind it could not be clearer as a matter of construction that the Addendum was to be an amendment to the Agreement and its execution a precondition to achieve this in line with article 11.9. That was reinforced by clause 3.4, indicating that subsequent amendments of the Agreement would be by written instrument executed by the parties. There was also clause 3.7, that the Addendum would be effective from "the date set forth above", in other words, as stated in the first draft, some date in May, or in the version which Mr Pilon signed, 4 June 2019; there was the text just above the signature blocks, referred to earlier; and there were the signature blocks themselves.

Subsequent events

75. It seems to me that none of the subsequent events, if relevant, lend any weight to the suggestion that the parties changed their objective intention that the Addendum needed to be signed to become binding. Little needs to be said about the June meetings. I have already stated that I accept Ms Shetty's evidence about the 4 June 2019 meeting in Mumbai, that she told Mr Gohel and the other Jamp representative, Ms Dave, that (in general terms) the Tizanidine deal was on hold. I have also concluded that during the meeting in Montreal the following day, despite some differences in the evidence of Mr Juneja and Mr Mahil, at the very least Mr Mahil said nothing to suggest that the Addendum did not need to be signed. Mr Mahil's failure to sign it then and there indicated the opposite. The basic point is that Mr

Juneja sought to have Mr Mahil sign the Addendum. In my view what occurred at the Montreal meeting is another subsequent matter that is relevant objectively to what the parties meant in their earlier emails, namely, that if the Tizanidine deal was to be binding the Addendum had to be signed.

76. In this regard there was also Mr Juneja's internal email on 12 June 2019, that before Jamp proceeded with appointing an internal regulatory lead they needed the Addendum signed by Unichem. As to the "in nego" email of the 22 July 2019 from Mr Gohel, Mr Juneja's evidence was that the use of that phrase reflected only that there was no signed agreement. I cannot accept this, when there is no suggestion that with any of the "in-nego" projects other than Tizanidine all that Jamp was waiting for was a signed agreement. The email confirms in my judgment that there was no binding agreement regarding Tizanidine. Finally, there is Mr Juneja's reaction when told of the Mint deal. Mr Morpuss submitted that this was consistent with a binding agreement having been reached and now broken. Rather in my view it is, in context, consistent with Mr Juneja's disappointment that Unichem had turned to Jamp's competitor for a deal, despite his best attempts to secure it for Jamp.

DAMAGES

77. Given the conclusion reached on the contract issue, the question of damages does not arise. However, this part of the judgment sets out my conclusions on the disputed issues should the matter go further. Their resolution turns on the evidence of the expert witnesses, which was extensive. As noted below, the experts referred during their evidence to information which was commercially confidential. That part of the proceedings was heard in private. There is no need to refer to any of that evidence in this judgment.

Areas of agreement and disagreement

78. Areas of agreement between Dr Tepperman and Mr Hodgen were that the appropriate way of estimating relevant losses was by calculating a discounted sum in respect of future profit based on estimated sales, less estimated fixed and variable costs; that the discount rate should be 10.3 percent; and that the period covered should be 10 years from ANDS approval.

79. In their joint statement dated 9 March 2021, matters agreed between Dr Tepperman and Professor Kilgallon included that there would be a prompt pay discount of 2 percent; the cost of Tizanidine would be CAD $3.20 per 100 tablet bottle (or CAD $0.032 per tablet); that the Abbreviated New Drug Application ("ANDS") fee for a Chemistry and Manufacturing submission to Health Canada would be CAD $30,670 in Scenario 1 (specific performance is not ordered) and CAD $36,835 in Scenario 2 (specific performance is ordered); that Canadian provinces would impose a formulary listing fee CAD $3,000; and that the dossier/licensing fee would be CAD $100,000.

80. There were four areas of disagreement between the experts: first, the share of the Tizanidine market in Canada which Jamp would have achieved alongside the existing provider of Tizanidine, AA Pharma, but for Unichem's alleged breach of contract; secondly, the level of rebates which Jamp would have provided to pharmacies to obtain market share; thirdly, the time to bring Tizanidine to the Canadian market, which included the timing of ANDS approval and of formulary listing; and fourthly,

the costs Jamp would have incurred to bring Tizanidine to market, which included bioequivalence testing and freight costs.

Market share

81. Dr Tepperman's evidence was that Jamp would have been able to enter the market with a share of 27.9 percent in month 1, increasing by 0.4 percent per month, until stabilising at 36.2 percent from month 36 in year 3 to the end of the agreement. His conclusions were based on a regression model contained in an article by Ali Shajarizadeh, Paul Grootendorst and Aidan Hollis entitled "Newton's First Law as Applied to Pharmacies: Why Entry Order Matters for Generics" (2015) 22 *International journal of the economics of business* 201 ("the Shajarizadeh study"). That study employs economic analysis to identify and quantify the average effects of the factors influencing share take up with market entrants in other generic drug markets in Canada.

82. In his report Professor Kilgallon's opinion was that the Shajarizadeh study was not a reliable way to forecast future market share and would provide misleading results. In cross-examination, however, he accepted that economic models as developed in the Shajarizadeh study were used to predict the future. His main criticism was that Dr Tepperman had excluded observations of other data and that one should always use available data rather than models such as the Shajarizadeh study.

83. In his reports Professor Kilgallon advanced specific criticisms of the Shajarizadeh study: first, the model did not really cover a small, mature market with prescription limitations as with Tizanidine; secondly, the data set in the model included generics from a wide range of therapeutic areas without the inclusion of muscle relaxants; thirdly, that the formulations and pack sizes in the model were diverse, including oral liquids and eye drops, and it was not possible to compare a single dose tablet like Tizanidine; and fourthly, more than half the data set comprised generics that entered the market alongside at least three other drugs, by contrast with a small volume market like Tizanidine where individual pharmacies may only stock on average a specific, very low number of bottles of tizanidine each.

84. These criticisms of the Shajarizadeh study were somewhat off beam, as Professor Kilgallon himself fairly accepted under cross examination. The prescription limitations with Tizanidine were a given and went to the size of the existing market, not the sharing out of the market between competitors; Tizanidine, a muscle relaxant, was, in fact, one of the drugs in the study; while the formulations and pack sizes in the study were diverse, oral liquids and eye drops were not included; of the markets in the study, 70 percent had only one first entrant; and around 80 percent of the Canadian pharmacy market is dominated by two large chains, so that dividing the number of bottles of Tizanidine by the number of pharmacies in Canada to a specific small number of bottles per pharmacy overlooks the importance of the purchase decision for these two large players.

85. Professor Kilgallon's other criticisms of the Shajarizadeh study were more to the point. Even if Tizanidine was included, it was the only muscle relaxant out of 255 drugs in the study, which covered a large number of therapeutic areas. Even if oral liquids and eye drops were not included in the study it ranged over diverse formulations and pack sizes. Just over half the sales in the study related to only two

companies, and it predominantly related to products in respect of which there was more than one entrant to the market, not just as in our case Jamp joining AA Pharma. Moreover, Dr Tepperman had to accept that after six to seven years after a first entrant the model produced invalid results even though that was precisely the position in this case where AA Pharma had been marketing Tizanidine for longer than that.

86. Professor Kilgallon's own approach was to use real world data. On that basis he calculated that Jamp would have achieved a market share of 7 percent in year 1, 10 percent in year 2, 12 percent in year 3, 14.7 percent in year 4, 17.3 percent in year 5, stabilising at 20 percent from year 6 onwards. For his real world data he relied on IQVIA, which is an international company which, inter alia, provides information to those in the healthcare industry ("the IQVIA data"). IQVIA had confidential data about the market share obtained by a previous new entrant with Tizanidine from 2006 to 2015. (That was Genpharm from November 2006 to July 2009, and Mylan from July 2009 to 2014.) Genpharm/Mylan captured only a very small share of the Tizanidine market and ultimately abandoned selling it.

87. I can understand Professor Kilgallon's preference for real world data. Dr Tepperman accepted that IQVIA data was helpful and reliable and could provide insight into issues like potential market share for a new entrant. In this case, however, its utility is limited for a number of reasons. First, the rebates paid to pharmacists by Genpharm/Mylan over the 2006-2015 period are unknown. The position, as Professor Kilgallon expressed it, is that rebates in Canada are a dark art. As we will see, however, both experts acknowledged that pharmacists' rebates are significant in the take up of a product. In cross-examination Professor Kilgallon accepted that it was possible that Genpharm/Mylan simply did not offer enough of a rebate to tempt pharmacists away from AA Pharma. Secondly, as Professor Kilgallon also accepted in cross-examination, Genpharm/Mylan may not have been interested in pushing Tizanidine, but might have decided that it was better to focus efforts where they could have a much bigger market impact.

88. Apart from the Shajarizadeh study and the IQVIA data, a third set of data about market share was that contained in Jamp's Green table, referred to earlier in the judgment. In his first report Professor Kilgallon said that the forecasts for the first three years in the Green table – which were described as 7, 10 and 12 percent in Mr Juneja's first witness statement – were objectively carried out and an accurate estimate of the likely market shares which Jamp would have expected to gain in the first three years of sale. As we have seen Mr Juneja made a calculation error and the forecasts in fact represented market shares of 15, 20 and 25 percent for the first three years. In his second witness statement Mr Juneja corrected this. As a result, Professor Kilgallon's evidence was that the Green table forecasts were backed by very little work to be reliable.

89. In my view Dr Tepperman's evidence about market share is to be preferred to that of Professor Kilgallon. The Shajarizadeh study is standard econometric analysis used by economists and others on a regular basis to make predictions about new situations as in the case of Jamp's entry into the Tizanidine market. Dr Tepperman explained in his evidence that he had some 20 years of experience in this type of analysis in Canadian markets after his PhD in economics from the University of Toronto, so that he was coupling the results produced from the Shajarizadeh model with a judgment built up from experience as to whether the figures produced seemed sensible. In this case, for

the reasons outlined, the IQVIA data about the previous market entrant in my view lacks the context which would make it a meaningful indicator of Jamp's market share should it have entered the Tizanidine market.

90. Moreover, Dr Tepperman's figures of likely market share have some support in those produced in Jamp's Green table in March 2019. As Mr Thomas underlined, the analysis behind the Green table was from Mr Juneja's evidence based on standard market share without detailed analysis and the use of real world data like that from IQVIA. On the whole, however, I accept Mr Morpuss's submission that while it did not constitute the detailed analysis carried out by experts, the Green table contained an indication of what experienced players in the market thought at the time and had the benefit of being produced when no litigation was in contemplation.

Rebates

91. It was common ground that Jamp would have offered rebates to pharmacies to persuade them to stock Unichem's version of Tizanidine instead of AA Pharma's. The issue was the level of rebates which Jamp would have provided to obtain the relevant market share. Dr Tepperman stated that a flat rate of 40 percent would be payable across all ten years. Professor Kilgallon contended that 60 percent would be payable in year one, reducing to 40 percent in years four to 10.

92. In support of his view Dr Tepperman used a widely cited study by the Canadian Competition Bureau in 2007 that the average rebate rate for pharmacies was 40 percent, and that while some rebates were as high as 80 percent in his opinion that was not the position in this case. Economic reasoning, he explained, was that rebates are related to the intensity of competition in the market, and that is linked to the number of generic companies competing for market share. At present the Tizanidine market had one generic provider, AA Pharma, and if Jamp were to launch there would be two generic suppliers. That in Dr Tepperman's view was a paradigmatic generic market with few competitors, in which economic factors would tend to support lower rebates. In the current sole source environment, it was reasonable to expect that AA Pharma offered rebates well below 40 precent.

93. Therefore, Dr Tepperman reasoned, it would be reasonable to expect that Jamp would be able to compete effectively by offering rebates consistent with the average of 40 precent. Should AA Pharma choose to increase rebates to meet the new competition, it could do so by increasing the level to Jamp's offering. In the resulting two-supplier market, there would be no further economic incentive to increase rebates. Dr Tepperman said that his opinion was supported by his experience of working on other cases in Canada over some 20 years, and that with a sole generic offering a rebate of 40 percent would be exceptionally high.

94. Professor Kilgallon also took the Canadian Competition Bureau average rebates of at least 40 percent as a basis for his assessment. He assumed that AA Pharma would be currently offering that level of rebates. In his view it would have offered that rebate when there was competition in the market and would not have varied it when it became the sole provider of Tizanidine. Pharmacists would not stock a relatively low volume drug with a restricted use if the rebates were below average. He then reasoned that Jamp would not make a significant, if any, market impact with a strategy of using that rate and might need to double it. Further, Professor Kilgallon reasoned that AA

Pharma would react strongly to Jamp's entry into the market. The relatively low volumes of Tizanidine and the vast numbers of pharmacies would help AA Pharma defend the business it had grown over its five-year period since 2015 as sole provider. To force real change in the ordering patterns of pharmacists, Professor Kilgallon opined that Jamp would therefore need to offer rebates at 60 percent in order to obtain a substantial market share.

95. In my view Dr Tepperman's reasoning is to be preferred. The fact is that since at least 2015 AA Pharma has had a monopoly in the Canadian market for Tizanidine. There has been no branded product since 2012 (that was Zanaflex), and as we have seen Genpharm/Mylan dropped out in 2015. In these circumstances it seems to be unlikely to be paying any substantial rebates, certainly not Professor Kilgallon's starting point of 40 percent. Even if AA Pharma had granted higher rebates prior to 2015 – and Genpharm/Mylan's market share was low at that point - it does not make business sense for it to have continued to have done so since 2015 when it has been the sole provider of Tizanidine in Canada. While some rebates might be given, there has been no rational basis for it to grant rebates at the market average of 40 percent. With Jamp's entry AA Pharma might increase its rebates, but it seems sensible that neither Jamp nor AA Pharma would offer more than the market average of 40 percent with Jamp still having the possibility of making inroads into the Tizanidine market.

Timing to market

96. Timing to market is relevant to the discounting of cash flows. The first aspect is how long after commencing bioequivalence studies in relation to Tizanidine Jamp would have made its ANDS submission for Health Canada approval. (Jamp's unchallenged evidence was that the bioequivalence studies would have begun in August 2019.) On the basis that, as he understood it, Mint was aiming to make its ANDS submission in mid-2021, Dr Tepperman said that but for the failure to proceed with the alleged contract Jamp would have made its submission by the same date.

97. In my judgment Professor Kilgallon had a better basis for identifying a date than Dr Tepperman, his own experience of making such applications and thus his understanding of what an ANDS application involves (bioequivalence study, preparation of dossier and so on). Originally, he had set the date as September 2021, but in cross-examination accepted June 2021 as a reasonable date. In my view that is the appropriate date when Jamp's ANDS submission to Health Canada would have been made.

98. The second timing issue is how long it would have taken for Health Canada to approve Unichem's Tizanidine for the Canadian market, and to obtain formulary listing in the provinces. On the basis of Health Canada information, the time taken to obtain its approval would be a period of 480 days should the application be for a "Chemistry & Manufacturing" ANDS, or 277 days should it be a "Comparative Studies" ANDS. A different fee was required to be paid to Health Canada depending on the type of submission.

99. Both Professor Kilgallon and Dr Tepperman had assumed that the submission to Health Canada would be a Chemistry and Manufacturing submission. Subsequent to the joint statement by the experts, Mr Jujena opined in his second witness statement that Jamp would have submitted a Comparative Studies submission, not a Chemistry

and Manufacturing submission. He said that a bio-equivalence study would have been required to be included in the submission to test how Unichem's Tizanidine product was absorbed into the bloodstream compared to the reference drug. In his experience, filing under this category was standard for a generic.

100. A Health Canada guidance document describes a Chemistry and Manufacturing data only submission as "based only on chemistry and manufacturing data for a drug that does not include a new active substance. ANDS or SANDS for a generic product supported by pharmaceutical equivalence data only (such as injectable solutions) in comparison to a reference product." The guidance describes a Comparative Studies submission as "based on comparative studies (e.g., clinical or non-clinical data, bioavailability data …) with or without chemistry and manufacturing data …ANDS or SANDS for a generic product supported by comparative bioavailability, pharmacodynamic, or clinical studies in comparison to a reference product."

101. In his second supplemental report, Dr Tepperman stated that he lacked the experience to give evidence on which type of submission Health Canada would require. In his report Professor Kilgallon had assumed that a Chemistry and Manufacturing submission was appropriate but did not address Mr Juneja's evidence which came later. When asked about it at the hearing, he maintained that a Chemistry and Manufacturing submission was what would be needed. He drew on his experience of obtaining approval, albeit from the Food and Drugs Administration in the United States, not from Health Canada.

102. It was common ground that the submission to Health Canada required a bioequivalence study and bioavailability data. In terms of the Health Canada guidance document that meant that the Comparative Studies route was appropriate, since it was not an application based upon pharmaceutical equivalence data only, even if the application also included chemistry and manufacturing data. While I accept Professor Kilgallon's expertise in obtaining drugs' approval elsewhere, and his point that the Health Canada guidance was precisely that, not as he put it "tramlines", it seems to me that there is no reason for Health Canada not to apply its guidance so that, as Mr Juneja stated, the ANDS application would be in the category of Comparative Studies and would take 277 days. The corollary of that is a different filing fee from that previously used in the experts' calculations.

103. That leaves the third relevant period, that for formulary listing. Dr Tepperman said three months, Professor Kilgallon said six. The only hard evidence about this seems to be that referred to by Professor Kilgallon, contained in a report from the Canadian Competition Bureau that in some provinces formulary listing can take a month or less but, in others, decisions are made on a quarterly or semi-annual basis. In cross-examination Professor Kilgallon accepted that a pharmaceutical company would launch in each province as soon as a listing was obtained, rather than waiting for it to occur in all Canadian provinces. In those circumstances I accept Mr Morpuss's submission that the middle-ground of three months between the quickest and slowest provinces is the appropriate period.

Additional costs

104. There was disagreement between the parties as to whether a bioequivalence study would cost CAD $80,000 or CAD $175,000. The former represents the estimate Jamp

made in May 2019 for an Indian study. The latter is Professor Kilgallon's estimate, based on a quotation from a Canadian clinical research organisation.

105. The evidence on both sides on this matter is unsatisfactory. Jamp's estimate is described in the internal email of 17 May 2019 as "tentative", and Professor Kilgallon highlights how it lacks details about the nature of the bioequivalence study contemplated. Professor Kilgallon's own estimate began with the figure of CAD $350,000 provided by a Canadian clinical research organisation, which he then halved in light of a research paper from the Indian Chambers of Commerce & Industry that such studies could be completed in India for 40-60 percent of the cost of first world countries. That might have been a sensible approach, but Professor Kilgallon's starting point of CAD $350,000 was based on documents which unfortunately he did not disclose: see *Commercial Court Guide*, H2.29.

106. In light of this, it seems to me that the appropriate figure is Jamp's CAD $80,000. It was a tentative figure, but as noted earlier in the judgment it was in an email from Jamp's assistant general manager of clinical development. As Mr Morpuss submitted it was the only real-world evidence available which directly related to Indian costs. It is the best evidence available to the court of the likely cost of the requisite bio-equivalence study to be conducted in India.

107. The other issue on additional cost concerned whether freight is 1 percent of gross sales (Dr Tepperman's assumed figure) or 8 percent of gross sales (Professor Kilgallon's figure).

108. In support of Dr Tepperman's assumed figure, Mr Morpuss urged that it closely matched what was contained in Jamp's Green table, referred to earlier in the judgment. There the transfer price - the price Jamp would pay to Unichem – is CAD $0.032 per tablet - and the sale price is CAD $0.3686 per tablet. (Professor Kilgallon accepted these figures.) The gross margin there of 90.45 percent, inclusive of freight costs, is taking freight costs (as Dr Tepperman explained) as 10 percent of the transfer price, not 10 percent of gross sales. To get to that figure, the freight estimate is $0.0032 per tablet, 10 percent of $0.032. That is 0.89 percent of the sale price of $0.3686, close to Dr Tepperman's estimate of 1 percent of gross sales. However, Dr Tepperman acknowledged in his third report that he had mistakenly understood that Jamp was only responsible for domestic shipping costs within Canada, not freight costs from India, which subtracts from the force of his evidence.

109. Professor Kilgallon's figure of 6-9 percent of gross sales was derived in part from his contacting a shipping company and requesting a quotation from it. Unfortunately, he did not disclose the relevant documentation and this basis for his opinion is to be discounted. However, unlike Dr Tepperman, Professor Kilgallon has had recent experience of shipping large quantities of pharmaceutical tablets from Italy to the United States, which in his evidence also supported the estimate of shipping costs at 6-9 percent of total market price. In light of this I prefer Professor Kilgallon's view on this issue.

ANCILLARY ISSUES

110. Given the conclusion reached there is no need for me to address at length the other issues the parties have raised. In brief if I had found that there was a contract between

the parties, I would have been reluctant to grant a prohibitory injunction to enforce the exclusivity provision in article 3.2 of the Agreement, preventing Unichem from supplying Tizanidine to Mint. Prohibitory injunctions often follow in such cases, but in the present circumstances, as Mr Thomas submitted, there is the possibility that coupling a prohibitory injunction with damages would constitute an excessively generous remedy for Jamp. There is also the public policy concern Mr Thomas raised: following this litigation, Unichem and Jamp might not work together productively, and consequently, if a prohibitory injunction were granted, Canadians might be deprived, at least for the time being, of the benefits of the competition provided through Mint being an additional supplier of Tizanidine to the market alongside AA Pharma. Nor would I have readily granted specific performance of the contract. Given its long-term nature specific performance in these circumstances would seem to require an excessive amount of supervision by the court: see *Chitty on Contracts*, paras 27-015, 27-018, 27-019 and 27-042.

CONCLUSION

111. For the reasons given, my conclusion is that the claim should be dismissed.