Virulite LLC (a limited liability company incorporated in Nevada, USA) v Virulite Distribution Ltd and another

[2014] EWHC 366 (QB)

QUEEN'S BENCH DIVISION

STUART-SMITH J

2–6, 9–13 DECEMBER 2013, 26 FEBRUARY 2014

Contract – Variation – Variation implied by conduct – Contract for distribution of pharmaceutical device – Defendant purporting to terminate contract – Whether contract had been varied by subsequent agreement – Whether defendant entitled to terminate contract – Whether defendant repudiated contract.

Contract – Damages for breach – Measure of loss – Claimant seeking damages for loss of future profits following alleged repudiation of distribution agreement by defendant – Loss of chance – Whether compounded discounting appropriate when assessing loss of future business.

The defendants (VDL), owners of the intellectual property in a cold sore treatment device, had entered into successive agreements with the claimant (LLC) granting LLC the right, inter alia, to distribute the device in the United States of America (USA) and elsewhere. At the material times, the device was not approved for sale in the USA by the relevant regulatory authority, the Food and Drug Administration (FDA). With a view to effecting such approval, the parties entered into their final agreement whereby LLC undertook responsibility to secure FDA approval; VDL agreed to supply LLC with the pre-requisite clinical data, and LLC agreed to pay VDL £25,000 by way of consideration following receipt of such data. Failure to pay such consideration would trigger a clause allowing VDL to terminate the agreement. Over the course of several years, the parties engaged in meetings and conversations with a view to progressing FDA approval. In the event, and before FDA approval was secured, VDL purported to terminate the agreement, citing LLC's failure to pay the sum of £25,000 following its submission of the pre-required clinical data. Thereafter, LLC brought a claim in damages against VDL in respect of what it alleged were substantial losses resulting from VDL's purported termination of the distribution agreement. The court was required to determine, inter alia, (i) whether the parties had agreed to vary the distribution contract so that LLC's payment of £25,000 was only due once FDA approval had been secured; and, (ii) if VDL was not entitled to terminate the agreement what loss, if any, had LLC suffered as a consequence of VDL's ex hypothesi repudiatory breach.

Held – (1) Where negotiations between parties went back and forth over a period of time following the conclusion of a contract, it was appropriate to apply an offer and acceptance analysis to their discussions. Whilst parties to such negotiations were not required to use the language of offer and acceptance, the implication of their not having done so might support the conclusion that there was no moment of contractually binding consensus between them. In the instant case, VDL had made an offer to LLC, subsequent

to their entering the distribution contract, that it could pay the relevant consideration fee once FDA approval had been secured. LLC had accepted that offer with the consequence that the parties' original contract had been varied and VDL was not entitled to terminate the agreement by reference to a failure to pay the consideration on receipt of the pre-required clinical data as per the original contract (see [72], [112]–[116], [146], below); *Tekdata Interconnections Ltd v Amphenol Ltd* [2010] 2 All ER (Comm) 302 applied.

(2) Where the loss of a chance was binary there was no obvious place for compounded discounting; but, where, as in the instant case, what fell to be assessed was the value of the loss of the chance of a business succeeding, then there was no principled reason to reject the conventional approach to such an evaluation. In the circumstances, it was informative to have regard to the effect that compounded discounting at given rates would have had in order to reflect the risks to LLC's business of launching the device. Based on an agreed expert evaluation of such an annual discount, the appropriate sum to award LLC in respect of its loss of chance was $1,900,000 (see [231], below); *Allied Maples Group Ltd v Simmons & Simmons (a firm)* [1995] 4 All ER 907 applied.

Notes

For repudiation of contracts generally, see 22 *Halsbury's Laws* (5th edn) (2012) para 560.

For damages for loss of chance generally, see 29 *Halsbury's Laws* (5th edn) (2014) para 377.

Cases referred to

Allied Maples Group Ltd v Simmons & Simmons (a firm) [1995] 4 All ER 907, [1995] 1 WLR 1602, CA.

Armagas Ltd v Mundogas SA, The Ocean Frost [1985] 1 Lloyd's Rep 1; *rvsd* [1985] 3 All ER 795, [1986] AC 717, [1985] 3 WLR 640, CA; *affd* [1986] 2 All ER 385, [1986] AC 717, [1986] 2 WLR 1063, HL.

Behzadi v Shaftesbury Hotels Ltd [1991] 2 All ER 477, [1992] Ch 1, [1991] 2 WLR 1251, CA.

Butler Machine Tool Co Ltd v Ex-Cell-O Corp (England) Ltd [1979] 1 All ER 965, [1979] 1 WLR 401, CA.

Central London Property Trust Ltd v High Trees House Ltd (1946) [1956] 1 All ER 256, [1947] KB 130.

Collier v P & M J Wright (Holdings) Ltd [2007] EWCA Civ 1329, [2008] 1 WLR 643.

Energy Venture Partners Ltd v Malabu Oil and Gas Ltd [2013] EWHC 2118 (Comm), [2013] All ER (D) 347 (Jul).

Gestmin SGPS SA v Credit Suisse (UK) Ltd [2013] EWHC 3560 (Comm), [2013] All ER (D) 191 (Nov).

Globe Motors Inc v TRW Lucasvarity Electric Steering Ltd [2012] EWHC 3134 (QB), [2012] All ER (D) 138 (Nov).

Great North Eastern Railway Ltd v Avon Insurance plc [2001] EWCA Civ 780, [2001] 2 All ER (Comm) 526.

Hall v Meyrick [1957] 2 All ER 722, [1957] 2 QB 455, [1957] 3 WLR 273, CA.

Hughes v Metropolitan Rly Co (1877) 2 App Cas 439, [1874–80] All ER Rep 187, HL.

I-Way Ltd v World Online Telecom UK Ltd (formerly Localtel Ltd) [2002] EWCA Civ 413, [2002] All ER (D) 114 (Mar).

Louinder v Leis (1982) 149 CLR 509, Aus HC.

McKay v Centurion Credit Resources LLC [2011] EWHC 3198 (QB), [2011] All ER (D) 88 (Dec).

Motor Oil Hellas (Corinth) Refineries SA v Shipping Corp of India, The Kanchenjunga [1990] 1 Lloyd's Rep 391, HL.

New Zealand Shipping Co Ltd v AM Satterthwaite & Co Ltd, The Eurymedon [1974] 1 All ER 1015, [1975] AC 154, [1974] 2 WLR 865, PC.

Rickards (Charles) Ltd v Oppenheim [1950] 1 All ER 420, [1950] 1 KB 616, CA.

Tekdata Interconnections Ltd v Amphenol Ltd [2009] EWCA Civ 1209, [2010] 2 All ER (Comm) 302.

United Bank Ltd v Asif (11 February 2000, unreported), CA.

Claim

The claimant, Virulite LLC (a limited liability company incorporated in Nevada, USA), brought a claim for damages for loss of profits arising from the purported termination of a pharmaceutical distribution agreement by the first and second defendants, Virulte Distribution Ltd and 1072 Technology Ltd. The facts are set out in the judgment.

Sam Grodzinski QC and *Matt Hutchings* (instructed by *Simons Muirhead and Burton*) for the claimant.

Oliver Segal QC and *Stuart Brittenden* (instructed by *Clarkslegal LLP*) for the defendant.

Judgment was reserved.

26 February 2014. The following judgment was delivered.

STUART-SMITH J.

INTRODUCTION

[**1**] For a number of years the main treatment for cold sores in the United Kingdom, the United States and elsewhere has been by the topical application of creams. Some are available over the counter ('OTC') while others are available only on prescription ('POM'). In the United States the dominant market leader is Abreva, which is available OTC.

[**2**] The defendant companies ('1072/VDL') have held and hold the patent and intellectual property rights in a device that provides an alternative means of treatment ('the device'). It is known as the Virulite device and is based on the use of infra-red light technology operating at 1,072 nanometres: hence the names of the defendant companies. When the device is held over a cold sore, light at the required frequency is emitted which has healing properties without the need to apply visible unguents.

[**3**] The claimant ('LLC') is a Nevada-based company established for the purpose of distributing the device. LLC and 1072/VDL entered into successive agreements for the distribution of the device in the United States and elsewhere. The last agreement, which is the subject of this action, was executed on 4 July 2006 ('the DLA'). It was terminated by 1072/VDL by notice dated 31 January 2011. At that date Food and Drug Administration (FDA) approval had not yet been obtained for the device and it was not being distributed by LLC in the United States or elsewhere. LLC disputes 1072/VDL's entitlement to terminate the DLA and claims substantial damages based upon the profits which it says it would have made if it had been able to distribute the device after October 2012, which is when FDA approval was obtained.

[**4**] 1072/VDL justified their termination of the DLA in early 2011 on the grounds that the sum of £25,000 should have been paid to them by LLC in

about late 2008. Under the terms of the DLA as executed, a failure to pay that sum as stipulated would be good grounds for termination. In this action LLC has not challenged the assertions that, according to the terms of the DLA as executed, the £25,000 was due and owing and that non-payment would provide contractual justification for termination. However it asserts that the DLA was subsequently varied in early 2009 so that the sum of £25,000 did not become due and payable before FDA approval was obtained, which had not happened by the date of termination. Alternatively it submits that, as a result of the communications between the parties upon which it relies as amounting to a variation, 1072/VDL were estopped from relying upon LLC's non-payment of the £25,000 as justifying the termination. If LLC is right on either argument it succeeds on liability, in which case questions of quantum arise. It is common ground that as a result of the termination LLC lost the chance to distribute the device or otherwise to exploit its rights under the DLA. LLC submits that it has lost very substantial sums. 1072/VDL submit to the contrary that LLC could never have made a profit or that its chances of doing so were so speculative that any award of damages should be negligible at best.

[**5**] The parties virtually agreed a list of issues for determination by the court and then made their submissions by reference to those issues. This helpful approach is reflected in the structure of this judgment which adopts the following format:

[6] During the hearing commercially sensitive and confidential information was introduced in evidence on terms that it was and should remain confidential to the parties and the court. The information related to a pharmaceutical company that is referred to in the judgment as Pharmaco. Detailed consideration of the material relating to Pharmaco is contained in a separate annexe that is confidential as set out above. The conclusions in the judgment take into account the information relating to Pharmaco and the judgment incorporates reference to that information to the extent necessary to explain the basis of those conclusions.

SUMMARY OF CONCLUSIONS

[7] For the reasons set out below this judgment concludes that:

(i) There was a contractual variation of the DLA which was concluded during a telephone conversation at the end of January or early February 2009, the effect of which was that the £25,000 payment did not fall due

until FDA clearance had been obtained. Failing that, 1072/VDL's offer that the payment be delayed until after FDA clearance was accepted by conduct in the period following late January/early February 2009.

(ii) If there had been no contractual variation, 1072/VDL waived reliance upon LLC's breach of contract in failing to pay the £25,000 on receipt of clinical data for the FDA submission or was estopped from relying upon it. The period of suspension continued until at least 18 November 2010, when 1072/VDL gave notice of intended termination.

(iii) The notice given on 18 November 2011 was not a valid notice under cl 22.2.1 of the DLA. To have been valid, 14 days' notice should have been given to terminate the period of suspension. When that period elapsed, the contractual mechanisms for termination pursuant to cll 18.3 and 22.2 would have been applicable.

(iv) 1072/VDL was not entitled to terminate the DLA on 31 January 2011. Its purported termination amounted to a repudiatory breach which LLC was entitled to accept on 4 April 2011.

(v) LLC had a real or substantial chance of making a success of the launch and subsequent selling of the device at a retail price of $79.99 and achieving the sales targets set out at Schedule 4 to the DLA or Mr Boghigian's lower range of predictions.

(vi) Applying *Allied Maples* principles (see *Allied Maples Group Ltd v Simmons & Simmons (a firm)* [1995] 4 All ER 907, [1995] 1 WLR 1602), I assess damages in the sum of $1,900,000 with interest to be added in the sum of $80,750.

FACTUAL BACKGROUND: LIABILITY

[8] The central issue on liability is whether the effect of the DLA was modified by subsequent communications that were either oral or contained or evidenced in e-mails. Most of the witnesses of fact have an interest in the outcome of the litigation and have had a long time to consider their evidence. As explained in greater detail below, it is possible to trace shifts in the positions being adopted by the parties from time to time. I therefore approach the evidence of the witnesses bearing in mind the importance of the documentary evidence: see *Armagas Ltd v Mundogas SA, The Ocean Frost* [1985] 1 Lloyd's Rep 1 at 43, 57 per Dunn LJ and Robert Goff LJ respectively and the recent observations of Leggatt J in *Gestmin SGPS SA v Credit Suisse (UK) Ltd* [2013] EWHC 3560 (Comm) at [15]–[24], [2013] All ER (D) 191 (Nov) at [15]–[24]. *The Ocean Frost* was a case involving allegations of fraud. No allegations of fraud are made in the present case, but the approach outlined by the Court of Appeal has general application when attempting to assess the reliability of witnesses of fact. I offer two additional observations in the light of these authorities. The first is that the nature of the documents that are being considered needs to be taken into account. At one end of the spectrum, formal contractual documents negotiated with the benefit of legal advice are given special primacy; but this case typically involves communications by e-mail sent by business associates without prior vetting by lawyers and without attempting to achieve full precision or formality. I shall bear that in mind at all times, and particularly when assessing whether or not LLC has proved that a sufficient degree of certainty (contractual or otherwise) was achieved in late 2008/early 2009 so as to affect the position clearly set out in the DLA. The second is that if, having had due regard to all of the evidence (including relevant documentation), the

court considers that a witness' evidence is reliable despite being in apparent conflict with other evidence, it should not shrink from making such a finding. *a*

The parties and witnesses: liability

[**9**] The claimant was established by Ms Louise Higginson and Mr Lance Field. They are both British citizens but had become partners in business and their personal lives while living in the United States and before becoming involved with Virulite. Ms Higginson is highly intelligent and had been in business since about 1991, having worked in retailing and for Compaq before meeting Mr Field. Before her involvement with Virulite, she had not previously been involved with the negotiation or execution of formal contracts, but she always knew that contractual obligations were binding and that the fact that she felt something should have happened before a payment was made was not a good reason for not complying with a contractual obligation to pay unless the contract said so. She is, however, first and foremost a businesswoman and, as such, had no compunction about trying to improve her (and LLC's) position where possible, including by delaying payments due to 1072/VDL whether with the prior agreement of Dr Dougal or 1072/VDL or not. She was in many respects a formidable witness, who had a clear appreciation of where her evidence fitted or did not fit comfortably with the documents. I formed the view that she was the primary driving force behind LLC although Mr Field also played a full part, including in negotiations with 1072/VDL. His evidence was less clear than that of Ms Higginson: I shall consider it more closely later in the judgment. Mr Stephen Mencanin was the third managing member of LLC. His evidence was less centrally important than that of Ms Higginson and Mr Field and the economical cross-examination to which he was subjected did not establish that his evidence was unreliable. LLC also called Mr Brent Noblitt, who had been used by LLC as its consultant advising on the obtaining of FDA approval. He gave his evidence by video-link from the United States. His evidence proved to be largely uncontentious. *b c d e f*

[**10**] Dr Gordon Dougal has at all material times been a GP practising in the north of England, which has been a full time occupation. He invented the device and initially developed it with Mr Haslam. He gave useful evidence about the dealings between LLC and 1072/VDL but was not heavily involved in the critical period in late 2008/early 2009. What emerged from his evidence was that, by the time of the DLA, he had some reservations about Ms Higginson and Mr Field because he recognised, correctly, that they were likely to try to push for commercial advantages in the business relationship as they had done in the past. *g*

[**11**] Mr Haslam sold his shares in 1072 to Pacer Components Ltd ('PCL') during 2008. The guiding lights of PCL were Mr Graham Rothon and Mr Chris Tassell. Mr Tassell became a director of 1072; Mr Rothon did not but acted for most of the relevant period as the representative of 1072/VDL in their dealings with LLC. Mr Rothon was, on any view, a poor witness whose evidence was confused and confusing on most important aspects. More than once he gave clear answers to clear questions on critical issues and then resiled from them minutes later. 1072/VDL submitted that this was because he had been like a rabbit caught in the headlights of the legal and forensic process. That was probably true to some extent, but it does not make the court's task any easier in trying to decide whether any part of his evidence was reliable and should be accepted. Mr Tassell's evidence was much clearer but it was Mr Rothon, and not Mr Tassell, who was directly involved in the critical negotiations with LLC. *h j*

1072/VDL also called Ms Susan D'Arcy and Mr Stephen Baker, who had been engaged by PCL and 1072/VDL to assist with the obtaining of FDA approval. Both gave evidence about their dealings with LLC. Of all the witnesses, Ms D'Arcy was the most prone to argue the case. I also consider it to have been established that she was prepared to be economical with the truth when trying to sell the merits of the Virulite device to others.[1] That does not of itself show that her evidence to the court was unreliable, but overall I formed the view that her evidence should be viewed with some caution unless supported by documents. In closing submissions LLC expressly excluded Mr Baker from the trenchant criticisms it made of the other lay witnesses called for 1072/VDL. It was right to do so, and I found Mr Baker to be a clear and helpful witness, though his evidence was largely peripheral to the central issues on liability.

[**12**] In the course of the evidence it was put to a number of the liability witnesses that they were deliberately telling untruths. I have reviewed each such allegation again for the purposes of writing this judgment. Although there is no doubt that all witnesses gave some evidence that was not accurate, I am not satisfied that any of the allegations of lying were made on sufficient grounds or are made out.

[**13**] This section outlines the relatively uncontentious background, leaving matters that are substantially disputed to be resolved when considering the liability issues in detail.

The period before the DLA

[**14**] The device was first launched in the United Kingdom in late 2001. The first distribution agreement was made on 14 November 2002 between 1072 (then known as Virulite Ltd) and LLC. Under that agreement LLC was granted the sole and exclusive right to distribute the device in the United States and Canada. 1072 was responsible for applying to the FDA for clearance, with Virulite USA giving necessary support and assistance in the application process. The costs of the application to the FDA were to be borne in equal shares by the parties. The agreement was to terminate automatically if FDA approval was not received within 24 months of the date of signing ie by 14 November 2004.

[**15**] By an addendum to the first distribution agreement made effective on 15 May 2003, VDL was added as a party and the obligations of the parties were materially changed. The term of the agreement was extended to ten years, which in the United States was to run from the date of FDA clearance. The territories were expanded to include Australia, New Zealand, Japan and the Middle East. In return, Virulite USA was to make three 'Consideration Payments' in the aggregate sum of £100,000. The first (£30,000) was to be paid by 1 September 2003; the second (£20,000) was to be paid by 31 December 2003; and the third (£50,000) was to fall due 90 days following receipt of FDA approval for sale of the device in the United States.

[**16**] The first consideration payment (£30,000) was not paid on time. On 8 January 2004 lawyers for LLC wrote what became known as the Whitman letter to Dr Dougal under the heading 'Anticipated New Agreement between [LLC] and [1072/VDL]'. It said that £30,000 was being held in a trust account and that £5,000 would be paid on receipt of (amongst other things) completed trial protocols for the device. In the event, the DLA was not signed for another two years. During that time a dispute arose about another device, known as the Restorelite, which LLC said that 1072/VDL had agreed to licence to LLC for

1 T6:172.4–175.23.

distribution. In addition, LLC was pressing 1072/VDL to make progress with the clinical trials that were necessary to provide the evidential basis for any application to the FDA. In March 2005 Dr Dougal e-mailed Ms Higginson saying that the trial which has subsequently been known as 'Hargate 1' had '1 site at present, 33 results to hand'. He said he was trying to accelerate recruitment by offering £120 per volunteer. Dr Hargate's peer-reviewed and published paper[2] states that follow up continued only to January 2005, although Dr Dougal says that he continued to try (unsuccessfully) to find ways of increasing recruitment after that. I accept that he tried and that he was unsuccessful.

[**17**] During a long meeting conducted at the telephone on 6 June 2005, Dr Dougal recognised the paramount importance of the clinical trials for which he was responsible. The parties also discussed the need for variations to their contract to be recorded in writing other than e-mails. Dr Dougal's stated reason for requiring alterations to the agreement to be signed and in writing was that his e-mail account was not secure.

[**18**] By the time of the DLA, nearly four years after the initial distribution agreement, patent protection had been applied for in the United States, but not obtained; and no application had been made for FDA clearance because the clinical data necessary to support the application was not yet available.

The DLA: 4 July 2006

[**19**] The parties were LLC and 1072/VDL. For present purposes the most important provisions were as follows.

(i) The commencement date was 'on the date that FDA or official regulatory approval is obtained in relation to the USA, Canada and Japan': cl 1.1.3. Separate provisions defined the commencement date in the rest of the territory.

(ii) The territory was divided between the 'Patent Areas'—namely the United States, Canada, Japan and Australia—and the 'Non Patent Areas'—namely all areas of the globe excluding the United Kingdom, Europe (East and West, including Russia) and the Nation of South Africa: cl 1.1.15 and Schedule 1.

(iii) The term was ten years from the commencement date unless terminated earlier: cl 1.1.14.

(iv) 1072/VDL granted LLC the exclusive right to distribute the device in the territory for the term, subject to the terms of the DLA: cl 2.1.

(v) The therapeutic aspects of the design of the device and any modified device were to be established by 1072/VDL: cl 2.11.

(vi) 1072/VDL were as a condition of LLC entering into the DLA to 'timely provide clinical and safety information reasonably in [their] possession or control … to enable applicable regulatory clearance or approval of the [device]'. They also undertook 'to provide timely updates of which [they become] aware regarding matters relating to the [device], including, but not limited to: new research, clinical findings … or any other information that may aide or impact [LLC] in the fulfilment of its obligations under [the DLA]': cl 6.

(vii) LLC was to pay a royalty of £5 per device sold, on a quarterly basis: cl 9.1. The DLA made provision for termination in default of payment: cl 9.4.

2 'A randomised double-blind study comparing the effect of 1072-nm light against placebo for the treatment of herpes labialis' (2006) 31 Clinical and Experimental Dermatology 638–641.

(viii) 1072/VDL 'acknowledges that it has been and shall continue to be solely responsible for the application for, and the issuance of, patents for the Technology, worldwide': cl 14.1.

(ix) LLC 'is responsible for the cost of obtaining FDA, Canadian Medical Device Body and Japanese Medical Device Body clearance for the [device]': cl 15.1.

(x) 1072/VDL 'shall be responsible for, and shall use its best endeavors in, pursuing and completing the required clinical trials demonstrating the efficacy of the [device]': cl 15.2.

(xi) LLC 'shall be responsible for, and shall use its best endeavors in, the processing and receipt of all other governmental clearances which may be required for the use of the Technology and the manufacture, use, distribution and sale of the [device] from the appropriate and applicable governmental and/or regulatory agencies within the Territory, including the [FDA]': cl 15.3.

(xii) [1072/VDL] 'must use [their] best endeavors expeditiously to provide to [LLC] all relevant, necessary data reasonably in [their] possession or under [their] control required for [LLC] to complete and submit such applications for approval and/or clearance': cl 15.4.

(xiii) 'Upon completion of such clinical trials and the delivery of the necessary information and data to [LLC], [LLC] shall make its best endeavors expeditiously to file and submit the applications for clearance to the FDA and the Canadian and Japanese Medical Authorities. [1072/VDL] and [LLC] recognize that time shall be of the essence': cl 15.5.

(xiv) 'In the event that regulatory clearance is not issued by the FDA, Canada or Japan for any reason, including [1072/VDL's] failure to provide Clinical Data for such clearance, [1072/VDL] shall refund to [LLC LLC's] payments to [1072/VDL] (as detailed in cl 18.2), in the following proportions: (2) The sum of £17,500 … for Japan; (3) the sum of £17,500 for Canada': cl 16.11.

(xv) 'In consideration for [1072/VDL's] Agreement to the foregoing, [LLC] and [1072/VDL] acknowledge that [1072/VDL] shall receive, as additional compensation, from [LLC] the following sum: (i) Five Thousand Pounds Sterling (£5,000) already paid, (ii) the sum of Ten Thousand Pounds Sterling (£10,000) within thirty (30) days after full extension of this Agreement, (iii) Ten Thousand Pounds Sterling (£10,000), within sixty (60) days thereafter, (iv) Twenty-Five Thousand Pounds Sterling (£25,000) after delivery of the clinicals to [LLC] for use in the submission of the FDA approval Application (and after review and acceptance of such clinicals by [LLC's] FDA consultant which shall be completed within fourteen (14) business days after delivery), and (v) an additional Fifty Thousand Pounds Sterling (£50,000), within ninety (90) days following the issuance of approval and/or clearance by the FDA for sale of the Product in the United States of America': cl 18.2.

(xvi) '… [1072/VDL] and [LLC] acknowledge and agree that in the event that any additional payments due under clause 18.2 are not made within thirty (30) days after any applicable due date, then in addition to such additional payment, [LLC] shall pay to [1072/VDL] a late fee of five percent (5%) of the total amount outstanding. If payment is not received in full in respect of both the additional payment and the late fee within ninety (90) days of the date the additional payment first became due, then [1072/VDL] may terminate this Agreement forthwith': cl 18.3.

(xvii) 'Either Party shall be entitled forthwith to terminate this Agreement with not less than sixty (60) days written notice to the other if … that other Party commits any material breach of any of the provisions of this Agreement and, in the case of a breach capable of remedy (which breach has continued for at least thirty (30) consecutive days), the other party fails to remedy the same within sixty (60) days after receipt of a written notice giving full particulars of the breach and requiring it to be remedied': cl 22.2.1.

(xviii) 'Any waiver by either party of a breach of any provision of this Agreement shall not be considered as a waiver of any subsequent breach of the same or any other provision thereof': cl 22.4.

(xix) 'Upon full execution, this Agreement shall contain the entire Agreement between [LLC] and [1072/VDL] regarding the Device … and shall supersede any negotiations or prior Agreements, (written or oral) regarding the subject matter of this Agreement': cl 26.1.

(xx) 'This Agreement shall not be modified in any way except by a subsequent written instrument signed by both parties': cl 26.4.

(xxi) In the DLA 'reference to writing includes fax and similar means of communication. Daily and ongoing business correspondence may be carried out via e-mail; provided that any modifications of this Agreement or any material alteration of the relationship between [1072/VDL] and [LLC] must be in written and executed form; not including email or fax': cl 1.4.7—underlining in the original DLA.

(xxii) 'Neither party's failure to exercise any power given to it under this Agreement or to insist upon strict compliance with any obligation under it, nor any custom or practice of [LLC] or [1072/VDL] shall constitute any waiver of any rights under this Agreement. Waiver by either party of any particular default by either party must be in writing and shall not affect or impair such party's rights in respect of any subsequent default of any kind. Delay by either party in exercising any right arising from any of [LLC's] defaults or omission to exercise them shall not affect or impair such party's rights in respect of those defaults or any default of any kind': cl 27.

[**20**] In summary, responsibility for obtaining patent protection lay with 1072/VDL. Responsibility for obtaining FDA clearance now lay with LLC but 1072/VDL was required to provide the necessary clinical data to enable LLC to obtain it. LLC was required to make royalty payments of £5 per device and the consideration payments. Failure to pay a consideration payment on time would trigger the provisions of cl 18.3. It could also constitute a material breach triggering the termination provisions of cl 22.2.1. Under cl 18.3 1072/VDL would be entitled to add a 5% surcharge 30 days after the due date for payment and to terminate if the full amount was not paid within 90 days of the date that the consideration payment first became due. Under cl 22.2.1 1072/VDL would be entitled to give notice of breach when the breach had continued for 30 consecutive days and, if the breach was not remedied in the meantime, terminate 60 days after LLC received the notice of breach. In either event, the DLA contemplated a minimum of 90 days between the first occurrence of the breach and the date of termination. The DLA was clear in stating that alterations in relations between the parties should be executed in writing in order to be effective and that e-mails and faxes should not be used for that purpose.

From the DLA to early 2009

[**21**] The first consideration payment under the DLA was recorded as having been paid before its execution. The second consideration payment was paid within time on 2 August 2006.

[**22**] In September 2006 news filtered through from the USPTO (United States Patent and Trademarks Office) that the United States Board of Appeals had confirmed the decision of the examiner which had the effect of limiting the scope of the United States patent application to the method of treatment rather than the device itself.

[**23**] In October 2006 LLC sent a long e-mail to Dr Dougal expressing concern at the USPTO rejection and at the delay in being able to launch an FDA application because of the absence of supporting clinical data. It made the point that LLC had been 'putting our hands in our pockets for 4 years & still have no clear indication as to when we can really start to recoup our outlay and make some money' and concluded that 'we are uncomfortable with paying the next £10,000 payment' (ie the third consideration payment under cl 18.2 of the DLA) 'at a time when we cannot clearly justify it … apart from Australia, there is no other patent for the "patent area" and there is no data for the FDA & no clear timeframe as to when we will get the same'. Dr Dougal did not respond to this e-mail but there was evidently a telephone conversation between him and Mr Field at some stage as Ms Higginson sent him a further e-mail on 21 January 2007 referring to it and to 'your suggestion' (ie Dr Dougal's suggestion) that LLC should make the payment of £10,000 in instalments. She asked if Dr Dougal was 'ok with' a proposal that the £10,000 should be paid in four instalments between 30 January and 30 April 2007. She also referred to royalty payments for Q1 and Q2 2007 which, in the event were not paid on time.[3] Dr Dougal did not reply to that e-mail save to point out that Ms Higginson had not factored in a late payment penalty. He did not take issue with the assertion that the proposal for payment by instalments was his suggestion, though he later rejected it when giving his evidence. During January and February 2007 LLC sent further e-mails to Dr Dougal asking him to confirm his agreement to the payment schedule. Dr Dougal did not reply by e-mail to any of them. The payments were made by LLC either on or within a few days of the dates in the proposed payment schedule.

[**24**] I find that Dr Dougal did not at any stage object to the payment by instalments or the payment schedule. Even if he was not the first to suggest it, he acquiesced in the proposal by his silence so that LLC reasonably took him to have agreed to it.

[**25**] In March 2007 a disturbing development took place. LLC had managed to reach an agreement with Walgreens for the online sale of the device before FDA approval. Walgreens is the largest chain of drug stores in the United States, with approximately 8,000 retail outlets and having sales and net earnings measured in billions of United States dollars. From about mid-2006 the device had been offered for sale online through Walgreens's site, initially at a retail price of $79 and subsequently at $99. Sales had been slow at the outset but March 2007 was the best month, with 275 devices being sold. LLC was hoping to achieve an exclusive agreement under which Walgreens would retail the device in its stores once it had FDA approval. Such an agreement, if achieved, would have been regarded by LLC as a major coup for the distribution of the

3 Ms Higginson's evidence was that the non-payment of the royalties was as a result of an error on her part and was not deliberate. I accept that evidence.

device because of Walgreens's network of stores and commercial clout.[4] However, in March 2007 lawyers for a competitor, Tyrell Inc, sent a letter to LLC laying the ground for an assertion that the Walgreens sales infringed the patent protection for a Tyrell device which treated skin lesions with heat. LLC recognised the letter as the start of a campaign against the Virulite device and correctly anticipated aggressive competition. Ms Higginson e-mailed Dr Dougal on 27 March 2007 requesting his technical support in order to rebut Tyrell's clinical claims and to ensure that Tyrell could not hijack the Virulite trade name. He did not respond. She followed up on 3 April 2007. This time he responded to Tyrell's lawyers pointing out that the Virulite device did not operate by the application of heat.

[**26**] LLC was so concerned by the intervention of Tyrell that it reviewed with its FDA consultant, Mr Noblitt, whether to continue to wait for further clinical information from 1072/VDL before making an application to the FDA or whether to change tack and to make a submission with the information that was then available, which essentially comprised the results of the Hargate 1 trial. After the meeting Ms Higginson sent a long e-mail to Dr Dougal on 10 May 2007 saying that LLC had been advised that it was 'in a position to risk making the submission for clearance' and requesting necessary information from 1072/VDL to support the submission as soon as possible. The worst case scenario was that the FDA would require more information and that a deposit payment may be lost; and that the FDA would find out about the pre-clearance sales through Walgreens and require LLC to cease and desist, with the possibility of a fine being levied.

[**27**] On 4 June 2007 Mr Field sent a further long e-mail. In it he made clear that LLC were despondent because of the lack of progress over a period of five years during which LLC had made substantial investment without a United States launch for the device being in prospect. He told Dr Dougal that, at Tyrell's prompting, the FDA had started investigating LLC, with the result that it had ceased the Walgreens online selling of the device; and he gave a clear and explicit warning that LLC's position in the United States was being put at risk of other products getting to the market before the device. The seriousness of the situation was summarised by the statements that 'while we have been waiting on the trial and the patent … Virulite is missing the boat'; and 'The United States needs a patent and FDA clearance as a matter of urgency before other products hit the market here and make a Virulite launch unworthwhile. We need the US patent and our FDA trial data this year.' He raised again the possibility of an early FDA submission and suggested that, if that was done, it was fair that 1072/VDL should contribute half the cost of the submission going forward.

[**28**] When Dr Dougal replied on 12 July, some five weeks later, he said that the patents were being pursued with due diligence and that he was intent on maximising the patent protection for the device. Turning to the question of clinical trials he said that 'the current trial is proceeding slowly' and referred to having applied to a hospital to have a resident researcher working there to speed up recruitment. This fell far short of conveying the true position. He suggested that they should next have a teleconference when they had good

4 The prospective financial consequences of such an agreement are now hotly contested and will be considered below in relation to quantum. What cannot be doubted is that LLC was pinning its strategy on Walgreens in 2006/2007.

quality clinical data on the current trial and a projected trial on the application of bacterial infection without giving any indication of when that might be.

[**29**] Mr Field replied on 16 August 2007 complaining of a lack of proper support from 1072/VDL, emphasising again the need for data from the clinical trials, and pointing out (correctly) that LLC had still not been given any status update on the cold sore clinical trial, which he said 'makes us very nervous & we are starting to wonder why you are avoiding giving info on this trial and instead starting other trials?' After what appeared to be a productive telephone call between Ms Higginson and Mr Field with Dr Dougal on 24 August 2007, Ms Higginson sent a summary on 27 August 2007 because 'we agreed that our meeting was informal, but I still believe in written recaps … This way, if we have misunderstood something, you can take the opportunity to clarify it to us'. As part of the recap (which was accurate as to the agreement reached) she wrote: 'We discussed the balance consideration payments and VUK agreed with VUSA that these can be "stalled" until patents are granted. Royalties must be paid under any circumstances. Gordon … I don't think we need an Addendum on this, but I would suggest that it is something we should confirm on a fax letter as 'a clarification of understanding.'

[**30**] Dr Dougal accepted in evidence that Ms Higginson's e-mail showed a remarkable degree of forbearance given what LLC had or, rather, had not received from 1072/VDL during 2007; but he did not reply to it. In evidence he said that only the £25,000 due under cl 18.2(iv) was discussed and not the £50,000 due under cl 18.2(v). That is certainly not what Ms Higginson's e-mail recorded and I doubt whether it is correct; but it is not necessary to resolve the issue since it is common ground that agreement was reached to 'stall' the payment of the £25,000, which is the critical payment for the purposes of this action. It is to be noted that Ms Higginson's suggestion of confirmation by a fax letter, if accepted, would not have complied with cl 1.4.7 which specifically excluded the use of faxes. However, Dr Dougal did not at any stage call either for a fax or for any other form of document to record the agreement and he accepted that, in the absence of a document, he expected LLC as his business associates to rely upon the agreement that they had reached during the conversation. His explanation for not calling for a formal document was that payment was not yet due under the agreement that had been reached. I do not accept that explanation: while it is conceivable that he might have called for a document if payment had then been due, his inactivity in relation to the payment of the previous £10,000 by instalments strongly suggests otherwise. In my judgment the real reason was that Dr Dougal recognised at the time that (as he said in evidence) in circumstances where 1072/VDL did not have the patents (or, he could have added, the clinical trial data) there was a need to be flexible to maintain credibility in the business relationship. He therefore agreed the change without requiring the formalities specified by the DLA.

[**31**] As 2007 gave way to 2008, LLC continued to press 1072/VDL for the necessary data, but none was provided. The next relevant event was Pacer's acquisition of 50% of 1072 and VDL which was announced to the press on 27 June 2008. LLC was not given any advance warning of the deal and was immediately concerned that it might give rise to a conflict of interest since Pacer was manufacturing and supplying the device and would now be closely involved in the licensing of the device to LLC as well. Because of her concerns about the introduction of a new force into the business relationship between 1072/VDL and LLC, Ms Higginson returned to the question of recording on paper the agreement about the stalling of the outstanding consideration

payments until after patents were achieved; and she drew up a draft agreement having pulled a copy of the DLA up on screen. In the event, although on 11 August 2008 Ms Higginson had told Dr Dougal what she was doing, her draft was never passed to 1072/VDL, and Dr Dougal did not pursue the matter.

[**32**] An important tele-conference took place on 27 August 2008 involving Mr Rothon and Mr Tassell for 1072/VDL and Ms Higginson and Mr Field for LLC. Ms Higginson sent an agenda in advance which first raised the possibility of 1072/VDL buying back some of LLC's licensing and distribution rights. That proposal never took flight. The alternative agenda included establishing a dedicated point of contact at 1072/VDL and minimum timeframes for 1072/VDL to respond to communications from LLC. In the event, from about now on Mr Rothon became the principal point of contact on behalf of 1072/VDL although his evidence (which I accept) was that decisions had to be and were taken by the directors, Dr Dougal and Mr Tassell.

[**33**] Item 5 on the agenda provided by Ms Higginson was: 'Consideration payments & patents: per verbal agreement with Gordon (tele-conference on August 23rd 2007) no further consideration payments shall be due until such time as patents are obtained (ie per "Patent Area" as defined in the licensing agreement), an addendum to the agreement to be executed to memorialise such agreement (draft to be forwarded)'. Item 7 stated:

> 'FDA submission: discussion regarding submission based on data recently made available from Hargate trial. FDA requirements were for 150 participants over minimum of 3 sites, with even distribution of participants over sites & even spread of A[ctive] v P[lacebo] at each site. Intended use statement was for "reduced healing time & pain relief". Based on incomplete data, we propose that Virulite UK cover the cost of the FDA submission with current data … if clearance is obtained, we will reimburse costs (up to agreed maximum).'

[**34**] Item 5 was regarded as key by Mr Rothon and Mr Tassell. As far as Mr Tassell was concerned, if Dr Dougal had agreed it, then it was agreed. Dr Dougal said in evidence that he could not remember a conversation about it but, if asked, he would have said that he had agreed to the £25,000 being 'stalled' until the achievement of patents. Mr Tassell was sure that either he or Mr Rothon discussed Item 5 with Dr Dougal. Mr Rothon said that he knew of the agreement but could not remember how he knew. Neither Mr Tassell nor Mr Rothon gave evidence that the agreement was limited to the £25,000 and not the £50,000 consideration payment.

[**35**] After the teleconference, the question of memorialising the agreement fell into abeyance and appears not to have been raised again. Ms Higginson sent an estimate of the costs of the FDA submission suggesting payment of half. On 12 September 2008 she e-mailed Mr Noblitt 'We have good news, the UK have agreed to cover 50% of the costs of making our submission.' In the event, Mr Noblitt's firm invoiced Pacer for 50% of his fees going forward and was paid by Pacer. In evidence, Mr Rothon said that this payment was made by Pacer as an additional investment by Pacer in 1072/VDL. In one sense that was correct, since it is apparent that Pacer was now providing the funds necessary for the continuation of 1072/VDL's business. There is an absence of contemporaneous evidence about any detailed discussion of the contractual position, which is unsurprising. 1072/VDL now submits that it had no part in the arrangement for the funding of 50% of Mr Noblitt's fees and that it was a free standing arrangement by Pacer with LLC. I am not convinced that anyone

thought in those formal terms at the time. The only clear indication is in the wording of Item 7 of the agenda, which talks in terms of Virulite UK providing the funding. When Mr Rothon was asked if he drew any distinction between Pacer and 1072/VDL at the time, his evidence was that he was unable to say one way or the other. To similar effect, Ms Higginson said in her witness statement that during the tele-conference 'we proposed that they ie Pacer or the defendants, should pay all the costs of the submission going forward'. There is no substantial evidence that Ms Higginson's original proposal that the funding should be provided by 'Virulite UK' was displaced by subsequent discussions. To the contrary, Mr Tassell's evidence was that, although the payments were to be made by Pacer, the agreement was a change to the strict obligations incumbent upon LLC under the terms of the DLA and Pacer paid the contribution on behalf of 1072/VDL. I do not treat that answer as determinative, but it supports the conclusion that the agreement was intended to affect the contractual relations between LLC and 1072/VDL. Although Ms Higginson said in her witness statement that, after she had sent details of the costs after the tele-conference 'Mr Rothon confirmed that Pacer would pay 50% of the costs of the submission, which they subsequently did', it seems probable on all of the evidence that the invoicing of Pacer (rather than 1072/VDL) was not a considered reflection of contractual agreements but was a sensible response to cash-flow realities: there was no point in Pacer making the payment into 1072/VDL and thereafter 1072/VDL paying the same relatively modest sums to Mr Noblitt.

[**36**] The significance of this point is that if the funding agreement can be seen as a variation of the contractual relations between LLC and 1072/VDL, then the DLA stipulated that it should be recorded in writing whereas, if the agreement was merely between Pacer and LLC and did not affect the obligations under the DLA, that stipulation did not apply. On the evidence summarised above, I conclude that it was the former and Mr Tassell was correct to recognise it as such.

[**37**] During September and October 2008 LLC continued to press Dr Dougal for a clinical summary of the clinical trial data that was to support the FDA application. On 1 October 2008 Dr Dougal sent a draft trial report and a spreadsheet showing the progress that had been made with the trial known as 'Hargate 2'. To LLC's dismay, the spreadsheet revealed that after recruiting 30 volunteers to the trial between the end of May and 5 November 2006, no further volunteers had been recruited until 14 January 2008. In evidence it became apparent that Dr Dougal had only kept in touch with progress periodically, contacting Dr Hargate every six months or so, and he had not become aware of the problem until about June 2007. As a result no steps to re-start the process of recruitment had been taken until about August 2007, with that process starting to bear fruit in January 2008 after a deliberate decision to avoid restarting in December 2007 because of potential disruption over the holiday period. This was not the impression that had been given by Dr Dougal in his e-mail on 12 July 2007 or at any time before 1 October 2008—almost four years after 14 November 2004, on which date the parties had originally contemplated that FDA clearance would have been obtained: see [14], above.

[**38**] On 8 October 2008, Mr Mencanin had e-mailed Dr Dougal emphasising the critical importance of the clinical trial summary of data. He told Dr Dougal that he had a meeting scheduled with Walgreens on 30 October at which he intended to raise their post-FDA purchase order from the initial

launch from 10,000 to a much higher number, based on Boots's experience in the United Kingdom since its launch of the device in September 2008. Mr Mencanin's evidence was that the deal with Walgreens was virtually done. But on 16 October 2008 disaster struck when Walgreens cancelled the meeting because their beauty department had decided to stock an item that did the same as the device. As predicted by LLC, Tyrell had got in first because of LLC's inability to market the device on the back of patent and FDA approvals. Mr Field wrote a strong e-mail to 1072/VDL pointing out that Walgreens had been LLC's largest route to market and that it was now probably lost for the lack of trial results; and he pointed to the failure to recruit between November 2006 and January 2008, concluding that 'I am now at the end of my patience with hearing any more excuses as to why we are not in the No. 1 position'.

[**39**] LLC decided that a submission to the FDA had to be made as a matter of absolute urgency and instructed Mr Noblitt's firm to expedite the submission with the data available, taking the view that it could not risk waiting for data from the United Kingdom any longer. Ms Higginson and Mr Field pressed repeatedly for action and information from 1072/VDL, with Mr Field sending another long e-mail on 19 October 2008 placing the blame for the delay at 1072/VDL's door and saying it had cost LLC millions of dollars. He again gave vent to LLC's state of frustration and dismay, saying 'We are at the end of our patience, utterly demoralized & have exhausted ourselves with the effort of maintaining momentum in a business that has spent almost seven years just waiting for its Principal to fulfil its obligations to us.' He proposed that Virulite UK should buy a 20% stake in LCC for $2 million, which was promptly rejected by Mr Rothon on behalf of Pacer.

[**40**] Mr Noblitt set to work preparing what was described as a 'submission lite', meaning a submission that was known to be light on detail but which it was hoped would start the submission rolling with the possibility of satisfying the FDA by the provision of further information later. It was submitted on 18 December 2008. That day Ms Higginson e-mailed Dr Dougal, Mr Tassell and Mr Rothon explaining that the submission would trigger an initial response which was anticipated to be either a request for information or a rejection of the submission on the basis of lack of sufficient data. She enclosed a list of required data and emphasised the imperative need for Virulite UK to prepare the missing pieces for immediate response to the FDA. She returned to the same theme on 13 January 2009 stating 'As per previous e-mails, the most likely scenario is that the FDA will reject the submission on the basis that we have not proved the case for the predicates &/or the lack of overall supporting data (… as explained this was a very "light submission") and we then petition for class II classification and de novo status and resubmit & provide additional data as requested'. She said that the FDA's published response time was 90 days but that recent response times had been nearer to 75 days, either of which would lead to an FDA response in March.

[**41**] Meanwhile Ms Higginson had flown to the United Kingdom for a meeting with Mr Rothon on 26 November 2008, which marks the start of the critical period of negotiations. They are considered in detail under Issue 2 below. At this stage I provide only a brief outline summary.

[**42**] Ms Higginson went armed with the data from the Hargate 2 trial, which she regarded as demonstrating a failure by 1072/VDL to pursue the clinical trials that had been seen on both sides as imperative in order to provide data for an FDA submission. She pressed Mr Rothon to agree to delay payment of the £25,000 consideration payment that would otherwise be payable under the

DLA on delivery of the clinicals for the FDA submission. Discussions about that delay, and other topics of controversy between the parties continued until late January/early February 2009 and are examined in detail below. After that period, 1072/VDL did not demand payment of the £25,000 consideration payment until 18 November 2010.

From early 2009 to termination in 2011

[**43**] The FDA response came on 26 February 2009, signed by Mr Neil Ogden, the FDA's chief of the General Surgery Devices Branch. It was not encouraging and included a request for additional information. Ms Higginson forwarded the response to Mr Rothon and Dr Gordon with a request for any clinical arguments in support. By about this time PCL had approached Ms D'Arcy and Mr Baker to act as FDA consultants. There followed a bizarre conversation on 3 March 2009 between Ms Higginson and Mr Rothon with Ms D'Arcy and Mr Baker, who had not yet been instructed to do anything in relation to the FDA process, listening in but not speaking and with their identities not being disclosed to Ms Higginson. Then on 7 March 2009, while still not instructed to do anything by either 1072/VDL or LLC, Ms D'Arcy e-mailed Mr Ogden at the FDA, providing information and raising questions that clearly (despite Ms D'Arcy's evidence to the contrary) referred to the device. A month later, Mr Baker wrote a critique of the existing FDA submission (raising many of the points that LLC and Mr Noblitt had been making for some time) which Ms D'Arcy checked and Mr Rothon sent to LLC in the form of a letter on 9 April 2009. Ms Higginson sent an exasperated reply the same day pointing out that many of the points were ones that LLC had been raising and expressing concern that Mr Rothon or Ms D'Arcy and Mr Baker had been in direct contact with Mr Ogden discussing LLC's submission without authorisation from LLC. Mr Rothon replied that the communications with the FDA 'was all done without any reference to Virulite, so no confidence was breached'. That was thoroughly misleading and unjustifiable given the terms of Ms D'Arcy's 7 March e-mail to Mr Ogden. He went on to suggest that 'our new colleagues' (meaning Ms D'Arcy and Mr Baker) would not be joining until June and October but that there was the possibility thereafter that they might take over the submission and deal directly with the FDA. Miss Higginson's response, if marginally ungrammatical, was clear: 'This is the most insulting and frankly I find your e-mail obstructive and defensive.' She delivered a stinging rebuke criticising the performance of 1072/VDL as principal, concentrating on their interference with the FDA, a lack of reciprocity in their dealings with LLC, and their contractual obligation to provide data to LLC to enable FDA clearance to be obtained.

[**44**] On 10 June 2009 the FDA notified Mr Noblitt's firm that, as expected and because of the lack of a clear predicate, LLC could not use the traditional 510k route to clearance. This notice triggered the filing of a de novo petition on 25 June 2009. With 1072/VDL's encouragement, Ms D'Arcy and Mr Baker (who had set up a consultancy called iSmart) became more involved with the progress of the submission so that by the autumn of 2009 they were instructed in place of Mr Noblitt's firm, having informed Ms Higginson that they had information that would ensure clearance.

[**45**] In July 2010 Ms D'Arcy informed LLC that a company called Omega was taking the device, probably initially in Europe. In subsequent correspondence LLC offered to discuss with Omega a possible involvement in countries covered by the DLA, including Australia and New Zealand, while

raising the possible difficulties that could arise if different pricing models were adopted in different countries. On 2 July 2010 Mr Field e-mailed Ms D'Arcy that 'If the UK wishes to promote the product … into any of our regions, it is quite simple. They should work out what it is worth to them, and thereafter make a written proposal to us.' This was forwarded to Mr Rothon who responded that he would discuss it with Mr Tassell and that 'The time is coming when we need to act on this issue'. In his witness statement Mr Rothon said that this was a reference to needing to act on LLC's inactivity in jurisdictions other than the United States. I reject that evidence, which does not fit with the context in which his e-mail was sent and is not supported by any other documentary evidence. The issue on which 1072/VDL needed to act was the potential overlap between Omega's plans and LLC's territories. In the event it appears that Omega's distributors were not enthusiastic about promoting the device; but at this hopeful stage in negotiations, that was not yet known.

[**46**] The Japanese patent for the device was granted in or about April 2009. The Canadian patent followed in May 2009. The United States patent was granted in June 2010.

[**47**] In September 2010, Ms D'Arcy told Ms Higginson that Pacer would be looking for a time scale for when LLC proposed to go to countries covered by the DLA other than the United States. This provoked a sharp response from Mr Field that 'once we have FDA clearance in hand, and a positive revenue stream has commenced, we will then commence with this phase of the business. We are under ZERO obligation to enter into … the regions listed in our contract at this juncture, irrespective of what Pacer may want.' Ms D'Arcy disputed that LLC had zero obligation in other regions. Mr Field replied calling for a proposal from Pacer for LLC to consider and attempting to park the issue of progress in other regions. There was further correspondence, in the course of which Ms D'Arcy warned LLC against making any direct approach to Omega at that stage, which advice Mr Field rejected on the basis that LLC should be entitled to speak to anyone who was contemplating selling into the territories allocated to LLC by the DLA. The correspondence was inconsequential and petered out. Ms D'Arcy's role in this correspondence appears to be equivocal, since she was at that stage retained by LLC to act on its behalf in relation to the FDA submission and yet corresponded as if on the 1072/VDL side of the fence. There was no correspondence from or on behalf of 1072/VDL complaining directly of inactivity by LLC in territories other than the United States.

[**48**] On 15 November 2010 Dr Dougal sent LLC the Canadian manufacturing approval certificate that had been issued with effect from 6 October 2010 under cover of an e-mail that made no substantive comment.

[**49**] On 18 November 2010 1072/VDL wrote to LLC in the following terms:

> 'RE: Distribution Agreement paragraph 18.2, 18.3, 22.2 and 22.2.1
>
> As per the above paragraphs the Principal has supplied the clinicals to the FDA consultant who accepted the clinical investigations and submitted the same to the FDA.
>
> Twenty five thousand pounds (£25000.00) was due to be paid to the Principal by the Distributor within 30 days of the clinicals being accepted by the FDA consultant.
>
> This payment is late and in accordance with paragraph 18.3 twenty six thousand two hundred and fifty GBP (£26250.00) is due for immediate payment to the Principal.

> The Distributor is in breach of the terms of the agreement and paragraph 22.2.1 applies. The breach has been for a period greater than 30 consecutive days. The Distributor is required to remedy the breach within 60 days of receipt of this correspondence failing which paragraph 22.2 of the agreement will be enforced.
>
> Payment details are attached.'

[**50**] The letter was accompanied by an invoice which cited cl 18.2 of the DLA stating that 'Clinicals have been supplied by the Principal to the Distributor's FDA consultant' and charging a 5% late payment fee pursuant to cl 18.3.

[**51**] Mr Tassell telephoned Mr Field on 2 December 2010. He proposed that LLC should commit to covering the costs of iSmart and, in return, the invoice would be withdrawn. Mr Field told him that LLC already had a remuneration agreement with iSmart in place and would not make extra payments; and he asked him to withdraw the invoice unconditionally, which Mr Tassell refused to do. Mr Tassell followed up with an e-mail in which he stated his understanding that 'if 1072 … were to cancel down the invoice for $25k (sic) recently sent, you would be prepared to make pre-agreed future monetary contributions towards the iSmart costs of your FDA application'. Mr Field replied that—

> '[t]he demand for UK Sterling Twenty Five Thousand needs to be retracted in its entirety, without any strings attached. We do not owe these monies, and as such we will not negotiate on something that is not due. My understanding of our call, was that you would speak with Gordon, in regards to retracting the demand.'

[**52**] A fuller and more formal response to the threat of termination was sent by LLC's United States attorneys on 6 December 2010. It contended that 'Not only is your assertion that a consideration payment of GBP25,000.00 is now due from Virulite LLC incorrect, but Virulite LLC is greatly concerned with your approach.' It complained of a lack of openness and cooperation, contrasting it with LLC's approach. LLC's specific comments included:

> 'Following a meeting with Gordon Dougal and Chris Tassell, Graham Rothon, in his email to Virulite LLC, dated January 22nd 2009 (on which Chris Tassell was copied), agreed to an amended payment schedule with Virulite LLC requiring that the payment of GBP25,000.00 be due 30 days from receipt of FDA clearance … The post-FDA payment schedule had been discussed and reference numerous times by the Principal (Graham Rothon) via email and verbally.
>
> *We also started to put together our future financial plans and I thought it would be good to outline our expectations from you once we gain FDA approval (which are in line with the contract we have with you)*
>
> *If we assume FDA approval is gained in March 2009:*
>
> 1. *25k to be paid by LLC to Virulite within 30 days. This is the delayed stage payment we agreed prior to FDA approval.*
> 2. *£50k to be paid to LLC 90 days after FDA approval. This is the final stage payment as per the contract.*
>
> The new payment schedule specifically superseded the original schedule under the Agreement. *No further consideration payments are due to the Principal until such time as the FDA clears the device for sale in the USA.*'

[**53**] By letter dated 31 January 2011 1072/VDL gave notice to terminate the DLA as follows:

'Re: Distribution and License Agreement—4 July 2006 (the "Agreement") Confirmation of Termination

Further to our letter to you dated 18 November 2010, we would like you to note that the Agreement is terminated due to your breach of Clause 18.2(iv) of the Agreement.

Please ensure that you comply with your obligations on termination, including the cessation of all marketing, advertising and promotion of the Product or the Technology, together with the use of the Trade Name and Trademark, save as expressly allowed under the Agreement.

Please acknowledge receipt of this letter.'

[54] FDA approval was received by a letter dated 18 October 2012. As an additional control the FDA required validation of the cleaning and disinfection instructions for the device to be validated; and there were other controls included. However, the FDA approval opened the way to the lawful marketing of the device in the United States.

ISSUE 1: THE EFFECT OF THE NO VARIATION CLAUSES IN THE DLA

(i) The parties agree that the provisions of cll 1.4.7, 26.4 and/or 27 of the DLA do not preclude any variation, waiver or promissory estoppel otherwise arising from taking effect.

(ii) Did they give rise on the facts of this case to an evidential presumption that the parties did not intend to vary cl 18.2(v) of the DLA and/or that the defendants did not intend the claimant to rely on the alleged representation or promise in January to February 2009, unless the same was contained in a written instrument signed by both parties?

(iii) If so, was such presumption displaced in either event on the facts?

The applicable principles

[55] The terms of the DLA are clear and reflect the agreed position of the parties at the time of the DLA; but the parties recognise that the DLA does not preclude any variation, waiver or promissory estoppel otherwise arising from taking effect. This recognition is correct on the authorities, including *I-Way Ltd v World Online Telecom UK Ltd (formerly Localtel Ltd)* [2002] EWCA Civ 413 at [7], [2002] All ER (D) 114 (Mar) at [7].

[56] The phrase 'evidential presumption' was coined by counsel in formulating the list of issues. It is not, so far as I am aware, sanctioned by authority. It is intended to convey the same idea as 1072/VDL's submission that 'a party seeking to displace the effect of such a clause faces a very high evidential burden of proving that there had been a common intention to vary the contract notwithstanding the existence of that clause—a burden which is all the more onerous if the clause has been specifically negotiated (and more onerous still, where its inclusion in the contract has been expressly required by the other party)'.

[57] Support for the proposition that there may be a high evidential burden on a party seeking to displace the effect of such a clause is provided by the judgment of Judge Mackie QC (sitting as a judge of the High Court) in *Globe Motors Inc v TRW Lucasvarity Electric Steering Ltd* [2012] EWHC 3134 (QB), [2012] All ER (D) 138 (Nov), a decision on an application for summary judgment. At [53] he said (obiter) that 'there could in theory be an oral variation, notwithstanding a clause requiring that to be in writing, but that the court would be likely to require strong evidence before reaching such a finding'.

[**58**] In *McKay v Centurion Credit Resources LLC* [2011] EWHC 3198 (QB), [2011] All ER (D) 88 (Dec) and *Energy Venture Partners Ltd v Malabu Oil and Gas Ltd* [2013] EWHC 2118 (Comm), [2013] All ER (D) 347 (Jul) it was either conceded or agreed that Judge Mackie QC's obiter dictum was correct. However, in *Energy Venture Partners* Gloster LJ went further in giving her view of the law (at [273]–[274]):

> '… as at present advised, I incline to the view that there can be an oral variation in such circumstances, notwithstanding a clause requiring written modifications, where the evidence on the balance of probabilities establishes such variation was indeed concluded.
>
> In many cases, such as *United Bank Ltd v Asif* [11 February 2000, unreported] (where the relationship between the parties was a formal banking relationship) the factual matrix of the contract and other circumstances may well preclude the raising of an alleged oral variation to defeat an entire agreement clause. In others, the evidence may establish on the balance of probabilities that the parties by their oral agreement and/or conduct have varied the basis of their contractual dealings, and have effectively overridden a written clause excluding any unwritten modification.'

[**59**] I do not understand Gloster LJ to mean that the existence of a particular form of agreement (as in *Asif*) will preclude the raising of the argument that an alleged oral variation should defeat an entire agreement clause. Rather, I understand her to be contrasting those cases where the facts are sufficient to establish that the parties have subsequently overridden the terms of the original contract and those where they are not. With that minor gloss I would respectfully adopt Gloster LJ's formulation of the law.

[**60**] Each case will be fact sensitive, depending upon the terms of the original contract and what has happened thereafter. To my mind, the fact that a clause was specifically negotiated or was insisted on by one party or the other (for a particular reason or no reason at all) may be a relevant factor; and the existence of a written clause excluding any unwritten modification will require the court to look closely both at whether the parties subsequently reached an agreement that would, if enforced, vary the effect of the original contract and also at whether in reaching that agreement the parties intended to enter into legal relations so as to vary the terms of their original contractual obligations. But it seems to me that, while all relevant facts should be given their due weight in assessing these questions and the burden of proof rests on the person who alleges that the original contractual obligations have changed, the standard of proof is and remains the balance of probabilities throughout. I would prefer not to adopt the use of 'strong evidence' or 'a very high evidential burden' since there is a danger that they may be treated as affecting the burden or standard of proof. Similarly, I would prefer not to adopt the phrase 'evidential presumption', though the intent behind it is clear. Rather, I adopt the approach that the court should give all relevant evidence its due weight when asked to find on the balance of probabilities that there has been a subsequent variation which has legal affect even though it does not comply with the formalities stipulated by the original contract. The terms of the original contract will always be material to that exercise; the circumstances in which those terms were negotiated and agreed may also be.

Issues 1(i) and 1(ii)

[**61**] The intention of the parties when the DLA was executed on 4 July 2006 is clear: variations in the contractual relations between the parties were to be recorded in writing, which excluded e-mails or faxes. The real issue is whether that intention changed with time. I will defer providing a final answer on that issue until the conclusion of Issue 2, by which time I will have considered the evidence relating to November 2008–February 2009 in detail. In this section I consider the context for those discussions, which is provided by what happened between July 2006 and November 2008 and later events that are said to cast light on the parties' intentions during the critical period.

[**62**] There were three occasions when, on the strict wording of the DLA, an adjustment to the contractual relations between the parties may have been required to be recorded in writing in order to be effective. The first was when LLC delayed the payment of the £10,000 which was due under cl 18.2(3) 60 days after the date of the DLA: see [23], above. I am not satisfied that Dr Dougal ever expressed agreement to the deferment or the payment by instalments though, as I have said earlier, his persistent failure to respond to LLC's e-mails may reasonably have been taken by LLC to be acquiescence with them. Given Dr Dougal's inaction, it is unsurprising that neither party suggested recording a variation in writing.

[**63**] The second occasion was when Dr Dougal agreed with Ms Higginson and Mr Field on 24 August 2007 that (at least) the £25,000 due under cl 18.2(iv) should be paid not on delivery of clinicals but on the obtaining of patent protection: see [29]–[30], above. On this occasion it is clear that Ms Higginson had the DLA in mind when she wrote to Dr Dougal on 27 August 2007. However, although this agreement was intended by the parties to alter their contractual relations, Ms Higginson did *not* suggest compliance with the DLA requirement for a written instrument signed and executed by both parties. Instead, she proposed that they should *not* have an addendum and that a fax (which would not satisfy the DLA requirements) would suffice. Dr Dougal did not respond requiring a compliant instrument in writing. In fact, he did not reply at all, though he accepted in evidence that he expected LLC to be able to rely upon the agreement he had reached despite the absence of a document. That approach was mirrored by Mr Rothon and Mr Tassell when they came to consider Item 5 of the agenda for the tele-conference on 27 August 2008. As far as Mr Tassell was concerned (he being a decision-taking director), if Dr Dougal had agreed the deferral of payment until patents were obtained, then it was agreed—there was no suggestion that it was not binding in the absence of a compliant written variation to the DLA.

[**64**] Item 5 of the agenda for the tele-conference on 27 August 2008 was the second time that Ms Higginson had broached the subject of recording Dr Dougal's agreement to defer the payment of the £25,000. I have no doubt that she broached it because of LLC's unfamiliarity with Pacer and out of concern that there should be some record of the agreement in case the new brooms decided to try to enforce cl 18.2(iv) as originally executed. It is also clear (if only from the use of the word 'executed') that she had the provisions of the DLA in mind and that she realised that executing an agreement in writing would give LLC complete protection. However, despite her agenda suggesting that she would forward a draft and the fact that she prepared one, she did not send it; and 1072/VDL did not call for one. I reject Dr Dougal's evidence that, in the absence of the written document, he did not consider there to have been a variation and that he 'decided for the time being not to

require LLC to pay the consideration payment before completing the patent registrations. However, this was [his] decision, not because the DLA had been varied preventing [him] from doing so.'[5] It is inconsistent with his evidence that he expected LLC to rely upon their agreement and with the evidence of Mr Tassell and Mr Rothon that they understood the agreement to have been reached. In circumstances where the parties were still working together and Pacer had come on the scene, if anyone on behalf of 1072/VDL had considered that the agreement to defer payment of the £25,000 until patents was obtained was of no effect unless there was a compliant written record, they would have required it to be brought forward and executed. Having seen Dr Dougal give evidence[6] I find that para 29 of his witness statement is retrospective reconstruction and is wrong.

[**65**] The third occasion when a compliant written record of variation may have been called for by the terms of the DLA was when it was agreed that 'Virulite UK' would fund half of Mr Noblitt's costs going forward: see [35], above. This agreement was treated as binding, with the consequence that Pacer discharged the 50% contribution. 1072/VDL submitted that there was no requirement for LLC to repay Pacer's outlay. That is correct and was because the alteration to the DLA that was effected meant that LLC was under no obligation to repay it.

[**66**] On these findings, by November 2008 there had been three separate occasions since the DLA when the parties had varied their financial arrangements without complying with the written formalities that it stipulated. I place limited weight on the first occasion because of the absence of clear and express agreement on the part of Dr Dougal. However, the second occasion (deferring until patents were approved) was the subject of express agreement, was intended to be relied upon and was in fact relied upon as binding by both parties going forward. And the third occasion was relied on as binding by 1072/VDL because Pacer discharged the 50% liability on their behalf. The absence of any compliant record in writing is the more striking given that, in relation to the second occasion, Ms Higginson raised the question of recording the agreement in writing first in August 2007 and then again a year later. On neither occasion did 1072/VDL take up the suggestion or do anything to suggest that it regarded a record in writing as being necessary. While that could in theory be consistent with 1072/VDL laying a trap for LLC and intending to rely upon the absence of a compliant written record, that is not the way that Dr Dougal, Mr Rothon or Mr Tassell were doing business.

[**67**] On all of the evidence I find that both sides were exercising the flexibility that is common among those who are attempting to work cooperatively, even in business relationships which are subject to some strains. I therefore approach the events of November 2008–February 2009 with the context set not merely by the provisions of the DLA but also by two occasions when the parties had chosen not to record express agreements in compliance with the DLA and a third occasion when LLC might reasonably have taken Dr Dougal to have acquiesced in the revised payment schedule for the £10,000 without requiring it to be recorded in writing in compliance with the DLA.

[**68**] 1072/VDL point to two pieces of evidence after February 2009 which they submit support their case on this issue. The first is Mr Field's e-mail to Ms D'Arcy on 2 July 2010: see [45], above. That did not state that a written

5 Dr Dougal's witness statement at para 29.

6 Particularly in the passage of evidence at T4/135–146.

proposal would be required to vary the DLA. It stated that if 'the UK' wished to promote the device into LLC's DLA territories then they should work out what it was worth to them and thereafter make 'a written proposal' to LLC. No doubt if the parties had agreed that some or all of LLC's rights should be bought out by 1072/VDL that would in due course have been the subject of a formal agreement; but in the e-mail Mr Field was looking at a much earlier stage of the process, namely that 1072/VDL should initiate discussions by proposing commercial terms. The second piece of evidence relied on by 1072/VDL reflects a later stage in the same process. On 9 September 2010 Ms D'Arcy sent an outline of commercial terms which she described as 'the proposal' and said 'if you agree with these we will put together an addendum to the contract'. The commercial terms being proposed covered most of the Far East, New Zealand, Latin America and South America and proposed a 3% royalty as the basis for recompensing LLC. It is obvious that such a substantial change in the arrangements between LLC and 1072/VDL would inevitably have had to be recorded formally as an addendum to or variation of the DLA. These communications do not shed light on the intentions of the parties in November 2008–February 2009.

[**69**] The evidence to which I have referred does not prove that the parties had irrevocably jettisoned the DLA requirements for writing by November 2008. It is therefore not possible finally to answer Issues 1(i) and 1(ii) before considering their dealings between November 2008 and February 2009 in detail. However, at this stage I conclude that by November 2008 the parties were not wedded to the DLA requirements for variations to be recorded in writing.

ISSUE 2: CONTRACTUAL VARIATION

Did the parties reach an agreement in January to February 2009 to vary cl 18.2(iv) of the DLA so that such payment was only payable after FDA clearance for the device was obtained ('the post-FDA offer'):

(i) Was the post-FDA offer made by the claimant at the meeting on 26 November 2008 and was it accepted by the defendants by e-mails dated 22 and 23 January 2009; or

(ii) Was the post-FDA offer made by the defendants in the e-mail of 22 January 2009 (confirmed by their e-mail of 23 January), and if so was it rejected by the claimant's e-mails in response, in particular Ms Higginson's e-mail of 28 January 2009?

(iii) Was the post-FDA offer made or confirmed by the defendants in their e-mail of 29 January 2009; and if so was it:

(a) rejected by the claimant in its e-mail in response that day; and/or

(b) accepted by the claimant during a telephone conversation Rothon/Field at the end of January or in early February 2009, or alternatively

(c) accepted by the claimant by its conduct in continuing to pursue the FDA application and expending money and resources doing so until about January 2011?

The parties agree that, if there was such an agreed variation, the claimant provided consideration for it.

The applicable principles

[**70**] Where the court does not have the luxury of a formal contract document that is agreed to constitute the entire contractual agreement, English law generally resorts to an analysis founded on the concepts of offer

and acceptance in order to determine whether there is a contract and, if so, on what terms. The justification for this analytical approach is that 'it has the great merit of providing a degree of certainty which is both desirable and necessary in order to promote commercial relationships': see *Tekdata Interconnections Ltd v Amphenol Ltd* [2009] EWCA Civ 1209 at [25], [2010] 2 All ER (Comm) 302 at [25] per Dyson LJ. It is applied even in circumstances which do not easily lend themselves to such an analysis. In such cases 'English law, having committed itself to a rather technical and schematic doctrine of contract, in application takes a practical approach, often at the cost of forcing the facts to fit uneasily into the marked slots of offer, acceptance and consideration': see *New Zealand Shipping Co Ltd v AM Satterthwaite & Co Ltd, The Eurymedon* [1974] 1 All ER 1015 at 1020, [1975] AC 154 at 167 per Lord Wilberforce.

[71] In this analytical approach an offer is typically 'an expression of willingness to contract on specified terms made with the intention (actual or apparent) that it is to become binding as soon as it is accepted by the person to whom it is addressed'; and an acceptance is 'a final and unqualified expression of assent to the terms of an offer', with the objective test of agreement applying to an acceptance no less than to an offer: see *Chitty on Contracts* (31st edn, 2013) paras 2–003, 2–027. With rare exceptions, no particular form of words is required in order to constitute offer and acceptance, as is clear from the fact that acceptance may be signified by conduct or even silence in appropriate cases. In particular, the parties may not use the words 'offer' or 'accept', the question being whether each has signified an intention to be bound by identical terms that can be identified objectively with suitable certainty. It is for that reason that the exercise undertaken by the court may be described as being 'to look at all the documents passing between the parties and glean from them, or from the conduct of the parties, whether they have reached agreement on all material points': see *Butler Machine Tool Co Ltd v Ex-Cell-O Corp (England) Ltd* [1979] 1 All ER 965 at 968, [1979] 1 WLR 401 at 404 per Lord Denning MR, in a 'battle of the forms' case.

[72] In a case such as this, where negotiations have gone back and forward, it is appropriate to apply an offer and acceptance analysis, for precisely the reasons given by Dyson LJ. While recognising that the parties to such negotiations were not required to use the language of 'offer' and 'acceptance', the implication of their not having done so may support the conclusion that there was no moment of contractually binding consensus ad idem.

[73] Issue 2(iii)(c) raises the issue of acceptance by conduct. The relevant principles are usefully summarised at *Chitty on Contracts* at 2–076. Silence is generally equivocal; but circumstances may arise where silence is sufficient to amount to acceptance of an offer. Similarly, a party's conduct when viewed in context may demonstrate acceptance of an offer: it will be a question to be decided on the particular facts of each case whether it has done so.

[74] The only other point to be noted at this stage is that it is entirely possible in the course of prolonged communications between parties that they may reach a contractually binding consensus at some intermediate point and then continue to communicate or negotiate going forward from that established consensus. However, where negotiations continue without interruption, that fact may contribute to the difficulty of establishing that the intermediate point represented a moment of contractually binding consensus: see *Chitty* at 2–028.

The approach to the evidence

[**75**] 1072/VDL places at the forefront of its submissions that LLC's case has undergone numerous iterations from the first response of its United States attorneys through the original particulars of claim, the witness statements of Ms Higginson and Mr Field, the amended particulars of claim, and finally the oral evidence. The references relied upon by 1072/VDL in closing submissions show significant developments and shifts in emphasis, which are reflected in the need for LLC to amend the particulars of claim late in the proceedings, though there is a degree of consistency in making the claimant's primary case by reference to an offer made by Ms Higginson on 26 November 2008 with acceptance on 22 January 2009, as was advanced in the United States attorney's original letter. In my judgment the developments with time are sufficient to require the court to be cautious when assessing the evidence: a broad brush approach is not appropriate.

[**76**] The other submission placed by 1072/VDL at the forefront of its submissions is that it is impossible to identify any consensus ad idem on the documents that passed between the parties. I bear that submission in mind at all times; but it is right also to bear in mind that the LLC does not rely solely upon the written communications between the parties: it also relies upon conversations, in particular the conversation in Cambridge on 26 November 2008 and what was described as the dog-walking conversation which is alleged to have occurred at the end of January or early in February 2009.

Negotiations between November 2008 and January/February 2009

[**77**] Before the meeting between Ms Higginson and Mr Rothon on 26 November 2008, the three managing members of LLC discussed their approach to the meeting. Mr Field's witness statement states what LLC's position was to be: 'Our agreed position that Ms Higginson presented to Mr Rothon at the meeting was that we had a potential lawsuit against [1072/VDL]. Consequently we would insist that all further consideration payments should be suspended until after FDA clearance had been obtained, and we were generating income from the sales of the CSD. Our position was that we did not want to make any further payments to Dr Dougal, and [1072/VDL], until we had some money coming in.' Mr Mencanin agreed in evidence that this represented his position. Ms Higginson's witness statement did not deal with the LLC pre-meeting discussions but when she came to give evidence she shaded the position as set out in Mr Field's statement by saying that delaying until there was a revenue stream was LLC's ideal position, with delaying until FDA approval being their fall-back position. Mr Field gave oral evidence to the same effect, which marked a clear shift from the position evidenced by his witness statement.

[**78**] Ms Higginson's account of the meeting in her witness statement is important. She printed off the results of the Hargate 2 trial, showing the gap in recruitment during 2007:

> 'I told Mr Rothon that we wanted any further Consideration Payments to the Defendants delayed until after we had income from sales of the CSD to pay towards these i e we would not pay these until after FDA clearance. I looked upon this as a point of principle because we had put so much effort into getting the FDA submission ready, that we believed it was wrong for Dr Dougal to expect us to make a payment to him when he was so at fault in the FDA trial process, in terms of the delays and the incompleteness of the data as provided.

> We also wanted the £50,000 Consideration Payment delayed. We did not see why we should make this payment to the Defendants without receiving an income. We were also concerned that we would no longer be first to market and that the Zeno device might obtain traction before we were able to launch. It looked as though it might now be much harder to make money out of the [device] post clearance. There was also a good commercial reason why we wanted both Consideration Payments delayed. We would have been obliged to pay £75,000 at the very time we were seeking to launch the product. I thought this might have had a detrimental effect on our ability to maximise sales of the CSD at the very time when we should be exploiting the commercial opportunity to the maximum. My position was that we wanted both the Consideration Payments delayed until we saw a financial return from sales of the CSD and at least until FDA clearance. I also reiterated the standing agreement with Dr Dougal that no payments would be made until patents were granted in the USA, Canada and Japan. Mr Rothon's position was that he thought it reasonable that we should not have to make any further Consideration Payments until clearance was obtained and he would speak to Mr Tassell and Dr Dougal about this.'

[**79**] Under cross-examination Ms Higginson developed her evidence that she had put forward a fall-back position while pushing for everything that she could get (ie delaying further consideration payments until there was an income stream). As she put it: 'That's what business people do.' She said of her meeting with Mr Rothon:

> '… having discovered the lengthy periods when the Hargate II trial had been interrupted and ceased, I showed him a printout of the spreadsheet with the data with the dates on it, realising that we had had no idea just how long there had been no activity going on in the pursuit of that trial. I said to him either "This is a lawsuit," or "There's a lawsuit here", but the solution is, you know, in my opinion quite easy: if we delay the payment until we receive FDA clearance, then any issues with this data not being good enough, being incomplete or taking this long will be negated because the FDA clearance will validate it all anyway. Ideally, what we want is not to pay anything more until we've got a revenue stream because we felt that we'd waited all this time for a revenue stream and not knowing that part of those—quite a significant part of those delays are caused by Dr Dougal not doing anything to pursue the clinical data …'

[**80**] According to Mr Field's witness statement, Ms Higginson told him that the meeting had gone well and that Mr Rothon had said that LLC's proposal sounded fair. It is to be noted that Mr Field's account of LLC's proposal in his witness statement did not include the fall-back position.

[**81**] Mr Rothon's witness statement gave little detail about the conversation on 26 November 2008 beyond saying that Ms Higginson requested that 1072/VDL put back the timing of the balance of the payments due under the DLA until LLC was in receipt of revenue. In his oral evidence he said he remembered that to be what she had said. Throughout his evidence he was consistent in saying that he would not have countenanced the suggestion that the consideration payments should be delayed until LLC was in receipt of an income stream.

[**82**] Two days after the meeting he sent an e-mail to the three managing members of LLC, copied to Mr Tassell and Dr Dougal, in which he outlined

from his perspective the major issues that had been discussed. The e-mail dealt first with geographic coverage: Mr Rothon felt that LLC should put more effort into countries outside the United States. The e-mail recorded that 1072/VDL and LLC appeared to be far apart on the issue of pricing, with LLC proposing a much higher price than 1072/VDL thought right. At the end of the e-mail he wrote:

> '10. Contractual payments from LLC to Virulite UK. Louise asked if the balance of payments could be changed and only become due when FDA and patent approval is achieved. This I will discuss with Chris and Gordon next week.'

[**83**] Mr Rothon's evidence was that his Item 10 was mistaken and did not accurately reflect what Ms Higginson had said. However, there is no obvious reason why Mr Rothon should have made a mistake so soon after the meeting. Furthermore, if Ms Higginson had not even mentioned deferral until FDA clearance as at least a fall-back position on which LLC would be prepared to agree, there is no reason why Mr Rothon should have mistakenly recorded Ms Higginson's request in these particular terms. If, on the other hand, Item 10 was accurate then it would be consistent with Mr Rothon being implacably opposed to deferring payment until there was a revenue stream (so that he refused to discuss it further and did not mention it in the e-mail) but considering that deferral until after FDA approval sounded reasonable (so that he was prepared to discuss it with Dr Dougal and Mr Tassell). The e-mail therefore provides material support for Ms Higginson's evidence about what was said at the meeting on 26 November 2008.

[**84**] Ms Higginson replied to Mr Rothon's e-mail on 1 December 2008 under the subject heading 'Pricing/FDA'. A fair reading of the e-mail as a whole reveals that, as was stated at its outset, LLC was troubled by what Mr Rothon had said. It also shows that what Ms Higginson was concentrating on was the sections of Mr Rothon's e-mail that had dealt with pricing and geographic areas other than the United States. Paragraph 6 was directed to Mr Rothon's suggestion that they should start marketing in Canada. At the end of that paragraph Ms Higginson wrote: 'We have already told you that we are not putting our hands in our pockets again until we start to see returns from the Virulite project. We're paying out for the FDA & we want to see that further investment realised.' 1072/VDL relies upon this extract as showing that Ms Higginson's sole proposal on consideration payments had been deferral until there was a revenue scheme. I disagree. Seen in its proper context, these sentences were not directed to the question of consideration payments but to the suggestion that LLC should start funding other countries than the United States. Much of the rest of the e-mail concentrated on pricing. There was no reference to the deferral of consideration payments. That is how Mr Rothon understood the e-mail: his response the next day[7] concentrated on pricing and did not mention consideration payments either, which he would probably have done if he had regarded Ms Higginson's e-mail as saying that LLC would only contemplate deferral of the consideration payments until there was an income stream. The position remained that Mr Rothon was to come back to LLC after he had discussed the issue of consideration payments with Mr Tassell and Dr Dougal.

7 C1/327.

[**85**] On 22 January 2009 Mr Rothon came back as he had said he would. Since this e-mail is relied upon by LLC as 1072/VDL's acceptance of LLC's fallback position I set the relevant parts out in full, summarising the rest in square brackets:

> 'Just a quick update regarding our discussions with Gordon yesterday and some developments we are planning for the future.
>
> The meetings with Gordon went well and we are all in agreement that gaining FDA approval is to be our major focus. [Mr Rothon disclosed that they had been in contact with two individuals—later revealed to be Ms D'Arcy and Mr Baker—and made observations on pricing for the device.]
>
> We also started to put together our future financial plans and I thought it would be good to outline our expectations from you once we gain FDA approval (which are in line with the contract we have with you.)
>
> If we assume FDA approval is gained in March 2009:
>
> 1. 25k to be paid by LLC to Virulite within 30 days. This is the delayed stage payment we agreed prior to FDA approval.
> 2. £50k to be paid to LLC 90 days after FDA approval. This is the final stage payment as per the contract.
> 3. …
> 4. …
>
> Comments welcome. Will get back to you when I have more info.'

[**86**] There are a number of points to be made about this e-mail.

(i) Mr Rothon said that, although he and Mr Tassell had discussed the matters in the first substantive paragraph with Dr Dougal, they had not discussed the matters following the words 'We also started to put together our future financial plans'. This was challenged by LLC. I do not find it necessary to resolve this dispute since it is common ground that the e-mail was written by Mr Rothon in his capacity as the appointed representative for 1072/VDL.

(ii) The e-mail is evidently the response on consideration payments that was promised by Mr Rothon in Item 10 of his e-mail on 28 November 2008.

(iii) The passage relating to consideration payments does not use the normal language of acceptance, stating instead 'our expectations from you once we gain FDA approval'. However, subject to points (iv) to (vi) below, there is a clear statement that 1072/VDL expect payment of the £25,000 to be made after FDA approval, which is what Ms Higginson had requested as LLC's fallback position.

(iv) The second sentence of numbered para 1 is oddly worded. But when read in context (including the second sentence of numbered para 2) it appears to be identifying the £25,000 payment as the payment that was now in delay when applying the agreed terms of the DLA (because the clinicals had been delivered to LLC).

(v) Numbered para 1 says that the £25,000 shall be paid by LLC to Virulite 'within 30 days'. There is no evidence that Ms Higginson had proposed that the post-FDA payment would be made within 30 days of approval.

(vi) The words 'If we assume FDA approval is gained in March 2009' have proved to be highly contentious. 1072/VDL submit that, viewed objectively, the obtaining of FDA approval in March 2009 was made a

condition precedent to the possible agreement or application of the terms set out below. LLC responds that there were no grounds for assuming that FDA approval would be obtained by March 2009 and that the information that had been provided to 1072/VDL demonstrated that such an assumption was unrealistic. Mr Rothon goes some way towards accepting that by saying that he was feeling optimistic when he wrote the e-mail.

(vii) The words 'comments welcome' at the end of the e-mail are not expressly limited to the first part of the letter. They support the submission that the e-mail was not an acceptance of Ms Higginson's proposal to defer payment until after FDA clearance but was a proposal by Mr Rothon of a number of terms for consideration by LLC.

[**87**] When considering whether the words 'if we assume FDA approval is gained in March 2009' are a condition precedent, it is necessary to take an objective view bearing in mind that the e-mail was written by a non-lawyer to non-lawyers and that it was written without attempting the precision of language that might be expected of a lawyer's communication. Adopting that approach, I do not consider that a party in the position of LLC and having LLC's knowledge at the time would reasonably have understood the meaning of the e-mail to be that deferring payment until after FDA approval was only acceptable to 1072/VDL if that approval was obtained before 1 April 2009, for a number of reasons. First, the previous line had referred to 1072/VDL's expectations 'once we gain FDA approval' without limitation as to time. Second, even allowing for imprecision in language, the words used did not say or necessarily imply that obtaining approval in March 2009 was a pre-requisite to any deferral. Third, while a detailed syntactical analysis shows that the words do not lead naturally to some other defined end point (e g a statement that if approval in March 2009 is assumed, certain payments have to be made by a specified date as opposed to a certain period after approval), Mr Rothon's confused language elsewhere (e g in the second sentence of numbered para 1) shows that such detailed syntactical analysis is inappropriate. Fourth, the lack of clarity and potential ambiguity in the words would have been reinforced in the minds of LLC by their clear understanding (which had been passed on to 1072/VDL) that there was no realistic prospect of approval being obtained then: so an offer that was contingent on approval in March 2009 was in reality no offer at all.

[**88**] A reasonable understanding that the reference to March 2009 was not an essential prerequisite to deferral would have been and is reinforced by a further e-mail which Mr Rothon sent to Mr Field the next day in which he said:

> 'I will do all I can to get the info you need from Gordon, as stated we are committed to getting FDA approval ASAP. It is my number 1 priority. Regarding the stage and royalty payments … what I really tried to say is 12 months after FDA approval we expect LLC to have paid us a minimum of £415k. This simply has to happen at the agreed timescales and if [you] have any issues committing to these payments I need to know now, not when we get FDA approval … Lance, look forward to your reply on this subject, now is the time to talk.'

Apart from there being no reference to March 2009, the reference to getting the information that LLC needed from Dr Dougal was a reference to the information that LLC had been asking for on the basis that it was necessary for the obtaining of FDA approval. Mr Rothon's e-mail therefore carried some recognition that, with only two months to the end of March 2009, LLC had still

not been provided with necessary information. Once again, Mr Rothon's e-mail did not use the language of offer and acceptance. However, taking all of the information known to the parties at that point, the e-mails of 22 and 23 January 2009 taken together were a clear statement that 1072/VDL was prepared to defer the £25,000 to after FDA approval provided it then was paid within 30 days and that 1072/VDL required the total of £415,000 to be paid within a year of approval.

[**89**] Mr Rothon followed up by a further e-mail on 28 January 2009 to Mr Field when he wrote: 'Don't forget I need your inputs today regarding the stage payments after FDA approval. If you would like to discuss this then call my mobile, but I need to know if you can comply.' His reference to compliance was raising the question whether LLC would have the money to enable it to comply. The language of the first sentence of the e-mail is the language of an ongoing discussion, although that does not determine the issue whether an agreement had already been reached.

[**90**] When she responded on 28 January 2008 Ms Higginson started by welcoming the fact that LLC and 1072/VDL were now agreed that making FDA clearance was the priority. That did not say or imply that they had agreed about deferral of the consideration payments (as Ms Higginson wrongly contended in her witness statement). She turned to the issue of consideration payments later in the e-mail. Since 1072/VDL submits that the e-mail was a rejection of any offer that had been made by Mr Rothon, I set out the material parts in detail, summarising other parts in square brackets:

> '*Consideration Payments:* When you & I met in November, I openly explained our concerns about the consideration payments and asked you to suggest a payment structure that would address all those concerns. *I should make it clear, we have absolutely no issue with the amount due or the fact that the balance payment shall be made, it is a question of timing and Principal milestones*. We do not feel that what you have suggested addresses our concerns & so I think a call to talk it over would be useful …
>
> - [The consideration payments were in exchange for the "Patent Area" and there had been delays in obtaining patents and avoidable delays that were not LLC's responsibility.] We're seeking some reciprocation of the patience we have given our Principal. The aim being to time the payments so as to enable us to launch product & have the revenue stream pay for the consideration, rather than go further out of pocket. You have told us that Pacer is finding it hard going financially & Pacer is a going concern with turnover … we on the other hand have kept Virulite LLC going since 2002, with no revenue stream.
> - [LLC was spending heavily on trying to break into Canada pre-clearance]
> - [Delay in providing clinical data was directly responsible for the loss of Walgreens, which may not be retrievable]
> - [LLC could not now negotiate similar post-clearance deals with other major retailers because it could not afford a repeat of Walgreens]
> - [Payments were broken down by reference to different countries] …
>
> I do think we are all on the same page here … & can find a mutually acceptable structure for consideration payments. But it cannot be forgotten that we are all in this position because clinical data has never been provided in a timely fashion.

My greatest regret to date is that you & I never had the opportunity to talk prior to your deal with Jim Haslam … I believe that every issue we now face could have been taken into consideration in your deal and we would all be moving forward at a different pace now.

Let Lance know a good time for yourself & Chris and we'll set up a conf call facility if needed.'

[**91**] When read in full and in context, what Ms Higginson was doing was keeping negotiations on deferring payment until there was a revenue stream open. She did not reject the terms that Mr Rothon had proposed but laid the ground for further discussion, which she hoped might lead to a shift in his position. While it was not a rejection of the terms set out by Mr Rothon, her e-mail also made no reference to those terms already being the subject of agreement between the parties. In cross examination she accepted that the parties had not achieved a mutually acceptable structure, but she explained that as meaning that LLC did not think that Mr Rothon had gone far enough and that, although he had agreed on 22 January 2009 to defer payment until after FDA approval, she was pushing for more.

[**92**] Mr Rothon replied on 29 January 2009:

'Comments appreciated.

I am encouraged that you have no issue with the Consideration payment and my assumption is that you will make full payment to Virulite once we have FDA approval. This simply must happen and is not for negotiation as I have previously stated and I appreciate your cooperation here.

Royalty payments are also not up for negotiation, we will insist on the contracted amount going forward. I will try to arrange a conf call next week to go over the other issues in your email when I have spoken to Chris.'

[**93**] Once again it is to be noted that the reference to FDA approval was not qualified by reference to time. Ms Higginson replied: 'Thanks for getting back to me. We'll look forward to hearing from you with some call times for next week. From our perspective the only issue for discussion is timing of the consideration payments.' Once again, Ms Higginson was keeping the subject of consideration payments open for further discussion. She did not reject deferral until after FDA approval; but nor did she say that it was already agreed.

[**94**] LLC says that there was then a telephone call between Mr Rothon and Mr Field while Mr Field and Ms Higginson were out walking their dogs in late January or early February. There is no mention of this conversation in the original letter from LLC's United States attorneys or in the original particulars of claim, both of which allege an earlier agreement to defer payment until after FDA approval. The amended particulars of claim asserts that Mr Rothon's e-mail of 29 January 2009 was an offer to defer which was accepted during the dog-walking conversation. There is no contemporaneous document which records or refers to the conversation.

[**95**] In his witness statement Mr Field said:

'I spoke to Mr Rothon, in an attempt to negotiate the best timeframe, from our standpoint, for the payment of the two remaining Consideration Payments. I used words to the effect that following clearance whatever we were obliged to pay to the Defendants within that year, we would have paid. Mr Rothon's response was that was what he wanted to hear, and wished me good luck. He then asked whether we would be able to make the royalty payments too, to which I replied we would, and he said that he

a was happy to hear that too. He did not mention March at all. I could not persuade Mr Rothon to delay the Consideration Payments beyond the period he had proposed in his email dated 22nd January 2009.'

[**96**] In evidence Mr Field spoke of this conversation as happening on 29 January, saying:

b 'We spoke on the 29th, [Mr Rothon] and I, and it was agreed. Then his position was made very—you know, that was his final position on it. The £25,000 would be delayed until FDA clearance had been obtained, but everything else was expected to be paid on time and that was it. There was no point me discussing it any further with him. It was done. That was his position on behalf of [1072/VDL].'

c When it was put to him that he had not at any stage said words to the effect 'Well, all right then, I suppose that's the deal we've agreed', he disagreed.

[**97**] Ms Higginson's evidence was that Mr Field described the conversation to her immediately after it happened:

'Mr Field told me that Mr Rothon would not budge beyond agreeing to
d delay the £25,000. The call lasted quite a long time. They discussed whether [1072/VDL] would agree to our requests to delay not just the £25,000 Consideration Payment, but also the £50,000 payment and linking it to revenue from sales of the [device]. In the event Mr Rothon would not agree to this, and the matter was left there. Accordingly, by the end of January 2009, or at the very latest early February, the issue over the £25,000
e Consideration Payment was put to rest.'

[**98**] In cross-examination she maintained her evidence that Mr Field had told her that Mr Rothon would not budge beyond delaying the £25,000.

[**99**] Mr Rothon's evidence was that the telephone conference that had been suggested in his e-mail of 29 January 2009 never took place and that no
f agreement was reached on the issue. In evidence he said that he had no recollection of a telephone conversation as described by Mr Field and Ms Higginson. His evidence about whether he had reached any agreement with LLC was full of inconsistencies. When being cross-examined about his e-mails on 22 and 23 January 2009 he first accepted that what he had been trying to say was that *whenever FDA approval was achieved* the sums would have
g to be paid and that he had agreed that with LLC.[8] After a short break he resiled from those answers and said that it was all subject to getting FDA approval in March 2009[9] and that he had merely made a proposal. Still later, while accepting that there was a dispute about whether or not he had stipulated March 2009, he agreed that as far as he was concerned, he reckoned that he had reached an agreement about deferring the £25,000; but soon thereafter he
h reverted to saying that he had made a proposal that had not been accepted by LLC.[10]

[**100**] Mr Field also gave evidence of a telephone conversation with Mr Rothon in May 2010 during which Mr Rothon asked him if LLC was okay with making the payments due under the DLA after clearance. Ms Higginson says that Mr Field told her of this conversation shortly after it happened. There
j is no document referring to or arising out of such a conversation.

8 T5/69–70.

9 T5/72.21–73.1.

10 T5/86.13–87.25.

[**101**] There is one further piece of evidence that bears on whether or not an agreement was concluded and, if so, what terms were incorporated.[11] On 29 November 2009, Mr Rothon sent an e-mail to Mr Tassell, Ms D'Arcy and Mr Baker under the subject heading 'What does FDA mean to us??'. In it he wrote 'I thought it might be a good idea to remind us all what FDA will mean to us, and these are minimum royalty payments that LLC need to achieve or they are in breach of contract.' He then set out a list of annual payments starting with 'Year 1 (when FDA approval is achieved) … £75k within 30 days to buy the licence and £340k in royalty within 12 months' and totalling £14.9 million. It is evident from the string of e-mails that followed that this e-mail was subsequently discussed by Mr Rothon with Ms D'Arcy and Mr Baker, and I reject the evidence to the contrary given by the witnesses for 1072/VDL. In his witness statement, Mr Rothon said that he reached the figure of £75k for year one by 'lumping together payments due before and after FDA approval without differentiating between the two'. In his oral evidence he offered a different explanation, namely that his e-mail looked at the global situation of what they could potentially get once they had both FDA approvals and patents. Basing herself on that e-mail, Ms D'Arcy included in a Pacer Therapeutics business plan produced in early 2010 that 'When FDA clearance is obtained … LLC do have payments that they have to make to Pacer. The conditions of the deal are that on clearance [LLC] pay Pacer £75k upfront and a £5.00 royalty on sales in the first year.' There is no evidence that Mr Rothon approved the business plan, though it seems likely that he and Mr Tassell would have seen it when it was produced.

[**102**] Standing back and reviewing all of the evidence, including those parts that I have expressly referred to above, I turn to make the necessary findings of fact that will enable me to answer Issues 1 and 2.

[**103**] I find as a fact that Ms Higginson made the post-FDA offer at the meeting on 26 November 2008. First, although it represented a fall-back position from the position that had been agreed with Mr Field and Mr Mencanin in advance, I have no doubt that Ms Higginson as the prime mover in the business and the person charged with conduct of the meeting had authority to adopt a fall-back position and would have done so when it became apparent that Mr Rothon would not countenance the suggestion of delaying payment until there was an income stream. It would have been in her nature as a businesswoman to do so, since she would always look to achieve the best result that she could. Second, I place significant weight on the terms of Item 10 of Mr Rothon's e-mail of 28 November 2008, for the reasons outlined at [83], above. Third, I think it unlikely that on 22 and 23 January 2009 Mr Rothon would have homed in on delaying until FDA approval was granted if the idea had not already originated from Ms Higginson. Fourth, there has been a measure of consistency since the original letter from LLC's United States attorneys, through the original particulars of claim and into Ms Higginson's witness statement that she did offer a fall-back position, even though I would accept that some of her witness statement is curiously worded and structured. Fifth, although I am sure that Ms Higginson will have pressed for deferral until there was a revenue stream, the reference to 'not putting our hands in our pockets' on 1 December 2008 does not sustain the weight that 1072/VDL seeks to place on it, for the reasons outlined at [84], above. I therefore accept

11 See *Great North Eastern Railway Ltd v Avon Insurance plc* [2001] EWCA Civ 780 at [29], [2001] 2 All ER (Comm) 526 at [29] per Longmore LJ.

Ms Higginson's evidence that she proposed that payment of the £25,000 should only become due when FDA approval was achieved and that Item 10 of Mr Rothon's e-mail on 28 November 2008 accurately recorded what had been discussed in the meeting.

[**104**] Mr Rothon's e-mails of 22 and 23 January 2009 were intended to be and were the occasions when he came back to Ms Higginson as he had said he would on 28 November 2008. I have found that, viewed objectively, the reference to March 2009 was not made a condition precedent or essential prerequisite to the acceptance or application of the terms there set out. I have also found that, taken together, the e-mails of 22 and 23 January 2009 were a clear statement that 1072/VDL was prepared to defer the £25,000 to after FDA approval provided it then was paid within 30 days and that 1072/VDL required the total of £415,000 to be paid within a year of approval. I therefore conclude that, as at that date, each party was in the position of being prepared to agree that the £25,000 could be deferred until after FDA approval. However, Mr Rothon's e-mails were not framed in language that can objectively be interpreted as an acceptance of LLC's offer, even allowing for natural and reasonable levels of imprecision in what he wrote. Instead, they were framed as a statement of what 1072/VDL expected LLC to agree to, which is materially different. Furthermore, they were not limited to the question of deferral of the £25,000 but covered other matters as well. I therefore conclude that, although both parties were then prepared to agree to deferral of the £25,000 until after FDA approval, and came within an ace of doing so, they had not agreed to do so by 23 January 2009.

[**105**] Going forward from 23 January, both parties had made a clear statement of their willingness to defer the £25,000 payment and it would have been open to either party to conclude an agreement by accepting the other's position. In particular (and by reference to the terms of Issue 2.2) Mr Rothon's e-mail of 22 January as confirmed by his e-mail of 23 January 2009 was a post-FDA offer by 1072/VDL. I have set out the relevant passage from Ms Higginson's e-mail of 28 January 2009 above and find that neither that e-mail nor any other e-mail from LLC rejected 1072/VDL's post-FDA offer. What Ms Higginson was astute to do was to keep negotiations open in the hope of doing better, without rejecting or jeopardising the Post-FDA position. This was as much by luck as by judgment because I accept that after 22/23 January 2009 she probably considered that deferral of the £25,000 was agreed. In one sense it was, in that it represented the position that both parties were prepared to adopt: unfortunately for her that sense was not contractual.

[**106**] Mr Rothon's e-mail on 29 January 2009 will only have reinforced LLC's understanding that 1072/VDL was prepared to defer payment of the £25,000 until after FDA approval and that 1072/VDL assumed that would happen. As such, it confirmed the post-FDA offer. Ms Higginson's e-mail in response did not reject the offer: it kept the subject of further negotiations on consideration payments open for further discussion. The post-FDA offer therefore remained open for acceptance or rejection.

[**107**] Despite the absence of contemporaneous documentary records, I find as a fact that there was a conversation between Mr Field and Mr Rothon broadly as described by Mr Field and Ms Higginson. I am influenced in reaching this decision by my overall assessment of Mr Field and Ms Higginson, which is that they have not lied about this conversation—though this does not mean that their recollection is complete or accurate in all respects; and by my assessment of Mr Rothon, which is that his evidence on this topic is much less

satisfactory than that of Mr Field and Mr Higginson. Second, the question of deferral of consideration payments was important and was up in the air after Mr Rothon's latest e-mails, and I consider it highly improbable that the parties just let it drop. Equally, having decided that a conversation took place between Mr Field and Mr Rothon on the issue of deferral of consideration payments, it seems highly unlikely that either Mr Field or Mr Rothon would have conducted the conversation exclusively by reference to deferring until there was an income stream and without reference to LLC's fall-back position. On that basis, when Mr Field said that Mr Rothon would not budge, I find that reflected a conversation in which he and Mr Rothon negotiated about whether 1072/VDL would budge from their previously stated position of being prepared to agree to defer payment of the £25,000 until after FDA approval. I find that at some point Mr Field faced the inevitable and said that LLC would pay whatever was due following clearance (which both men would have understood to mean FDA clearance) and Mr Rothon said words to the effect that that was what he wanted to hear and wished Mr Field luck. That was sufficient to indicate that he agreed to what Mr Field had just said. Applying the analysis of offer and acceptance, Mr Field's statement was an acceptance of Mr Rothon's offer to defer until FDA clearance and Mr Rothon's response was confirmation that he understood and was content with that acceptance. The parties agree that LLC provided consideration for the agreement, without specifying what that consideration was.

[**108**] Neither party reprised the agreement in an e-mail or otherwise. This is a surprising omission, not least because of Ms Higginson's earlier statement of support for recaps; but it is not so surprising as to require a conclusion that no agreement was reached. The parties were still on reasonable working terms; the issues had been extensively canvassed already by the e-mail exchanges since November 2008; and the parties doubtless considered that the deal was done and got on with their lives and their work. I am confident that the agreement was meant to be relied on and to affect the parties' contractual relations and that, in the light of the previous experience to which I have referred earlier in this judgment, neither party felt it necessary to record the agreement in accordance with the requirements of the DLA in order for it to be effective.

[**109**] My conclusion is not dependant upon, but is supported by, the terms of Mr Rothon's e-mails in November 2009. Their terms are clear and reflected his knowledge that he had reached an agreement with LLC that £75,000 (ie the £25,000 and the £50,000 consideration payments) were to be paid after FDA approval had been achieved. His two inconsistent explanations that tried to avoid this conclusion are wrong and are rejected.

[**110**] The conversation was not relied upon in the United States attorney's letter in December 2010 or the original particulars of claim. It would have been more comfortable for LLC if it had been. However, it is plain that LLC has throughout regarded the 26 November 2008 meeting and the response on 22/23 January 2009 as the prime foundations for its case, which is a sufficient explanation for the contents of the United States attorney's letter. In the event, those exchanges did not quite amount to a contractual agreement, although they laid the ground for what came after.

[**111**] As a further fall-back position, LLC submitted that it accepted the post-FDA offer by continuing to pursue the FDA application and expending money and resources doing so until about January 2011. Since it is not necessary for me to decide this issue given my findings thus far, I do not deal with it at any length. In this context, it is important that LLC had since

mid-2007 been expressing its (justifiable) frustration about 1072/VDL's failure to provide clinical data and other support, and that the discovery of the lack of progress on the Hargate 2 trial had led Ms Higginson (whose evidence about the meeting I accept) to assert to Mr Rothon on 26 November 2008 that 1072/VDL's failures created a conflict that could end in a law suit. At the end of the period of negotiations from November 2008, the position was reached that 1072/VDL was expressing its willingness to continue to be bound by the terms of the DLA provided that LLC paid the £25,000 after FDA approval but would budge no further. After the period of negotiations, LLC dropped its complaints about 1072/VDL's prior lack of performance and continued to fulfil its other obligations arising under the DLA.[12] 1072/VDL asserts that LLC continued because it believed that the device had great potential. That is a partial explanation of LLC's willingness to continue; but the evidence as a whole supports the conclusion that LLC's dropping of its complaints and its future co-operation with 1072/VDL in the pursuit of FDA clearance (including the accommodation of 1072/VDL's favoured FDA consultants) is also referable to LLC's acceptance of 1072/VDL's offer to defer the £25,000 consideration payment. If, therefore, I had concluded that no agreement had been reached by the end of Mr Field's dog-walking conversation with Mr Rothon, I would have held that LLC accepted 1072/VDL's offer by continuing to pursue the FDA application and expending money and resources doing so until about January 2011. To my mind, it does not matter whether a lawsuit, as threatened by Ms Higginson on 26 November 2008, would have been successful or not. It was a threat that was capable of exercising leverage and having value for LLC; and the dropping of the threat and continued cooperation was a benefit to 1072/VDL arising out of the negotiations.

CONCLUSIONS ON ISSUES 1 AND 2

[**112**] Issue 1(i): while I respectfully question the use of the term 'evidential presumption', the burden rests on LLC to show on sufficient evidence that the terms of the DLA were varied without a written instrument signed by both parties, notwithstanding the provisions of cll 1.4.7, 26.4 and/or 27 of the DLA.

[**113**] Issue 1(ii): LLC has discharged the burden on the facts, as summarised under Issue 2.

[**114**] Issue 2(i): the post-FDA offer was made by LLC at the meeting on 26 November 2008. It was not accepted by 1072/VDL by e-mails dated 22 and 23 January 2009.

[**115**] Issue 2(ii): the post-FDA offer was made by 1072/VDL in the e-mail of 22 January 2009 (confirmed by their e-mail of 23 January). It was not rejected by LLC's e-mails in response.

[**116**] Issue 2(iii): the post-FDA offer was confirmed by 1072/VDL in their e-mail of 29 January 2009. It was not rejected by LLC in its e-mail in response that day. It was accepted by LLC during a telephone conversation between Mr Rothon and Mr Field at the end of January or in early February 2009. Alternatively, if it was not accepted during that conversation, it was accepted by LLC by its conduct in continuing to pursue the FDA application, dropping its prior complaints about 1072/VDL's lack of support, and expending money and resources doing so until about January 2011.

12 Accepted by 1072/VDL, subject to the qualification 'more or less': written closing submissions, para 46.

ISSUE 3: WAIVER/PROMISSORY ESTOPPEL

3.1 Did 1072/VDL clearly represent or promise to LLC in January to February 2009 that the payment of £25,000 due under cl 18.2(iv) of the DLA would only become payable after FDA clearance for the device was obtained?

3.2 Did 1072/VDL intend LLC to rely on the above representation or promise?

3.3 Did LLC rely on such representation or promise?

If so,

3.4 Was it in all the circumstances inequitable for 1072/VDL to insist upon payment of £25,000 at any time before FDA clearance; or could they terminate the suspensory effect of their promise prior to FDA clearance?

3.5 If 1072/VDL were able to terminate the suspensory effect of their promise prior to FDA clearance by giving reasonable notice to pay the £25,000, did the letter of 18 November 2010 constitute reasonable notice, or did it constitute only an invalid notice of breach?

3.6 If the letter of 18 November 2010 did constitute reasonable notice to pay, was the effect of that notice such that the £25,000 payment obligation:

3.6.1 Should be treated as only falling due for the first time after a reasonable period from 18 November 2010?

3.6.2 Should be treated as having arisen on 18 December 2008, so that the effect of the letter of 18 November 2010 was to put LLC immediately in breach of the DLA?

[**117**] In the light of my findings under Issue 2, it is not necessary for the claimant to rely upon waiver or estoppel. This section proceeds on the assumption that, contrary to my findings under Issue 2, no contractual variation occurred.

LLC's pleaded case on estoppel

[**118**] LLC's case is lightly sketched at paras 18–19 of the amended particulars of claim. It is alleged that by the words and conduct relied upon by LLC as giving rise to a contractual variation, 1072/VDL represented to LLC that they would not require payment of the consideration payment of £25,000 until after the receipt of FDA clearance and the claimant relied on such representation by submitting and pursuing the FDA application and expending money and resources doing so until about January 2011 and by failing to make provision for such payment. In those circumstances it is alleged that 1072/VDL waived compliance with the time limit in cl 18(2)(iv) and/or were estopped from contending that LLC was in breach of that clause.

[**119**] 1072/VDL makes the obvious and immediate point that LLC cannot have relied upon representations made in January 2009 when instructing Mr Noblitt to prepare the FDA submission in and from 16 October 2008 and submitting it to the FDA on 18 December 2008. That is correct but, for reasons that appear below, is not the end of the issue.

The applicable principles

[**120**] The leading statement of principle is contained in the speech of Lord Goff in *Motor Oil Hellas (Corinth) Refineries SA v Shipping Corp of India, The Kanchenjunga* [1990] 1 Lloyd's Rep 391 at 399:

> 'Equitable estoppel occurs where a person, having legal rights against another, unequivocally represents (by words or conduct) that he does not intend to enforce those legal rights; if in such circumstances the other party acts, or desists from acting, in reliance upon that representation, with

a the effect that it would be inequitable for the representor thereafter to enforce his legal rights inconsistently with his representation, he will to that extent be precluded from doing so.'

For the most part, these principles give rise to no controversy; but some points have become the focus of argument.

b *Acting in reliance*

[**121**] It is not necessary for LLC to show that it has acted to its detriment. What is required is that a party's acts (or desisting from acting) should make it inequitable for the representor thereafter to enforce his legal rights inconsistently with his representation.

c *When does the doctrine suspend and when does it extinguish rights?*

[**122**] The effect of a representation is generally revocable: see *Chitty on Contracts* 3–082, 3–095 to 3–097. As *Chitty* makes clear, the determinative consideration is whether it is inequitable *in all the circumstances* for the representor to enforce his rights inconsistently with his representation. Those d circumstances will include, but are not limited to, the precise terms of the representation, how the representee has responded to the representation, and whether it remains possible for the representee to comply with his original obligation.

[**123**] Where, as in *Hughes v Metropolitan Rly Co* (1877) 2 App Cas 439, [1874–80] All ER Rep 187 the representation has been in the nature of an e open-ended forebearance, the effect will generally be to suspend the representor's ability to rely upon the underlying contractual obligation and any breach of it until reasonable notice is given that brings the period of suspension to an end. When the period of suspension is ended, the representor will be allowed to rely upon the underlying contractual obligation as from that date, but he is generally not entitled to enforce the obligations as if they had been in f full force during the period of suspension. So in *Hughes*, the appellant's representations in November and December 1874 had the effect of suspending the notice issued in October 1874 to the respondents requiring them to repair premises within six months. That period of suspension did not come to an end until 31 December 1874, until which time the operation of the notice was waived. Time ran under the notice from the end of the period of suspension; g but no time during the period of suspension could retrospectively be relied upon by the appellant: see (1877) 2 App Cas 439 at 447, [1874–80] All ER Rep 187 at 187 per Lord Cairns LC. It could therefore be said that the effect of the suspension was to extinguish the appellant's right to rely upon the rights that would otherwise have accrued to him during the period of suspension.

h [**124**] In *Collier v P & M J Wright (Holdings) Ltd* [2007] EWCA Civ 1329 at [37], [2008] 1 WLR 643 at [37] Arden LJ cited the decision of Denning J in *Central London Property Trust Ltd v High Trees House Ltd* (1946) [1956] 1 All ER 256, [1947] KB 130 as a case where the effect of resiling would be sufficiently inequitable that the right to recover the original debt was not merely postponed but extinguished. At first sight, the representation in *High Trees* was j a simple forebearance by a landlord agreeing to accept a reduced ground rent, which was duly paid. However, Denning J interpreted the landlord's promise as being 'that the ground rent should be reduced to £1,250 a year as a temporary expedient while the block of flats was not fully, or substantially fully let, owing to the conditions prevailing' as a result of the war. The landlord gave notice by letter dated 21 September 1945 requiring full payment of the rent going

forward and arrears of over £7,000. Denning J allowed the claim going forward, because the war conditions no longer prevailed; but he refused the claim for the arrears. In reaching that conclusion he said:

> 'If it had been a case of estoppel, it might have been said that the estoppel in any event would end with the ending of the conditions to which the representation applied, or alternatively only on notice. But in either case it is only a way of asking what is the scope of the representation. I prefer to apply the principle that the promise, intended to be binding, intended to be acted on and in fact acted on, is binding so far as its terms properly apply. It is binding as covering the period down to early 1945, and from that time full rent is payable.' (See [1956] 1 All ER 256 at 259, [1947] KB 130 at 136.)

[**125**] *High Trees* would be a clearer factual example of the extinguishing effect of a representation if the landlord had given notice at a time when the war conditions still prevailed and had been held not to be entitled to recover the full ground rent until they ceased to prevail at some point in the future. It seems to me that there is scope for confusion in the use of the terms 'suspensory' and 'extinguishing' in this context, since a representation may be revocable, and in that sense suspensory, while effectively extinguishing the representor's right to rely upon his contractual rights during the period of suspension. However, the approach adopted by Denning J in the passage set out above, supports the proposition that the terms of the representation are highly material when deciding whether it is suspensory (ie revocable) or extinguishes the representor's right (ie irrevocable) to rely upon a breach of the established terms of the underlying contract going forward. While the law of waiver and estoppel has been extensively developed since *High Trees*, I consider that there may be a material difference between an open-ended forebearance and a promise not to enforce until a particular date is reached or a particular set of circumstances prevails when considering whether it is inequitable to allow the representor to rely upon the original rights and obligations arising under the contract.

The effect of giving notice

[**126**] There is a dispute about the legal effect of giving notice if it is held that, until the time of notice being given, 1072/VDL waived reliance upon LLC's breach of contract in failing to pay the £25,000 in accordance with the terms of the DLA or is estopped from relying upon that failure. Although LLC was distinctly unhappy at Dr Dougal's failure to progress the Hargate 2 trial so that it became necessary to make the submission 'lite', it has not joined issue with 1072/VDL on their assertion that, in the absence of a contractual variation, LLC was in breach of the terms of the DLA as executed because of its non-payment of the £25,000. It is common ground that a waiver or estoppel in these circumstances does not mean that there is no breach; it merely has the effect that 1072/VDL cannot rely upon the breach as a basis for the remedies that would otherwise have been available. Starting from this point of common ground, 1072/VDL submits that the effect of the notice it gave on 18 November 2009 was to render time for payment of the £25,000 of the essence and to allow 60 days for payment, which it submits is reasonable notice, failing which it was entitled to terminate the DLA.

[**127**] In support of this submission, 1072/VDL relies upon three authorities which support the proposition that a party to a contract may, in appropriate circumstances, give notice making time the essence of the contract. In *Hartley*

v Hyams [1920] 3 KB 475, time was originally of the essence of the contract so that when the supplier failed to deliver by 15 November 1918, the purchaser could have taken that failure as entitling him to terminate the contract. Instead the purchaser persistently complained of the delay and asked for better deliveries, thereby leading the supplier to believe that the contract still subsisted and to act on that belief at expense to himself. When the purchaser gave notice without warning in March 1919 cancelling the contract it was held that he had waived his right to insist on delivery by 15 November 1918 and was estopped from alleging that the period for delivery had terminated on that date. McCardie J held that the purchaser could have given notice in March 1919 fixing a reasonable time within which the supplier was required to supply the undelivered balance of the contract goods, but had not done so. It is implicit in his reasoning and ruling that, if notice had been given and not complied with, it would have been the supplier's failure to deliver after the giving of notice that would have entitled the purchaser to terminate.

[**128**] *Rickards (Charles) Ltd v Oppenheim* [1950] 1 All ER 420, [1950] 1 KB 616 is direct Court of Appeal authority for the proposition that where time is of the essence of a contract for the sale of goods and, on the lapse of the stipulated time, the buyer continues to press for delivery thus waiving his right to cancel the contract, he has a right to give notice fixing a reasonable time for delivery, thus making time again of the essence of the contract: see [1950] 1 All ER 420 at 423, [1950] 1 KB 616 at 623–624 per Denning LJ. However, the giving of such notice does not entitle the buyer retrospectively to rely upon the seller's breach of contract in the period of the waiver or estoppel, since that is the breach which is waived or he is estopped from relying upon. To hold otherwise would retrospectively cancel the effect of equity's protection, which is unconscionable. The requirement that the buyer give notice fixing a reasonable time for delivery, thereby once again making time of the essence of the contract, has the practical effect that the time on which he is entitled to rely starts to run from the date on which notice is given, not from the date of the original and waived breach.

[**129**] This is made clear by the third authority upon which 1072/VDL relies. In *Behzadi v Shaftesbury Hotels Ltd* [1991] 2 All ER 477, [1992] Ch 1, the Court of Appeal held that a purchaser of land under an agreement, which specified a time for performance of an obligation without making the time of that performance the essence of the contract, was entitled to serve a notice giving a reasonable time for performance and making that time the essence of the contract: he did not have to wait until a reasonable time after the original breach before serving notice. In reaching this conclusion the Court of Appeal relied upon Australian authorities which provided the rationale and an 'entirely satisfactory basis' for the decision: see [1991] 2 All ER 477 at 489, [1992] Ch 1 at 15–16 per Nourse LJ. In particular Nourse LJ ([1991] 2 All ER 477 at 489, [1992] Ch 1 at 15) cited with approval a passage from the judgment of Mason J in the decision of the High Court of Australia in *Louinder v Leis* (1982) 149 CLR 509 at 526, which was also cited with agreement by Purchas LJ ([1991] 2 All ER 477 at 501, [1992] Ch 1 at 30):

> 'Accordingly, delay beyond the stipulated date will give rise to a liability in damages. But because equity treats the time stipulation as non-essential, mere breach of it does not justify rescission by the innocent party and will not bar specific performance at the suit of the party in default. *Unreasonable delay in complying with the stipulation in substance amounting to a repudiation is*

essential to justify rescission. It is to this end that, following breach, the innocent party gives notice fixing a reasonable time for performance of the relevant contractual obligation. *The result of non-compliance with the notice is that the party in default is guilty of unreasonable delay in complying with a non-essential time stipulation. The unreasonable delay amounts to a repudiation and this justifies rescission*.' (Emphasis added)

[**130**] *Behzadi* was a case where the contract itself did not make time for the performance of the obligation in question the essence of the contract. In such a case the contractual route for the innocent party is clear: it is open to him by giving notice to make time of the essence so that failure to comply with the notice is taken as repudiation of the contract. It is, however, important to note Nourse LJ's observation ([1991] 2 All ER 477 at 487, [1992] Ch 1 at 12) that the description of a notice making time of the essence of the contract 'is not quite accurate. That is because one party cannot vary the terms of the contract on his own. In reality the notice is given in order to bring to an end, by equitable means, equity's interference with the legal rights of the parties.' To the same effect Purchas LJ said ([1991] 2 All ER 477 at 496, [1992] Ch 1 at 24):

> 'What, then, is the effect of serving a so-called notice "making time of the essence"? *It certainly does not make time of the essence so far as the obligations in the contract of sale are concerned, since one party cannot unilaterally vary the terms of the contract*. It cannot be served until after there has been a breach by the defaulting party either of the term fixing the date for compliance, or of the implied term where the contract is silent as to the date for performance. The notice has in law no contractual import. With the modern practice of including standard conditions into contracts for sale of land, occasions when a date is not prescribed for completion or for the performance of intermediate steps (e g delivering an abstract of title) have become increasingly rare. It is only in such cases that the reasonable time for performance term can be imported into the contract. *In most cases, therefore, the effect of the notice will be to give the defaulting party an opportunity to perform his obligations under the contract*. However, I see no reason for the imposition of any further period of delay after the breach of contract has been established by non-performance in accordance with its terms before it is open to a party to serve such a notice. The important matter is that the notice must in all the circumstances of the case give a reasonable opportunity for the other party to perform his part of the contract.'

[**131**] The contract in the present case includes contractual mechanisms and routes to termination in case of breach of contract under cll 18.2, 18.3 and 22.2. In that respect it differs from the contracts in each of the three authorities upon which 1072/VDL rely. In *Hartley* and *Charles Rickards*, the original contracts made time for the delivery of the goods the essence of the contract but included no contractual provisions about how the contract should be terminated in the event of breach. In *Behzadi* time was not originally of the essence and there were no contractual provisions for termination after breach of the non-essential implied term requiring delivery within a reasonable time. The absence of contractual mechanisms for termination in those cases is, to my mind, a critical distinction. Although the three authorities establish that in contracts where there is no contractual mechanism for termination after breach, giving reasonable notice to perform establishes a period after which the law will hold that the party in breach has repudiated his contract, it does not follow that an innocent party to a contract which *does* provide such a

mechanism can set up a termination 'on reasonable notice' by giving notice to the party in breach to perform. The reason why the distinction is critical is that, in the latter case, the party giving notice would be varying the terms of the contract unilaterally by substituting non-performance after a reasonable time as the basis for termination in place of the contractual mechanism.

[**132**] Assuming that waiver or estoppel is established in the present case, what 1072/VDL waived (or is estopped from relying upon) was the right to rely on LLC's breach of contract in not paying the second consideration payment after delivery of the clinicals for use in the FDA approval application. Therefore, although 1072/VDL is correct to submit that the payment was 'due' under the terms of the DLA, the effect of the waiver or estoppel is that 1072/VDL is not entitled (even after giving notice) retrospectively to rely upon the fact that the payment was 'due' during the period to which the suspension applied, which covered the whole period from the date of breach to the date of notice. Assuming also that it is not inequitable for 1072/VDL to bring that period of waiver or estoppel to an end by giving notice, the first date on and from which 1072/VDL could conceivably rely upon the fact of non-payment as a breach of contract would be the date of giving notice. The contract provides the mechanisms for termination once 1072/VDL is entitled to rely upon LLC's breach of contract and, both under cll 18.2 and 18.3 and under cl 22.2, the minimum period to termination is 90 days. If 1072/VDL were to be permitted to terminate only 60 days after giving notice, it would mean either that it was permitted to vary the terms of the contract or that the giving of notice effectively removed the protection of the waiver or estoppel 30 days before the notice was given. Neither of these conclusions is contractually acceptable in the light of the explanation of the principles underlying the authorities upon which 1072/VDL relies as provided by Nourse and Purchas LJJ in *Behzadi*.

[**133**] If therefore 1072/VDL waived or was estopped from relying on the failure by LLC to pay the £25,000 on and from the date of delivery of clinicals, then it was not open to 1072/VDL to terminate the DLA until at least 90 days after the conclusion of whatever period of notice was reasonable to bring any period of waiver and/or estoppel to an end so that, from that date, 1072/VDL was entitled to rely upon LLC's non-payment of the £25,000 consideration payment as being a breach of cl 18.2.

A reasonable period of notice

[**134**] A slightly different approach to the same problem is to ask what would have been a reasonable period of notice for 1072/VDL to give on 18 November 2010. There is limited authority on what impact, if any, an express contractual provision for termination after breach may have upon this question. In *Hughes* (1877) 2 App Cas 439 at 448, [1874–80] All ER Rep 187 at 188 Lord Cairns LC took the provision of the lease requiring six months' notice to repair as being 'that which according to the view of the parties was a reasonable time for the execution of such repairs'. Lords O'Hagan, Selborne and Blackburn agreed. Lord Blackburn added ((1877) 2 App Cas 439 at 453, [1874–80] All ER Rep 187 at 190):

> 'I think the very object for which the stipulated time of six months was named, was to prevent that uncertainty in saying what would be a reasonable time, and to enable one of the parties to know that he had got six months to do the repairs in, even if that was more than was needed, and to enable the other to know that whether it turned out to be either too much or too little, the repairs were to be done within that time.'

[**135**] The giving of notice may be intended to serve two functions. The first is to bring the period of suspension to an end so that, from that date, the party giving notice may rely upon his contractual rights. The second is to fix a time after the suspension is ended for compliance by the other party, failing which the other party will be taken to have repudiated the contract. The extracts from *Hughes* to which I have just referred do not address the first of these purposes. Turning to the second, where the parties have agreed what is to happen in the event of breach, and (as here) those provisions are directly applicable, I am not persuaded that the question of 'reasonable notice' in the second sense applies at all: the conditions of the contract prevail. In other cases (as was the case in *Hughes*), the contractual agreement may not be directly applicable as a mechanism that applies in the event of breach. However, even so, *Hughes* indicates that the terms of the contract should always be highly influential and will usually be determinative when determining what period is reasonable. This seems entirely consistent with the modern emphasis of the courts upon respecting the terms of agreements freely negotiated by commercial parties to complex contracts.

Issue 3.1: Did 1072/VDL clearly represent or promise to LLC in January to February 2009 that the payment of £25,000 due under cl 18.2(iv) of the DLA would only become payable after FDA clearance for the device was obtained?

[**136**] On my findings of fact, as set out above, 1072/VDL made its position plain on a number of occasions.

(i) By the e-mail on 22 January 2009, they stated that their expectation was that LLC would pay the £25,000 within 30 days of FDA approval.

(ii) On 23 January 2009 Mr Rothon clarified that what he meant was that LLC should pay a total of £415k within 12 months of FDA approval, which would have included the £25,000.

(iii) On 29 January 2009, Mr Rothon wrote that his assumption was that LLC would make full payment of the consideration payments 'once we have FDA approval'.

(iv) During the dog-walking conversation Mr Rothon made clear that he would not budge from his previously stated position, which was that payment should be made after FDA approval.

[**137**] In my judgment, these statements (whether taken singly or cumulatively) constituted a clear representation and promise to the claimant in January to February 2009 that the payment of £25,000 due under cl 18.2(iv) of the DLA would only become payable after FDA clearance for the device was obtained. 1072/VDL intended them to be taken as such, which is why Mr Rothon asked Mr Field in about May 2010 if LLC was okay with making the payments due under the DLA after FDA clearance. It also explains the terms of the 'What does FDA mean to us??' e-mail on 29 November 2009. LLC understood them as such, and got on with the job.

Issue 3.2: Did 1072/VDL intend LLC to rely on the above representation or promise?

[**138**] The negotiations in late 2008 and early 2009 were serious and intended to be taken seriously. On the one hand, LLC had significant complaints about what it perceived, with justification, to be 1072/VDL's failure to support it and to provide the necessary clinical data in good time (or at all). On the other hand, Dr Dougal (at least) was conscious of the need for flexibility in a business relationship where FDA clearance, originally anticipated for 2004, was still far off because of the lack of clinical data; and 1072/VDL considered that the DLA

royalty fee of £5 per device was a very beneficial deal. Both sides, therefore, were engaged in serious negotiations aimed at ensuring the continuance of their business relationship. 1072/VDL's witnesses did not at any stage suggest that the proposal to delay the consideration payment until after FDA clearance was not to be taken seriously. Their case at trial was that achieving FDA approval by March 2009 was a condition precedent to their proposals being implemented and that no agreement was reached, on which I have made my findings above.

[**139**] I find that 1072/VDL intended LLC to rely on the representation or promise.

Issue 3.3: Did LLC rely on such representation or promise?

[**140**] Ms Higginson and Mr Field were challenged about what they would have done if 1072/VDL had not agreed to deferral. They accepted that LLC could have paid the money if required to do so and that they still had faith in the device as a potential money-spinner. It is, however, to be remembered that Ms Higginson went to the meeting on 26 November armed with the printout from the Hargate 2 trial and that she started off with the battle cry that this was a potential lawsuit. For the same reasons as set out at [111], above, I find that LLC did rely upon the representation or promise and demonstrated that reliance by carrying on with the process of attempting to get FDA approval, which proved to be long and difficult despite the intervention of iSmart, and continuing to expend money and resources with a view to the distribution of the device while dropping the complaints that they had been making in the period to early 2009. The dropping of the complaints is not essential to my finding of reliance but supports it.

Issue 3.4: Was it in all the circumstances inequitable for 1072/VDL to insist upon payment of £25,000 at any time before FDA clearance; or could 1072/VDL terminate the suspensory effect of their promise prior to FDA clearance?

[**141**] The following matters seem to me to be most material to be brought into the balance.

(i) The terms of the representation defined the end point: no payment was to be made *until after FDA approval*. It was not like the representations of open-ended forebearance, such as in *Hughes* or *Charles Rickards*. Where a representation is open-ended, but is not obviously intended to be perpetual, it is easy to conclude that it may be revoked on reasonable notice. However, where the party making the representation has defined the duration of its application, as in this case or in *High Trees*, and the other requirements of waiver or estoppel are satisfied, it seems to me to be less than self-evident that it is equitable to revoke the representation part-way through its defined duration.

(ii) The nature of the representee's reliance: 1072/VDL points to Mr Field's evidence that LLC would have been in a position to pay the £25,000 had it had to do so during the period to 18 November 2010. The point is well made and I place minimal weight upon the fact that LLC did not make provision for doing so. However, I have found that LLC relied upon the representation or promise sufficiently to give rise to the equitable protection of waiver or estoppel. By the time that notice was given, LLC had invested significant (but unspecified) amounts of time and resources at least partially because of the representations; and those investments could not and would not readily be undone.

(iii) The duration of the period of suspension that had passed: the parties had been operating on the basis of the representations being in place from late January/early February 2009 to October 2010—a period of 20 months.

(iv) The reasons for the giving of the notice: 1072/VDL's case is that it gave notice because it was dissatisfied with LLC's performance, particularly in relation to its refusal to invest in launching the device in Canada before FDA approval had been obtained. There is no document in evidence which refers to this or any other reason for the giving of the notice. Mr Tassell made clear, in a considered answer, that not merely was there no document in evidence but that no document (including any privileged document) exists that would evidence 1072/VDL's asserted reason for giving notice. Furthermore, there is little correspondence from 1072/VDL to LLC pressing LLC to progress matters in Canada and none threatening termination before notice was served on 18 November 2010. In this state of the evidence, I am not satisfied that 1072/VDL's evidence about its reasons for termination is correct. I am not in a position to make a clear finding about what was 1072/VDL's true reason, for want of documentary or reliable oral evidence. However, when considering whether it was inequitable for 1072/VDL to revoke its representation or promise, it seems to me to be more important that very little had changed during 2009 and 2010 to justify a change of tack by 1072/VDL. In particular, LLC's unwillingness to 'put its hand in its pocket' to develop other jurisdictions before getting FDA approval had been well flagged and had been the subject of specific negotiations before 1072/VDL made its representations: see [84], above. That had not changed.

[**142**] I consider that where, as here, the representation defined its intended duration and substantial reliance sufficient to give rise to waiver or estoppel has been shown over a significant period, a positive justification will generally need to be shown if revoking the representation part-way through is not to be characterised as inequitable. That is because the court's first instinct should be to encourage commercial (and other) parties to comply with their promises and to foster commercial certainty and trustworthiness. No justification is apparent here. I consider that in all the circumstances the balance falls decisively in favour of the conclusion that it was inequitable for 1072/VDL to insist in late 2010 on payment of the £25,000 consideration payment at any time before FDA clearance.

Issue 3.5: If 1072/VDL were able to terminate the suspensory effect of their promise prior to FDA clearance by giving reasonable notice to pay the £25,000, did the letter of 18 November 2010 constitute reasonable notice, or did it constitute only an invalid notice of breach?

Issue 3.6: If the letter of 18 November 2010 did constitute reasonable notice to pay, was the effect of that notice such that the £25,000 payment obligation:

3.6.1 Should be treated as only falling due for the first time after a reasonable period from 18 November 2010?

3.6.2 Should be treated as having arisen on 18 December 2008, so that the effect of the letter of 18 November 2010 was to put LLC immediately in breach of the DLA?

[**143**] If, contrary to my finding on issue 3.4, it had been open to 1072/VDL to serve notice requiring payment of the £25,000 before FDA clearance, two questions may arise. The first is what would have been a reasonable period after the giving of notice before it would be equitable for 1072/VDL to rely

upon LLC's non-payment of the £25,000? My answer to this question is conditioned by my conclusions that (a) the effect of the waiver or estoppel was that 1072/VDL could not retrospectively reintroduce reliance upon the fact that the payment had been 'due' in the period until the suspension was terminated and (b) once the suspension was terminated and 1072/VDL was entitled to rely upon LLC's breach from then on, the contractual routes to termination under cll 18.3 and 22.2 would apply: see [131]–[132], above.

[**144**] In favour of a short period is that the contractual mechanism under cl 18.3 gave 30 days before the 5% would operate, while the mechanism under cl 22.2 gave LLC 30 days before 1072/VDL could serve notice of intention to terminate 60 days thereafter. In favour of a longer period is that the waiver or estoppel had been in place for 20 months and the notice was given without warning. Balancing these considerations, I conclude that a reasonable period of notice would be 14 days: in other words, the suspensory effect of the waiver or estoppel would cease 14 days after notice was given.

[**145**] If I were wrong in my conclusion that the contractual mechanisms would then become operative, the second question would arise, namely what would be a reasonable period from the end of the suspensory period before 1072/VDL could terminate the contract. If that question arose, I would hold that a reasonable period from the end of the suspensory period would be 90 days, adopting the same reasoning as that of Lord Cairns LC and Lord Blackburn in *Hughes*.

ISSUE 4: ENTITLEMENT TO SERVE DEFAULT NOTICE AND TO TERMINATE

4.1 Were the defendants entitled to serve the default notice under cl 22.2.1 of the DLA on 18 November 2010?

4.2 Were the defendants entitled to terminate the DLA on 31 January 2011:

4.2.1 under cl 22.2.1; or

4.2.2 under cl 18.3?

[**146**] My primary finding is that there was a contractual variation such that the £25,000 was not payable until after FDA clearance: see Issue 2. It follows that payment was not yet due and there was no basis for serving the default notice under cl 22.2.1 on 18 November 2010. Had I concluded that there had been no contractual variation, 1072/VDL would have waived or been estopped from relying upon the fact that the payment had been 'due' since delivery of the clinicals and from requiring payment to be made until 14 days after the service of notice terminating the suspension. On that basis too, payment was not due on 18 November and there was no basis for serving the default notice under cl 22.2.1 on 18 November 2010: it could not be served until 30 days after the termination of the period of suspension ie at least 44 days after 18 November 2010. The notice was therefore invalid.

[**147**] By 31 January 2011 1072/VDL had failed to serve a valid notice under cl 22.2.1 and were therefore not entitled to terminate the DLA under that clause. Furthermore, 90 days had not passed since termination of the period of suspension, with the result that 1072/VDL were not entitled to terminate the DLA on 31 January 2011 pursuant to cl 18.3.

CONCLUSIONS ON ISSUES 3 AND 4

[**148**] In the light of my conclusions on Issue 2, Issue 3 does not arise. If it did, my conclusions would be as follows.

[**149**] Issue 3.1: 1072/VDL clearly represented or promised to LLC in January to February 2009 that the payment of £25,000 due under cl 18.2(iv) of the DLA would only become payable after FDA clearance for the device was obtained.

[**150**] Issues 3.2 and 3.3: 1072/VDL intended LLC to rely upon the representation or promise and LLC did so.

[**151**] Issue 3.4: It was inequitable in all the circumstances for 1072/VDL to insist on payment of the £25,000 before FDA clearance because of a combination of the nature of the original representation or promise, LLC's reliance upon it during the 20 months since February 2009 and the absence of any demonstrated reason or justification for demanding earlier payment.

[**152**] Issues 3.5 and 3.6: In the light of my conclusions on issue 3.4, these issues do not arise. If they had done so, my conclusions would be that the letter of 18 November 2010 did not constitute valid notice to terminate the suspensory period of the waiver or estoppel or to give rise to a right to terminate. 14 days' notice should have been given to terminate the suspensory period. Once the suspensory period had been terminated, the contractual mechanisms under cll 18.3 and 22.2 applied. If they had not applied, 90 days would have been a reasonable period after which 1072/VDL could have terminated. On any view, 1072/VDL was not entitled to terminate on 31 January 2011.

[**153**] Issue 4.1: 1072/VDL were not entitled to serve the default notice under cl 22.2.1 of the DLA on 18 November 2010.

[**154**] Issue 4.2: 1072/VDL were not entitled to terminate the DLA on 31 January 2011 either pursuant to cl 22.2.1 or pursuant to cl 18.3.

[**155**] It is agreed that, on these findings, the purported termination on 31 January 2011 amounted to a repudiatory breach of the DLA, which LLC was entitled to accept on 4 April 2011.

Quantum

ISSUE 5: WHAT LOSS, IF ANY, HAS THE CLAIMANT SUFFERED IN CONSEQUENCE OF THE DEFENDANTS' EX HYPOTHESI REPUDIATORY BREACH?

5.1 How many units of the 'permanent' device would the claimant have sold (principally in the United States) during the term of the DLA?

5.2 At what retail and wholesale price would the units have been sold?

5.3 What would the costs of sale per unit have been?

5.4 What level of marketing expenditure would have been required to generate those sales?

5.5 As sub-issues to the above:

5.5.1 Is the device a 'me too' product—ie not offering a materially different value proposition from what is already on the market? As part of this question: in order to have sufficient differentiating claims from the market leader in the United States, Abreva, are superior medical claims for the device required, or could it achieve this effect with differentiating marketing claims (as the only light therapy treatment for cold sores which has obtained FDA clearance)?

5.5.2 Do the sales data for Walgreens provide a useful guide as to the viable price points for the device in the United States; and if so how?

5.5.3 Do the existing sales data for the United Kingdom and Europe provide a useful indication of the potential for sales of the device in the United States; and if so how?

5.5.4 Do the market research studies commissioned by Boehringer Ingelheim and others provide a useful guide as to the viable price points for the device in the US; and if so how?

5.5.5 How is the total available market to be calculated; in particular could the device have grown the market, and if so how?

5.6 What percentage chance did the claimant have of making the sales referred to above and/or what percentage reduction should be applied to reflect the lack of certainty that they would have made those sales?

5.7 Had the DLA not been terminated, what chance, if any, is there that the defendants would have sought to negotiate to pay the claimant a royalty for the release of the claimant's rights under the DLA? If so, what chance is there such negotiations would have resulted in the parties agreeing such release and on what terms as to royalty (or otherwise) payable to the claimant?

5.8 Is the claimant entitled to claim wasted expenditure, and if so on what basis and in what amount?

The DLA requirements and LLC's case

[**156**] Schedule 4 of the DLA set out sales targets for the various territories. The size of the Canadian market is about 10–15% of the size of the United States market.[13] The targets for the USA and Canada combined were as follows:

(i) 12 months after the commencement date (which for the USA was the date of FDA approval): 50,000 units;
(ii) 24 months after the commencement date: 150,000 units in total;
(iii) 36 months after the commencement date: 280,000 units in total;
(iv) 48 months after the commencement date: 440,000 units in total.
(v) 60 months after the commencement date: 640,000 units in total;
(vi) thereafter 300,000 units per annum.

[**157**] Clause 10.1 provided that if, during the first 36 months from the commencement date, the number of products sold by LLC in any area fell short of the sales targets then, unless LLC paid a sum equal to the resulting deficiency in royalty payments for that area within 90 days of the end of the applicable year, 1072/VDL could terminate the right to that area on giving 30 days' notice. After 36 months, if any of the sales targets were not reached by LLC then LLC would lose all rights to the territory in question unless LLC verified to 1072/VDL's reasonable satisfaction that the target was unrealistic, in which case it was to be reassessed.

[**158**] LLC's case, based on the expert evidence of Mr Boghigian, is that it would have achieved sales in the United States as set out in the table below, at a retail price of $79.99 and a wholesale-to-retail mark-up of 35%. The annual sales figures for which it contends are as follows:

13 See F1/191–192.

	Lower Range: Units	Lower Range: Revenue	Upper Range: Units	Upper Range: Revenue
Year 1	100,000	5,900,000	100,000	5,900,000
Year 2	207,332	12,233,000	304,664	17,975,000
Year 3	236,524	13,955,000	352,048	20,771,000
Years 4–10	300,000	17,000,000	300,000	17,700,000

In the light of these figures, it has not been suggested by LLC that the sales targets for the United States and Canada in Schedule 4 of the DLA are unrealistic.

[**159**] 1072/VDL contends that the retail price of $79.99 is far too high and would have ensured that negligible sales would have been achieved, which would have entitled them to terminate the DLA. They go further and say that there is no retail price at which the device could have been successfully marketed that would have enabled LLC to make a profit. The major points of difference between the parties are the price that could realistically be charged and the marketing spend that would have been required in order to launch and sustain the device. As a result of these differences, and because Mr Bell considers that the purchase of a device would then take the purchaser out of the market, he projects higher sales at a much lower price in the early years, with sales falling off to well below Mr Boghigian's projections thereafter.

The applicable principles

[**160**] It is common ground that LLC's claim is to be assessed by reference to the principles developed in and since *Allied Maples Group Ltd v Simmons & Simmons (a firm)* [1995] 4 All ER 907, [1995] 1 WLR 1602. There is no need for any detailed examination of those principles here. LLC submits that, when reviewing the evidence and making findings of fact, the court should mirror the approach sometimes taken in the context of claims in tort and be generous to the innocent party. In my judgment there is no real scope or justification for such an approach when assessing damages for breach of contract after a trial has examined all available evidence in detail and when the burden of proof remains on the claimant throughout.

The expert evidence

[**161**] The primary evidence was that of Mr Boghigian and Mr Bell, who found few points of agreement. This polarisation stemmed from the fact that Mr Boghigian sees the device as a 'breakthrough' product (ie one that is capable of driving a paradigm shift in consumers' perceptions and buying habits) while Mr Bell is convinced that it is a 'me too' product (ie an addition to the market which does not offer any differentiating qualities so as to cause a breakthrough). Each has had long and wide-ranging experience in the United States, including relevant experience of bringing products into a crowded pharmaceutical market. Of the two, Mr Boghigian was more ready to take on board good points when they were put to him; and Mr Bell sometimes appeared to shift from a position of giving evidence of his expert opinion to arguing the case for 1072/VDL. I formed the impression that, although both experts had been informed of their duties as experts under the Civil Procedure

Rules (CPR), Mr Bell's relative intransigence may have reflected cultural differences in the perception of how litigation should be conducted on the other side of the Atlantic. While I take these features into account in my assessment of the expert evidence, they are not so serious as to cause me to reject the evidence of either witness wholesale: each had much to contribute and did so.

[**162**] There was, however, one feature of Mr Bell's evidence that requires separate treatment. He was asked by the solicitors acting for 1072/VDL to supplement his own opinion with the opinions of other experts in the field. As a result, he sent to a number of correspondents a short and non-technical YouTube promotional clip about the device with an online survey which asked questions about their perception of the device, offering prescribed answers by drop-down boxes. In e-mails thanking them for agreeing to participate Mr Bell gave his correspondents an undertaking that their identities would remain confidential. When the correspondents had completed the online survey, Mr Bell spoke to them about their responses and kept notes of their replies. He then provided as an annexe to his report a summary of the responses which he had received and relied upon that material in support of his opinions.

[**163**] When his report was exchanged, LLC's solicitors wrote to 1072/VDL's solicitors requiring that the anonymous experts be identified, with details of their expertise, and requiring the provision of all communications between Mr Bell and his correspondents. Although he was aware of these requests, Mr Bell did not ask the correspondents if they were prepared to be identified. 1072/VDL's solicitors refused LLC's requests stating that the correspondents had 'only agreed to speak to [Mr Bell] on the understanding that they would remain anonymous'. This was materially inaccurate since there is no evidence that any of them made anonymity a condition of their participation.

[**164**] Ultimately, LLC tried again early during the trial and, after court hours on day 5, 1072/VDL offered to provide the identity of the correspondents and brief details of their expertise on condition that the information would be kept confidential and that LLC would not try to contact any of the eight correspondents either directly or indirectly. LLC agreed to these terms. However, when Mr Bell came to give evidence on day 6, it became apparent that his notes had still not been provided. They were provided overnight, by which time Mr Bell was in the middle of his cross-examination.

[**165**] There are a number of fundamental problems arising out of this sequence of events.

(i) It is, as 1072/VDL's legal team should have known, quite unacceptable under the provisions of the CPR for Mr Bell to have sought to rely upon information for the purposes of his report without identifying the source of the information.

(ii) The correspondents were not told about the duties of experts providing evidence to the English court and the information with which they were provided was inadequate to enable them to form any worthwhile expert opinion.

(iii) Mr Bell's notes of his conversations (which went directly to the issues on which he was canvassing their opinions) should have been disclosed, whether or not they were annexed to his report.

(iv) It was wrong of 1072/VDL's solicitors to inform LLC that the experts had only agreed to participate on condition that they would remain

anonymous. I do not know precisely how this information came to be given, but proper inquiries by the solicitors should have revealed to them that this was not the case.

(v) Mr Bell should have been asked by the solicitors to go back to his correspondents to ask if they would agree to their details being given. I infer from the fact that he did not go back to his correspondents either on receipt of the first letter from LLC's solicitors or during trial that he was not asked to do so.

(vi) It was unsatisfactory that the offer of disclosure made during the trial was made only on condition that LLC should not contact the correspondents. Given the circumstances of their participation and the wholesale failure to comply with proper procedures, there was no good reason to prevent LLC at least attempting to make contact with the correspondents.

(vii) Once further details were provided it became clear that there were significant questions to be asked about whether or to what extent some of the correspondents had relevant experience that qualified them to be treated as experts.

(viii) Last but by no means least, Mr Bell's summary accounts in his disclosed report on a number of occasions failed accurately to reflect the information that had been provided to him by his correspondents.

[**166**] Mr Segal QC rightly accepted that things had gone wrong. That is blindingly obvious. However, for the purposes of a judgment on quantum the real problem is what impact the involvement of the correspondents has on the evidence of Mr Bell. He was adamant that he relied upon the contribution of the experts only as support for views which he held anyway. That may be so, but the fact that he included their contributions shows that he regarded them as material. In my judgment, the wholesale disregard for proper procedure and the consequent unfairness to LLC in depriving it of essential information about the correspondents until Mr Bell was in the course of giving his evidence leads directly to the conclusion that the contribution of the correspondents should be disregarded altogether. It also affects my attitude to Mr Bell's own evidence in three respects. First, while I acknowledge that the sequence of events would have been driven (or at least overseen) by 1072/VDL's legal team, I do not think that he can escape all responsibility for what happened, particularly in his failure to go back to his correspondents to request them to agree to being identified. Second, the comfort that he attached to the contribution of the correspondents must be discarded. That said, however, I have formed the clear view that Mr Bell was right in maintaining that the views he expressed were views that he held independently of the contribution of his correspondents. Third, the inaccuracy of his summary accounts of his dealings with his correspondents makes me examine his evidence generally with extra care, particularly when that evidence is not objectively verifiable. I approach his evidence on that basis.

[**167**] Ms Pincott is a chartered accountant who reported and gave oral evidence called by LLC. She was heavily dependent upon information from LLC which she took as the basis of her calculations of LLC's potential losses. She adopted Mr Boghigian's figures for sales and price, since that was in his field of expertise and not hers. She considered the costs that were proposed by LLC (including, importantly, marketing spend) and applied her expertise to whether or not they were reasonable. Her opposite number, Mr Holland,

attended trial but was not called. It was agreed that his evidence should be taken as if he had been called but LLC had elected not to cross-examine. There were few issues of principle dividing Ms Pincott and Mr Holland. Each offered calculations of loss based upon various different assumptions, and further illustrative permutations were submitted after the hearing.

[**168**] All of the experts founded their evidence on a fairly limited supply of primary evidence, to which I now turn.

The Walgreens online trial

[**169**] Between April 2006 and May 2007 the device was sold online through Walgreen's website. 1,567 devices were sold in total. There was an upward curve of sales from a handful per month at the outset, starting to rise in September 2006 and peaking at a maximum of 275 in March 2007. The device retailed at $79 (with a wholesale price to Walgreens of $59)[14] until April 2007 when, at the suggestion of Walgreens, it was increased to $99 (with a wholesale price of $73). Sales fell back in April 2007, which is likely to have reflected the increase in price. Sales stopped in May 2007, which I find was related to the intervention of Tyrell and the actual or anticipated intervention of the FDA. The FDA was interested because these were pre-clearance sales and therefore unauthorised.

[**170**] It is common ground that the website offering the device for sale made a number of claims that have not subsequently been authorised and would not be allowed under the terms of the FDA clearance that has been obtained. Those claims included that use of the device can prevent cold sore eruption if used during the tingling phase; that complete pain relief is experienced by most people within minutes; that it was risk free and had zero side-effects; that repeated use may reduce the recurrence rate of cold sores; and that the device has an anti-biotic effect on viruses. The main clinical claim approved by the FDA and used for the Walgreens trial is that the device shortens healing time.[15]

[**171**] There is a conflict of evidence about what marketing was carried out to support the online Walgreen's sales. I find that LLC supported the sales by spending $4,500 per month on Google pay-per-click; customers accessing the Virulite website were redirected to Walgreens; and a supportive article was printed in Prevention Magazine. Walgreens sent out some 'box-stuffers' advertising the device, but in the light of Mr Mencanin's evidence I am not satisfied that the number sent out was as high as 300,000. On 28 February 2006 Mr Mencanin e-mailed his main contact at Walgreens to say that an e-mail 'skin' (a form of opt-in e-mail advertising) had been launched that morning to 15 million Health & Beauty e-mail accounts, which would take three weeks to send. His evidence was that he later discovered that this skin did not take place: the firm that was due to execute it gave LLC the run around and was unable to provide any evidence that they had done it. This is consistent with what was written in the Frederick Hall opinion on value in February 2008, which refers to periodical ad spots on Walgreen's website and stuffing leaflets in outbound orders but to no other brand awareness campaign. I find that no or no significant skin was sent out.

[**172**] LLC's evidence is that Walgreens were enthusiastic about the device and were contemplating marketing it in-store at a retail price of $129.

14 Mr Mencanin's evidence was that the wholesale price was $53 but the sales documents evidence $59.

15 It is agreed that other claims could be made now, including to emphasise the different mechanism of action and absence of messy creams, that the device is permanent and can provide up to 50 treatments, and that no subject's cold sore got worse: see Boghigian/Bell joint statement.

Published data on Walgreens Inventory Turnover Ratio reveals the number of turns of inventory at 6.98 which suggests that, to meet Walgreen's in-store requirements, the device would have to sell at a rate of about seven units per store. There is evidence that 'within three months the device became the website's bestselling cold sore remedy, bypassing the market leader, Abreva'[16] though the source of that information is not clear. 1072/VDL relies upon an exchange of e-mails in January 2007, which it interprets as meaning that Walgreens were concerned that the device could not be differentiated from other cold sore treatments.[17] However, read in context, what Walgreens meant was that a draft advertisement failed to differentiate between the device and other cold sore treatments and needed to be improved so that it did. Support for LLC's case that Walgreens were enthusiastic is provided by an e-mail from Mr Field to 1072/VDL dated 19 October 2008, immediately after Walgreens had backed out, in which he said that 'in recent discussions Walgreens were forecasting an initial PO of 60,000 units. We had agreed the retail price would be $129 and we would wholesale to Walgreens for $82.'

[**173**] I do not detect any lack of enthusiasm for the device at any stage before the intervention of Tyrell. When the Walgreens's deal collapsed Mr Mencanin sent a strongly worded e-mail to Andrea Collaro at Walgreens on 16 October 2008 which was certainly not calculated or likely to endear him to the recipients. But his evidence, which I accept, is that a number of people have moved on and that he has remained able to do business with Walgreens since then. What is common ground is that the proposed deal with Walgreens in 2008 was very favourable in a number of respects that would be unlikely to be replicated in any later deal. In particular, Walgreens was prepared to pay 30% of the wholesale price on submitting its initial order, which was unusually favourable.

[**174**] In 2012 Ms D'Arcy and Mr Baker re-approached Walgreens with a view to Walgreens stocking the device. After a limited presentation the correspondence was equivocal and appears to have petered out in about November 2012 after a request for further information from Walgreens. While it is clear that Walgreens were open to considering whether or not to stock the device now that it had FDA approval, the disclosed correspondence does not enable any further inferences to be drawn. On 7 October 2013 a Mr Bobber of Walgreens e-mailed Mr Mencanin asking for an update on FDA approval of the device. Again, this suggests a willingness to consider the device, but does not go further than that.

Boots and other sales in the United Kingdom

[**175**] Boots is a national retailer. It has been selling the device in-store since about September 2008. According to Ms D'Arcy, in the period from 2008 to November 2013 Boots sold 74,840 devices, an average rate of slightly under 14,500 per annum. In the 55-week (13 month) period to 24 November 2012 Boots sold 13,430 devices, at a weekly average rate of 244. In the 49 week (11 month) period to 2 November 2013 Boots sold 12,189 devices, at a weekly average rate of 248. The device was stocked and sold from about 1,300 stores, which indicates an average turnover rate of between 9 and 10 per store per

16 F2/524.

17 F3/590–593.

annum over the two years. The average retail price during that time has been almost exactly £35 per device (£35.11 in the first period and £34.87 in the second).

[**176**] When Boots first started marketing the device, there was considerable optimism for much higher sales than have in fact been achieved. On 3 October 2008 Mr Rothon e-mailed Mr Field and others reporting that Boots's Oxford Street and Covent Garden stores were selling more than 30 devices per day per store. Mr Field reported information to Ms Higginson and Mr Mencanin, which he said came from Mr Rothon: Pacer and Dr Dougal were said to be confident that sales via Boots would be 50,000–60,000 units in the first year. Such levels of sales were never forthcoming.

Boehringer Ingelheim

[**177**] Boehringer Ingelheim ('BI') is a leading German pharmaceutical manufacturer. Before FDA clearance was achieved, BI showed interest in the device which led to discussions during 2012 about their distributing the device, possibly on a world-wide basis. BI carried out concept testing for the device in the United States, Germany, Japan and China. The purpose of the research was to obtain information about the prevalence of cold sores, frequency of suffering, product awareness and usage, and initial purchase interest for two product variants including price. The sample size was 2,000 per country, representative of the general populations, and the testing was carried out in July 2012. BI tested two concepts. The first, Concept D (which was taken during trial to mean disposable), concentrated on effective prevention and had as its primary claim that the device 'reduces likelihood of the outbreak of cold sores at first signs.' It was said to be 'the first medical light therapy to help prevent outbreaks when used at the first signs and to shorten healing process of active sores by up to 3 days'. It was said to be designed to be used for up to five cold sore applications. The second, Concept P (which was taken to mean permanent), concentrated on shortening healing time and had as its primary claim that the device 'cuts your cold sore healing time by up to 3 days'. The device was said to be covered by a three-year warranty, which emphasised its durability.

[**178**] The summary of results included that 'the acceptance levels of both concepts are on an average level in the US and in China, in Germany and Japan only below average'. The main strength of the product ideas was said to be the expected shortened healing time (a claim which was on a par with those made for Abreva). The purchase intention was said to be 'rather average' in Germany, the United States and Japan. Both concepts were perceived to be 'very new and different'. The price sensitivity measurement 'shows that the planned prices of both concepts are far beyond acceptance'. The optimum price for the United States was said to be $25, or $30 as a maximum, which contrasted with the planned price of $34.95 for the disposable device and $58.95 for the disposable device. The purchase intention at the planned price for the permanent concept was 'quite low in all countries, a confirmation that the intended price is clearly too high'. The conclusion of the report included that 'Both concepts initiate a low to average purchase intention unpriced … But the planned prices, especially for the [permanent concept] are far beyond acceptance in all countries'. Recommendations included that the 'concepts would only be promising, if there was a possibility to lower the prices to an acceptable level'. Another recommendation was that 'the inconvenient size of the product could be a purchase barrier, as it turned out to be a weakness, especially in

comparison to the currently used products against cold sore'. These findings were against the background that most respondents were satisfied with the product that they had last used and the re-purchase intention for the product used last was 'quite high'.

[**179**] The report provided the detailed findings of the research, which provides additional insights.

(i) Of the United States sample of 2000, 36% (730) suffered cold sores either rarely (28%), often (6%) or very often (2%). These proportions were very similar to those obtained in Germany.

(ii) Of the United States cold sore sufferers (730), 16% suffered from cold sores once every two or three months, 12% once a month, and 7% several times a month (almost always). The remainder of the 730 (567) suffered less often. Again the figures were very similar to those in Germany.

(iii) Episodes of cold sores lasted longer among heavy (frequent) sufferers than among light sufferers, and heavy sufferers in all countries suffered from much more symptoms than light sufferers. Of the 163 sub-group of heavy sufferers in the United States, 90% described their cold sore episodes as either very bothersome or extremely bothersome.

(iv) 61% of cold sore sufferers in both the United States and the Germany sample had treated their cold sore symptoms with medication within the last 12 months. That sub-divided so that 90% of the 163 heavy sufferers and 52% of the 567 less heavy sufferers had treated their symptoms with medication in that period.

(v) 82% of the United States sample of cold sore sufferers and 79% of the German sample perceived the permanent device as being either 'extremely new and different' or 'very new and different'.

(vi) 90% of the cold sore sufferers allocated to the permanent concept regarded it as being either 'much better than' (25%), 'somewhat better than' (49%) or 'just like' (16%) their existing medication, but these views were expressed without having used the device.

(vii) With the permanent concept unpriced, and on the assumption that the price would be acceptable, 52% of the allocated sample said they would definitely or probably buy the device. With an allocated (retail) price of $58.95, 35% of the allocated sample of heavy sufferers said that they would definitely or probably buy the permanent device and a further 16% said they might or might not buy it. These results did not meet BI's predetermined action standards, which required 25% of United States correspondents to say they would definitely buy or 55% to say that they would either definitely or probably buy the device.

Pharmaco

[**180**] The details relating to Pharmaco are contained in the confidential annexe.

The size of the United States market

[**181**] The wholesale value of cold sore treatments sold in the United States in 2012 was $128.3 million. The percentage increase in value in recent years has been 3% (2010), 2% (2011) and 4% (2012). In US$ terms, the market has increased by 85% between 2002 and 2012 and by 16% between 2007 and 2012. The volume of sales in 2012 was 12.6 million packs. That was 2% down on 2011 and 13% down on 2007. During that period, sales of Abreva have increased from 5.8 million packs in 2007 (40% market share by unit sales) to 6.7 million packs in 2012 (53% market share by unit sales). In 2012 Abreva had 74%

market share by revenue. Abreva is marketed by GlaxoSmithKline ('GSK') and retails at around $19, sometimes being discounted. Abreva enjoys patent protection which will run out in 2014. When that happens, the price is likely to fall. It is common ground that a pack of Abreva may be used to treat 2.5 outbreaks. If that is applied as an order of magnitude to the 12.6 million packs sold in 2012, those products could be used to treat about 31.5 million outbreaks.

[**182**] The BI research invites high level inferences about the number of heavy cold sore sufferers in the United States' population of about 314 million. That figure is probably too high a starting point because the BI research was conducted on a sample aged from 16–65 and it is not self-evident that those aged under 16 or over 65 would have the same incidence of cold sores. However, leaving that to one side for the moment, BI's 8% suffering from cold sores either often or very often, if extrapolated to the population level would result in a group of about 25 million. If 16% of those suffered cold sores once every three months, 12% once a month and 7% (say) twice a month, that would suggest that those heavy cold sore sufferers suffered about 94 million outbreaks per year.[18] BI's research indicated that 90% of heavy cold sore sufferers had treated their cold sores with medication over the past 12 months. Even if they had bought only one pack each (and ignoring those lighter suffers who had also used medication), sales of medication should have far exceeded 12.6 million packs in 2012. This reinforces the conclusion that it is not appropriate to extrapolate the BI data to a population of 314 million when attempting to identify the number of heavy cold sore sufferers who might form part of a prospective market for the device.

[**183**] Miss D'Arcy's evidence was that BI started by considering that the market for heavy cold sore sufferers, which is the obvious target market for the device if marketed as a 'permanent' device, was 13 million and that the figure was later revised down to 11 million after release of information by Walmart. Her evidence (which has documentary support on this point) was that Pharmaco also considered the market to be 11 million heavy cold sore sufferers.[19] In an e-mail to BI on 1 February 2012, Miss D'Arcy had referred to a population of 13.25 million recurrent sufferers, that figure being based upon two published papers that are not before the court. She described them as 'the "low hanging fruit" that appear to purchase the device in the initial marketing stages'. She later reduced her estimate to 12.1 million recurrent sufferers on the basis of further information and discussions with BI.

[**184**] Miss D'Arcy also gave evidence that, in terms of volume of treatments sold, the United States market was similar in size to that of the United Kingdom, despite the population of the United States being many times greater than that of the United Kingdom. Her only explanations for this curious equivalence were that the retail price in the United Kingdom is lower than in the United States and that the United States market is less mature because consumers in the United Kingdom have been exposed to cold sore preparations for longer than in the United States. While the price differential would explain a lower take-up in the United States, her evidence about relative maturity is more problematic, not least in the light of the decline in absolute terms in the number of treatment packs sold per annum in the last decade in the United States, which cannot sensibly be attributed to a lack of maturity in

18 (25m x 16% x 4) + (25m x 12% x 12) + (25m x 7% x 24) = 16m + 36m + 42m = 94 million.

19 T6/149.

the market. Her evidence suggests that there should be scope for some expansion of the market with maturity; but the sales figures over the last decade do not suggest that current medications are likely to achieve any dramatic inroads into the untapped market, and support Pharmaco's observation that there is a barrier because not all heavy cold sore sufferers are presently prepared to invest in medication for their problem. There is no reason to believe that the incidence of cold sores in the United States differs markedly from that in the United Kingdom: to the contrary, the evidence of similar incidence rates in the United States and Germany supports the inference that incidence rates in the United States and the United Kingdom will also be similar. I therefore infer that the population of cold sore sufferers in the United States is many times greater than that in the United Kingdom, although I accept Ms D'Arcy's uncontradicted evidence that the volume of cold sore treatments sold is similar in each country.

[**185**] Mr Bell was adamant that the available market should be taken at 12.6 million units per annum. On all the evidence I would agree with him if one was considering the introduction of another 'me-too' product into the market, since a straight-forward 'me-too' product would have no characteristics that might cause additional consumers to enter the market in any numbers. The question therefore arises whether there is anything about the device that might lead to an expansion of the market driven by its introduction. I deal in the next section with the question whether the device is a breakthrough product and conclude that in some respects it is. There is evidential support for the view that introducing the device as a disposable device would lead to attrition of existing sales of less than 100%, which suggests an expansion in the market overall. However, and particularly because of the premium price which forms the basis of LLC's case, I do not consider that LLC has demonstrated a substantial chance that the introduction of the device as a 'permanent' device would lead to significant expansion of the market. According to the BI research, heavy cold sore sufferers who are the target market for the device are already the most likely to be buying medication. While some who are not may be attracted by the new technology that the device offers, the evidence does not justify a finding that those people will be very numerous.

[**186**] On this evidence, I conclude that, although there is a population of about 11 million heavy cold sore sufferers in the United States, a significant proportion are not buying medication or, if they do, are not buying it regularly. The evidence does not establish that introduction of the device would tap into a significant number of those who are at present not buying medication. It follows that the market should be taken as being in the region of 12.6 million packs (or medication for about 31.5 million outbreaks) with some scope for modest expansion on the introduction of the device and as the market matures further.

Is the device a breakthrough product?

[**187**] In order to have the effect of a breakthrough product it is common ground that the device needs to have characteristics that are distinctly different from its competitors and will drive a change in perception and buying habits. When selling into the pharmaceutical market in the United States, the claims that are authorised to be made by the FDA will be vitally important in establishing the product's characteristics. In Mr Boghigian's words: 'Products that cause a paradigm shift are those that offer unique advantages and superior outcomes. A paradigm shift usually involves a new scientific method that

replaces the old.' And 'The key to marketing a drug or medical device successfully, that rises to the top of its class … is to establish the value to consumers and patients. The value proposition is a statement of value that is to be delivered with the product. It is what makes it different and unique from existing competitive products on the market. It explains how this product will help solve a medical need or improve the outcomes. It delivers specific benefits that are quantifiable and reinforces with the customer why they should purchase the product.' I accept the general thrust of this evidence.

[**188**] The medical claims that are authorised by the FDA to be made on behalf of the device fall short of those that were made during the Walgreens on-line trial. The authorised claims about shortening healing time are at best equivalent to those made on behalf of Abreva. In addition, there are medical claims that Abreva can make about mitigation of symptoms (ie tingling, pain, burning and/or itching) that cannot be made on behalf of the device at present. That may reflect the lack of clinical research carried out by 1072/VDL; and Pharmaco's research suggested that further claims might become authorised in the future. But, at present, the device cannot claim to deliver a superior clinical outcome.

[**189**] I bear in mind that, before matters became litigious, both LLC and 1072/VDL believed that the device had real potential as a breakthrough product. It is easy to understand LLC's excitement (which was shared by 1072/VDL) as initial reports and projections came through from Boots in late 2008, and with a favourable deal thought to be all but done with Walgreens. I also bear in mind that 1072/VDL and iSmart have continued to sing the praises of the device in their attempts to get it distributed by others. However, only limited weight can be placed on the parties' early hopes or what has been said, particularly by Ms D'Arcy, about the breakthrough possibilities of the device when trying to sell it. Greater weight is to be given to the objective evidence of the limited market research that has been undertaken and the expert evidence.

[**190**] The feature of the device that is distinctively different is the technology. Having emphasised the need for superior outcomes in his main report, Mr Boghigian continued to maintain that a market for the device could be created on the basis of its unique technology and on the basis of additional claims that could be made without infringing FDA approvals (eg that no subject's cold sore got worse, the prolonged use of the 'permanent' device, there are no side effects, it is portable and easy to use with no messy creams, and it is cost-effective for the heavy user.). Mr Bell relies on evidence of low customer dissatisfaction with current treatments and the lack of distinguishing claims. He also claims support from the research carried out by BI and Pharmaco and the experience of Boots and others in the United Kingdom.

[**191**] I agree that the research carried out by BI and Pharmaco is relevant. To my mind the most relevant findings from the BI research for these purposes were that (a) 74% of the cold sore sufferers allocated to the permanent concept regarded it as being 'much better than' or 'somewhat better than' their existing medication, with 25% considering it to be 'much better than' and (b) at a price of $58.95, 35% of the allocated sample of heavy cold sore sufferers said that they would definitely or probably buy the permanent device. However, (c) the researchers suggested that $25–30 was the optimum price and (d) the size of the device was seen by consumers as a drawback.

[**192**] The Pharmaco research, based on a price of $58.50 for a device providing five applications disclosed that (a) the technology was regarded as a breakthrough, (b) purchase intentions were above average for a device, (c) on

use the device more than met expectations and had strong product performance ratings but (d) the size of the device was again seen as sub-optimal.

[**193**] The Boots experience, where cream-based treatments are cheaper than in the United States, suggests that the device has a place in the United Kingdom market priced at £35 (US$55). Early predictions of sales of 50,000–60,000 units proved unduly optimistic. There is no direct evidence of what sums are spent on marketing. On 6 November 2008 Mr Rothon wrote that Boots intended to announce the device in *The Times*'s health supplement and would release various Boots flyer type promotions to its advantage card clients. On 14 December 2009, Mr Baker wrote to a contact at GSK that the only promotional activity Boots had carried out was a third saving between September and December 2008 and that there had been no recorded promotional activity, although the device was a 'champion brand' for Boots. Ms Pincott was instructed that no significant marketing or brand investment has gone into the promotion of United Kingdom sales. On the available evidence, those instructions were correct.[20] 1072/VDL has incurred no marketing expenditure on the device apart from maintaining its website.

[**194**] In the course of the trial Mr Grodzinski QC offered Mr Bell the analogy of electric shavers being introduced into the wet-shave market. The electric shaver has a distinctive technological edge and avoids the mess of wet shaving, but delivers no appreciable improved outcome in the quality of the shave. Its capital cost is much greater than an individual wet razor, but its longevity equals things out. It has established a place in the market, though it cannot expand the market to any extent. When taxed with this analogy, Mr Bell was initially unwilling to recognise its relevance. While asserting that the nature of the claims that can be made was more important with an FDA approved product than with shaving materials, he eventually conceded that the electric shaver is not a 'me too' product.

[**195**] The picture that emerges from this limited market research and the evidence of the experts is clear. The LED technology is distinctive and new and would be seen by some (though not necessarily all) as beneficial in itself because it avoids the use of creams. It is portable and reasonably discrete to use, though I agree that a person would be unlikely to want to sit using the device for minutes on end in a public place such as a bus, and I regard the suggestion that users might wish to collect devices in different colours as if they were a technological fashion accessory as completely fanciful. The buying intentions disclosed by the BI and Pharmaco market research support the view that the device would have a place in the market, as does the experience of Boots in the United Kingdom. The BI research supports the view that a price well below $59 would be optimal for maximising sales; but the Pharmaco research supports the view that substantial sales could be achieved with a device branded for five applications at that price. I therefore conclude that the device is not a 'me too' product, that it has a potential place in the United

20 Boots were the main and most successful supplier in the United Kingdom: hence my concentration on them. The device was also taken by Mentholatum and Lloyds. Mentholatum invested just under £200,000 in advertising. Lloyds set a lower price than Boots and discounted that price for the first three months. In addition Lloyds ran in store promotions. There is no evidence that Lloyds advertised externally. Neither Mentholatum nor Lloyds have made a long term success of selling the device.

States market, but that it is unlikely to cause a paradigm shift in buying habits that would materially expand the market, at least in the absence of significant expenditure on marketing and brand awareness.

Retail and wholesale pricing

[**196**] LLC has consistently seen the device as a premium product providing a 'permanent' solution, with a price to match, which created an immediate conflict of interest with 1072/VDL for whom lower pricing would mean increased unit sales and £5 royalties under the DLA. It advances its claim on that basis.

[**197**] In a business plan prepared in August 2006, before the trial with Walgreens, LLC projected a wholesale price of $59 and a retail price of $79. After the Walgreen's experience, LLC raised its sights further. On 28 November 2008 Mr Rothon e-mailed Ms Higginson that 'you need to accept that the product has a market value of around $55 max'. Ms Higginson's response was '$55 is ludicrous'. After trenchant criticism of Boots's pricing strategy she explained the reasons why LLC looked to a higher price. There were two main strands to her argument. First, assuming that retailers would want a mark-up of 60% on their wholesale price, a retail price of $55 would represent a wholesale price of $34.40 which was 'not enough for a very basic marketing budget, let alone any profit'. Second, she relayed the advice of Walgreens that the device should launch at $129 and asked the rhetorical question: 'So who's right?'

[**198**] LLC has not deviated from this approach. The spreadsheet that accompanied the initial letter of claim adopted a wholesale price per unit of $53 dollars, that was intended to reflect a retail price of $79, giving the retailer a mark-up of 49%, which is excessive in the light of the agreed expert evidence that a retailer would expect a 35–40% mark-up on the wholesale price. It now advances its claim on the basis of a wholesale price of $59, which would lead to a retail price of $79.65 (35% mark-up) to $82.60 (40% mark-up).

[**199**] LLC submits that the device is cost effective at this price. There are many illustrative permutations that can be adopted. First, if the device is assumed to be good for 50 applications, it could adopt a price multiple of 20 over a pack of Abreva or other medications.[21] On this approach, the device is cost effective retailing at around $80. Second, if it is assumed that the life of the device will be the same as the proposed three year warranty period, a consumer would need to spend just short of $27 per annum before the device became cost effective: this would equate to 1.4 packs of Abreva at present prices, sufficient to treat approximately 3.4 outbreaks of cold sores. The BI research suggests that this would be a cost effective alternative for somewhere between 19 and 35% of cold sore sufferers provided that they were already buying medication regularly, which many do not: see [179](ii) & (iv), above. Once the price of Abreva falls on its losing patent protection, the balance will shift. If it is assumed (as 1072/VDL emphasises) that the device is to be sold as a permanent device, the balance of cost-effectiveness shifts back in the direction of the device once more (though the prospects for repeat sales diminish correspondingly).

[**200**] The price being claimed by LLC is lower than was advised by Walgreens. 1072/VDL submits that no weight can be placed upon the Walgreens trial at all because it was conducted on the basis of false claims.

21 50 device applications = 2.5 Abreva applications x 20.

Mr Boghigian's initial report attributed the sales that were achieved to the claims that had been made, a proposition with which Mr Bell agreed. What is impossible to know is the extent to which the sales were attributable to (a) the claims that would in due course be permissible, (b) the claims that would not be permitted by the FDA clearance, and (c) the technological and non-clinical advantages that may have been perceived by customers. The evidence requires the conclusion that some sales would not have been made but for the inflated claims; but it neither requires nor permits the conclusion that no sales or no significant sales would have been achieved if the Walgreens trial had been conducted on the basis of the FDA-approved medical claims. Similarly, while Walgreens's enthusiasm for the device should be discounted to some extent because it was founded on unauthorised claims, it would in my judgment be unrealistic to discount it altogether. The numbers of units sold were small in absolute terms; but, on the evidence, the device became the bestselling cold sore medication sold on-line with the limited advertising that I have described above. Walgreens know their business and there is no justification for attributing all of their enthusiasm and their assessment of the appropriate price to the unwarranted claims.

[**201**] Mr Bell gave evidence that sales would be adversely affected because the present packaging is ill-suited to presentation in-store on the J-hooks that are typically used by Walgreens (or other major retailers in the United States), and that, because of the premium price, the device would be displayed in secure cabinets (as an anti-theft measure) away from the creams with which it would be meant to compete. I am far from convinced that packaging would be allowed to be an obstacle to successful sales; and, to the extent that he is right about the need to display the device in secure cabinets, I can only assume that Walgreens would have been conscious of that when suggesting a retail price of $129 and that this consideration did not deter them.

[**202**] I accept that, at a retail price of about $80, a reasonable case can be made for the device being cost effective for a heavy cold sore sufferer when compared with the competing creams. The case will still be presentable after Abreva loses its patent protection and comes down in price in and after 2014. The precise take-up is not calculable with mathematical precision, but the BI research in the United States and the Boots experience in the United Kingdom suggest that there are consumers who will pay a premium price for the device.

[**203**] For these reasons, I assess LLC's claim on the basis that the device would have been marketed by LLC at a retail price of $80 (bar 1 cent) and that, while sales would be sensitive to price, this price would not of itself prevent the device from achieving a place in the United States market.

Marketing spend

[**204**] LLC's letter of claim was accompanied by a spread-sheet prepared by Ms Higginson before the involvement of Mr Boghigian or Ms Pincott. The spreadsheet assumed a wholesale price of $53 and projected sales and marketing spend as set out below:

Year	DLA Sched. 4	Units projected	Revenue projected $	Marketing projected $[22]	Marketing as % of Revenue[23]
1	50,000	60,984	3,232,121	650,154	20
2	100,000	121,968	6,464,304	1,286,809	20
3	130,000	158,558	8,403,574	1,669,797	20
4	160,000	195,149	10,342,897	2,053,296	20
5	200,000	243,936	12,928,608	2,565,617	20
6	300,000	365,904	19,362,912	3,833,926	20
7	300,000	408,593	21,655,429	4,282,836	20
8	300,000	439,085	23,271,505	4,599,913	20
9	300,000	469,577	24,887,581	4,916,990	20
10	300,000	487,872	35,887,326	5,107,235	14
Total	2,140,000	2,951,626	156,436,178	30,969,573	20

[**205**] In January 2012 Ms Higginson produced a different version of the spreadsheet adopting $33 as the wholesale price for the device. I accept her evidence that this was an exercise that she undertook to see whether a profit could be made if a wholesale price of $33 (which had been suggested by 1072/VDL) was adopted. The revised spreadsheet projected sales and marketing spend as follows:

22 Website costs + Marketing and MDF + Samples.

23 Rounded to the nearest 1%.

Year	DLA Sched. 4	Units projected	Revenue projected $	Marketing projected $	Marketing as % of Revenue
1	50,000	46,720	1,541,760	643,823	42
2	100,000	93,440	3,083,520	1,177,341	38
3	130,000	140,160	4,625,280	1,524,965	33
4	160,000	175,200	5,781,600	1,619,265	28
5	200,000	192,720	6,359,760	1,308,690	21
6	300,000	202,356	6,677,748	1,204,618	18
7	300,000	202,356	6,677,748	1,110,436	17
8	300,000	197,386	6,513,742	922,442	14
9	300,000	190,675	6,292,275	893,348	14
10	300,000	182,381	6,018,561	704,707	12
Total	2,140,000	1,623,394	53,571,995	11,111,821	21

[**206**] The cover sheet setting out Ms Higginson's assumptions for this version of the spreadsheet appears to suggest that a marketing spend of 42% should be adopted, but it evidently was not. Instead, Ms Higginson adopted a declining rate of marketing spend, which resulted in a decline in the absolute spend from year 6 onwards. The two websites to which the cover sheet referred support a marketing spend of about 20%, one stating that 'retail and pharmaceuticals lead the spending, with many of these companies spending more that 20% of net sales. The overall average is reported to be 4–6%.' As can be seen, Ms Higginson adopted a rate above 20% in years 1–5 and below it thereafter.

[**207**] Ms Pincott, relying primarily upon the expertise of Mr Boghigian, adopted 5% of retail price for MDF,[24] representing the direct contribution to the retailer. In addition, she allowed between $30,000 and $50,000 per annum for website costs and pay per click Adwords campaigns. For promotions and advertising she allowed:

(i) in years 1 and 2: the higher of $2 million or 20% of wholesale price;

(ii) in year 3: the higher of $2 million or 15% of wholesale price;

(iii) in years 4–10: 15% of wholesale price. This was taken on the basis that the use of internet and own-promotion by consumers (such as YouTube) may provide effective yet low cost marketing and brand awareness.

[**208**] LLC's 2006 business plan contemplated a promotion campaign that would include feature articles and product reviews, direct mail to buying

24 Equivalent to 6.875% of wholesale price assuming a wholesale-to-retail mark-up of 37.5%.

groups and advertisements in trade publications, and integration with physician and pharmacist materials, once FDA clearance had been obtained. It contemplated relatively inexpensive short television advertisements through Cable TV networks, focusing on California in the first instance. There is no reference to web-based or e-mail advertising, which probably reflects the relative immaturity of those media in 2006. It projected unit sales, revenues and advertising/promotion spend as follows:

Year	Units projected	Revenue projected $	Marketing projected $	Marketing as % of Revenue
2007	9,900	670,527	83,000	12
2008	40,000	2,709,200	600,000	22
2009	84,000	5,689,320	600,000	10

[**209**] The 2008 opinion of value predicted an initial media blitz and marketing spend of $10 million for years 1 and 2, $6 million for years 3 and 4, and $4 million for year five. Combined selling and administration expenses were projected to be over 48% of all revenues generated for the first five year period and 27.3% for year six and beyond. This level of spend was projected to generate sales in years 1 to 5 of 160,198, 343,334, 492,879, 597,804 and 662,463 units respectively, an aggregate total of 5,175,819 over the five years. Average selling price was projected to be $76 per unit,[25] generating annual sales of over $12 million in year one and rising to $50.3 million in year 5. Ms Higginson's evidence, which I accept, was that the exercise being undertaken by Mr Hall was to look at what a major pharmaceutical company would spend and to see what their costs of capital would be. She accepted that the unit sales figures being projected were in the ballpark of what she would have hoped to achieve if LLC had been in charge of selling the device,[26] but they are well ahead of Mr Boghigian's figures on which LLC's claim is based.

[**210**] It is common ground that there would be a non-linear relationship between marketing spend and achieved levels of sales. There are also a number of reasons that suggest the need for significant marketing expenditure if the device is to catch on in the United States. Those reasons include the dominance of Abreva, which itself is supported by a $20 million annual marketing spend; the likelihood that GSK would move to protect Abreva by retaliatory marketing; the likely fall in the price of Abreva (and its competitor products) when Abreva loses its patent protection in 2014; the relatively low level of dissatisfaction with existing medications; the lack of differentiating clinical claims; the consequential need for advertising to create brand awareness; and the fact that patent protection for the device runs out in 2018, so that the window of opportunity is short.

25 Being the average of the price of goods sold to wholesalers ($70) and direct to retailers ($82).

26 1072/VDL relies upon an answer from Ms Higginson at T3/95.14–17 as meaning that Ms Higginson thought that Mr Hall's estimate of marketing spend was very conservative. I am not convinced that she was referring to marketing spend; rather, I suspect that she understood the question to refer either wholly or in part to the projected sales figures and that her understanding would have been reinforced by the subsequent question.

[**211**] Mr Bell was adamant that it was not feasible to market the device with a soft launch. As he put it, 'in the US market it's not a learn as you go market … The way it works in the US is if you want to be … in 8,000 Walgreens' stores, that you need to meet minimum hurdle rates', which he identified as a turnover rate of approximately seven units per store per annum (or 56,000 units for 8,000 stores). His experience was that it was a complete misconception for a small manufacturer to think that it could spend a little on marketing and 'learn as you go'. His opinion was that a marketing spend of $20 million per year for the first four years would be required to persuade a relatively limited number of consumers to pay even $30 in any significant numbers. Such expenditure is clearly not feasible on the projections being put forward by LLC. Even if it was, Mr Bell considers the model of a 'permanent' device to be doomed because each sale will remove the purchaser from the market, thereby shrinking it permanently for the future.

[**212**] Mr Boghigian's directly relevant experience was of bringing to market a product to compete with Aleve (a pain relief treatment for osteoarthritis). The intention was to acquire 5–7% market share in 12–18 months with what he regarded as a 'me-too' product against a well-established market leader. The marketing spend was substantial, and measured in millions of dollars. The projected revenue from a 5–7% market share is not known.

[**213**] The parties have not attempted to calculate what percentage of the 2012 market (measured by unit) would be represented by the various sales projections that have been advanced by LLC. It is not possible to make a unit-based comparison since it is not known how many individual cold sore sufferers contribute to the 12.6 million units sold; it is therefore impossible to determine how many of those unit sales would be eliminated by each purchase of the device. Furthermore, while I reject Mr Bell's evidence that the sale of a device should be regarded as taking that consumer out of the market permanently, no exact alternative period has been established on the balance of probabilities. My instinct is that purchasers of the device would on average be taken out of the market for about three to four years, allowing for loss, breakage or other possible reasons for replacement: but that is no more than instinct informed by the evidence that has been presented. What is clear is that sale of a 'permanent' device is intended to and would take the consumer out of the market for a period that should be measured in years.

[**214**] In these circumstances, the only estimate that can be made is of projected revenue from sales of the device as a proportion by value of the 2012 market value of $128.3 million. This will give some insight into the impact of the projected sales on the market, but does not provide an accurate reflection of market share. Subject to those constraints, and assuming a wholesale price of $59 for the device, the projected sales represent the following % by value of the 2012 market:

Year	DLA Sched. 4	Lower Range	Upper Range	Claim Letter
1	2.3	4.5	4.5	2.5
2	4.6	9.5	14.0	5.0
3	6.0	10.9	16.2	6.5
4	7.4	13.8	13.8	8.1
5	9.2	13.8	13.8	10.1
6	13.8	13.8	13.8	15.1
7	13.8	13.8	13.8	16.9
8	13.8	13.8	13.8	18.1
9	13.8	13.8	13.8	19.4
10	13.8	13.8	13.8	28.0

[**215**] When viewed overall, the evidence points in the direction of a marketing spend of at least 20%, for a number of reasons. First, the Boots experience shows that, in the absence of any substantial marketing, the device can maintain a position in the market but not make substantial inroads. Second, given the market dominance of Abreva, a soft launch is not feasible for the device: it is necessary to create some brand awareness. Third, the device will be in competition with Abreva which is supported by an annual marketing spend of $20 million or about 20% of revenue. Fourth, it is likely that if the device were to make inroads in the market in competition with Abreva to the extent indicated by any of the illustrative projections in [214], above, GSK would retaliate with additional marketing to shore up its market leader. Fifth, the figures in the Hall opinion of value are of some interest. That opinion projected much more aggressive unit sales into a market that in 2008 was considerably smaller in value than it was in 2012, and the wholesale price being suggested ($70) was higher than now suggested by LLC's claim. In those circumstances expenditure of 48% of revenues in years 1 to 5 and 27.3% for years six and beyond is understandable. It does not support the need for equivalent percentage expenditure in support of the figures being projected by LLC's claim, still less the suggestion that a minimum spend of $20 million per annum for four years is necessary. Sixth, Ms Higginson's selection of 20% expenditure when compiling the spreadsheet for the letter of claim may be taken as her view of the minimum marketing spend that could realistically be advanced in her claim document. Seventh, there is some documentary support for marketing spend in excess of 20% on product launches in the pharmaceutical industry. Eighth, when Ms Higginson reviewed her letter of claim spreadsheet to see if she could work the figures so that LLC would make a profit on the basis of a $33 wholesale price, she maintained roughly comparable sums of marketing expenditure for the first three years, although that led to the percentage of revenue being spent on marketing being markedly increased, which suggests that she recognised the need for an irreducible

minimum spend in the early years. Ninth, the working assumption on which LLC's claim is based is that, in addition to LLC's marketing spend, it will have a substantial partner (such as Walgreens was intended to be) which will contribute to the presentation of the device to the public.

[**216**] On the basis of this material, I have come to the conclusion that, for there to be a realistic prospect of a successful launch and subsequent promotion of the device, budgeted marketing spend would have to be in excess of 20% of wholesale revenues. Ms Pincott's adoption of the higher of $2 million or 20% for years 1 and 2, in addition to which there is an additional 6.875% of wholesale price contributed by MDF and $30,000 to $50,000 for other marketing costs appears realistic. If the device makes headway, I consider that it will be necessary to continue to support it at such levels, because of the need to continue to build market awareness in the face of Abreva and GSK's likely response to the device's success. It is therefore necessary to budget for the higher of $2 million or 20% of wholesale revenues in addition to MDF and the other marketing costs throughout years 1 to 10.

[**217**] In her calculations, Ms Pincott assumed that the device would be launched 12 months after FDA clearance. I consider that may be pessimistic since LLC would have taken steps to line up a deal before clearance was obtained and the only necessary delay to the launch after FDA clearance was about three months to ensure compliance with the conditions of clearance. I bear that in mind while accepting Ms Pincott's assumption for the purposes of calculation.

Other costs of sales

[**218**] There is a measure of agreement on other costs of sales, but some matters remain in dispute.

(i) Cost of goods: In 2009 LLC obtained a quote of $10.65 per device for an order of 150,000, reducing to $10.03 per device for an order of 1,000,000. In February 2012, Ms D'Arcy told BI that the cost per device would be $7.20 for 500,000 units. In September 2012, BI proposed that Pacer should supply at $8.40 per device for quantities under one million: Pacer's reaction is not known. There is reference elsewhere to a price of $4 being feasible for a quantity of 500,000. Ms Higginson gave evidence that she considered that LLC could have got the cost of goods down to $7 per device, with which Ms D'Arcy felt she had to agree. On all of this evidence, it is clear that there are likely to be economies of scale that effect the price and that the quote obtained in 2009 does not appear to be the lowest price that could have been obtained for a launch in 2013. Viewed overall Ms Pincott's approach of taking $10 as a starting point and reducing by $0.25 per annum for economies or downward competitive pressures appears reasonable.

(ii) Shipping and administration: Ms Pincott took $1 per device. There does not appear to be any validation or justification for that figure. I would adopt $1.50 per device shipping and administration as included in the Hall opinion of value.

(iii) The royalty payment to 1072/VDL: the expert accountants have agreed the £5 royalty under the DLA at $8 per device. The terms of the DLA were very beneficial to 1072/VDL and it is unlikely in the extreme that it would have agreed to a lower royalty being substituted.

(iv) LLC negotiated with iSmart that they would be paid 5% of the difference between revenue and cost of goods for the first three years of sales.

(v) Retailers' mark-up: 37.5% on wholesale price, which is the mid-point of the typical range in the United States.

(vi) Tooling costs as included in Ms Pincott's report are agreed.

(vii) Salaries: in her report, Ms Pincott included salaries for the directors in her valuation of Mr Boghigian's projections. She did this because it is standard practice to do so when valuing a business. There is no reason to depart from this approach when dealing with the volumes projected by Mr Boghigian. If volumes had been at or about the level required by Schedule 4 of the DLA, unit sales would have been about 20% down on the Boghigian projections.[27] Although salaries would not be a true variable, it is reasonable to assume that salaries would not have been as high with the lower unit sales as with the Boghigian projections. I would therefore apply a reduction of 15% to the Boghigian salary projections when calculating salaries for the Schedule 4 projections.

(viii) Company cars: Ms Pincott did not include the cost of company cars in her original report. Ms Higginson included provision in her spreadsheet to accompany the letter of claim (which projected sales well above Mr Boghigian's lower range) but not in her later spreadsheet which projected a much more stringent regime. No direct evidence was given about whether or not company cars would be purchased and I suspect that it would depend at least in part on how profitable the business proved to be. The best assessment I can make is to include 50% of the provision made by Ms Higginson in her letter of claim spreadsheet.

(ix) Insurance costs: the version of Ms Higginson's spreadsheet that accompanied the letter of claim included 'General Business Insurance' at $6,000 per annum, which is plainly inadequate for all insurances for a business of this type. A much larger allowance was included in the second version, which was said to be for 'General business and product liability insurance'. Ms Pincott included in her report provision which she said was based on statements for liability cover of $10m, based on information provided by Ms Higginson. I accept the provision adopted by Ms Pincott after her discussion with Ms Higginson.

(x) Other overheads and costs were taken by Ms Pincott from the second version of Ms Higginson's spreadsheet. 1072/VDL submits that where the second version adopts lower costs than the first, it should be ignored since it was the product of Ms Higginson massaging figures. However, Ms Pincott reviewed the figures and was prepared to endorse them; and I do not consider it to be self-evident that there was no 'fat' in the figures put forward in the first version of the spreadsheet. Mr Holland supports the adoption of the figures from the first version. I note that the second version of the spreadsheet projected fewer unit sales than the first, and also that the projected sales in the first version were broadly similar to the quantities required by Schedule 4 of the DLA and lower than the sales projected by Mr Boghigian's lower estimate for years 1–5. Thereafter they were significantly higher than those estimated by either of Mr Boghigian's estimates or those required by Schedule 4. With these variables, I do not consider that the estimates in the first version can be regarded as being set

27 Boghigian: 2,343,858; Schedule 4: 1,840,000: see Schedules supplied by accountants after hearing.

in stone to the exclusion of those in the second. In my judgment a reasonable and proportionate response is to split the difference where differences exist.

(xi) The experts agreed that there should be a 12% compounded annual discount, representing a 5% discount for accelerated receipt and a 7% discount that they would apply in a valuation of the prospective business if it was being conducted by an established pharmaceutical company. This approach is conventional when carrying out a net present value calculation assessing the future performance of a business. Any other risk associated with LLC's not being an established pharmaceutical company falls to be considered later as contributing to the risk that it would not succeed in bringing the business to success.

A real or substantial chance?

[**219**] I have held that the device is not a 'me too' product, that the technology is distinctive and new and that it has a potential place in the market while being unlikely to cause a paradigm shift in buying habits that would materially expand the market in the absence of significant expenditure on marketing and brand awareness. At present it is and remains the only device which has FDA approval, and has patent protection until 2018. I recognise that if the scale of sales achieved during the Walgreens online trial and by Boots (which I regard as the most relevant sources of data relating to actual sales) were replicated, LLC would fail to achieve the DLA sales targets and the venture would not be profitable for LLC or 1072/VDL. However, I consider that there are solid reasons for concluding that LLC had a real or substantial chance of making a success of the launch and subsequent marketing of the device, making the assumptions as to pricing and costs identified above.

[**220**] The sales targets in Schedule 4 of the DLA were negotiated at arm's length and represented the parties' reasonable assessment in July 2006 of what would be achievable. By then, they had been in association since 2002 and the initial date for FDA clearance in 2004 had passed without their being anywhere near ready to make a submission. Only limited weight can be attributed to this assessment, since it predated either the Walgreens's trial or any sales through Boots. However, apart from the dispute about pricing, there is no evidence that either party later considered the DLA sales targets to be unrealistic; and there is no evidence that 1072/VDL was simply sitting back waiting for LLC to fail with a view to recouping damages for breach of the DLA targets.

[**221**] It was central to LLC's thinking that the launch would be in conjunction with a major partner. That could be either a retailer such as Walgreens or a major pharmaceutical company. LLC's formulation of its claim on quantum assumes wholesale sales to a retailer, which I accept as being the more likely option; but it does not follow that it was the only one. While the evidence shows that the deal that LLC thought it would conclude with Walgreens before the intervention of Tyrell was favourable to an extent that was unlikely to be repeated, I see no reason why a major retailer should not conclude that the device should be stocked, particularly in the light of Mr Bell's evidence that if targets were not met, the device would be delisted and unsold stock returned, thereby minimising the risk to the retailer. Although the evidence is sparse, not least because 1072/VDL have been pursuing other options since termination of the DLA, there is evidence that Walgreens has not lost interest in the device, to the extent that its interest in taking it on may be

rekindled. And if, during the period from termination of the DLA to FDA clearance and beyond, Walgreens had proved unreceptive, there are other major retailers who I am confident that LLC would have approached.

[**222**] It is possible to put the DLA sales targets and other projections into context by considering the turnover of stock that would be required if the device were to be stocked in 8,000 Walgreens's stores. To achieve the DLA first year requirement, the stores would have to sell just over six devices per store. That may be compared with Walgreens's standard requirement of 6.98 turns of inventory and with Boots's experience of turning over about 9–10 devices per store per annum at a lower price but without any significant marketing spend or promotion.

[**223**] Sales are obviously price sensitive, but the proposed retail price of $79.99 would not be prohibitive, for the reasons discussed above. In particular, I take into account (a) Walgreens's view in 2008 that the device should sell in store for over $120, (b) the BI research indicating take-up by 35% of heavy sufferers at a retail price of $58.95, (c) Pharmaco's projections of sales generating $58 revenue per device, and (d) Boots's levels of sales achieved without significant marketing spend or promotion.

[**224**] For the purposes of illustration and considering whether there was a real and substantial chance of success, I have assumed total marketing spend in excess of 27% of wholesale revenues, which provides significant differentiation from the United Kingdom experience. There remains the risk, as advocated by Mr Bell, that this level of marketing spend would prove too lean. While I have no hesitation in rejecting his evidence that an initial spend of $20 million per annum was required, I accept that there is risk associated with the lower level of marketing spend that I have adopted.

[**225**] Pharmaco's market research indicated that consumers who tried the device felt that it more than met their expectations. That is consistent with the BI research indicating that 74% of the cold sore sufferers allocated to the permanent concept thought it better than their existing medication and that, subject to price, 52% would be inclined to buy it.

[**226**] Ranged against these features, there is the possibility that LLC might have failed to find a partner, though I think this unlikely. Launching the device into a market so dominated by Abreva would clearly risk retaliation from GSK. Furthermore, given that the device was to be sold as a permanent device, unit sales would have the effect of taking their purchasers out of the market for a period of years, though not permanently as Mr Bell contended. Maintaining sales at 13.8% of the 2012 market by value would be a significant task and one which is likely to be dependant upon the marketing spend and presentation of the device creating significant brand awareness. Although it is a significant task, it is not one that takes the entire business plan from the realms of having a real or substantial chance of success into the realms of the purely speculative or fanciful. There is also the fact that, if LLC failed to achieve the DLA Sales Targets, 1072/VDL would be entitled to terminate in accordance with the terms of the DLA. However, even this is not straightforward because the royalty provisions of the DLA were very favourable to 1072/VDL so that, if they removed LLC, they could not expect to replicate them. It would therefore not be obvious that every failure to meet the sales targets would result in termination. That said, the risk of termination is a risk to be taken into account.

[**227**] Attempting to balance all the considerations that have been advanced on either side, and adopting the assumptions as to pricing and costs that I have

set out above, I have concluded that there was a real and substantial chance that LLC would have achieved the DLA Schedule 4 sales targets for North America, whether by sales in the United States alone or in Canada as well. I do not consider that Mr Boghigian's upper range was realistic in years 2 and 3, but I do consider that there was a real and substantial chance that his lower range predictions would have been achieved, though the predictions are more aggressive than the DLA Schedule 4 sales targets[28] and the chance was accordingly less good. Similarly, I consider that the projections in Ms Higginson's first spreadsheet were realistic for years 1 to 5, but not thereafter.

[**228**] Discounting to reflect the risks of failure is necessarily imprecise. In addition to the agreement of the experts that there should be a 12% annual compound discount, further reductions require to be made to reflect the additional risks attributable to the device being launched by LLC rather than by a major pharmaceutical company. The parties made broad brush submissions on this point, with LLC submitting that there should be no substantial reduction because it would be launching a patented device for which there is a ready market with the benefit of FDA approval. To the contrary, 1072/VDL submits that LLC's prospects require a very substantial discount because of the risks inherent in a small business launching a start up product in the face of likely opposition from a dominant market leader backed by the financial might of GSK.

[**229**] I have found that there is substance in the concerns expressed by Mr Bell and 1072/VDL, even though I have not accepted the full force of his evidence and their submissions. The DLA Schedule 4 requirements, Mr Boghigian's projections and years 1 through 5 of Ms Higginson's first spreadsheet all involve annual increments in the early years, with Schedule 4 and Mr Boghigian settling thereafter on 300,000 units per year. In a perfect world, the evidence might permit individual assessments of the risk of success or failure in each year, which could then be valued. However, the evidence in this case does not permit so detailed an approach. Also, in a case such as this where there are so many variables, it would give spurious accuracy to try to attach individual discount rates to individual risk factors, and I will not do so. Two points need to be clarified. First, because of a combination of the annual increments in the early years and the fact that sales of a 'permanent' device will have an effect on future sales by taking people out of the market, the risk of failing to meet the various projections increases with time. Second, a conclusion that LLC had an X% chance of meeting a projection as a whole is of itself uninformative about where and to what degree the risks may lie along the time-line of the projection. In general terms, and taking into account the first point just made, if LLC had an X% chance of meeting a projection as a whole, it implies that it had a better than X% chance of achieving the projection up to an earlier point, since the risks of failure in each period are cumulative in leading to the conclusion that the overall prospect of reaching the end of the projection is X%.

[**230**] An illustrative analogy might be given by comparing (a) the binary outcome in *Hall v Meyrick* [1957] 2 All ER 722, [1957] 2 QB 455 where, if proper advice had been given, the deceased may have expressed his will as being made in contemplation of marriage rather than leaving his widow to claim under

28 By the following factors: Year 1—95%; year 2—106%; year 3—82%; year 4—86%; year 5—50%: see [214], above.

intestacy rules and (b) the more complicated outcome that would in theory arise if, say, a sportsman were prevented from competing in a tournament where, in addition to the prize for the winner, progressing through each round would lead to increased recovery of prize money. In *Hall v Meyrick* there was only one chance to be assessed, namely the chance of the will being appropriately changed; but the sportsman may lose an A% chance of progressing to the second round, a B% chance of progressing to the third, and so on until, finally, he has lost an X% chance of winning the final.

[**231**] LLC submits that the *Allied Maples* approach does not work by compounded discounting. That is, in my judgment, an oversimplification. What the court is doing in such cases is assessing the value of the chance that a claimant has lost. Where the lost chance is binary there is no obvious place for compounded discounting; but where, as here, what is being assessed is the current value of the loss of the chance of the business succeeding, there is no principled reason to reject outright the conventional approach to such an evaluation—and the experts have agreed that it is appropriate to adopt that approach, at least to the extent of the 7% annual discount that would attach if the device were being launched by a major pharmaceutical company. While I accept that the application of the *Allied Maples* approach normally results in the adoption of one overall figure representing the value of the chance of achieving a particular outcome, it seems to me that it is informative to have regard to the effect that compounded discounting at given rates would have if, for example, the experts had been able to agree on an appropriate rate to reflect LLC's risks. To that end, the table set out below, which is derived from Ms Pincott's schedules, illustrates the effect of discounting at 5%, 12% and 25% compound,[29] by setting out the resulting discount factor year on year.

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	Yr 11
5%	0.9294	0.8852	0.8340	0.8029	0.7646	0.7282	0.6936	0.6605	0.6291	0.5991	0.5706
12%	0.8437	0.7533	0.6726	0.6005	0.5362	0.4787	0.4274	0.3816	0.3407	0.3042	0.2716
25%	0.7155	0.5724	0.4579	0.3664	0.2931	0.2345	0.1876	0.1501	0.1200	0.0960	0.0768

[**232**] Further illustrative assistance can be derived from Ms Pincott's schedules. Applying a 5% annual compound discount leads to a discounted net profit over a projected period of production of ten years in the order of 68% of undiscounted net profit.[30] Applying 12% leads to a discounted net profit over the same period which is in the order of 41% of undiscounted net profit.[31] Applying 25% leads to a discounted net profit over the same period which is in the order of 20% of undiscounted net profit.[32] The precise figures will vary depending upon the variables that are adopted when computing undiscounted net profit. That said, these illustrative figures help in providing some information about how relative risks impact upon prospective net profit.

[**233**] Subject to the risk of termination, the conclusion I would reach would be that the value of LLC's lost chance of achieving the Schedule 4 Sales Targets

29 The figures for 5 and 12% are taken from Ms Pincott's supplementary schedules filed after the hearing. The figures for 25% are taken from F2/451. Mr Holland's figures are marginally different, reflecting different start dates; but the differences are immaterial.

30 25,096/37,305 = 67.69%: see Ms Pincott's Supplementary Appendix 4.1a with 5% discount.

31 15,245/37,074 = 41.12%: see Ms Pincott's Supplementary Appendix 4.1a with 12% discount.

32 12,074/59,035 = 20.45%: see F2/451.

in their entirety is fairly represented by discounting their full value by in the region of 60% and that their prospects of achieving Mr Boghigian's lower rate projections were slimmer than that, because of the more aggressive projections in years 1–5. While I accept the force of LLC's submissions about the advantages enjoyed by the device when coming to be launched, the considerations that drive LLC's chances down to this level are primarily: (a) LLC's lack of an established track record or financial muscle and the consequential need to find a suitable partner; (b) the start up nature of the business; (c) the difficulties inherent in tackling Abreva; (d) the possibility that the provision for marketing that I have made will prove insufficient; and (e) the difficulties caused by the effects of the device being 'permanent'. They mean that a substantial further discount is required over and above the discounts agreed by the experts. Taking into account all of the risk factors that have been discussed in this judgment that are attributable to the fact that it was LLC running this start up business, I draw some comfort in assessing the *Allied Maples* discount from the fact that a discount in the region of 60% is the same order of magnitude as a further 12% annual compounded discount. That is not determinative but seems to be within a reasonable range when added to the 7% already built into the experts' agreed position by reference to a major pharmaceutical company.

[**234**] The risk of termination needs to be brought into consideration when valuing the lost chance because, if 1072/VDL terminated, no further profits would be made by LLC, which is not taken into account in the figures calculated by the accountants. Once again, any pretence of mathematical precision would be spurious. Conceptually, the solution is clear: if in year 1 there is an X% chance that LLC would not meet the Schedule 4 sales targets, there would be a Y% chance that 1072/VDL would terminate the DLA so that the only profits that LLC could make would be those made in year 1.[33] Assuming that the risk of failing to meet the sales targets is constant and cumulative year on year (which is by no means certain), a further process of compounded discounting could be applied to assess the chances that LLC would survive to have the opportunity to meet the sales targets in each successive year. In the absence of any expert evidence to assist the court in determining what further rate of discount would be appropriate I can only observe that my progress so far takes account of two compounded discounts for the risk of failure, namely the experts' 7% compound per annum and my further discount in the region of 60% which approximates to a further 12% compound per annum; and that the mathematical application of further compounded discounting for the risk of termination at a level approaching 20% per annum would substantially reduce LLC's net recovery.

[**235**] In this fluid and unsatisfactory state of affairs, I repeat that I do not consider that there is scope for mathematical precision either in relation to my initial discount or in relation to a further discount for the risk of termination. I remain of the view that LLC had a substantial chance of success for which it should be compensated. Taking into account all of the considerations I have set out above, I assess LLC's prospects as being fairly represented by reference to discounts of 70% (for the Schedule 4 projections) and 80% (for Mr Boghigian's lower rate projections). Viewed another way, I assess that LLC's prospects of

33 Y is probably less than X for the reasons already given at [226], above.

achieving the Schedule 4 projections were 50% better than its prospects of achieving Mr Boghigian's lower rate projections, largely because of Mr Boghigian's more aggressive projections in the early years.

[**236**] For the avoidance of any doubt, in reaching these conclusions I have taken into account 1072/VDL's submission that the evidence relating to Pharmaco shows that it is wrong to conclude that LLC had any real or substantial prospects of making a profit or complying with the requirements of Schedule 4. While I accept that Pharmaco and LLC are in very different positions, both in relation to their position in the market and in their view of how the device could or should be marketed, I consider that Pharmaco's continued interest in the device lends some support to LLC's case that there is a real future for the device as it has projected.

[**237**] The experts have agreed that applying the assumptions on 'Other Costs of Sales' that I have set out above to the Schedule 4 projections lead to a loss of profit of $4,637,000, which being discounted by 70% gives a figure of $1,391,100; while Mr Boghigian's lower rate projection leads to a loss of profit of $10,795,000, which being discounted by 80% gives a figure of $2,159,000. These figures are not identical, which is to be expected—not least because the assessment of loss of a chance is necessarily imprecise. Also, to my mind, it is not to be expected that the chances of two different outcomes will lead to the same valuation, since a claimant's prospects of achieving one outcome may be more valuable than its prospects of achieving another. In the event, the two outcomes are not so far apart as to cast doubt on the process that has led to them: discounting Mr Boghigian's lower rate projections by 85% would have led to a figure of $1,619,250 which, to my mind, is surprisingly close to the discounted Schedule 4 projection, and I have resisted the temptation to adjust the discount factors that I had settled on before knowing how the figures would turn out.

[**238**] Allowing for the necessary imprecision of the process and the figures it has produced, it would not be sufficient simply to take the higher figure as the appropriate figure for damages. Instead, the court's overall assessment of the value of the chance lost by LLC should adopt a figure in between the two but towards the higher end of the range, reflecting the fact that both calculations indicate the loss of substantial value but that the figure based on Mr Boghigian's projection indicates a loss approaching that figure.

[**239**] On this basis, I conclude that an appropriate award of damages adopting the principles established by *Allied Maples* is $1,900,000. I then stand back and consider separately whether this appears overall to be a reasonable sum to award for the loss of a relatively speculative prospect of achieving very high returns. To my mind, it is reasonable.

Alternative formulations

[**240**] If 1072/VDL had managed before FDA clearance to find a partner who was interested in marketing the device on a global or multi-national scale it may have been in their interests to renegotiate the DLA so as to give the new partner access to the United States (and, possibly, other territories covered by the DLA). Valuing LLC's business for the purpose of renegotiation would have been as difficult and imprecise then as it is now, but the fact that 1072/VDL wanted to renegotiate in such circumstances would of itself give LLC some leverage. Conversely, if LLC had lost the will or the means to continue under the DLA, 1072/VDL would have been in a strong position because of the £5 royalty provision. Although some discussions were carried out between LLC

and Ms D'Arcy they had not advanced to an extent that makes the outcome of those discussions predictable; nor do they enable the court to determine what royalty payments may have been agreed in all or any of the possible permutations of fact that might have led to negotiations. For these reasons, I consider that LLC's claim is better assessed as set out above and do not feel compelled to try to conjure a figure on this alternative basis.

[**241**] Given my findings on LLC's primary claim it is also not necessary for me to consider LLC's alternative formulation of a claim for wasted expenditure, and I do not do so.

Interest

[**242**] The accountants agreed calculations of interest for the Schedule 4 and Boghigian projections each of which approximated to 4.25% overall to the end of December 2013. Applying that rate, interest on an award of $1,900,000 is $80,750. That figure may require adjustment because of the date on which this judgment is delivered.

CONCLUSIONS ON ISSUE 5

[**243**] Issue 5.1: there is a substantial chance that it would have sold the number of units predicted by Mr Boghigian's lower range.

[**244**] Issue 5.2: the retail price would have been $79.99 which would have given the retailer a 37.5% mark-up on the wholesale price.

[**245**] Issue 5.3: the costs of sale per unit would have been as summarised at [218], above and as set out in the agreed calculations provided by the experts.

[**246**] Issue 5.4: the required level of annual marketing spend was (a) the higher of $2 million or 20% of wholesale revenue plus (b) MDF at 5% of retail or 6.875% of wholesale revenue plus (c) $30,000–50,000 for other marketing costs.

[**247**] Issue 5.5.1: the device is not a 'me too' product. The medical claims that can be made about shortening healing time at present are at best equivalent to those made by Abreva, and there are claims that Abreva can make that are not presently open to the device. The technology is distinctively different and the device has a place in the United States market without being likely to cause a paradigm shift in buying habits that would materially expand the market in the absence of significant expenditure on marketing and brand awareness.

[**248**] Issues 5.5.2, 5.5.3 and 5.5.4: the sales data for Walgreens, the sales data for Boots and the market research studies provide evidence that is relevant to determining the viable price point for the device, for the reasons set out above. I have taken into account data about other sales in the United Kingdom and in Europe but do not find that they provide valuable insights into what may happen in North America.

[**249**] Issue 5.5.5: the available market is to be calculated by reference to the 12.6 million units sold in 2012 allowing for modest expansion attributable to (a) further maturing of the market and (b) the prospect that the device might lead to a slight increase in the numbers of those entering the market.

[**250**] Issue 5.6: LLC had a 40% chance of complying with the sales targets set out in Schedule 4 of the DLA and lesser chance of achieving Mr Boghigian's lower rate projections. However, the effect of the termination provisions in the DLA requires to be reflected in the overall assessment of LLC's chance of making its projected net profits. I therefore assess damages by reference to the

a Schedule 4 targets discounted by 70% and Mr Boghigian's lower rate targets discounted by 80%. In the result I assess damages in the sum of $1,900,000 with interest to be added in the sum of $80,750.

[**251**] Issue 5.7: not determined.

[**252**] Issue 5.8: not determined.

b *Claim allowed.*

Andrew Moroney Barrister