Court File No. CV-16-11358-00CL

***ONTARIO***
**SUPERIOR COURT OF JUSTICE**
**COMMERCIAL LIST**

IN THE MATTER OF THE *COMPANIES' CREDITORS ARRANGEMENT ACT*, R.S.C. 1985, c. C-36, AS AMENDED

AND IN THE MATTER OF A PLAN OF COMPROMISE OR ARRANGEMENT OF FIRSTONSITE G.P. INC.

Applicant

# BOOK OF AUTHORITIES OF THE APPLICANT

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Ontario Superior Court of Justice

1455202 Ontario Inc. v. Welbow Holdings Ltd.

2003 CarswellOnt 1761, [2003] O.J. No. 1785, [2003] O.T.C. 396,
122 A.C.W.S. (3d) 932, 33 B.L.R. (3d) 163, 9 R.P.R. (4th) 103

# 1455202 Ontario Inc. (Applicant) and Welbow Holdings Ltd. and Bowdek Holdings Ltd. (Respondents)

Cullity J.

Heard: April 14, 2003
Judgment: May 8, 2003
Docket: 03-CV-245995CM3

Counsel: Christopher E. Reed for Applicant
Sharon M. Addison for Respondents

Subject: Property

**Headnote**

**Landlord and tenant — Assignment of lease — Covenant restricting assignment — Reasonableness of withholding consent**

Tenant operated cafe and bar in leased premises — Tenant received offer to purchase business and sought landlord's consent to assignment of lease to purchasers — After long negotiations, landlord withheld consent on grounds that proposed assignee did not have history of successful business operation and insufficient evidence had been provided to determine assignee's net worth — Landlord also gave as grounds that there was material risk that assignee would not be able to successfully carry on business and, generally, that insufficient information had been provided to permit it to make determination concerning any of these matters — Tenant applied for determination that landlord had unreasonably withheld consent to assignment — Application dismissed — Landlord based reasons for withholding consent on conditions in three clauses in lease — Ability of proposed assignee to carry on business successfully was inferentially addressed in two of conditions and ability to provide financial backing for its obligations was addressed in third condition — These three conditions should be considered as defining and delimiting grounds on which landlord could reasonably withhold consent to assignment in so far as these attributes of assignee were concerned — Court should be slow to substitute its judgment for business judgment of landlord — Sufficiency of assignee's business experience was recurring theme throughout negotiations and there was nothing to suggest that landlord did not conduct negotiations in good faith — Information provided by tenant as to assignee's business experience was extremely cursory — Landlord was entitled to seek such information and when it was not forthcoming, to base its decision on totality of information it did receive — In circumstances, tenant had not discharged its burden of proving that withholding of consent was unreasonable.

**Table of Authorities**

**Cases considered by *Cullity J.*:**

*Ashworth Frazer Ltd. v. Gloucester City Council* (2001), [2002] 1 All E.R. 377, [2001] W.L.R. 2180 (U.K. H.L.) — referred to

 

*Bickel v. Duke of Westminster*, [1976] 3 All E.R. 801, [1976] 3 W.L.R. 805, [1977] Q.B. 517 (Eng. C.A.) — referred to

*Bromley Park Garden Estates v. Moss*, [1982] 2 All E.R. 890, [1982] 1 W.L.R. 1019 (Eng. C.A.) — referred to

*Dominion Stores Ltd. v. Bramalea Ltd.*, 38 R.P.R. 12, 1985 CarswellOnt 736 (Ont. Dist. Ct.) — referred to

*Federal Business Development Bank v. Starr*, 41 R.P.R. 151, 55 O.R. (2d) 65, 28 D.L.R. (4th) 582, 1986 CarswellOnt 685 (Ont. H.C.) — referred to

*Jo-Emma Restaurants Ltd. v. A. Merkur & Sons Ltd.*, 7 R.P.R. (2d) 298, 1989 CarswellOnt 612 (Ont. Dist. Ct.) — referred to

*Pimms Ltd. v. Tallow Chandlers in London (City)*, [1964] 2 All E.R. 145, [1964] 2 Q.B. 547 (Eng. C.A.) — referred to

*Shields v. Dickler*, [1948] 1 D.L.R. 809, [1948] O.W.N. 145, 1948 CarswellOnt 134 (Ont. C.A.) — referred to

*Slanly v. Ward* (1913), 29 T.L.R. 714 (Eng. C.A.) — referred to

*Sundance Investment Corp. v. Richfield Properties Ltd.*, [1983] 2 W.W.R. 493, 24 Alta. L.R. (2d) 1, 27 R.P.R. 93, 41 A.R. 231, 1983 CarswellAlta 4 (Alta. C.A.) — referred to

*Town Investments Underlease, Re*, [1954] Ch. 301, 18 Conv. & Prop. Law. 201 (Eng. Ch. Div.) — referred to

*Welch Foods Inc. v. Cadbury Beverages Canada Inc.*, 2001 CarswellOnt 747, 140 O.A.C. 320 (Ont. C.A.) — referred to

*Whiteminster Estates v. Hodges Menswear* (1974), 232 E.G. 715 — referred to

*Zellers Inc. v. Brad-Jay Investments Ltd.*, 2002 CarswellOnt 3128 (Ont. S.C.J.) — referred to

**Statutes considered:**

*Commercial Tenancies Act*, R.S.O. 1990, c. L.7
s. 23 — considered

APPLICATION by tenant for determination that landlord had unreasonably withheld consent to assignment of lease.

***Cullity J.*:**

1 The sole issue in this application is whether the Landlord has unreasonably withheld its consent to an assignment by the Applicant (the "Tenant") of its lease of space (the "Premises") at 56 Wellesley Street West, Toronto. The lease expires on August 31, 2005. The Tenant has an option to renew it for a further period of 10 years at a current market rent for similar premises in the vicinity at the time notice of the exercise of the option is given to the Landlord.

2 Under section 5.01 of the lease, the Premises are to be used and operated " . . . in a reputable and first class manner solely for the business and purpose of a licensed restaurant and serving food and beverages for consumption both on and off the Premises....".

  

3 The Tenant has been operating a café and bar on the Premises pursuant to an assignment, dated April 1, 2001, from a previous Tenant.

4 By letter dated November 15, 2002, the solicitor for the Tenant advised the Landlord's manager ("Dundee") that the Tenant had accepted an offer from 1547224 Ontario Inc (the "Purchaser") to purchase the Tenant's business operated in the Premises. The Landlord's consent to the assignment of the lease was requested. After negotiations among the parties, and solicitors for the Landlord and the Tenant, Dundee ultimately notified the Tenant on February 27, 2003 that the Landlord declined to provide its consent to the assignment.

5 The application to the court was made pursuant to section 23 of the *Commercial Tenancies Act* RSO 1990, Chapter L.7:

> "23. (1) In every lease made after the 1st day of September, 1911, containing a covenant, condition or agreement against assigning, underletting, or parting with the possession, or disposing of the land or property leased without licence or consent, such covenant, condition or agreement shall, unless the lease contains an express provision to the contrary, be deemed to be subject to a proviso to the effect that such licence or consent is not to be unreasonably withheld.
>
> (2) Where the Landlord refuses or neglects to give a licence or consent to an assignment or sub-lease, a judge of the Ontario court (General Division), upon the application of the tenant or of the assignee or sub-tenant, made according to the rules of court, may make an order determining whether or not the licence or consent is unreasonably withheld and, where the judge is of opinion that the licence or consent is unreasonably withheld, permitting the assignment or sublease to be made, and such order is the equivalent of the licence or consent of the Landlord within the meaning of any covenant or condition requiring the same and such assignment or sublease is not a breach thereof.":

6 Specific provisions with respect to assignments and subleases are contained in Article XI of the lease. These provide, in part, as follows:

> "11.01 CONSENT NEEDED: The Tenant will not, during the said Term or any renewals thereof:
>
> (a) assign this Lease in whole or in part
>
> . . .
>
> to or in any favour of any person . . . without the prior written consent of the Landlord, such consent not to be unreasonably withheld. . . . . In deciding whether to give its consent to an assignment or subletting, the Landlord may refuse to give its consent if:
>
> (i) the proposed assignee or subtenant:
>
> (A) does not have a history of successful business operation in the business to be conducted in the Premises;
>
> (B) does not have a good credit rating and a substantial net worth; or
>
> (C) is not able to finance its acquisition of its interest in the Premises and its operations in the Premises without a material risk of defaulting under this Lease and in a manner that will enable the proposed assignee or subtenant to carry on business successfully in the Premises throughout the term;
>
> . . . .
>
> (iii) the Landlord does not receive sufficient information from the Tenant or the proposed assignee or subtenant to enable it to make a determination concerning the matters set out above.
>
> 11.02 HOW CONSENT OBTAINED: In requesting the Landlord's consent pursuant to Section 11.01 herein, the Tenant shall provide the Landlord with all information that it may reasonably require, as set out above, including a true copy of any

 

agreement to assign, or agreement to sublease. Such information may pertain to the identity to the proposed assignee, . . . the nature of its business, and information pertaining to the financial strength of its covenant, and such other information as the Landlord shall, from time to time, acting reasonably, require. The Landlord shall maintain confidentiality in respect of all such information received. The Landlord will, within thirty (30) days after having received such notice and all such necessary information, notify the Tenant in writing either that:

(a) it consents to the Transfer;

(b) it does not consent to the Transfer; or

(c) it elects to cancel this Lease in preference to giving consent.

. . . "

7 On December 6, 2002, at an early stage in the negotiations between the parties, a representative of Dundee, on behalf of the Landlord, indicated that consent to the assignment would be given if a number of conditions were satisfied. In the course of the negotiations, the great majority of these conditions - some of which would have involved additions or alterations to the terms of the lease - were either abandoned or resolved to the satisfaction of the parties. At different times, at the request of Dundee, credit references, information with respect to the net worth of the principals, Mr. and Mrs. Harish and Rajni Verma, who would guarantee performance of the Purchaser's obligations and who would be involved in the operation of the business, and a very brief description, without details, of their previous experience in operating similar businesses, were provided. At the insistence of Dundee they also submitted a business plan that outlined their goals, the opportunities they saw for increasing sales and cash flow projections.

8 In the letter of February 27, 2003, when notifying the solicitor for the Tenant that the Landlord was withholding its consent, an officer of Dundee stated:

"The Landlord is unable to provide its consent to the tenant for the following reasons:

(1) the tenant is presently in default of the lease for failure to perform certain conditions;

(2) the proposed assignee does not have a history of successful business operation in the business to be conducted in the Premises;

(3) insufficient information has been provided to determine if the proposed assignee has a substantial net worth;

(4) there is a material risk that the proposed assignee will not be able to successfully carry on the business;

Insufficient information has been provided to permit the Landlord to make a determination concerning the matters set out above."

9 In determining whether the Landlord has unreasonably withheld consent, I believe the following propositions are supported by the authorities cited by counsel and are of assistance:

1. The burden is on the Tenant to satisfy the court that the refusal to consent was unreasonable: *Shields v. Dickler*, [1948] O.W.N. 145 (Ont. C.A.), at pages 149 - 50; *Sundance Investment Corp. v. Richfield Properties Ltd.*, [1983] 2 W.W.R. 493 (Alta. C.A.), at page 500; cf. *Welch Foods Inc. v. Cadbury Beverages Canada Inc.* (2001), 140 O.A.C. 320 (Ont. C.A.)., at page 331. In deciding whether the burden has been discharged, the question is not whether the court would have reached the same conclusion as the Landlord or even whether a reasonable person might have given consent; it is whether a reasonable person could have withheld consent: *Whiteminster Estates v. Hodges Menswear* (1974), 232 E.G. 715, at pages 715 - 6; *Zellers Inc. v. Brad-Jay Investments Ltd.* (Ont. S.C.J.), at para 35.

2. In determining the reasonableness of a refusal to consent, it is the information available to - and the reasons given by - the Landlord at the time of the refusal - and not any additional, or different, facts or reasons provided subsequently to

  

the court - that is material: *Bromley Park Garden Estates v. Moss*, [1982] 2 All E.R. 890 (Eng. C.A.), at page 901 - 2 *per* Slade L.J.. Further, it is not necessary for the Landlord to prove that the conclusions which led it to refuse consent were justified, if they were conclusions that might have been reached by a reasonable person in the circumstances: *Pimms Ltd. v. Tallow Chandlers in London (City)*, [1964] 2 All E.R. 145 (Eng. C.A.), at page 151.

3. The question must be considered in the light of the existing provisions of the lease that define and delimit the subject matter of the assignment as well as the right of the Tenant to assign and that of the Landlord to withhold consent. The Landlord is not entitled to require amendments to the terms of lease that will provide it with more advantageous terms: *Jo-Emma Restaurants Ltd. v. A. Merkur & Sons Ltd.* (1989), 7 R.P.R. (2d) 298 (Ont. Dist. Ct.); *Town Investments Underlease, Re*, [1954] Ch. 301 (Eng. Ch. Div.) - but, as a general rule, it may reasonably withhold consent if the assignment will diminish the value of its rights under it, or of its reversion: *Federal Business Development Bank v. Starr* (1986), 55 O.R. (2d) 65 (Ont. H.C.), at page 72. A refusal will, however, be unreasonable if it was designed to achieve a collateral purpose, or benefit to the Landlord, that was wholly unconnected with the bargain between the Landlord and the Tenant reflected in the terms of the lease: *Bromley Park Garden Estates v. Moss*, above, at page 901 *per* Dunn L.J. )

4. A probability that the proposed assignee will default in its obligations under the lease may, depending upon the circumstances, be a reasonable ground for withholding consent. A refusal to consent will not necessarily be unreasonable simply because the Landlord will have the same legal rights in the event of default by the assignee as it has against the assignor: *Ashworth Frazer Ltd. v. Gloucester City Council*, [2001] H.L.J. No. 57 (U.K. H.L.).

5. The financial position of the assignee may be a relevant consideration. This was encompassed by the references to the "personality" of an assignee in the older cases see, for example, *Slanly v. Ward* (1913), 29 T.L.R. 714 (Eng. C.A.); *Dominion Stores Ltd. v. Bramalea Ltd.*, [1985] O.J. No. 1874 (Ont. Dist. Ct.)

6. The question of reasonableness is essentially one of fact that must be determined on the circumstances of the particular case, including the commercial realities of the market place and the economic impact of an assignment on the Landlord. Decisions in other cases that consent was reasonably, or unreasonably, withheld are not precedents that will dictate the result in the case before the court: *Bickel v. Duke of Westminster*, [1976] 3 All E.R. 801 (Eng. C.A.), at pages 804-5; *Ashworth Frazer Ltd. v. Gloucester City Council*, above, at para 67; *Dominion Stores Ltd. v. Bramalea Ltd.*, above, at para 25.

10 Here, I believe, the starting point should be the terms of Article XI of the lease and, in particular, those of clauses (A), (B) and (C). It is clear that the Landlord purported to rely on these clauses - and subparagraph (iii) - as the bases for its refusal set out in the letter of February 27, 2003. In my opinion, the additional reason provided by the Landlord in the letter - that the Tenant was in default of an obligation to perform certain renovations to the Premises - would not, in the circumstances, be sufficient in itself to justify the Landlord's refusal to consent. Nor, do I believe that, in view of the substantial measure of agreement that had been reached on this question, it would have been a crucial consideration.

11 The other three reasons set out in the letter followed quite closely the words of clauses (A), (B) and (C). The letter states, in the first place, that each of the three conditions had not been satisfied. It is then said that the Landlord had not been provided with sufficient information to enable it to make a determination with respect to them. I understand this to mean that the Landlord did not believe that the conditions had been satisfied and that, in any event, the information provided was inadequate to establish the contrary. This is consistent with the affidavits sworn on behalf of the Landlord in which it was said that, having reviewed the material and information provided by the Tenant, Dundee was not satisfied that the Purchaser had the necessary experience to operate the business successfully or would be able to do so without a material risk of a default under the lease.

12 Although in Mr. Reed's submission, the Landlord's conclusion could not be considered to be reasonable on the basis of the information that had been provided to it, he also challenged the relevance, and the legitimacy, of the Landlord's consideration of the ability of the Tenant to carry on the business successfully.

13 From the commencement of the negotiations, the Landlord had required the Tenant to provide a detailed business plan. In a letter of December 18, 2002, the Tenant's solicitors took the position that there was no requirement "in the lease or otherwise" for the provision of such a plan and that, in any event, that the Landlord's indication that it would consent on certain conditions was binding on it notwithstanding the conditions. They characterized the Landlord's request as an attempt to interfere with the sale of the business. The Landlord's solicitors responded on January 17, 2003 that its consent was conditional and that the conditions had not been met. Their letter continued:

> "You make various references in your letter to the landlord attempting to "interfere with the sale of the business". This accusation is inaccurate and unwarranted. The landlord does not object to the sale of the business per se. However, your clients' business is the only food use in the building. The Landlord is therefore naturally concerned that the assignee be able to demonstrate that it has the financial ability and business experience and acumen to carry on the business "in a reputable and first class manner", as required by the lease. To date, it has not done so. Virtually all the conditions in the landlord's letter are directed to this point."

14 After further requests were made for a business plan, a document purporting to be such was provided to the Landlord in January, 2003. In a letter of January 24, 2003, after the statement of affairs and financial information had been provided to the Landlord, and after at least one of the meetings between the parties and their representatives, the vice-president of Dundee referred to an agreement that the Tenant would provide further information relating, among other things, to the financial capability of the Purchaser to support the operation of the restaurant and pay the rent, the business knowledge and capability of the Purchaser to operate the restaurant in a first class manner and a complete business plan. The letter stated that the previous application was refused as the information it provided was disorganized and incomplete. In response, the solicitor for the Tenant asserted that sufficient detail had been provided.

15 On February 6, 2003 a vice-president of Dundee replied that, based on the information provided, the business experience of Mr. and Mrs. Verma was, in the judgment of the Landlord, inadequate to enable them to operate the business successfully. Further information was, again, requested. The letter also stated that the business plan that had been provided had many flaws and that it ignored the fact that another tenant - a design school - that generated a large amount of custom for the cafe would be leaving the building in August, 2003. The letter continued:

> "For the business plan to ignore this important fact makes the financial forecast presented unachievable. As it is, the plan shows negative earnings for the first year with sales slowly building to create profitability in the future. With sales actually likely to drop off significantly, it would appear that there would be no profit through the balance of the term of the current lease. As a landlord, it is very difficult to accept an assignment of a lease to what appears to be a business that has a high probability of failure, irrespective of the fact that there are personal guarantees of the principals of the business. In order to approve the assignment we will require a plausible business plan that shows how the assignee plans to deal with the departure of the design school and increase sales in order to reach a level of profitability within a reasonable period."

The letter stated, further, that, in view of the inadequacy of the information relating to the business experience of the principals, more evidence was needed in order to assure the Landlord that the business could be operated successfully by the Purchaser.

16 The Tenant's solicitor replied in letter of February 14, 2003 which, among other things, stated:

> "A business plan was and is not a requirement in order to obtain the Landlord's consent. It was provided only as an accommodation and your opinion regarding the future viability of the business has no bearing on the provision of a consent."

17 In response to the request for further evidence of the business experience of Mr. and Mrs. Verma, the solicitor's letter merely communicated his belief that the Purchaser met the requirements of clause 11.01 (a) (i) (A) of the lease and stated that, if the Landlord did not consent to the assignment, a court application would be commenced. No further information was provided prior to the Landlord's final refusal letter of February 27, 2003.

  

18 In Mr. Reed's submission, the position taken by the Tenant's solicitor with respect to the Landlord's entitlement to a business plan was correct. Although section 5.01 required the Tenant to use and operate the premises in a first class manner, there was no covenant by the tenant to operate the business profitably. While, in determining whether to grant a lease to the original tenant, the Landlord could, no doubt, have treated this as a material consideration, it was not, in the absence of a provision to this effect in the lease, part of the bargain between them that burdened the rights that the tenant was entitled to assign, subject to the Landlord's reasonable withholding of consent. Mr. Reed submitted, further, that, independently of the conditions in clauses (A), (B) and (C), it would not have been reasonable for the Landlord to withhold consent on this ground and that, properly construed, the clauses did not authorize this to be done.

19 In counsel's submission, the three clauses were carefully drafted to set out exhaustively the considerations relating to the operation of the business and the financial position of the proposed assignee that might justify the Landlord's refusal to consent. These considerations were limited to the specific factual questions in each of the causes. Clause (A) was concerned with the previous business experience of the proposed assignee, clause (B) with its credit rating and net worth and clause (C) with its ability to finance the acquisition of the business and its operations.

20 On the basis of this interpretation, it would not be permissible for the Landlord to consider the likely profitability of the business other than by reference to the three specific factual questions.

21 I have found this to be a difficult question but, on balance, I believe that Mr. Reed's submission that the conditions in the three clauses were intended to be exhaustive is correct. If this was not the intention - so that the Landlord could reasonably withhold consent if, for any reason, it was not satisfied that the proposed assignee would carry on the business profitably - it would have been a relatively simple matter for this to be stated. Such a provision would, however, have permitted the Landlord to refuse consent if, for reasons unconnected with the express conditions in the three clauses, it reasonably considered that the business was no longer viable. This would not have entitled the Landlord to terminate the lease and I do not believe it was authorized to withhold its consent to an assignment on this ground. The ability of the proposed assignee to carry on the business successfully was inferentially addressed in conditions (A) and (C) and its ability to provide financial backing for its obligations in conditions (B) and (C). I believe these conditions should be considered as defining and delimiting the grounds on which the Landlord can reasonably withhold consent to the assignment in so far as these attributes of the assignee are concerned.

22 However, it does not follow that the ability of the Purchaser to carry on the business successfully is irrelevant. The contrary is implicit in clauses (A) and (C). The conditions in the three clauses are, I believe interconnected and each does not have to be considered separately from the others. In particular, in considering whether the condition in clause (A) was satisfied, I believe the Landlord was entitled to measure the sufficiency of the business experience of Mr. and Mrs. Verma with reference to their ability to operate the business successfully. Similarly, in deciding under clause (C) whether the Purchaser was " able to finance . . . its operations in the Premises without a material risk of defaulting under this Lease and in a manner that will enable the proposed assignee . . . to carry on business successfully in the Premises throughout the term", I believe the Landlord was entitled to take into consideration the information it received with respect to the conditions in clauses (A) and (B) and to make its decision on the basis of such information.

23 In determining whether the Landlord could not reasonably arrive at the conclusions set out its final letter of February 27, 2003, I believe the court should be slow to substitute its judgment for the business judgment of the Landlord. Although, in my opinion, the conditions contained in Dundee's early letter of December 6, 2003, extended beyond the limits of reasonableness, I am satisfied that, subsequently, when deciding to withhold consent, the Landlord had regard to the conditions in section 11.01 and weighed the information it had previously received with respect to each of them. If the question was simply whether Mr. and Mrs. Verma had sufficient assets to enable them to acquire and operate the business without a material risk of defaulting in the payment of rent, the reasonableness of the Landlord's decision might well have been more difficult to justify. However, the sufficiency of their business experience was a recurring theme in virtually all of the correspondence from Dundee and I am satisfied that ultimately, as stated in the responding affidavit sworn on behalf of the Landlord, it was a decisive factor.

24 The negotiations between the parties had been quite extensive and there is nothing in the evidence to suggest that the Landlord did not conduct them in good faith. Its valid concerns about the adequacy of Mr. and Mrs. Verma's business experience were repeatedly communicated to the Tenant's solicitors but, to a large extent, they fell upon deaf ears, when their legitimacy was not rejected. The information relating to the principals' business experience was extremely cursory. That with respect to the experience of Mr. Verma outside Canada was impossible for the Landlord to verify without more details and no response was received to its request for further information in the letter of February 6, 2003. The Landlord was entitled to seek such information and, when it was not forthcoming, to base its decision on the totality of the information it had received. For the reasons already given, additional facts provided to the court in an affidavit sworn by Mrs. Verma are not relevant to the issue I have to determine - namely, the reasonableness of the Landlord's decision at the time it withheld consent.. In the circumstances, I do not believe the court should characterize the decision to withhold consent to be one that could not have been reached by a reasonable person.

25 For these reasons, I find that the Tenant has not discharged the burden of proving that the Landlord's refusal to consent to the assignment was unreasonable. In consequence, the application is dismissed.

26 Costs may be spoken to, or if counsel would prefer to make submissions in writing, I will receive the submissions of counsel for the Landlord within 14 days of the release of this endorsement and those of counsel for the Tenant within a further seven days.

*Application dismissed.*

**End of Document**

# Tab 2

Neutral Citation Number: [2014] EWCA Civ 302

Case No: A3/2013/1387

**IN THE COURT OF APPEAL (CIVIL DIVISION)**
**ON APPEAL FROM THE HIGH COURT**
**QUEEN'S BENCH DIVISION**
**COMMERCIAL COURT**
**THE HONOURABLE MR JUSTICE POPPLEWELL**
**2011 Folio 312**

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: Thursday 20th March 2014

**Before:**

**THE RIGHT HONOURABLE LORD JUSTICE LONGMORE**
**THE RIGHT HONOURABLE LORD JUSTICE PATTEN**
and
**THE RIGHT HONOURABLE LORD JUSTICE CHRISTOPHER CLARKE**

- - - - - - - - - - - - - - - - - - - -

**Between:**

| | |
|---|---|
| **BARCLAYS BANK PLC** | **Respondent** |
| **- and -** | |
| **UNICREDIT BANK AG (FORMERLY KNOWN AS BAYERISCHE HYPO-UND VEREINSBAND AG) & ANR** | **Appellants** |

- - - - - - - - - - - - - - - - - - - -

(Transcript of the Handed Down Judgment of
WordWave International Limited
A Merrill Communications Company
165 Fleet Street, London EC4A 2DY
Tel No: 020 7404 1400, Fax No: 020 7831 8838
Official Shorthand Writers to the Court)

- - - - - - - - - - - - - - - - - - - -

**Mr Robin Knowles QC & Mr Edmund King** (instructed by **Quinn Emanuel Urquhart & Sullivan**) for the **Appellant**
**Mr David Railton QC & Mr Giles Wheeler** (instructed by **Addleshaw Goddard LLP**) for the **Respondents**

- - - - - - - - - - - - - - - - - - - -

Hearing dates: 25th & 26th February 2014

Judgment

**Lord Justice Longmore:**

1. This appeal raises the question of what is "commercially reasonable" in the context of determinations made by parties to financial instruments.

2. Basel I (1988) and Basel II (2004), the so-called Basel Accords, have sought to achieve a measure of international consistency in relation to minimum capital requirements for banks. They have been drawn up by a committee of banking supervisory authorities established by the central bank governors of ten separate countries including Germany, Austria and Italy. The defendants (and appellants) are German and Austrian Banks regulated by what I will call "BaFin" in Germany and what I will call "FMA" in Austria respectively. They are both controlled by UniCredit SpA which is regulated by the Bank of Italy and it is convenient to refer to the defendants compendiously as "Unicredit".

3. A bank which wished in 2008 to transfer or mitigate its credit risk in a pool of assets and in turn reduce its regulatory capital requirements could do so by what is called "synthetic securitisation". By using this process, the bank could transfer the credit risk of a portfolio of assets to a third party by the use of credit default swaps or guarantees without removing the portfolio of assets from its balance sheet. The transfer would, however, enable its capital requirements to be reduced. In the present case Unicredit transferred the credit risk in certain of their assets to Barclays Bank Plc ("Barclays") who would make quarterly payments to Unicredit in respect of relevant portfolio losses and in return Unicredit paid quarterly premiums to Barclays. There were three such guarantees given by Barclays as Guarantor to Unicredit. The losses which Barclays guaranteed to pay were called "Credit Protection Payments".

4. The initiative to execute the first guarantee came from Unicredit SpA in Milan which was under pressure from the Bank of Italy to improve what was called its "tier one capital ratio". This improvement was required to be effected by 30th September 2008 which, it will be remembered, was a time of considerable financial turmoil. By that date the cash securitisation market was effectively closed. In December 2008 two further guarantees had been agreed and executed. They were amended and re-stated in April 2009 but nothing turns on that.

5. The essential structure of the guarantees was that, in exchange for the premiums, Barclays would make quarterly payments to Unicredit in respect of the first losses suffered by reason of credit defaults on a portfolio of obligations designated as the "Reference Portfolio". The amount of the premiums payable by the defendants was determined in such a way as, over the lifetime of the guarantees, was intended to exceed the total of the Credit Protection Payments and Barclays would not, therefore, be exposed to the credit risk on the first tranche of the Reference Portfolio. Nevertheless the structure of the transaction apparently persuaded the regulators that Unicredit had effectively transferred the risk and qualified for "RWA relief", so called because the banks' assets were assigned a percentage risk weight reflecting their credit risk.

6. The judge explained that this structure did not mean that Barclays assumed no risk because (1) they agreed to accept the risk of the "super senior" tranche of the portfolios (said to be "a very remote risk") and (2) if interest rates increased in a

dramatic way, there could be a difference between Barclays' total exposure on the first tranche and the premiums they received (said to be "unlikely").

7. The lifetime of two of the guarantees was 11 years and 19 years for the other guarantee, but provisions were agreed entitling Unicredit (in events that were likely to happen) to bring them to an end after a period roughly equivalent to the weighted average life of the loans in the portfolio which was expected to be about 5 years. Barclays could therefore expect to earn five years worth of premium and fees under the guarantees. Clause 12.1 of the guarantees granted this right of optional termination in four separate events, two of which required Barclays' prior consent

> "such consent to be determined by [Barclays] in a commercially reasonable manner."

It is this clause which is at the centre of the dispute between the parties. The two events requiring Barclays' consent were Regulatory Change and what was called a "10% Clean-up Call Event". The other two events, not requiring Barclays' consent, were the Substitution Event Date and the Weighted Average Life Termination Date both defined in the guarantees. The three guarantees referring to the respective defendant as "the Bank" and Barclays as "the Guarantor" were on essentially identical terms and I will therefore only quote the terms of the guarantee given to the German bank.

8. The full clause 12.1 is as follows:-

> "12. OPTIONAL EARLY TERMINATION
>
> 12.1 Optional Early Termination by the Bank
>
> If:
>
> (a) the Substitution Event Date occurs, provided that:
>
> (i) the balance of the Accumulation Ledger minus the Maximum Pending Credit Protection Amount is greater than zero as at that Substitution Event Date; or
>
> (b) a Regulatory Change occurs in respect of the Bank, provided that the Bank has obtained the prior consent from the Guarantor, such consent to be determined by the Guarantor in a commercially reasonable manner; or
>
> (c) a 10% Clean-up Call Event occurs, provided that the Bank has obtained the prior consent from the Guarantor, such consent to be determined by the Guarantor in a commercially reasonable manner; or
>
> (d) the Weighted Average Life Termination Date occurs, provided that the balance of the Accumulation Ledger minus the Maximum Pending Credit Protection Amount

is greater than zero as at that Weighted Average Life Termination Date,

and provided further that the Bank has obtained such consents to terminating this Guarantee as it has deemed necessary (in its sole and absolute discretion) which may include, but is not limited to, consent of the Federal Financial Services Supervisory Authority [BaFin] or any successor thereof,

the Bank may, by not less than 5 Business Days notice to the Guarantor, and provided that the event described in sub-paragraphs (a) to (d) is then continuing, designate any of the applicable Substitution Event Date, Weighted Average Life Termination Date or, in the case of paragraphs (b) and (c), the next following Payment Date as an Optional Early Termination Date."

9. It is agreed that at the date of each guarantee, Barclays entered as profit in their books the discounted value of 5 years' fees and it is also agreed that a Regulatory Change occurred within the definition of that term in the guarantees. On 14th June 2010 the defendants sought Barclays' consent to an early termination on 30th June 2010 as a result of Regulatory Change. Barclays responded on 23rd June 2010:-

> "Although early termination of the Agreement was contemplated in the Agreement, it is clear that the parties intended the Agreement to continue for a substantial period of time. Unicredit cannot reasonably expect Barclays to consent to termination so early in the term of the Agreement, in circumstances where this would deprive Barclays of a significant proportion of the overall revenue that it had bargained for and thus result in material economic detriment to Barclays."

Unicredit responded by saying that it was not reasonable for Barclays to refuse consent in circumstances in which the Regulatory Change resulted in Unicredit no longer receiving capital relief by virtue of the guarantees. They said that Barclays unreasonable refusal was a waiver of the consent requirement and 30th June was to be designated as the Optional Early Termination Date. Unicredit ceased paying premiums on that date and contend that the guarantees ended on that date. Barclays have always maintained that the guarantees have not been terminated and remain in force.

**The Judgment**

10. In the light of earlier correspondence between the parties the judge held (para 43) that Barclays' refusal of consent was not to be regarded as a refusal to consent on any terms but as a statement that the price of its consent was that it should be paid the balance of its fees for a five year period discounted for present payment, just as had been posted in its books. He also held that (para 41) it would have cost Barclays about €7.45 million to close out the existing hedge transactions entered into as a result of the guarantees, although Barclays would have been saved about €2.5 million in future payments if the guarantees had terminated at 30th June 2010. He further held

(para 46) that Unicredit's reaction to Barclays' letter of 23rd June was not to offer any payment to Barclays as the price of its consent to early termination. That was despite Unicredit's later concession in the face of the court (recorded in para 69 of the judgment) that it would have been reasonable for Barclays to recover its out of pocket costs of unwinding the hedges in place, at least if those costs exceeded the amounts saved as a result of early termination, as the judge had found they did.

11. The judge held in broad terms that Barclays had withheld its consent to early termination in a commercially reasonable manner and that the defendants' purported designation of 30th June 2010 as the Optional Early Termination Date was invalid and of no effect. He held importantly that Barclays were entitled to take primary account of their own interests in determining whether to consent to termination.

12. Barclays had also alleged that it was a common understanding between the parties that the guarantees would last 5 years and that they would therefore receive premiums over that 5 year period. This was the foundation of a plea by Barclays of estoppel by acquiescence or estoppel by convention. The judge accepted that that was Barclays' understanding but he said it was not a shared understanding. The plea of estoppel accordingly failed. But the judge regarded the fact that Barclays had had that understanding as supporting his view that Barclays had refused their consent to an early termination in a commercially reasonably manner.

**The submissions on appeal**

13. Unicredit have 3 grounds of appeal saying that the judge was wrong:-

    i) to hold that Barclays was entitled to give precedence to its own commercial interests and thereby to exclude the interests of Unicredit in refusing to consent to early termination;

    ii) to hold that Barclays was entitled to demand a sum equal to the entire (discounted present value of the) fees that it would have received if the guarantees had continued for five years; and

    iii) in failing to give effect to an Entire Agreement clause which provided:-

    > "20.1 Entire Agreement
    >
    > This Guarantee, together with the Credit Support Agreement, constitutes the entire agreement and understanding of the parties with respect to its subject-matter and supersedes all oral communication and prior writings with respect thereto."

14. There was considerable debate before us and below on the question whether clause 12.1(b) was to be regarded (1) as conferring a contractual discretion on Barclays so that the principles of contractual discretion cases applied, as exemplified by Abu Dhabi National Tanker Co v Prudent Star Shipping Ltd (The Product Star (No. 2) [1993] 1 Lloyds Rep 397 or (2) as equivalent to conferring a discretion to which the principles of AP Picture Houses v Wednesbury Corporation [1947] 1 KB 223 applied or (3) as analogous to landlord and tenant cases, such as International Drilling Fluids Ltd v Louisville Investments (Uxbridge) Ltd [1986] 1 Ch. 513, in which there is a

covenant against e.g. assignment without the consent of the landlord "such consent not to be unreasonably withheld", or (4) as requiring Barclays to make an objectively "commercially reasonable" determination. Although interesting this debate was not, in my view, ultimately helpful since the meaning of the clause has to be determined as a matter of construction of this particular contract in its particular context.

**The construction of clause 12.1(b)**

15. The critical factor in the present case is that the person who has to act in a commercially reasonable manner in determining whether consent is to be given is "the Guarantor" namely Barclays itself. It is from Barclays that consent is to be obtained and it is Barclays who has to determine whether that consent is to be given, albeit in a commercially reasonable manner. It is the manner of the determination which must be commercially reasonable; it does not follow that the outcome has to be commercially reasonable although, if it is not, that would no doubt cause one to look critically at the manner of the determination.

16. One then has to ask whether, in determining whether or not to consent to early termination, Barclays can take account of its own interest in preference to the interest of Unicredit. To my mind the answer is that it can, because any commercial man whose consent to a course of action is required but to whom the determination (whether to give that consent) is entrusted would think it commercially reasonable to have primary regard to his own commercial interests.

17. Mr Robin Knowles QC for Unicredit submitted that the purpose of requiring the determination to be made by Barclays in a commercially reasonable manner was to require Barclays to have regard to the interests of Unicredit as its counterparty in order that a mutual (or a mutually satisfactory) outcome could be achieved. Attractively as the submission was put, it is impossible to see how it could work in practice. Bankers, as commercial men, have a keen instinct for where their own interests lie. But if they are asked to have regard to the interests of the other party to the contract, how do they begin to assess what those interests are, let alone weigh those interests in comparison to their own interests? If the clause is to work in the way Mr Knowles suggests, there would have to be some method of discovering and assessing the counterparty's interests. The obvious way to do so would be to ask the counterparty what their interests were. But is Barclays to be expected to take the answer at face value? That might be beneficial to the counterparty but not be a balanced or accurate assessment of the counterparty's interest. Could Barclays ask that the counterparty's account of its own interests be backed up with documentary evidence? If so, it might be a long process; if not, it might lead to an unfair result. If this sort of exercise were envisaged, one would expect a neutral third party to be allotted the task of determining whether consent should be given but that is not what the clause says.

18. Of course the requirement that consent be determined in a commercially reasonable manner must be intended to be a control exercise of some kind. If, therefore, Barclays had said that they would not consent at any price or if it had said that they wanted 11 years' (or 19 years' as the case might be) fees as being the full term of the guarantees, that might well not have been "commercially reasonable". But that is not this case.

19. It is not easy to express a test for commercial reasonableness for the purpose of this (let alone any other) contract but I would tentatively express it by saying that the party who has to make the relevant determination will not be acting in a commercially reasonable manner if he demands a price which is way above what he can reasonably anticipate would have been a reasonable return from the contract into which he has entered and which it is sought to terminate at an early date.

20. If, therefore, it is necessary or helpful to determine into which of the 4 categories, set out in paragraph 14 above, the present clause falls, I would assign it to category (2) as I think the judge did in para 67(4) of his judgment. This seems to me to accord, moreover, with previous decisions of this court or similar clauses such as Ludgate Insurance Co v Citibank N.A. [1998] Lloyd's Rep I.R. 221, paras 35-36 per Brooke LJ, Gan Insurance Co Ltd v Tai Ping Insurance Co Ltd (No. 2) [2001] 2 All E.R. Comm 299 paras 64, 67 and 73 per Mance LJ, Paragon Finance Plc v Nash [2002] 1 WLR 685 para 41 per Dyson LJ and Socimer Bank Ltd v Standard Bank Ltd [2008] Bus L.R. 1304 paras 61-66 per Rix LJ. This latter authority indicates that there is in any event little difference between categories (1) and (2).

21. Mr Knowles submitted that the words "commercially reasonable" were used in many contexts (he instanced the definition of "Close-Out Amount" in the ISDA 2002 Master Agreement) and submitted that they should, therefore, be construed in an objective sense or at least in a sense that required the determiner of the question of consent to make its determination by balancing the parties' interests. But I do not think it useful to construe the words in this contract by reference to their use in other contexts, nor do I think it by any means inevitable that the construction put on the words in this case will necessarily apply in those other contexts, which may anyway use slightly different words. Parties to contracts such as these (or, indeed, ISDA contracts) can, in any event, look after their own interests and contract on different terms if they wish to do so.

**Commercially reasonable demand in fact?**

22. It follows that the price which Barclays demanded as the price of its consent cannot be said to have been determined by it in a commercially unreasonable manner. It was entitled to have regard to its own commercial interest; it did not refuse consent outright; the price it sought was not out of line with the reasonable return it could have expected had the contract run its expected course. The fact that Unicredit could probably have determined it after 5 years as of right only serves to underline that not unreasonable expectation.

23. Mr Knowles submitted that it would have been more reasonable for Barclays to have required payment of their notional loss of profit over the period of 5 years rather than 5 years of fees. But in the first place that was never an offer made by Unicredit who never made any counter-offer at all and, secondly, it would not have been an easy calculation to make. I have already mentioned that Unicredit conceded that Barclays could, on any view, have sought to recover the cost of unwinding the hedges already in place (to the extent that such costs exceeded any gains made by early termination) but that was not on offer either. As it was Barclays claim for the present value of 5 years' worth of fees without any deduction for the excess of the costs of closing the existing hedge transactions over the amounts saved by early termination seems to be a rough and ready assessment of its loss of profit. In these circumstances, it is, in my

judgment, impossible to say that Barclays did not determine whether or not it should consent to early termination in a commercially reasonable manner. On the contrary, in my judgment, it made its determination in what was a commercially reasonable manner.

24. Mr Railton QC for Barclays submitted that the lack of any offer or counter offer from Unicredit meant that Barclays determination had automatically been made in a commercially reasonable manner and that that would be the case, even if Barclays had not initially made the first offer of the sum for which they would give their consent. I would not accept either of those submissions. I have already said that the wording of the clause is intended to be a control exercise, even if it is not a rigorous one. If Mr Railton were correct, it would amount to giving Barclays a virtual carte blanche to do what it wanted and that cannot be correct.

**Entire Agreement and Understanding Clause**

25. The judge, while holding that Barclays' understanding that the contract would last for 5 years and that they would receive 5 years of fees was not an understanding shared by Unicredit, nevertheless considered that understanding to be part of the background against which Barclays made their determination to withhold consent to early termination in a reasonable manner. Mr Knowles submitted that to use Barclays' understanding in that way was inconsistent with the Entire Agreement Clause which provided that the terms of the written guarantee constituted "the entire agreement and understanding of the parties with respect to its subject matter".

26. On the facts of this case, this is something of a non-point. The question is whether Barclays determined to refuse their consent in a commercially reasonable manner. That question cannot realistically be decided by reference to the relevant party's understanding of the length of time for which the contract would last. If the understanding is not commercially reasonable, the fact that it was the understanding of Barclays would not make the determination one which was reached in a commercially reasonable manner. No more is it the case that, if the understanding is commercially reasonable, Barclays can rely on their own understanding to that effect to make their determination a determination which is reached in a commercially reasonable manner.

27. Perhaps more to the point is this. The entire agreement clause is concerned with identifying the terms of the contract. The use of the phrase "constitute the entire agreement and understanding" is intended to exclude any evidence or argument to the effect that the terms of the contract are to include any mutual understanding that is not recorded in the contract. It is not intended to exclude admissible evidence or argument about the way in which parties exercise rights given to them by the terms of the contract.

28. Courts have tended to construe entire agreement clauses strictly. A clause framed in the way in which it is framed in the contract with which this case is concerned would not, for example, preclude a claim for misrepresentation because that is not a claim which depends on a term of the contract which is not expressed in the contract, see Axa v Campbell Martin [2012] Bus L.R. 203 paras 84 and 95 per Rix LJ. Consistently with this approach, the clause has, in my view, no relevance to the way in which parties may exercise rights given to them by the contract.

29. Even if, however, this is wrong and the clause is to be construed as precluding any reliance by Barclays on its own understanding of the length of time the contract was likely to last, that cannot decide the case in favour of Unicredit. The question still remains whether Barclays determination to require 5 years' premiums was reached in a commercially reasonable manner. For the reasons given earlier, it was and the fact that the judge may have had regard to an irrelevant matter in reaching his own conclusion does not make any difference to that.

**Conclusion**

30. I would therefore dismiss this appeal.

**Lord Justice Patten:**

31. I agree.

**Lord Justice Christopher Clarke:**

32. I also agree.

# Tab 3

2010 ONSC 3576
Ontario Superior Court of Justice

Drosophilinks Consulting Inc. v. Canadian National Railway

2010 CarswellOnt 4232, 2010 ONSC 3576, [2010] O.J. No. 2654, 190 A.C.W.S. (3d) 75

# Drosophilinks Consulting Inc. and Aldo Forgione (Plaintiffs) and Canadian National Railway Company and Canadian National Railway Properties (Defendants)

Newbould J.

Heard: June 18, 2010
Judgment: June 21, 2010
Docket: 06-CV-315122-0000

Counsel: Evert Van Woudenberg, Jane Sirdevan for Applicant
Orlando M. Rosa for Respondent

Subject: Contracts; Property; Civil Practice and Procedure; Torts

**Headnote**

**Real property --- Sale of land — Agreement of purchase and sale — Interpretation of contract — General principles**

**Real property --- Sale of land — Agreement of purchase and sale — Interpretation of contract — Merger**

**Real property --- Sale of land — Completion of contract — Obligations of vendor — General principles**

**Real property --- Sale of land — Remedies — Vendor and purchaser applications — Practice and procedure — Miscellaneous**

**Torts --- Negligence — Duty and standard of care — Duty of care**

**Torts --- Negligence — Occupiers' liability — Duties and obligations — Statutory duty**

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s. 1 "occupier" — considered

s. 3(1) — considered

s. 3(3) — considered

**Rules considered:**

*Rules of Civil Procedure*, R.R.O. 1990, Reg. 194
R. 20 — referred to

R. 20.02(2) — referred to

***Newbould J.*:**

1 The defendants move for summary judgment dismissing all claims against them. This action involves land owned in North Bay by Canadian National Railway Company (CN) that was sold by Canadian National Railway Properties (CNRP), a special purpose subsidiary of CN that was used to sell the lands, to Drosophilinks Consulting Inc. (DCI). It is alleged that there were environmental problems with one of the parcels sold by CN known as the Main Street lands. Damages are claimed by DCI for breach of contract and by the plaintiff Aldo Forgione under the *Occupiers Liability Act*, at common law and for breach of an alleged duty of good faith owed to him.

2 CNRP was dissolved in December 2004 after the sale and before this action was commenced. It is alleged that CNRP was the agent of CN and its alter ego and that any liability of CNRP is a direct or vicarious liability of CN.

**Agreement to sell**

3 By agreement dated the April 14, 2003, Aldo Forgione in trust agreed to purchase properties located in the City of North Bay for a purchase price of $305,000. One of the lands purchased was the Main Street lands formerly occupied by a tenant of CN, Norcan Machine Works. In the purchase agreement, the Main Street lands had an allocated value of $50,000.

4 Schedule B of the agreement contained a number of terms. The meaning of these terms, including an indemnity clause, is central to the issues on this motion. Included were clauses 1 (a) to (g.).

  

5 Sub-paragraph 1(a) provided that the lands were being sold on an "as is" basis and that no representations were being made by the vendor in respect to the condition of the lands:

> 1(a) The Vendor makes no representations or warranties of any kind, either expressed or implied, as to the condition of the soil, the subsoil, the ground and surface water or any other environmental matters, the condition of the property or the condition of any structures, if any, or any other matters respecting the site whatsoever, including the use to which it may be put and its zoning. The Purchaser shall accept the property and any improvements thereon in an "as is" condition.

6 The vendor agreed to deliver all environmental reports and other documents within 10 days from the acceptance of the agreement:

> 1(d) The Vendor agrees to deliver to the Purchaser within ten (10) days of acceptance of this Agreement all environmental reports, plans and other documents relating to the property in its possession...

7 Sub-paragraph 1 (b) and (c) provided that the purchaser was required to conduct its own due diligence and could within 30 days terminate the agreement:

> 1(b) The Purchaser shall be allowed thirty (30) days from the date of acceptance (the "Conditional Period") to satisfy himself with respect to all matters respecting the condition of the soil, the subsoil, the ground and surface water or any other environmental matters, the condition of the property or the condition of structures thereon, if any, ...
>
> 1(c) If for any reason the Purchaser is not satisfied with respect to such matters within the Conditional Period, he may deliver a notice ("Notice of Termination") to the Vendor indicating that he is not satisfied with respect to such matters and desires to terminate this Agreement and release the Vendor from any further obligations. Upon delivery by the Purchaser of a Notice of Termination to the Vendor, this Agreement shall be at an end and the Vendor shall return the deposit to the Purchaser without interest or deduction and neither party shall have any further obligation to the other respecting the Agreement.

8 Sub-paragraph 1(e) provided that if the purchaser did not deliver a notice of termination within 30 days, it was deemed to waive all requisitions regarding the property save title matters and to accept responsibility for all conditions related to the property:

> 1(e) In absence of delivering a Notice of Termination within the Conditional Period, the Purchaser shall be conclusively deemed to have waived all requisitions concerning any matters relating to the property save for matters going to title and the Purchaser accepts full responsibility for all conditions related to the property, and the Purchaser shall comply with all orders relating to the condition of the property issued by any competent government authority, court or administrative tribunal, including any order issued against the Vendor.

9 Sub-paragraph 1(f) contained an indemnity clause. Its meaning is contested. It provides:

> 1 (f) The Purchaser shall be responsible for and hereby indemnifies and saves harmless the Vendor and Canadian National Railway Company from any costs, including legal and witness costs, claims, demands, civil actions, prosecutions, or administrative hearings, fines, judgments, awards, including awards of costs, that may arise as a result of the damage or contamination to the property following the closing and the Vendor shall be responsible for and indemnify and save harmless the Purchaser from all costs, claims, and other damages including any order issued in connection with the condition of the property, or any loss, damage, or injury caused either directly or indirectly as a result of the condition of the property before closing.

10 Sub-paragraph (g) contained a merger clause, the meaning of which is also contested:

  

> 1 (g) This clause 1 of this Schedule "B" shall not merge but shall survive the closing of this transaction and shall be a continuing obligation of the Purchaser.

11 On April 28, 2000, two weeks after the agreement, CN provided a number of environmental reports to Mr. Forgione which clearly indicated environmental problems. The plaintiffs claim that an environmental report (the CRA report) was not provided by CN to Mr. Forgione. This is somewhat contested, as is the effect of it not being provided, if that was the case. The plaintiffs submit that Mr. Forgione was led to believe that any PCB environmental problem had been cleared up. [1]

12 In any event, the purchaser did not deliver a notice of termination pursuant to sub-paragraph 1 (c) of schedule B and the agreement closed on September 30, 2003. The plaintiff DCI took title to the Main Street property. At the time of the closing, CN provided an acknowledgment that all reports, maps, sketches and surveys of the property in CN's possession or control had been delivered to the purchaser or would be delivered within one week.

13 The plaintiffs claim that in late July 2005, Mr. Forgione discovered a trailer on the Main Street property that contained transformers containing PCBs that exceeded federal and provincial guidelines. It is accepted that these transformers were there when the sale to DCI closed, although CN says that at the time of the sale, it thought that the property had previously been successfully decommissioned of environmental problems. It is claimed that DCI has incurred substantial expenses to comply with an order of the Ministry of the Environment, that Mr. Forgione has suffered personal damages as result of coming into contact with the PCBs and that he has suffered damages by reason of a lessening in value of the other properties that he purchased from CN in North Bay due to the notoriety of the PCB problem at the Main Street property.

**Issues**

***(a) Contractual Claim of DCI***

14 DCI claims that CN is required to indemnify it from the expenses incurred by it in dealing with the PCBs because of the provisions of the latter part of sub-paragraph 1 (f) which provides:

> ...and the Vendor shall be responsible for and indemnify and save harmless the Purchaser from all costs, claims, and other damages including any order issued in connection with the condition of the property, or any loss, damage, or injury caused either directly or indirectly as a result of the condition of the property before closing.

15 In interpreting a contract, the goal is to determine the intent of the parties by reference to the words that they chose. The plain meaning of the words is to be given effect, read harmoniously and in the context of other provisions of the contract, and in light of the factual matrix as a whole. Interpretations that give effect to all the terms of a contract should be preferred over interpretations that render one or more terms superfluous or ineffective. A commercial contract should be interpreted in a manner that accords with sound commercial principles, good business sense and that does not result in absurdities. While evidence of the factual matrix is generally admissible and relevant to the construction of a contract, extrinsic evidence as to the meaning of a contract is inadmissible unless there is an ambiguity. See generally *Toronto Dominion Bank v. Leigh Instruments Ltd. (Trustee of)* (1998), 40 B.L.R. (2d) 1 (Ont. Gen. Div. [Commercial List]), aff'd (1999), 45 O.R. (3d) 417 (Ont. C.A.) and *SimEx Inc. v. IMAX Corp.* (2005), 11 B.L.R. (4th) 214 (Ont. C.A.).

16 Regarding the objective of giving effect to all of the words in a contract, a court should attempt if at all possible not to reach an interpretation that would render a term ineffective. In *Scanlon v. Castlepoint Development Corp.* (1992), 11 O.R. (3d) 744 (Ont. C.A.) Robins J.A. stated:

> To the extent that it is possible to do so, it should be construed as a whole and effect should be given to all of its provisions. The provisions should be read, not as standing alone, but in light of the agreement as a whole and the other provisions thereof: *Hillis Oil & Sales Ltd. v. Wynn's Canada Ltd.*, [1986] 1 S.C.R. 57 at p. 66, 25 D.L.R. (4th) 649 at p. 655. **The court should strive to givemeaning to the agreement and "reject an interpretation that would renderone of its terms ineffective"**: *National Trust Co. v. Mead*, [1990] 2 S.C.R. 410 atp. 425, 71 D.L.R. (4th) 488 at p. 499.

 

(emphasis added)

17 CN's position is that the clear intent of the agreement as contained in paragraph 1 of schedule B is that DCI purchased the property on an "as is" basis without any representation or warranty as to the environmental condition of the property and that once DCI declined to deliver a Notice of Intention within 30 days of the agreement, it was deemed to accept responsibility after closing for all conditions regarding the property. It takes the position that the language in the indemnity contained in sub-paragraph 1(f) is not inconsistent with that and that it allocates responsibility based on the timing of a claim being made. If a claim was made before the closing CN is responsible for the claim and is required to indemnify DCI. If the claim was made after the closing, DCI is responsible for the claim even though the claim related to the condition of the property before the closing.

18 CN further says that the indemnity provided by CN in favour of DCI in subparagraph 1(f) is superfluous because at common law property remains at the risk of a vendor until closing and thus DCI was already provided that protection. CN further takes the position that the indemnity by CN in favor of DCI in that subparagraph merged on the closing to be of no further force and effect and that because of subparagraph (g), only the obligation of DCI in subparagraph (f) continued after the closing.

19 I do not accept CN's interpretation of the indemnity provision, for the reasons that follow.

20 The clause provides that CN will indemnify DCI from all costs, claims... or any loss... caused... as a result of the condition of the property before closing. The phrase "before closing" modifies the words "the condition of the property". It does not modify the words "all costs, claims...". The plain meaning is that if DCI suffers damages as result of the condition of the property as it existed before closing, the vendor is to indemnify the purchaser.

21 Likewise, the clause provides that DCI will indemnify CN against costs that may arise as result of damage or contamination to the property following the closing. I do not accept the interpretation placed on the clause by CN that DCI is to indemnify CN for contamination to the property that occurred before the closing if the claim was made after the closing.

22 Can this interpretation of the indemnity clause live in harmony with the provisions in paragraph 1 of schedule B, including sub-paragraph (a) that there are no warranties or representations regarding the condition of the property and that it is being purchased in an "as is" basis? If these provisions cannot stand together in a harmonious interpretation of the contract as a whole, what is a court to do in interpreting the contract? In *BG Checo International Ltd. v. British Columbia Hydro & Power Authority*, [1993] 1 S.C.R. 12 (S.C.C.), LaForest and McLachlin JJ. stated the following relating to the interpretation of clauses in a contract said to be inconsistent:

> It is a cardinal rule of the construction of contracts that the **various parts of the contract are to be interpreted in the context of the intentions of the parties as evident from the contract as a whole**: K. Lewison, The Interpretation of Contracts (1989), at p. 124; Chitty on Contracts (26th ed. 1989), vol. 1, at p. 520. **Where there are apparent inconsistencies between different terms of a contract, the court should attempt to find an interpretation which can reasonably give meaning to each of the terms in question.** Only if an interpretation giving reasonable consistency to the terms in question cannot be found will the court rule one clause or the other ineffective: Chitty on Contracts, supra, at p. 526; Lewison, supra, at p. 206; *Git v. Forbes* (1921), 62 S.C.R. 1, perDuff J. (as he then was), dissenting, at p. 10, rev'd [1922] 1 A.C. 256; *Hassard v.Peace River Co*-operative Seed Growers Association Ltd., [1954] 2 D.L.R. 50 (S.C.C.), at p. 54. **In this process, the terms will, if reasonably possible, bereconciled by construing one term as a qualification of the other term:** *Forbesv. Git*, [1922] 1 A.C. 256; Cotter v. General Petroleums Ltd., [1951] S.C.R. 154. A frequent result of this kind of analysis will be that general terms of a contract will be seen to be qualified by specific terms — or, to put it another way, where there is apparent conflict between a general term and a specific term, the terms may be reconciled by taking the parties to have intended the scope of the general term to not extend to the subject-matter of the specific term.
>
> (emphasis added)

23 An interpretation of paragraph 1, including sub-paragraphs 1(a) and (f), that can reasonably give meaning to each provision is that while CN was not prepared to make any representation or warranty regarding the condition of the property, and required

  

DCI to close if no notice of termination was delivered, it was prepared to indemnify DCI if it turned out the after the closing that there was a problem with the property before the closing of the sale to DCI..

24 There is no indication in the agreement to say that the intention of the parties was that sub-paragraph (a) or any other sub-paragraphs should override or trump the second half of subparagraph (f) which provides an indemnity by CN in favour of DCI. Nor would I so construe it that way. To do so would be to render the indemnity in favour of DCI ineffective. Such an interpretation is to be avoided if at all possible.

25 CN takes the position that the merger provision in sub-paragraph 1(g) means that only the obligations of the purchaser DCI contained in paragraph 1 of schedule B survived the closing. That sub-paragraph provides:

> 1 (g) This clause 1 of this Schedule "B" shall not merge but shall survive the closing of this transaction and shall be a continuing obligation of the Purchaser.

26 In effect, CN interprets the clause to refer to the "obligation of the Purchaser only", so that any obligation on the part of CN merged with the closing. It relies on the principle as set out in *Richview Construction Co. v. Raspa* (1975), 11 O.R. (2d) 377 (Ont. C.A.) that conditions in an agreement of purchase and sale merge on closing unless the agreement says otherwise and that under sub-paragraph (g) only obligations of the purchaser CDI survived the closing.

27 I do not accept this interpretation of sub-paragraph (g). The first part of the sentence provides clearly that the entire clause 1 shall not merge but survive the closing. That would include sub-paragraph (f) with its indemnity in favour of DCI. The sentence does go on to provide that it shall be a continuing obligation of the purchaser, but that does not expressly state that only obligations of the purchaser in clause 1 continue.

28 In order to construe all of the provisions in clause 1 of schedule B in a commercially reasonable manner that reflects the intention of the parties, it is necessary to understand how the agreement, and particularly sub-paragraph 1(f) of schedule B, came into being.

29 It is agreed that the second half of sub-paragraph (f) providing a CN indemnity in favour of DCI was added by the parties from a standard CN form of agreement. Mr. Forgione was a lawyer familiar with the CN form as he had previously acted for someone who bought property from CN, and he wanted changes to it. All of paragraph 1 in schedule B to the agreement was taken from the standard CN form except for sub-paragraph (f), which was changed. The change to the form can be seen by looking at the agreed sub-paragraph (f), with the deletions and insertions marked:

> (f) The purchaser shall be responsible for and hereby indemnifies and saves harmless the Vendor and Canadian National Railway Company from any costs, including legal and witness costs, claims, demands, civil actions, prosecutions, or administrative hearings, fines, judgments, awards, including awards of costs, that may arise as a result of the..... ~~condition of~~ damage or contamination to the property following the closing and the Vendor shall be responsible for and indemnify and save harmless the Purchaser from all costs, claims and other damages, including, any order issued in connection with the condition of the property, or any loss, damage or injury caused either directly or indirectly as a result of the condition of the property before closing.

30 Without these changes being inserted in the standard form agreement, one can understand why sub-paragraph (g) referred only to paragraph 1 surviving the closing and being an obligation of the purchaser. The entire paragraph 1 in the standard CN form involved only obligations or steps to be taken by the purchaser and thus the reference to clause 1 being a continuing obligation of the purchaser made sense. But with sub-paragraph (f) being changed to contain an indemnity of CN in favour of DCI, it would make no sense to construe sub-paragraph (g) to mean that the indemnity obligation of CN did not survive closing. A reasonable interpretation of sub-paragraph (g) is that the entire clause 1 survives the closing, whatever is in clause 1, including the indemnity of CN.

31 CN has referred to correspondence and discussions of the parties leading to the change in the CN standard form of agreement in its submissions as to the proper interpretation of sub-paragraph 1(f). However, this evidence of prior negotiations

  

and discussions is inadmissible. Generally the factual matrix which is admissible does not include evidence of negotiations. See *I.T.T. Industries of Canada Ltd. v. Toronto Electric Commissioners*, [1981] O.J. No. 53 (Ont. C.A.) and *Toronto Dominion Bank v. Leigh Instruments Ltd. (Trustee of)* (1998), 40 B.L.R. (2d) 1 (Ont. Gen. Div. [Commercial List]) at para 405 ( per Winkler J. as he then was); aff'd (1999), 50 B.L.R. (2d) 64 (Ont. C.A.).

32 The fact that the parties took a standard form of agreement and added a provision to it, without more, is in my view part of the factual matrix surrounding the making of the agreement that may be looked at in construing the agreement, and neither party contended otherwise. This does not involve getting into what went into the negotiations leading to the changes to the form that were agreed. For a useful discussion of this issue, see Geoff R. Hall, *Canadian Contractual Interpretation Law* (1st ed., Lexis Nexis) at pp. 20-21 and 66.

33 CN also relies on the evidence of Mr. Longo who negotiated and signed the agreement on behalf of CN as to what he believed the clause to mean, but this evidence of subjective intent is not admissible. See *Toronto Dominion Bank v. Leigh Instruments Ltd. (Trustee of)*, *supra*, at para 406 and *Mifsud v. Owens Corning Canada Inc.*, [2003] O.J. No. 3866 (Ground J.) and the cases referred to.

34 CN has also contended that if there is an ambiguity as to the meaning of the agreement that cannot be resolved by interpreting its terms as a whole, the *contra proferentem* rule should apply "against the person making the amendment" and thus DCI's interpretation of the CN indemnity should not be accepted.

35 The *contra proferentem* rule applies only if there is an ambiguity in the terms of the contract in question and in circumstances in which the party relying on the principle did not participate in the drafting of the document and had no opportunity to modify its language. See *McClelland & Stewart Ltd. v. Mutual Life Assurance Co.*, [1981] 2 S.C.R. 6 (S.C.C.), at 15 per Estey J. and *Hillis Oil & Sales Ltd. v. Wynn's Canada Ltd.*, [1986] 1 S.C.R. 57 (S.C.C.), at 68 per LeDain J. Moreover it is a rule of last resort. See *Consolidated-Bathurst Export Ltd. c. Mutual Boiler & Machinery Insurance Co.* (1979), [1980] 1 S.C.R. 888 (S.C.C.), at 901 per Estey J.

36 In this case, I have concluded that there is no ambiguity that cannot be resolved by an interpretation of the agreement as a whole. If that were not the case, both parties participated in the drafting of the clause in question, or had an opportunity to modify its language, and therefore the *contra proferentem* rule would not apply.

37 Moreover the fact that the indemnity was added to the form after Mr. Forgione was aware of environmental problems is some indication supporting his claim that the indemnity was to have real meaning after closing. An indemnity clause in favour of DCI only covering claims made prior to the closing would be of little benefit to DCI. Indeed CN acknowledged in argument that the CN indemnity on its interpretation would be surplusage because the common law would provide that protection anyway. Such an interpretation is to be avoided if possible.

38 In the result, in my view the indemnity of CN in favour of DCI in sub-paragraph 1(f) of schedule B of the agreement continued in force after the closing and is broad enough to cover claims that arose after the closing from conditions on the property prior to the closing. Thus on that basis the motion on summary judgment to dismiss that claim must fail. I make no comment on whether DCI can establish liability on the part of CN or what the damages were that can be proven.

39 DCI claims not only on the indemnity but also makes a claim arising from an acknowledgment delivered by CN on the closing that all reports, plans, maps, sketches and surveys of the property in CN's possession or control had been delivered to CDI or would be on or before October 6, 2003. DCI claims that not all reports were delivered by CN that it had in its possession, and in particular the CRA report dealing with PCB issues. It also refers in its statement of claim to "an oral confirmation of a lack of problem".

40 The agreement of purchase and sale contained a standard entire agreements clause which included a provision that there were no representations or warranties other than as expressed in writing in the agreement. Clause 2 of schedule B provided that information provided by CN to the purchaser and comments made by staff of CN were for the assistance of the purchaser, but

  

that CN made no representations or warranties about and took no responsibility for the accuracy or completeness of information it had provided. Thus any evidence of any representation made prior to the closing of the agreement would contravene the parole evidence rule and be inadmissible.

41 DCI takes the position, however, that the acknowledgment of CN provided on closing that all reports had or would be provided to DCI was a representation not covered by the entire agreements clause and that any damages it suffered as a result of relying on the representation are recoverable. I have considerable doubts about this claim of DCI because assuming the acknowledgment provided on closing was a representation that could be the subject of a claim, there is little if any evidence of any reliance by DCI on such a representation. The acknowledgment stated that all reports had or would be produced within a week after the closing, and thus even the CRA report that DCI complains was not provided to it could have been provided after the closing. There was no actionable misrepresentation regarding the lack of delivery of that report prior to the closing because of the entire agreements clause that would have enabled DCI not to close and no actionable representation regarding the lack of delivery of the report under the acknowledgment delivered on closing that would have enabled DCI not to close. However, the issue of reliance was not really canvassed during the argument and was a question raised by the court, and thus I am reluctant without a full evidentiary record to conclude that DCI could not establish some reliance arising from any lack of compliance with the acknowledgment delivered on closing.

***(b) Personal claim of Mr. Forgione***

*(i) Occupiers Liability Act claim*

42 Mr. Forgione's first claim is under the *Occupiers' Liability Act* R.S.O. 1990, c. O.2. ("*Act*"). He claims that in 2005, two years after the closing of the sale of CN to DCI, he was harmed when he went onto the property and came into contact with PCB's that were on the property before the sale. He claims that it is sufficient for liability under the *Act* that CN put the PCB's on the property, or allowed them to remain there, while it owned and controlled the property, and is liable under the *Act* to someone who later entered the property after CN sold it.

43 S. 3 of the *Act* provides:

> 3.(1) A n occupier of premises owes a duty to take such care as in all the circumstances of the case is reasonable to see that persons entering on the premises, and the property brought on the premises by those persons are reasonably safe while on the premises.
>
> . . . . .
>
> (3) The duty of care provided for in subsection (1) applies except in so far as the occupier of premises is free to and does restrict, modify or exclude the occupier's duty.

44 S. 1 of the Act defines an "occupier" as follows:

> "occupier" includes,
>
> (a) a person who is in physical possession of premises, or
>
> (b) a person who has responsibility for and control over the condition of premises or the activities there carried on, or control over persons allowed to enter the premises, despite the fact that there is more than one occupier of the same premises; ("occupant")

45 I am told that despite a diligent search, there are no cases under the *Act* dealing with whether a person who has sold land can be liable for damages caused to someone who entered the property after the sale.

46 It seems evident that by virtue of the definition of an occupier, it must be someone who (a) is in physical possession of the property or (b) who has control over the condition of the premises or activities carried on or control over persons allowed to enter the premises. CN is none of these. The fact that an occupier is defined to include someone who has control over persons

 

allowed to enter the premises is an indication that someone who does not control who can enter the premises is not an occupier for the purposes of the *Act*.

47 Section 3(3) permits an occupier to avoid the duty of care set out in s. 3(1) if he or she is free to exclude such liability and does so. CN would be in no position to act under s. 3 (3) once it had sold the land to DCI unless under the agreement it retained control of the property in some way, which it did not.

48 The statutory duty on occupiers is to take reasonable care to make the premises safe. See *Waldick v. Malcolm*, [1991] 2 S.C.R. 456 (S.C.C.) at para 33 per Iacobucci J. CN would be in no position after selling the property to make the premises safe. It would be for DCI to do so. In my view, Mr. Forgione has no claim under the *Act* against CN. If he has any claim under the *Act*, it is against DCI.

49 Moreover, Mr. Forgione has not put forward any cogent evidence of personal injury. On his discovery on September 13, 2007, a little over two years after the alleged incident in 2005, he said he was abandoning his claim for personal injury. At that time he said he had not touched any of the substances that were in what he described as canisters but that he had felt nausea when he opened one of them. However on his discovery on April 17, 2009 he said he had not intended to abandon his claim for personal injury. He said that the incident was in 2004 and that his arms and feet came into contact with PCB oil. He then said he had gloves and shoes on and that his hands did not touch any oil. He said that there had been a leak from a PCB facility into water on the floor and while he had running shoes on, his feet got wet. He said he did not go to the hospital in North Bay but when he returned to Toronto he went to his doctor who put him on to several other doctors and that he had visits with doctors for about 18 months. He also referred to an attendance at a hospital when he came down with sever pains, pains from what he did not say. He said stress resulted in a variety of problems, including emphysema, and said the stress related to a dispute with someone else, the death of his father and his protracted illness, which led to full blown depression for a while. He concluded by saying he did not have physical ailments directly as a result of exposure to PCBs but that he may suffer from psychological trauma.

50 Understandably, Mr. Forgione was asked to produce all clinical records of any physician or health care provider, any hospital records and any medical documentation supportive of his claim for personal injury. He was also requested to provide a copy of an OHIP summary. His counsel took these requests under advisement after Mr. Forgione said these things would not be of assistance as he was not claiming any physical injury. However, nothing was later provided on his behalf, either records of any kind or a statement that the requested records would not be produced.

51 Although the burden of establishing that there is no genuine issue requiring a trial is on the moving party, a responding party to a motion for summary judgment is required under rule 20.02(2) to set out, in affidavit material or other evidence, specific facts to show that there is a genuine issue requiring a trial. A party has an obligation to put its best foot forward and a judge must take a hard look at the evidence to determine whether the evidence raises a genuine issue requiring a trial. The authorities were recently canvassed after the rule 20 amendments by Karakatsanis J. (as she then was) in *Hino Motors Canada Ltd. v. Kell*, [2010] O.J. No. 1105 (Ont. S.C.J. [Commercial List]) and *Cuthbert v. TD Canada Trust*, [2010] O.J. No. 630 (Ont. S.C.J.).

52 It is contended that CN could have moved to compel Mr. Forgione to produce the relevant medical records. That may be, but in my view that is no answer on this motion for summary judgment, and I am entitled to draw an adverse inference from the failure of Mr. Forgione to produce any of those records. See *Indcondo Building Corp. v. Steeles-Jane Properties Inc.* (2001), 14 C.P.C. (5th) 117 (Ont. S.C.J.).

53 In this case, Mr. Forgione has not provided any affidavit evidence of any kind in support of his claim for personal injury. The failure of Mr. Forgione to produce any medical records or even an OHIP summary of visits to health care professionals or hospitals cannot be ignored, particularly given the quality of evidence he gave on his two examinations for discovery as to his alleged injuries. A party is not entitled on a motion for summary judgment to say that more and better evidence will be available at the trial. See *Pizza Pizza Ltd. v. Gillespie* (1990), 75 O.R. (2d) 225 (Ont. S.C.J.). The inference I draw is that the existing medical records would not be helpful to his case, and that he is unable to show that there is a genuine issue requiring a trial as to his alleged personal injury.

  

54 On the record before me, I find that there is no air of reality to the claim.

*(ii) Duty of care*

55 Mr. Forgione claims that CN owed him a duty of care not to contaminate the property it sold to DCI. This claim is described as a duty of neighbourliness. He claims that as a result of CN's breach of this duty, and the notoriety in North Bay caused by PCB problems on the Main Street property, he has suffered personal damages in that two other properties in North Bay acquired from CN by companies which he owns and controls have been negatively affected with decreasing land values. This claim is asserted in his statement of claim, but there has been no evidence put forward of any kind on his behalf to support this claim for damages.

56 Apart from saying that the duty of care is one of neighbourliness as established in *McAlister (Donoghue) v. Stevenson* [(1932), [1932] All E.R. Rep. 1 (U.K. H.L.)], no argument of any kind was directed to the principles or tort liability dealt with in *Cooper v. Hobart*, [2001] 3 S.C.R. 537 (S.C.C.) and *Martel Building Ltd. v. R.*, [2000] 2 S.C.R. 860 (S.C.C.). Any decision that a duty of care would be owed by a vendor of land to a shareholder of another company that acquired a different parcel of land from the vendor would require an analysis of the *Anns* principles as discussed in those cases. Without any argument of any kind on this point being made, I am reluctant to express any decision on the point, and decline to do so, as it is unnecessary.

57 Assuming there is enough evidence to establish that a trial is required to determine whether any such tort liability could be extended to the facts of this case, Mr. Forgione has failed to provide any evidence whatsoever to support the allegation of damage to the other properties that were acquired. In those circumstances no trial is required on this claim.

*(iii) Duty of good faith*

58 Mr. Forgione claims that CN owed him a duty of good faith which was breached by failing to advise of the PCB contamination problem on the Main Street property. It is claimed that this duty arose from the contract between CN and Mr. Forgione in trust that resulted in the sale of the Main Street property to DCI.

59 I do not accept that in law there could be any such claim. Mr. Forgione was not personally a party to the agreement. He signed it in trust and DCI took title to the property.

60 Moreover, Canadian law has not recognized a general duty of good faith independent from or contrary to the terms of contract. In *Transamerica Life Canada Inc. v. ING Canada Inc.* (2003), 68 O.R. (3d) 457 (Ont. C.A.) O'Connor J.A. stated the following:

> [53] I agree with Transamerica that Canadian courts have not recognized a standalone duty of good faith that is independent from the terms expressed in a contract or from the objectives that emerge from those provisions. The implication of a duty of good faith has not gone so far as to create new, unbargained-for rights and obligations. Nor has it been used to alter the express terms of the contract reached by the parties. Rather, courts have implied a duty of good faith with a view to securing the performance and enforcement of the contract made by the parties, or as it is sometimes put, to ensure that parties do not act in a way that eviscerates or defeats the objectives of the agreement that they have entered into: see GATX, supra; Greenberg, supra; Gateway Realty, supra.

61 In the contract of purchase and sale, apart from the entire agreements clause, paragraph 2 of schedule B provided that while information was being provided to the purchaser, CN made no representations or warranties about and took no responsibility for the accuracy or completeness of information provided. To find liability on a duty of good faith to make full disclosure would run contrary to this provision. The fact that this provision merged on closing does not assist Mr. Forgione, as his claim is based on the contract of purchase and sale. Nor does the acknowledgment provided to DCI on the closing.

Even if there were a duty of good faith owing to Mr. Forgione that was breached, Mr. Forgione has failed to establish any basis for personal injury cause to him, for the reasons stated previously, that would require a trial.

 

**Conclusion**

62 The motion to dismiss the claim of DCI against CN is dismissed. The motion to dismiss the claim of Mr. Forgione against CN is allowed. As success has been divided, there shall be no order as to costs.

Footnotes

1 The agreement contains an entire agreements clause and the admissibility of this evidence is thus an issue.

# Tab 4

Neutral Citation Number: [2011] EWHC 2895 (Comm)

Case No: 2008 FOLIO NO.877

**IN THE HIGH COURT OF JUSTICE**
**QUEEN'S BENCH DIVISION**
**COMMERCIAL COURT**

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 07/11/2011

**Before :**

**MR JUSTICE HAMBLEN**

- - - - - - - - - - - - - - - - - - - - -

**Between :**

**(1) PORTON CAPITAL TECHNOLOGY FUNDS** — **Claimants**

**(2) PORTON CAPITAL INC.**

**(3) PLOUGHSHARE INNOVATIONS LIMITED**

**- and -**

**(1) 3M UK HOLDINGS LIMITED** — **Defendants**

**(2) 3M COMPANY**

- - - - - - - - - - - - - - - - - - - - -
- - - - - - - - - - - - - - - - - - - - -

**Stephen Phillips QC and Matthew Parker** (instructed by **DLA Piper**) for the **Claimants**
**Mark Howard QC and Simons Salzedo QC** (instructed by **Simmons & Simmons LLP & Dorsey & Whitney (Europe) LLP )** for the **Defendants**

Hearing dates: 15,16,20,21,22,23,27,28,29,30 June 2011. 1,4,5,6,7,11,12,13,14,18 July 2011. 29 September. 3 & 4 October 2011

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# Judgment

**Mr Justice Hamblen :**

## Introduction

1. On 14 February 2007 the First Defendant ("3M UK") agreed to buy the entire shareholding of Acolyte Biomedica Limited ("Acolyte") under a Share Purchase Agreement ("the SPA"). The Claimants were some, but not all, of the shareholder vendors ("the vendors"), representing a total of 60.4% of the shareholding.

2. The consideration for the shares was £10.4m in cash and an earn out payment based on net sales for the calendar year 2009. Acolyte's only commercial product, and the only one relevant to the present claim, was BacLite MRSA, a diagnostic assay used for the purpose of detecting MRSA. In the event, the Acolyte business was not successful and it was terminated in December 2008. There were therefore no net sales in 2009.

3. The Claimants allege that the failure and termination of the business involved breaches of contract on the part of 3M UK, that the wrongful termination was knowingly induced by the Second Defendant ("3M US"), and that the Claimants have lost their 60.4% share of the net sales which should have been achieved, which they claim would have been in the region of £32m or US$56.45m.

4. The case of the Defendants (together, or when unnecessary to distinguish, "3M") is that they have always acted in good faith and in accordance with the SPA. They were entitled to terminate the business in circumstances where they had requested consent and offered compensation and the vendors reacted unreasonably. The reasons that no earn out became payable were the failings of BacLite MRSA itself and the fact that the market moved against that product. On any view, net sales in 2009 could only ever have been at a very low level.

5. The principal issues for decision are:

Was 3M in breach of its contractual obligation diligently to seek regulatory approval for BacLite?

Was 3M in breach of its contractual obligation actively to market BacLite?

Did the vendors act unreasonably in withholding consent from the Defendants to terminate the Acolyte business in late 2008?

How and when did the SPA come to an end? Did either party accept the other's repudiation and if so which?

How much would the net sales of BacLite in 2009 have been if 3M had performed its obligations under the SPA and the Acolyte business had continued through 2009?

Did 3M US knowingly induce breaches of contract by 3M UK?

## General Background

*Acolyte*

6. Acolyte was established in around 2000 as a joint venture between the UK government and a venture capital fund. It was formed with the intention of exploiting certain technology first developed by the Defence and Evaluation Research Agency ("DERA"), part of the UK Ministry of Defence, at Porton Down in Wiltshire. The technology in question was based upon the activity of the adenylate kinase enzyme, which is present in all organisms.

7. In August 2001, Acolyte recruited its first employee, Mr Stephen O'Hara, as its chief scientific officer. Mr O'Hara had been chief scientist in microbiology at Southampton University Hospital from 1987 to 1997. Subsequently, Dr William Mullen joined Acolyte in November 2002 as Chief Executive Officer.

8. By July 2003, Acolyte had developed a prototype product for the detection of a range of harmful organisms, but it then began to develop a product which would focus exclusively on the detection of MRSA (albeit with scope to be expanded in due course to detect other organisms). In January 2004, Acolyte raised a further £3.7 million in investment, at which point the Second Claimant became a major shareholder in the company. The Third Claimant was established in April 2005 as an investment arm of the UK Ministry of Defence and it too subsequently became a shareholder in Acolyte.

9. At the trial the Claimants called Mr O'Hara and Dr Mullen as witnesses of fact. They also called Mr John McKinley, the Chairman and Director of Acolyte from September 2006 until its sale to 3M UK. In addition they called as experts Professor Richard James, Professor of Microbiology at the University of Nottingham, and Dr David Huckle, a consultant in strategic marketing and business development covering all areas of Biotechnology and Life Sciences.

*3M*

10. The 3M group is a large multinational organisation which carries on business across six business segments: industrial and transportation; health care; display and graphics; consumer and office; safety, security and protection services; and electro and communications. According to its 2007 Annual Report, it employed 76,239 people and achieved a net operating income of US$4.1 billion on sales of US$24.5 billion.

11. As part of its Health Care Business, 3M supplies medical and surgical supplies, skin health and infection prevention products, drug delivery systems, dental and orthodontic products, health information systems and microbiology products. In 2005, 3M set up a business unit in order to expand its Health Care Business into a new market: Medical Diagnostics. At this time, 3M was developing its own PCR (Polymerase Chain Reaction) platform for the rapid detection of MRSA, known as Fastman. Subsequently, in December 2006, 3M entered into an agreement with Response Biomedical to commercialise its RAMP testing platform, which was subsequently launched as the Rapid Detection Flu A+B Test in October 2008. The acquisition of BacLite was part of 3M's expansion into Medical Diagnostics.

12. At the trial 3M called the following factual witnesses: Ms Cassie Jacobson, clinical research manager for 3M's Infection Prevention Division's new product development programme; Dr Bob Brennan, senior microbiologist with 3M's Medical Division; Dr Tushar Kshirsagar, Product Development Manager at 3M; Dr David Whitman, Lab Manager for the 3M Biodetection Department; Mr Brian Anderson, 3M's Global Marketing Manager for Medical Diagnostics; Mr Mark Whitworth, 3M's European Business Leader, Infection Prevention; Mr James Ingebrand, 3M's Medical Division Infection Prevention business unit director; Mr Peter Robinson, a consultant engaged by 3M to support the commercialisation of BacLite and later 3M's Technical Services Leader for the European, Middle East and Africa area; Mr James Collier, a sales and marketing consultant engaged by 3M to provide sales training and marketing support in relation to the launch of 3M's Medical Diagnostic business and later 3M's European Business Development Manager for Medical Diagnostics; Dr Jan Kluytmans, a Consultant Microbiologist at Amphia Hospital in Breda in the Netherlands and Professor of Medical Microbiology and Infection Control at VUmc Medical University, Amsterdam; Dr Bart Gordts, who at the material time was the Head of Microbiology at AZ Sint-Jan

Hospital, Bruges in Belgium; Ms Maggie Skyrme, who at the material time was Deputy Manager, then acting Manager, then Laboratory Manager of the Department of Microbiology at Salisbury Hospital in the UK. 3M also called as experts, Mr Thomas Tsakeris, a consultant to the medical device industry with respect to US FDA (Food and Drug Administration) regulations and procedures; Mr Kenneth Powell, a consultant providing business development support in the identification, evaluation and commercialisation of new business opportunities in the clinical diagnostic, life sciences and medical device market segments; and Dr Brian Stammers, a healthcare industry consultant.

*MRSA*

13. MRSA stands for methicillin-resistant *Staphylococcus aureus*. It is a form of bacteria which is resistant to antibiotics. *Staphylococcus aureus* (abbreviated to *S.aureus*) is a species of bacteria. Methicillin is a form of the penicillin antibiotic (within the class of antibiotics known as beta lactam antibiotics). *S.aureus* that is not resistant to methicillin, ie that is methicillin-sensitive, is known as MSSA.

14. *S.aureus* is carried in the nose or on the skin of around 30% of the population. Mere carriage of the bacteria does not cause any harm to the individual unless it develops into an infection. Because of its resistance to many conventional antibiotics, an infection of MRSA is particularly harmful and can lead to death.

15. One of the methods by which hospitals seek to control the spread of MRSA is by screening for MRSA colonisation. A common method of such screening is by taking a nasal swab from a patient, which is then tested for MRSA using one or more of a number of different testing methods. As at February 2007, when 3M acquired Acolyte, the most widely used MRSA screening tests were:

    i) Traditional Culture: a swab is rubbed onto the surface of an agar plate containing Mannitol Salt Agar (MSA). The salt present in the agar will discourage the growth of most bacteria apart from *Staphylococci*. Unlike most other forms of *Staphylococci*, however, *S.aureus* also has the ability to ferment mannitol, so any *S.aureus* bacteria will appear as yellow-coloured colonies on the MSA plate and be surrounded by a yellow halo. This method then requires further tests to be carried out in order to distinguish between MSSA and MRSA, which means that a result is not available until 48-72 hours after the swab is streaked onto MSA. As a result, alternative tests were developed which combined the use of MSA and a selective antibiotic (such as oxacillin) to prevent the growth of MSSA, which enabled presumptive MRSA results to be reported without an additional step. One example of such a selective test is MSA-Ox, which is an agar plate comprising MSA with added oxacillin.

    ii) Chromogenic Agars: these are variants of the selective traditional culture tests. Like MSA-Ox, they use selective antibiotics (such as oxacillin or cefoxitin) in order to distinguish between MSSA and MRSA. The leading chromogenic agar is known as CHROMagar MRSA which in February 2007 was able to produce MRSA results within 24-48 hours.

    iii) PCR or Molecular Tests: whereas the culture tests described above are phenotypic (in that they detect the property of a bacteria, such as resistance to methicillin), PCR tests are genotypic, in that they detect a target DNA sequence of MRSA bacteria. For this reason, they are also known as 'molecular tests'. PCR tests are capable of producing results within 1-2 hours,

but were much more expensive than traditional culture tests or chromogenic agars. During 2007-2008, two PCR-based MRSA tests were available on the market. They were the GeneOhm, produced by Becton Dickinson, and the GeneXpert, produced by Cepheid.

16. With all of the tests above, a negative result could be treated as a confirmed negative, meaning that the hospital could proceed on the basis that the patient was free from MRSA. In February 2007, any positive result, however, was only a presumed positive, meaning that additional confirmatory tests were required to confirm that the sample was in fact positive for MRSA. The confirmatory tests generally took an additional 24 hours (although quicker tests were also available).

*The BacLite Test*

17. The first version of the BacLite MRSA test was launched by Acolyte in May 2005. BacLite is a diagnostic assay, meaning that it is a test for the purposes of detecting an organism. It is intended to detect the presence of MRSA in nasal or groin screening swabs to aid in the prevention and control of MRSA infections in hospitals. It is not intended to detect or diagnose infections. In summary, the test works as follows:

    i) First, a swab is taken from the patient. The swab can then be stored for up to 24 hours before continuing with the assay process.

    ii) The swab is then placed into a selective culture medium—or 'broth'—a liquid which is designed to encourage the growth of MRSA, but inhibit the growth of bacteria which are not methicillin resistant. The broth is incubated for a period of two hours at 37° C to allow any MRSA to grow.

    iii) Two samples are then taken from the broth and placed into adjacent wells on a typical laboratory plate (known as a microtitre dish). The dish is then placed into the BacLite processor and undergoes a process whereby the fluid contents of the well are washed away leaving only any MRSA cells behind.

    iv) At that stage, fresh broth is added to both wells and the contents of one of the wells are incubated in the presence of an enzyme called lysostaphin, which breaks down the cell walls of any MRSA present and releases the enzyme adenylate kinase. If any adenylate kinase is released, it will produce a chemical reaction with other chemicals added to the well, which will release light (bioluminescence). The BacLite processor takes a reading of the light emitted from this well, which provides a base reading.

    v) The second well is then incubated for a further two hours at 37°C to allow any MRSA to grow further before carrying out a further lysostaphin incubation and taking a second light reading.

    vi) If the light level of the sample in the second well has increased sufficiently compared with that of the first well, the BacLite processor will produce a positive result for the presence of MRSA.

18. This process, from the beginning of the first incubation stage to the production of a result, was claimed to take five hours. As with the alternative forms of test above, BacLite produced a confirmed negative result, meaning that the hospital could proceed on the basis that the patient was free of MRSA, or a presumed positive

result, upon which a further confirmatory test would be carried out in order to confirm for the presence of MRSA.

19. BacLite was perceived to have a strong 'value proposition' in that it was much faster than culture, and even the newer chromogenic agars, but it was significantly cheaper than the PCR-based tests.

*Performance of MRSA screening tests*

20. The reliability of a test for MRSA is measured in terms of its sensitivity and specificity. In order to determine the reliability of a particular test, it is necessary to measure its performance in comparison to some other reliable method for testing for the presence of MRSA. Such other method is known as the 'comparator'.

21. The sensitivity of the test is the proportion of the true positive results produced by the test to the number of positive samples, as identified by the comparator. So, if in a sample of 100 patients, a test correctly identifies 9 out of the 10 patients carrying MRSA, the test has a sensitivity of 90% (9/10). The one patient that was incorrectly diagnosed as being negative for MRSA is known as a false negative.

22. The specificity of the test is the proportion of negative samples produced by the test to the number of true negative results, as identified by the comparator. So, if in a sample of 100 patients, the test correctly identifies 85 of the 90 patients as being negative for MRSA, the test has a specificity of 94% (85/90). The 5 patients that were incorrectly identified as being positive for MRSA are known as false positives. In this example, therefore, the test would have produced a total of 14 positive results (9 true positive and 5 false positive) and 86 negative results (85 true negative and one false negative).

23. It was common ground between the parties that data from a product's manufacturer as to its performance will generally be more favourable than that produced by an independent study of a product.

*Clinical Studies of BacLite and EU Regulatory Approval*

24. In order to obtain approval to sell BacLite in the European Union ("EU"), it was necessary to satisfy the requirements of the *In Vitro* Diagnostic Medical Devices Directive 98/79/EC (the 'IVD Directive'). The IVD Directive came into force on 7 June 2000 and compliance in the UK became mandatory on 7 December 2003. The IVD Directive identified various categories of device to which different requirements applied, and BacLite fell within the category to which Annex II applied. This required clinical studies of the device to be carried out before it could be marketed for sale in the EU.

25. The clinical trials of the first version of BacLite took place in April and May 2005 and involved nasal swabs taken from patients at three hospitals in the UK. The swabs taken at St Bartholomew's Hospital and Salisbury District Hospital were tested using BacLite by the staff in the microbiology departments of those hospitals. The swabs taken at Southampton University Hospital were tested by staff at Acolyte's laboratory at Porton Down. BacLite's performance was compared to that of MSA-Ox, which was the current method recommended by the British Society of Antimicrobial Chemistry and had been widely used as a screening medium for MRSA. Of the 1377 swabs tested, BacLite achieved a sensitivity of 93.4% and specificity of 95.7% in comparison to the MSA-Ox test.

26. An updated version of BacLite was introduced in January 2006. At that stage, it was only necessary to demonstrate that there had been no substantial negative variation in performance when compared to the original BacLite assay. In December 2005, therefore, nasal swabs were collected from 220 patients at one hospital, and around 50% of the swabs were spiked with various levels of MRSA to increase the number of positive test results. The process of "spiking" a swab involves adding a known quantity of MRSA to the swab so as to ensure that this swab will produce a positive result. In this trial, the two BacLite processors showed 95.3% agreement with similar sensitivity and specificity values when compared to culture.

27. The third version of BacLite was launched in April 2006, in which a new broth formulation was introduced. A further trial was carried out to demonstrate that this change had not significantly impacted BacLite's performance. A study was carried out on nasal samples from 216 patients, of which 50% were again spiked. The new broth formulation produced a sensitivity of 85.3% and specificity of 96.4%. The sensitivity increased to 89.2% with a minor change to the interpretative algorithm.

28. The fourth and final version of BacLite, BacLite MRSA Rapid+ (known as the 'International Formulation'), was launched in January 2007. On this occasion, further clinical studies involved taking 213 nasal screening swabs and 167 groin swabs from patients at three UK hospitals (St Bartholomew's Hospital and Salisbury District Hospital again, and Chelsea & Westminster Hospital). The comparator used on this occasion was MSA-Ox, with further standard confirmatory tests for MRSA. These swabs produced a performance of 100% sensitivity and 96.9% specificity for nasal swabs. A further 99 spiked swabs (including 49 nasal swabs) were also added to the study, and all of the 479 samples were then tested by Acolyte staff at its laboratory in Porton Down. With the spiked swabs taken into account, the overall performance of BacLite MRSA Rapid+ with nasal swabs was 94.6% sensitivity and 96.9% specificity.

29. On this basis, the BacLite MRSA Rapid+ assay was fully approved for sale throughout the EU.

*The Sales Cycle and Early Sales of BacLite*

30. In 2005 there was no uniform approach to screening for MRSA in the UK, let alone worldwide. While there was growing public and political awareness of the problem, each hospital had its own policy on screening. Some hospitals carried out universal screening, others screened only high-risk patients. Some hospitals used traditional culture methods, others chromogenic agars, while others were starting to adopt the new PCR-based tests.

31. The process of selling a new diagnostic assay to a particular hospital is time consuming and complex. With BacLite, the process began with identifying a prospective customer and establishing that the BacLite test might in principle be part of a suitable testing regime for that hospital. Because BacLite was designed to work with batches of samples, it was unlikely to be economic for use by a small hospital screening only a few patients for MRSA each day. The next stage was to engage the customer's interest in BacLite and persuade the customer to carry out its own clinical evaluation of the test. This required the participation of various 'stakeholders' within the hospital's administration: the laboratory manager, the clinical microbiologist and the head of infection prevention.

32. During the clinical evaluation, the customer would be able to compare the performance of BacLite with its current methods of MRSA screening. This would enable it both to assess BacLite's clinical performance (in terms of sensitivity and specificity), but also its ease of use and the extent to which it fitted within the hospital's existing working practices (or to which those practices might need to be modified in order to accommodate BacLite). Although BacLite was marketed, first by Acolyte and subsequently by 3M, as an easy to use assay, it was a sensitive and sophisticated piece of diagnostic equipment that required some care in its use. A failure properly to follow the instructions for using it might result in it producing aberrant results. It was therefore important for the distributor to provide guidance and support for the trial process.

33. If BacLite's performance in the customer trial was to the hospital's satisfaction, this was known as a successful technical close. Having shown that BacLite performed as advertised, however, it was still necessary to demonstrate that it was a viable commercial proposition. It would be necessary to present a business case for the purchase of BacLite: to show the hospital that it represented a cost-effective means of MRSA screening at that particular hospital. Only upon the successful completion of this stage of the negotiation would a sale result. The overall sales cycle—from the first approach to the customer to a successful commercial close—was estimated to take between 9 and 12 months.

34. In conjunction with specific customer sales, it was also important to market BacLite more generally. One way of doing this was to enlist the support of influential scientists and clinicians, to trial BacLite and publicly to endorse its performance claims. Such influential individuals are known as Key Opinion Leaders ("KOLs").

35. Acolyte achieved the first sale of BacLite to Salisbury Hospital in 2005. Salisbury was to remain BacLite's "flagship" customer. To seek further sales, Acolyte appointed BioStat Limited as exclusive UK distributor for BacLite. In the period from May 2005 through until the 3M acquisition in February 2007, BioStat secured two further customers, London Independent Hospital and Lister Hospital. The latter used BacLite for research purposes only.

*3M's acquisition of Acolyte*

36. In 2006, 3M expressed an interest in acquiring Acolyte and its new diagnostic platform, BacLite. Discussions about a possible acquisition began in around September 2006 (under the codename 'Matchbox').

37. At the same time, 3M carried out due diligence on the company and its product. Dr Brennan, the Senior Microbiologist in 3M's Medical Division, visited Acolyte's laboratory at Porton Down and watched BacLite in action. Dr Whitman, the Lab Manager within the Medical Division, was also involved in reviewing the technical aspects of BacLite.

38. Dr Brennan also received reports from several UK hospitals at which BacLite was being used at the time to discuss their experience, including the London Independent Hospital, St Bartholomew's and Salisbury.

39. In around September/October 2006, 3M prepared an internal presentation for the purposes of obtaining formal approval to submit a bid to purchase Acolyte. At that stage, 3M valued the company at £87.8m. The presentation noted that BacLite was

in a "High Growth Market Space" and that the global market for infectious disease IVDs had been worth US$6.2 billion in 2004.

40. In November 2006 3M and Acolyte exchanged notes on sales forecasts. Both were projecting forecast sales of around £22 million for 2009, although the sources of sales were different. On 10 January 2007, 3M provided the shareholders with further sales projections (with the caveat that they should not be relied upon by the shareholders). 3M forecast worldwide revenues of the BacLite MRSA test of US$13.10m in 2008 and of US$28.03m in 2009.

41. On 7 November 2006, 3M wrote to Mr McKinley with a non-binding offer to buy Acolyte for £10.4m initial consideration, £600,000 to be paid over two years to the holders of stock options and up to £41,250,000 contingent upon the sales of Acolyte's products in the third year after closing.

42. On 23 January 2007, 3M prepared a further internal presentation seeking PAR III approval to complete the acquisition on broadly the terms already offered. The presentation recorded that since the initial non-binding offer, 3M "began detailed due diligence the week of November 11, 2006", that it had "Conducted onsite diligence at their UK facilities at Porton Down" and "Onsite visit included interviews with Management and all employees, as well as a comprehensive review of data room materials". 3M had also "confirmed" Acolyte's consolidated value (now stated to be £81.5m). That valuation was based on forecast sales of £6.157m in 2008 and £17.554m in 2009.

43. Mr Brad Sauer, the head of 3M's Health Care Business, and Mr Chuck Kummeth, who had an executive responsibility for the BacLite business, gave a final presentation to 3M's board of directors in February 2007. They sought the board's approval to proceed with the purchase for £10.4m plus an earn out based on 2009 sales capped at £41m. That approval was granted and the acquisition went ahead.

*The Share Purchase Agreement*

44. The SPA was concluded on 14 February 2007. Under that agreement, 3M UK acquired all of the shares in Acolyte. By clause 3.1, 3M UK agreed to pay initial consideration of £10.4m. By clause 4.1, 3M UK also agreed to make "Earn-Out Payments" to the vendors. These were to comprise:

> 1. "(i) 100% of the Earnout Product Net Sales up to a maximum amount of £41,000,000, less (ii) the total amount of all Employee Incentive Payments."

45. The term "Earn-Out Products" was defined in clause 1.1 as "those products that fall within the definition provided in Schedule 7" and comprised all products based on Acolyte's bioluminescence technology, including BacLite and its associated products and any further products that 3M might develop based on that technology.

46. The term "Net Sales" was defined in clause 4.2 as:

> "... the net sales amount included in the consolidated statement of income of [the Second Defendant] ... and its consolidated subsidiaries for the fiscal year ended December 31, 2009, under accounting principles generally accepted in the United States of America ("US GAAP") with respect solely to Earn-out Products ..."

47. By clause 4.3, 3M's independent accountants were to prepare an "Earn-out Report" containing a statement of the Earn-out Product Net Sales with whatever supporting documentation they deemed prudent to incorporate. 3M UK was to use its reasonable endeavours to procure that the Earn-out Report should be delivered to the vendors by 1 March 2010 (clause 4.3).

48. There was also provision for the calculation of the Earn-out Product Net Sales to be disputed by the First Claimant, acting with at least two of three other identified shareholders, defined as a "Vendor Majority" in clause 29.4. In order to do so, the Vendor Majority was required to give notice to 3M UK following receipt of the Earn-out Report: clause 4.4. In that event, there was provision for an expert to be appointed to determine the amount of the Earn-out Product Net Sales: clause 4.6(b). Such determination would then constitute the "Agreed Financial Statements": clause 4.6(b). If there was no challenge to the Earn-out Report under clause 4.4 of the SPA, the original Earn-out Report would constitute the "Agreed Financial Statements": clause 4.5.

49. 3M UK was then required to pay the amount due by way of Earn-out Payments under clause 4.1 within 10 business days of the Agreed Financial Statements being constituted: clause 4.7.

50. In relation to the Earn-out Payments, clause 4.1 made clear that "The parties understand that this payment is contingent upon the future performance of the Company and therefore is not guaranteed." Notwithstanding this, 3M UK undertook certain express obligations in relation to the marketing and sale of BacLite, which were intended to protect the vendors' interest in receiving the Earn-out Payment. By clause 4.14, 3M UK undertook that, in the period to 31 December 2009:

> 2. "(a) the Earn Out Products are actively marketed (a) in the United States, the European Union, Canada, and Australia (the "Major Markets") and (b) those countries where 3M has obtained regulatory approval to do so;
>
> 3. (b) (to the extent required) regulatory approval is diligently sought for the Earn Out Products in the Major Markets;
>
> 4. (c) the business selling the Earn Out Products is supported by resources from the following functional areas within the Purchaser's Group: Marketing, Communications, Information Technology, Technical Service, Legal, Tax and Accounting to a similar overall degree as such resources are made available to other businesses within 3M's Medical Division;
>
> 5. (d) the sales representatives for the Earn-out Product will be compensated for the sale of the Earn-out Product in the same general manner as sales representatives in 3M's Medical Division are compensated for the sale of other 3M products;
>
> 6. (e) as soon as reasonably practical after Completion, a training module will be developed for sales representatives selling the Earn-out Products which will be commensurate in standing with the training modules for sales representatives of other products sold by the 3M's Medical Division;
>
> 7. (f) marketing and other training and customer support materials will be prepared to support the sales of the Earn Out Products, will be kept

> reasonably current and will be of an overall standard and quality similar to those used to support the sale of other products within the 3M infection prevention business unit;
>
> 8. (g) the Earn Out Products will be sold as "3M" branded products ..."

51. Clause 4.15 further confirmed:

> 9. "Except as expressly set forth in Clause 4.14, the Vendors acknowledge that the [First Defendant] is under no obligation or duty to conduct its business in a manner that increases the amount payable under this Clause 4. Each Vendor hereby acknowledges and agrees that the Earn-Out Payment is contingent on [Acolyte's] future performance and is not guaranteed."

52. The Claimants' case centred on clauses 4.14(a) and (b). They contended that 3M UK failed to seek regulatory approval in the US, Canada and Australia "diligently" and that it failed to ensure that BacLite was "actively marketed" in all the "Major Markets".

53. By clause 4.14(i), 3M UK undertook:

> "(i) without the written consent of the vendors, which shall not be unreasonably withheld,
>
> (i) [Acolyte] shall not ... cease to carry on its business or the business of the development and marketing of the Earn Out Products ..."

54. By letters dated 14 July and 15 August 2008, 3M invited the vendors to consent to the cessation of the development and marketing of the Earn Out Products. The vendors declined to provide such consent. 3M's case was that such consent was unreasonably withheld by the vendors and that it was therefore released from its obligations under the SPA, alternatively that the vendors thereby repudiated the SPA, which repudiation it accepted. The Claimants' case was that the vendors were entitled to withhold their consent, that they did not repudiate the SPA and that the SPA was repudiated by 3M.

*Events Following Acquisition: Marketing in Europe*

55. Following the acquisition of Acolyte, 3M publicly launched its new Medical Diagnostics business unit on 12 March 2007. At that stage, the global business manager for Medical Diagnostics was Ms Angie Dillow, although she left 3M in May 2007 and was replaced in August 2007 by Mr Jeff Hillins. Ms Dillow and subsequently Mr Hillins had day to day responsibility for the overall management of Acolyte within 3M. Ms Dillow and Mr Hillins reported to Mr Kummeth. Mr Brian Anderson was the global marketing manager, assisted by Ms Catherine Lathem. On the technical side, Dr Whitman was the Laboratory Manager for 3M's Biodetection Department, with responsibility for the diagnostics and hardware department of the Medical Division. Dr Brennan reported ultimately to Dr Whitman.

56. Together, Ms Dillow (and subsequently Mr Hillins), Mr Anderson, Dr Whitman and Mr Bob Davis (the global manufacturing manager) comprised the Global Business Team for Medical Diagnostics, with ultimate responsibility for BacLite. The Global Business Team were based at 3M's offices in St Paul, Minnesota. Mr

James Ingebrand also had responsibility for BacLite, as the director of Infection Prevention within 3M's Health Care Business, and he too reported to Mr Kummeth.

57. In the UK, 3M retained a number of Acolyte's employees, including Mr O'Hara, Acolyte's chief scientific officer, who became Director of Microbiology, also reporting to Dr Whitman and Dr Nick Foote, a microbiologist who had been closely involved in the development of BacLite. They fell under the control of 3M's existing UK office in Loughborough, where Mr Gary Stapleton was Business Director of Healthcare Markets and Mr Mark Whitworth was European Business Development Manager.

58. Prior to its acquisition by 3M, Acolyte's UK distributor was Bio-Stat. It had originally been retained in May 2005 and was responsible for the marketing and distribution of BacLite in the UK. 3M intended to use its own local subsidiary in each of the countries in which it was intending to market BacLite, and it terminated the distribution agreement with Bio-Stat. At the same time, 3M retained Mr James Collier, a microbiologist with sales and marketing expertise, who had previously provided marketing consultancy services to Bio-Stat in relation to Acolyte. Mr Collier was subsequently employed by 3M between September 2007 and December 2008. 3M also retained Mr Peter Robinson, again initially as a consultant and then as an employee. He too had provided marketing and customer support services to Bio-Stat in relation to Acolyte prior to the acquisition.

59. 3M launched BacLite in Europe at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), which took place in Munich over 2 to 4 April 2007. Mr O'Hara gave a presentation on BacLite along with two KOLs, including Dr Jan Kluytmans, a Professor of Epidemiology of Nosocomial Infections in Amsterdam.

60. Ms Lathem prepared a Global Launch Plan for BacLite. Within the 'Product Summary' she set out the key features of BacLite. She included a table showing the respective performance of the various forms of culture and PCR tests, including their sensitivity and specificity claims. According to that table, the cost of the PCR tests was US$30-45 per test, while the culture tests were US$7-10. BacLite was priced at US$14 per test. The plan anticipated that BacLite would be launched in the US in April 2008, in Canada in June 2008 and in Australia by the end of September 2008.

61. The new 3M Medical Diagnostics department did not have any existing sales team in Europe, so it became necessary to hire new sales reps to start the process of marketing BacLite throughout Europe. In the event, this took some time.

62. It was the Claimants' case that 3M made little effective progress in the marketing of BacLite between February and September 2007 and that sales momentum created prior to the acquisition was lost. They contended that in effect the marketing of BacLite in Europe only really started in around September 2007 when 3M undertook its first European customer evaluation.

63. On 11 September 2007, 3M carried out a routine 'Deep Dive Review' of the Medical Diagnostics department. According to the presentation prepared for that review, 3M remained optimistic about the prospects for the new Medical Diagnostics business and recorded that the value proposition and customer acceptance was "Very Strong!".

64. 3M also commissioned market research into the MRSA screening market and the opportunity for BacLite. In the UK, on 17 September 2007, Lighthouse produced a report, which summarised market reactions to BacLite. This was an initial small study based on 11 interviews. It indicated interest in BacLite as described, but also some doubts. The full report issued on 29 October 2007, based on 75 interviews, made similar points and confirmed "a strong interest in trial across a broad sector of hospitals". It also pointed out that 85% of respondents said that they acted only on confirmed positives.

65. In a presentation dated 26 September 2007, Ms Dominique Gilsoul recorded the progress that 3M had made in marketing BacLite to date, noting that it had a "Very Strong and Confirmed Value Proposition". She set out the progress on various customer accounts in the UK, Germany, France, the Netherlands and the Middle East, including the three confirmed customers (Salisbury, LIH and Lister) and one customer about to sign (Chelsea & Westminster).

66. Another important UK development in October 2007 was the publication of Lord Darzi's interim report on "Our NHS Our Future" which stated the UK Government's intention to introduce MRSA screening for all elective admissions in 2008. The Claimants contended that this meant a greater market opportunity for BacLite. 3M contended that in reality it meant that all hospitals would be forced to invest in the cheapest systems to carry out mass screening of low risk patients which would make them less likely to choose the "middle ground" BacLite system.

67. Meanwhile, 3M was also making preparations to build a new manufacturing facility in Loughborough, to take over from Acolyte's existing operations at Porton Down. The transition to this new facility was eventually completed in around July 2008.

*Seeking Regulatory Approval in the United States*

68. In the meantime, 3M had been taking steps to obtain regulatory approval to sell BacLite in the US. In order to do so, it was necessary to obtain clearance from the FDA under section 510(k) of the Federal Food, Drug & Cosmetic Act. By section 510(k), the manufacturer of a medical device must allow the FDA to determine the substantial equivalence of the device to a device which is already legally on sale in the US, known as a 'predicate device'. It will often be necessary for the manufacturer to perform clinical studies with the device in the US to demonstrate such "substantial equivalence". The manufacturer can apply for what is known as an Investigational Device Exemption (IDE).

69. Based at 3M's offices in St Paul, Ms Linda Johnsen had responsibility for regulatory matters. On the scientific side, Ms Cassie Jacobson was clinical research manager for 3M's new Medical Diagnostics business and she was primarily responsible for organising the clinical studies that would be required to obtain FDA approval. She was assisted by various technical staff, including Ms Jennifer Cartony, Mr Bill Lindroos, Dr Tushar Kshirsagar and Mr Dan Morse, all based in St Paul.

70. The internal PAR III presentation made on 23 January 2007 had anticipated that regulatory approval would be obtained in the US and the Rest of the World (ROW) within 6 months of acquiring Acolyte. At around the same time, Ms Dillow estimated that approval would be obtained in the US by early 2008.

71. 3M commenced preliminary studies of BacLite at the Marshfield Clinic in Marshfield, Wisconsin in around June 2007. These were described as "kicking the tyres" and according to Ms Jacobson were aimed at getting BacLite into a potential customer's hands in order to identify areas for optimisation. The Claimants contended that this "beta testing" should have been used as an opportunity to review how BacLite performed in the US and to inform the planning and conduct of the formal clinical studies for the purposes of obtaining FDA approval.

72. Prior to commencing those clinical studies, 3M prepared a Pre-IDE submission to obtain the FDA's advance agreement to the format of the proposed studies. On 1 June 2007, Ms Johnsen wrote to the FDA enclosing 3M's Pre-IDE submission. At that stage, 3M was proposing to use MSA-Ox coupled with tube coagulase testing and MIC testing as the 'comparator': to determine whether each sample was in fact MRSA positive and so provide the benchmark against which BacLite's sensitivity and specificity could be measured. MSA-Ox had been used as the comparator in the previous clinical studies in the UK. 3M was to change the comparator to MSA following a meeting between the team responsible for the development of the Fastman device and the FDA. The FDA had indicated that cefoxitin disk was the "gold standard" for confirming MRSA. In the light of this indication, following internal discussions, it was decided to use the cefoxitin disk as the means of confirming MRSA. At the same time, the decision was taken to change the original screening medium from MSA-Ox to MSA. The Claimants contended that this change should not have been made.

73. Following a meeting with the FDA on 10 August 2007, 3M finalised its Clinical Study Protocol for the proposed clinical studies in the United States.

74. The clinical studies commenced at five US sites in around October 2007 on a rolling basis. The sites were Wake Forest (in Winston-Salem, North Carolina), AIM (Atlanta Institute for Medical Research in Atlanta, Georgia), Wayne State University (Detroit, Michigan), Denver Health (Denver, Colorado) and the University of Maryland Medical Centre (Baltimore, Maryland).

75. In the week beginning Monday 19 November 2007 it was discovered that BacLite had been producing unexpectedly poor results across the US clinical study sites. In particular, BacLite appeared to be achieving a sensitivity of around 50%, instead of the expected 95%. The following Monday, 26 November 2007, 3M took the decision to halt the clinical studies until the cause of the poor performance could be determined.

76. 3M started to investigate the possible causes of the poor performance. Various possibilities were identified including the comparator method (MSA) and the confirmatory test (cefoxitin disk diffusion) used, failure to maintain the incubation temperature at 37°C, and the age of the swab when it was tested (BacLite's instructions for use recommended the use of swabs up to 24 hours old). 3M's statistician, Mr Dan Morse, suggested that, by a process of 'logistic regression', the odds of a false negative increased by 6% per hour of swab age. These factors were noted at a meeting of the Medical Diagnostics Global Business Team on 18 December 2007. Pending resolution of the problem with the US clinical studies, 3M put on hold any efforts to obtain regulatory approval in all other countries worldwide.

77. 3M held a meeting on 18 January 2008 to review the progress of their investigations and to determine whether to re-start the US clinical studies of BacLite. It was decided that further investigations were required.

78. In the meantime, the BacLite business was coming under increasing pressure at 3M's more senior management levels. 3M maintained an internal monthly forecast for all of its businesses known as the 'Blue Book'. Where businesses failed to fulfil their projected revenues (or exceeded projected costs), this could readily be identified by the senior management. The first 'Blue Book' forecasts for Acolyte had been prepared by Mr Whitworth and Ms Gilsoul, but during 2007, Acolyte had started to fall behind its forecasted sales.

79. On 23 January 2008, Mr Sauer circulated an email to the Health Care Business executives, noting that 2008 would be "a very tough year" for the company. He instructed them to squeeze costs, stop hiring additional staff, and to err on the side of under-investing. Mr Sauer pointed out that Acolyte was falling behind its forecast performance (the Blue Book) and that "We cannot tolerate this".

80. On 25 February 2008, 3M approached the FDA to ask whether it would be acceptable for the Clinical Study Protocol to be changed so as to use MSA-Ox as a comparator instead of MSA. 3M held telephone conferences with the FDA on 26 and 28 February 2008, and the FDA confirmed that MSA-Ox would be a suitable comparator.

81. On 7 March 2008, the US clinical team met to discuss the options available in terms of beta testing and the potential restart of the US clinical trials. In advance of that discussion, the team prepared and circulated slides detailing the potential options available and recommending that 3M undertake parallel "beta testing" with the original comparator, MSA-Ox, both with a normal incubation of five hours and with an extended incubation time. The extended incubation was to test whether that extended period would improve the accuracy of the result in terms of sensitivity.

82. Acolyte's failure to keep up, at that stage, with the revenues that had originally been forecast continued to cause concern at the most senior levels within 3M. On the 7 March 2008, Mr George Buckley, 3M's Chief Executive, emailed Mr Sauer, noting that "Acolyte also seems to be going nowhere and I wonder if we should not just pull the plug". Mr Sauer responded on 8 March 2008 and recorded that Mr Buckley's note was not a surprise and was warranted. Mr Sauer stated that he had been working on a plan to shake things up including to "shoot diagnostics". Mr Buckley told Mr Sauer that with Acolyte "its time to fish or cut bait", instructing him to give the infection prevention team "some tough timing and costs targets and tell them to deliver or tell them that we are likely pulling the plug".

83. On 10 March 2008, Ms Jacobson emailed Mr O'Hara and Dr Foote and confirmed that there had been an agreement at the meeting on 7 March 2008 to go forward with "beta testing", but that it would be with extended incubation only. The clinical team agreed to a maximum of four weeks beta testing and then a decision on whether to "go/no-go" on the restart of the US clinical trials would be made. Ms Jacobson recorded that if specificity dropped too low, "they will likely hold off on a US product and tell the team to take a year to improve the product".

84. On 12 March 2008 Ms Jacobson wrote to Mr Mike McLaughlin and stated that "Given our US budget and resource constraints, as well as commercialisation

challenges in Europe, it seems to me to make good sense to not move forward with a pivotal clinical in the US at this time. I think that Europe should continue to commercialise and gain market understanding, while the US and Acolyte technical teams work towards a Gen 2 product that has a winning value prop [sic] for the US and global market". Mr Hillins told Mr Kummeth and Mr Ingebrand on 13 March 2008 to confirm that the US clinical team had considered whether 3M should invest in a pivotal study for FDA submission and a launch campaign with the product as it currently stood. Mr Hillins recorded that 3M's "proposed position currently is no and we should focus resources to other development and clinical activities on this and other diagnostic platforms".

85. On 26 March 2008, the first of three clinical sites identified by 3M to undertake beta testing with MSA-Ox enrolled its first patient. However, on the following day, 3M 'definitively' decided to formally stop the continued testing of BacLite in the United States. From that date onwards, there was no further attempt by 3M to seek regulatory approval for BacLite in either the United States or Canada.

86. Subsequently, the 3M clinical team worked on a 'BacLite Technical Report' during April 2008. Dr Brennan circulated a version of this report for comments on 22 April 2008. The final version of the report was completed in around June 2008. The 'Technical Report' drew various conclusions about the failure of the US clinical studies in November 2007.

*Decision to cease Acolyte business*

87. In April 2008, Mr Sauer arranged for another Deep Dive Review to take place in June 2008 into 3M's diagnostic business, including BacLite and 3M's other diagnostic products, RAMP and Fastman. Prior to that review taking place, 3M confirmed the reallocation of its clinical resources following the decision to end beta testing and not to restart the US clinical trials.

88. The 'Deep Dive Review' of the Medical Diagnostics took place on 9 June 2008 and was led by Mr Sauer. It was 3M's case that it was at this stage that the decision was taken to seek the vendors' consent to cease Acolyte's business. The Claimants maintained that the decision to cease the Acolyte business, or at least to stop the global commercialisation of BacLite, had already been taken in March or April 2008. Furthermore, while 3M did continue to seek the vendors' consent over the following months, the Claimants contended that it had in practice substantially abandoned the business of marketing BacLite by June 2008 at the latest.

89. On 25 June 2008, Mr Mark Schroer of 3M telephoned Mr John McKinley, the designated representative of the vendors under the SPA, and told him that 3M was concerned about the performance of BacLite and asked him to gauge whether the vendors might be prepared to consent to the cessation of Acolyte's business. On 14 July 2008, Mr Kummeth wrote formally to Mr McKinley requesting the vendors' consent to 3M ceasing Acolyte's business under clause 4.14(i)(i) of the SPA. The three main justifications advanced to justify that decision were: (i) BacLite's inadequate performance, (ii) a change in the market dynamics and (iii) the disproportionate costs being incurred by 3M in continuing the business. Mr McKinley met Mr Kummeth and other 3M executives on 30 July 2008 at the annual meeting of the American Association for Clinical Chemistry in Washington DC. Mr Kummeth followed that up with an email to Mr McKinley on 6 August 2008, reiterating 3M's request for consent under clause 4.14(i)(i).

90. On 7 August 2008, Mr Whitworth wrote to Ms Gilsoul and requested a "conservative" estimate of the likely income from BacLite's existing customers for 2009. Mr Gilsoul responded on 8 August 2008 with estimated income for 2009 of US$1,021,000 based on the existing eight accounts and including no amounts for additional instrument sales or trial revenue.

91. On 15 August 2008, 3M sent a further letter to Mr McKinley (this time from Mr Ingebrand). He restated the reasons why 3M was seeking consent and attached an 'Exhibit A' as further justification for that request. In that letter, 3M offered to pay the shareholders US$1.07m, which "has been calculated based on estimated 2009 sales from where the business is as of August 2008. It reflects the maximum sum that the vendors are likely to be entitled to under Section 4.1 of the Acquisition Agreement and is, accordingly, a sum which 3M considers to be non-negotiable". He requested the vendors to provide their consent by 28 August 2008, failing which the offer would be withdrawn and 3M would "Take such actions as it deems necessary to cease, significantly scale back or dispose of the Acolyte business".

92. In response, certain vendors instructed McDermott Will & Emery (MWE), attorneys in Washington DC. On 25 September 2008, MWE responded to the letter of 15 August 2008, indicating that their clients were not prepared to provide their consent unless 3M was prepared to pay the maximum potential earn out of £41m.

93. 3M replied on 7 October 2008 providing further information in relation to the BacLite business and there was further correspondence with MWE. On 31 October 2008, 3M wrote again "to further explain and summarize 3M's position in relation to the current dispute" and again sought the vendors' consent. MWE replied on 12 November 2008, contending that 3M was already in breach of its obligations under the SPA and indicating that their clients would "seek their damages as a result". In the circumstances, they said that they did not demand 3M to continue to perform its obligations under the SPA. The Claimants relied on that letter as constituting an acceptance of 3M's repudiation of the SPA. 3M contended that it was itself a repudiation of the SPA.

94. On 8 December 2008, 3M announced that it was ceasing the BacLite business, with effect from 31 December 2008.

## The Issues

### Was 3M in breach of its contractual obligations diligently to seek regulatory approval for BacLite?

95. The SPA required 3M diligently to seek regulatory approval to sell BacLite in the US and Canada (no further approval was needed in Australia or the EU). The Claimants contended that 3M's obligation to act diligently must be construed as incorporating an obligation to act with all reasonable expedition in relation to each of these markets. They stressed that because the Earnout Payment was fixed for sales during 2009, it was essential to the vendors that 3M acted promptly in obtaining regulatory approval. Any delay would mean that even if approval was obtained in a particular market by the beginning of 2009, the sales during 2009 would be lower in that market than they would have been if 3M had acted promptly.

96. In oral opening the Claimants submitted that the obligation to act diligently required 3M to act not only with reasonable expedition but also with reasonable care. In closing they stressed these two "key elements" and relied upon Ms

Jacobson's statement in evidence that "diligently means both being quick about it as well as using good judgment". In their Particulars of Claim they contended that 3M was obliged to seek regulatory approval "with the care…to be expected of an experienced and competent entity specialising in the development of infection prevention…"

97. 3M contended that in the context of this contract, the obligation to act diligently is not a high standard of perfection or even any specific standard of expertise, but simply a requirement of reasonable application and industry.

98. I agree with 3M that "diligently" in this context means with reasonable application, industry and perseverance. It does not involve any distinct requirement of reasonable care. Indeed it would be difficult to specify any particular standard of care appropriate to a task such as obtaining regulatory approval. As the passage from Ms Jacobson's evidence makes clear, this is a task which involves matters of judgment, about which people may reasonably differ. Further, if some standard of care was intended to be imposed one would expect it to be clearly stated and defined. However, in considering the Claimants' case on the facts I shall assume in their favour that it does require the exercise of reasonable care.

99. It was the Claimants' case that 3M was in breach of this obligation in relation to the first round of clinical studies commenced in October 2007 in four key respects:

i) as a result of a misunderstanding as to the FDA's requirements, which it never sought to clarify, 3M changed the comparator from MSA-Ox (as used successfully throughout the UK trials) to MSA, thereby introducing a new and untested risk to the protocol;

ii) having made a fundamental change to the comparator against which BacLite's performance would be assessed, 3M failed to carry out any pre-clinical study to ensure that BacLite would perform effectively and/or that US sites would be able to operate the protocol effectively, despite having an obvious opportunity to do so at Marshfield;

iii) 3M knew that temperature was an important factor in the operation of BacLite, but 3M failed to ensure that the study sites properly followed the temperature requirements of the Clinical Study Protocol;

iv) more generally, 3M failed properly to monitor the progress of the clinical studies, so as to ensure that the protocol was being followed at all of the sites and to ensure that BacLite was performing as expected.

100. The Claimants further contended that, having halted the initial clinical studies in November 2007 and established that the substantial cause of BacLite's poor performance was a combination of the above factors, 3M simply decided in March 2008 not to pursue regulatory approval for BacLite in the US in its then form. It did so, having regard to its wider commercial interests, but without any regard to its contractual obligation to the Claimants or their interests in receiving the Earnout Payment for sales of BacLite during 2009.

101. Had 3M properly carried out the original clinical studies, the Claimants contended that it would have obtained FDA approval by the end of 2007 and would have launched BacLite in the United States in January 2008. Alternatively, if 3M had re-started the clinical studies reasonably promptly after identifying the failures of the

original studies, it would have obtained regulatory approval in the US by mid-2008 and would have launched BacLite in the US by June 2008.

102. 3M denied both the alleged breaches of the SPA and the case on causation.

*(1) Choice of MSA as Comparator*

103. The Claimants submitted that in circumstances where BacLite had previously been tested against MSA-Ox in all UK clinical studies, and in which it was currently being tested against MSA-Ox at Marshfield, the decision to change the comparator was one that required particularly careful thought and should only have been taken on very clear grounds. 3M's witnesses recognised that the prudent thing to do would be to follow the UK clinical study protocol as closely as possible. Instead, 3M decided to change the comparator from MSA-Ox to MSA, as a result of a simple misunderstanding of the FDA's requirements. There was no consideration of the various factors set out above. 3M focused exclusively on the question of what would be acceptable to the FDA and, having misunderstood the FDA's requirements, failed to obtain clarification on the point.

104. The alleged misunderstanding of the FDA's requirements arose out of the FDA's reported statement that "Cefoxitin Disk was the only gold standard in their opinion for confirming MRSA. If you don't compare against this product then you can not make any clinical sensitivity or specificity claims." It was said that 3M misunderstood the difference between a confirmatory test and a comparator and wrongly concluded that this meant that MSA-Ox (which used oxacillin rather than cefoxitin) would not be a "gold standard" comparator.

105. It was stressed that that misunderstanding could easily have been clarified with the FDA, but it never was. In Professor James' view, "3M's choice of comparator was a serious mistake that needlessly prejudiced the prospects of BacLite successfully obtaining regulatory approval in the USA."

106. The first documentary reference to the possibility of changing from MSA-Ox to MSA was in Mr Lindroos' invitation to a telephone conference on 7 August 2007: "2. "Gold standard" testing – what constitutes a gold standard? Should we plate on MSA instead of MSA-Ox?". Following the meeting on 7 August 2007, Mr Lindroos referred to the discussion about changing the comparator from MSA-Ox to MSA as follows:

> 10. "... the question of what to inoculate for the initial culture is open to question and is not addressed in the standards. Acolyte used MSA in previous studies. The current clinical protocol calls for initial cultures on MSA-Ox; however, after our discussion, we are leaning toward changing to MSA. This may have implications for our internal registrations as well, which Cassie is checking on."

107. The participants in that telephone conference were Mr Lindroos, Ms Jacobson, Dr Foote and Ms Cartony. The Claimants pointed out that Mr Lindroos does not record the basis on which the decision was taken to change to MSA and submitted that it appears to have been prompted by the FDA's requirement for the use of a cefoxitin disk, but while this was regarded as the gold standard for *confirming* for the presence of MRSA, there was no gold standard for *screening* for MRSA. This was therefore no justification for changing the comparator.

108. The most detailed explanation of the reason for the change to MSA was given by Ms Jacobson. She said that they had been reviewing what their competitors had been using as comparators and that they were generally using a non-MRSA selective medium and a confirmatory step, such as the cefoxitin disc. Further, as far as she could discover, there was not a single US laboratory that used MSA-Ox as a screening method. She further said that it had been pointed out that MSA had the potential to pick up more strains and potentially damaged bacteria that would be missed by MSA-Ox. As stated in an email from Dr Foote on 2 August 2007: "MSA-Ox is not a gold standard: for instance, BacLite can pick up salt intolerant or mannitol negative strains that are missed by MSA-Ox". She said that because of the greater sensitivity of MSA to MRSA the consensus was reached that it should be used to avoid any concerns that the FDA might have about using MSA-Ox or another selective medium.

109. In the light of Ms Jacobson's evidence, which I accept, it is apparent that a considered and reasoned decision was reached to use MSA. In particular the view was taken that this would provide a better comparison to competitor products and would be likely to be favoured by the FDA. In the event the FDA did say that they were "pleased to see 3M's latest version of the clinical study summary and agreed that the materials identified (Mannitol Salt Agar, Latex Agglutination and Cefoxitin Disk) are acceptable and recognised".

110. As events in 2008 were to show, the FDA would in fact have accepted MSA-Ox as the comparator. Further, the investigations carried out following the failure of the US clinical trials identified the change in comparator as a potential contributing factor. In addition, as was accepted in evidence, the prudent course was to follow the UK clinical study protocol so far as possible. However, at the time 3M had no reason to believe that the change in comparator would materially affect BacLite's performance. In particular, no concern was raised at the time by either Dr Foote or Mr O'Hara, the people who had the most extensive technical knowledge of BacLite.

111. Mr O'Hara explained that he had understood that the FDA had stated that MSA-Ox would not be acceptable as a comparator and therefore there was nothing that could be done. However, that is no reason why he could not have raised concerns about the change, if he had had them. The reality is that he did not have such concerns. As he accepted in cross-examination, "we did not anticipate it as a problem". If that was his understanding, then 3M can hardly be criticised for sharing it. At the time 3M reasonably saw the change as being "minor" but "positive".

112. Although, with the benefit of hindsight, it would probably have improved the prospects of the US trials being successful if MSA-Ox had been used as the comparator, I find that the change was made as a result of a reasoned and reasonable judgment and that at the time 3M had no reason to believe that the change would give rise to problems. Indeed, Professor James accepted that the proposal to use MSA and cefoxitin was within the range of reasonable approaches for a person in 3M's position. I find that the change involved no failure on the part of 3M to exercise reasonable care or to seek regulatory approval with reasonable application, industry and perseverance.

*(2) Lack of Pre-Clinical Study*

113. The Claimants contended that, having taken the decision to change the comparator from MSA-Ox to MSA, 3M failed to carry out any form of pre-clinical study to ensure that this would not negatively impact performance. 3M had the opportunity to do this at Marshfield, but it failed to make use of that opportunity. Had it done so, the issues with the choice of MSA as comparator and the lack of proper temperature control could have been identified and resolved.

114. The Claimants stressed that 3M had advice at the time that Marshfield should be used as a pre-clinical study, which it ignored. On 1 June 2007, Ms Jacobson forwarded the draft protocol for Marshfield to Mr O'Hara and asked him to "let me know if you see any concerns with their protocol". Mr O'Hara replied the same day with his "brief comments" made within the text of the protocol:

i) Under the heading "SPECIFIC AIMS", Mr O'Hara commented "my thoughts were that this was a beta site to kick the tyres and give us a database for the 510K. If so I would focus on nasal swabs. If other swabs are taken these should be analysed separately".

ii) Under the heading "Standard Operating Procedures (SOPs), and the use of MSA-Ox as a comparator, Mr O'Hara said: "(check MSA ox concentration as it is often higher in USA). Need to try to fit this comparable to the FDA submission so we get no surprises during the 510K".

115. The Claimants submitted that Mr O'Hara was thereby advising that the protocol to be used at Marshfield should be as close as possible to that to be used at the clinical study sites and that it should be used to generate data.

116. Ms Jacobson agreed that the purpose of the trials was to "kick the tyres", but she did not understand that they should be used to generate data. She said that they were intended to be "a means of getting the product in to a customer's hands to identify areas for optimisation". These were "Investigator Initiated Trials", which meant no monitoring by 3M. There was an issue as to whether this was explained to Mr O'Hara, and he was certainly told that it was to be an "internal study". He also raised no issue at the time of the trials about the lack of data being produced.

117. The Claimants submitted that once 3M took the decision to change the comparator to the untested MSA, it became imperative to conduct some pre-clinical testing to ensure that this would not create issues. However, as already found above, at the time 3M reasonably believed that the change in comparator would not materially affect BacLite's performance.

118. As Ms Jacobson explained in evidence, carrying out pre-clinical trials would not have been normal in the US, especially where there was already a large scale UK clinical study and the product was being sold in the UK. 3M believed in BacLite and it understandably did not foresee that BacLite would have difficulty reaching basic performance standards in clinical trials. Against this background, I find that the decision not to carry out pre-clinical trials was a reasonable one, and that it involved no failure on the part of 3M to exercise reasonable care or to seek regulatory approval with reasonable application, industry and perseverance.

*(3) Temperature*

119. The protocol for the US clinical studies stated that the laboratories should follow the BacLite Instructions for Use ("IFU"), which were annexed to the protocol itself. Under section 12, 'Assay procedure', the IFU referred to the need for certain

processes to be carried out at 37°C. Among the materials required was a "37°C static incubator". The IFU stated that "The covers for the Processor must be closed during operation". They also contained the express warning:

> 11. "16. Limitations ... Deviations in timings and temperature of the incubation steps may have an impact on the sensitivity and specificity of the assay ..."

120. Mr Robinson's evidence was that the clinical study sites had been instructed to set their incubators at 37°C and to maintain an actual incubating temperature of 35°-37°C.

121. The question of whether it was critical to maintain a temperature of 37C had been raised with Dr Foote and Mr O'Hara, as reflected in the following email exchanges:

i) On 17 September 2007, Ms Cartony emailed Dr Foote and Mr O'Hara:

> 12. "In the instructions for use, the incubation temperature is listed as 37°C. I was recently asked by a site if they could incubate the bijoux bottles and microtiter plate at 35°-37°C. Is this acceptable? Should there be an incubation range in the IFU?"

ii) The response from Dr Foote to Ms Cartony on 17 September 2007, copied to Mr O'Hara was as follows:

> 13. "I think it depends on what they mean by 35°-37°C. Our incubators are nominally 35°-39°C but in actual fact they are almost always at 36°-37°C so the bulk of the validation work was done in this range.
>
> 14. We did experiments with an earlier version of the assay at controlled temperatures of 35°, 37° & 39°C. There was a slight tendency for RLU values to increase with incubation temperature, therefore there is a risk increased false negative results at 35°C and increased false positives at 39°C. We cannot quantify the effects but they are likely to be slight. It is impossible to extrapolate accurately from in-house analytical studies to clinical performance data – we can only look for trends. And the trends show that 37°C is the optimal temperature.
>
> 15. Bottom line: I would suggest that 35°-37°C is acceptable but the closer to 37°C they can achieve, the better the results will be. 36°-38°C would be preferable.
>
> 16. I don't think we can put a range in the IFU. We cannot guarantee that the performance will be unchanged over any particular range. The information we have shows that 37C is optimal and that higher or lower temperatures might adversely affect performance (slightly)."

iii) Ms Cartony then forwarded that to Ms Jacobson on 17 September 2007, indicating that she was "concerned about this".

iv) Ms Jacobson then emailed Dr Brennan, Dr Kshirsagar and Mr Hart, copying Ms Cartony and Mr Lindroos, but not either Dr Foote or Mr O'Hara, on 18 September 2007:

> 17. "Based on [Dr Foote's] note below I think we should discuss plans on how to address this issue. Typically there is a range of temp for a given incubator in a clinical lab. If the assay is sensitive to temp, do we need to include this type of work in the analytical work that [Dr Brennan] and [Dr Kshirsagar] are doing? At this point in time we are going to allow a range of 35-37 for the reproducibility study and we will see what happens. But the contract labs will be asked to target 37C during the study. During the clinical study it will probably be more difficult because we will need to use existing incubators at the sites and they will most likely be 35-37C.
>
> 18. Please let me know your thoughts."

v) Dr Brennan replied to all of the correspondents (though not Dr Foote or Mr O'Hara) on 18 September 2007 as follows:

> "I would have to agree with [Dr Foote] in that trying to accurately quantify the effects of this small temperature range (35-37) would be extremely difficult, especially given such a short incubation period (4 hrs) ... we are probably looking at 2 to 3 doublings during our four hour incubation period, which would make it very difficult to accurately assess the effects of a 1 to 3 degree temperature difference on the assay outcome. What is know about S.aureus is that at temperatures below 35C, lag time can be increased and growth rates decreased ...".

122. The upshot of these exchanges was explained by Ms Jacobson as follows:

> 19. "Based on our clinical team's consultation with Dr Foote and Dr O'Hara, regarding incubation temperature, I emailed the clinical trial team and included Dr Brennan, Dr Foote and Dr O'Hara and noted that we would allow a range of 35°C to 37°C for the US clinical trial. Following this email, 3M issued a "Microbiology Guidance Document" on October 3, 2007, and disseminated this document to the clinical sites, which required the clinical sites provided an "incubator, capable of maintaining 35°C – 37°C for BacLite analysis"."

123. As a result of these exchanges it was understood that maintaining a temperature of 37°C was not critical and that 35°-37°C would be acceptable. There was therefore no strict instruction or monitoring to ensure that 37°C was maintained.

124. In the event, none of the five clinical study sites maintained a temperature of 37°C, as reflected in a spreadsheet compiled by 3M showing the temperatures at which the sites were operating. In the 'Situation Report' that he prepared on 10 December 2007, Mr Robinson noted that there were deficiencies at every one of the five sites:

> 20. "Discussion: All sites have issues relating to the standard operating protocol for the BacLite assay in that optimum required temperature of 37°C is not being maintained throughout the assay".

125. Temperature was one of the issues which were identified in the post trials investigations as potentially contributing to poor results.

126. The Claimants contended that the failure to maintain proper operating temperature arose because the US clinical study sites were either given an instruction that contradicted the clinical study protocol and the specific training they had received, or 3M simply failed to monitor the sites properly to ensure that they were

complying with the protocol when it knew that temperature was an important factor. In either case 3M failed to exercise diligence.

127. In the light of the email exchanges with Dr Foote I do not accept that 3M should have ensured that a temperature of 37°C was so far as possible maintained. This raised a practical issue because incubators in the US are commonly operated at 35°C rather than 37°C. Inquiry had been made of Dr Foote as to whether a temperature of 37°C was critical. His reply was that, whilst 37°C was the optimal temperature, 35°-37°C was acceptable and that any effects were likely to be slight. Mr O'Hara, who was copied on this exchange, raised no concern about this, or at least none that was communicated to 3M. Strict adherence to 37°C was therefore reasonably understood as not being critical.

128. In all the circumstances I find that instructing or allowing the clinical sites to maintain a temperature of 35°-37°C rather than 37°C involved no failure on the part of 3M to exercise reasonable care or to seek regulatory approval with reasonable application, industry and perseverance.

*(4) Failure to Monitor*

129. The Claimants stressed that 3M's Clinical Study Protocol provided that 3M would monitor the progress of each study. They submitted that it was therefore 3M's specific obligation to inspect the clinical sites and ensure that they were complying with the protocol. Had it done so, it should have discovered the deviations in the protocol in relation to temperature and in relation to the amount of useable data being generated.

130. Mr Robinson had emphasised the importance of monitoring in an email to Linda Homan on 25 September 2007:

> 21. "I can't emphasise enough how important this work is to myself and the whole team, we fully recognise the importance of the FDA submissions and the proposals for the VA work and we really do want to make sure that you have any support you need from us.
>
> 22. Absolutely key to the studies is the daily monitoring of the data files and this really does require experience which your team will gain with time but which at the moment you don't have.
>
> 23. For this reason I would ask that you please keep us updated and make sure that we are involved in the monitoring processes so that we don't allow spurious results to corrupt our dataset by failing to respond to indications of problems.
>
> 24. It is vital that the datafiles from every instrument are monitored daily for the first few weeks and I would suggest that due to the importance of the work, this should continue throughout the study period".

131. This email was forwarded by Ms Homan to Ms Lindroos and Ms Jacobson, commenting "He has emphasized the importance of monitoring the data in the past and I tend to agree that we need a well defined process in place to monitor the data frequently". Mr Cem Yurttas then added: "I think that is a great idea to check if there is anything out of the ordinary going on".

132. In relation to monitoring, 3M took the following steps:

i) 3M visited each site before the trials, spending several days training personnel there. This included ensuring that each site performed four practice runs of the assay under close supervision and a return visit being made after the initial training.

ii) After the trials commenced, 3M monitored them by receiving results through Electronic Data Capture and by receiving print outs from the BacLite equipment.

iii) 3M assigned personnel to monitoring these trials and these staff carried out specific monitoring visits at each site after the trials commenced.

133. Although BacLite's performance data (its sensitivity and specificity) was being supplied to Mr Morse on an ongoing basis, up until mid-November 3M was not monitoring that data for unexpected results.

134. This was originally stated to be because it was not until then that sufficient data had been gathered to generate meaningful specificity and sensitivity statistics. In cross examination Ms Jacobson gave a further reason for this, namely that this would have been inappropriate under international clinical practice ("ICH") guidelines, unless specifically included in the protocol, because there would have been a risk of introducing bias into the study.

135. The Claimants submitted that this evidence should be rejected as it was allegedly inconsistent with Ms Jacobson's statement, was inconsistent with what actually happened, and was not supported by any contemporaneous documents.

136. I accept, however, Ms Jacobson's evidence that this was a relevant factor at the time. The relevant guidelines do preclude interim analyses unless this has been built into the protocol, as Professor James accepted.

137. In summary, the trial results were being received through Electronic Data Capture and being monitored by Mr Morse. He could not reasonably be expected to seek to draw any conclusions from the recorded results until a reasonable body of results had been received. Further, because of the requirements of the ICH, and the need to avoid bias, he needed to be careful not to intervene unless and until it was clear that something was going wrong. That is what he did in mid November 2007.

138. Further, the trials were commenced on a rolling basis and even if performance monitoring had been carried out earlier it would not have identified problems much earlier than they were in fact identified.

139. I accordingly find that there was no failure to exercise reasonable care or to seek regulatory approval with reasonable application, industry and perseverance in relation to monitoring and, even if there was, that it made no material difference.

*Conclusion on criticisms of US clinical trials*

140. I conclude that even if the obligation to seek regulatory approval "diligently" imported an obligation to do so with reasonable care there was no failure to exercise such care in relation to the US clinical trials. If errors were made, they were errors of judgment and did not involve want of reasonable care. I further find that the clinical trials were conducted with reasonable expedition and with reasonable application, industry and perseverance. What is reasonable depends on all the circumstances and expedition cannot be judged in absolute terms. I

accordingly find that the conduct of those trials involved no breach of the obligation diligently to seek regulatory approval.

*Whether regulatory approval was diligently sought after the termination of the US clinical trials*

141. In the light of the poor results of the US trials there was no doubt that the trials had to be stopped for the causes of the problems to be investigated. Mr O'Hara confirmed orally his written evidence that this was the right decision as far as he was concerned.

142. The outcome of the initial investigations was summarised at the meeting of the US clinical team on 18 January 2008. The presentation prepared by Ms Jacobson identified three key findings from the investigations to date. The first two were the temperature and swab age issues. The third concerned the use of the cefoxitin disc test that the study sites had been using to test for the presence of MRSA on the MSA comparator plates. When two of the isolates that had been reported as MRSA were tested again, it was discovered that they were in fact MSSA (and that BacLite had correctly reported the sample as negative for MRSA). The explanation for this was that they were on the borderline for a positive result on the cefoxitin disk, falling almost exactly on the 21mm point distinguishing between MRSA and MSSA. It was also recognised that the use of MSA instead of MSA-Ox as a comparator might adversely have affected BacLite's performance. At that stage, the team decided to carry out further investigation rather than re-starting the clinical studies immediately. Mr O'Hara confirmed on 24 January 2008 that he agreed with that judgment and that he did not expect to find any "silver bullet" to fix the issues. A team including Mr O'Hara was set up to urgently drive further analysis.

143. Mr O'Hara reported the results of the US investigations in an Update presentation dated 6 February 2008. He set out the key points as follows:

> "• Multiple factors impacting to different extents at each site
>
> • Maintaining 37°C during entire 5hr process appears to be critical
>
> • Age of Swab appears to be important
>
> • The odds of a false negative increase 6% per hour
>
> • The MSA primary screening appears to be a more sensitive comparator than the comparator used in UK studies (MSA-OX)
>
> • The Cefoxitin disc confirmatory method is reporting some MSSA as MRSA (potentially as many as 30%)
>
> • The MIC's of US strains appear lower than those experienced in UK studies (NB US strains tested were from FN set only)"

144. This summary reflects the fact that there was no single or easy answer to the issues thrown up by the US clinical trials.

145. On 11 February 2008, 3M decided to ask the FDA for approval to change back to MSA-Ox as a comparator, and on 12 February 2008, Mr Hart provided Dr Whitman with an update, expressing the view that improving incubation temperatures and changing the comparator "will be the fast way to achieve the sensitivity and specificity we need". Dr Whitman replied, noting that it was clear to him "that we absolutely have to go back to the FDA to discuss comparator confirmation method as this appears to be one of our best levers".

146. Also on 12 February 2008, Ms Jacobson emailed Mr O'Hara, reporting that "the ship is changing course" and that "we now have people on board regarding the need to pursue changing the comparator method rather than trying to "fix" the assay". Subsequently, on 15 February 2008, Ms Jacobson emailed Mr Hillins, indicating that she was positive about changing the comparator, that swab age "is a huge factor and we still may not get 90% sens due to that variable. The beta testing will be absolutely critical", but that she was "very hopeful right now".

147. Further to the decision taken on 11 February 2008, Ms Johnsen sent various documents to the FDA on 25 February 2008, including a document setting out 3M's rationale for seeking to change the comparator back to MSA-Ox. A telephone conference with the FDA took place on 28 February 2008, at which the FDA approved the use of MSA-Ox as a comparator.

148. In the meantime, a Technical Review Meeting took place on 25 February 2008. There was an update on the additional testing that had been taking place at Marshfield since December 2007, although this had been using MSA and not MSA-Ox. There was also further information in relation to swab age, including a graph of the data from Acolyte's D14 report and two graphs showing the outcome of at least part of the experiments that Dr Brennan was conducting at that time. The slides stated that using MSA-Ox as a comparator, and BacLite's normal incubation time, was a 'low risk' technical option.

149. A review meeting was held on 7 March 2008, where it was noted that in the US swabs were likely to be batched and held overnight. If BacLite suffered from the swab age factor which had been identified this would mean that satisfactory results were unlikely to be achieved without some change to the assay. It was accordingly decided to proceed with further beta testing on the basis of an extended incubation period and then re-visit the question whether to re-start clinical trials.

150. This gave rise to serious concerns about whether BacLite had any prospect in the US market if it could no longer be sold as a 5 hour assay. The beta testing at Marshfield and 3 other sites ran up to the end of March 2008. The results were not considered good enough to justify re-starting the clinical trials. Even when the Marshfield clinic used only fresh swabs, MSA-Ox as the comparator, and had a dedicated incubator set at precisely 37°C, it achieved only 75% sensitivity. A scientific team including Mr O'Hara produced the BacLite Technical Report exploring what the US experience showed. Its conclusions included that running the assay at 35°C instead of 37°C negatively impacted on performance, that performance was improved by lengthening the assay to 6 hours, and that MSA-Ox was inferior to MSA at detecting MRSA, so that BacLite might achieve apparently better results if it was compared to MSA-Ox.

151. 3M's investigation between the end of November 2007 and the end of March 2008 was thorough and diligent, as Mr O'Hara agreed. As summarised in the Technical Report, the investigation showed that a number of substantial issues remained.

152. 3M, therefore, decided that the present version of BacLite would not be likely to obtain FDA approval or to make any headway in the US market. The company decided to look at improving the product or developing a new generation of it, and any further US trials were postponed. Work continued on planning the next developments with a view to creating a viable product.

153. I accept that no material criticism can be made of 3M's investigations between the end of November 2007 and the end of March 2008 and that there was no failure to exercise reasonable care or diligently to seek regulatory approval during this period.

154. I also accept that there were good reasons for 3M's decision to suspend the US trials and to concentrate on developing a next generation product. However, the consequence was that as from the end of March 2008 no further steps were taken in the US to seek regulatory approval for the BacLite product as it was. This was the product which 3M had undertaken to seek regulatory approval for, and it was no longer seeking to do so.

155. It was 3M's case that there was no breach of the obligation to diligently seek regulatory approval as it would have been futile to continue to seek to do so because FDA approval would never have been obtained for BacLite in the light of the performance issues which had been identified in the US clinical trials and further testing, and in particular the swab age issue. Alternatively any breach of the obligation was of no consequence for the same reason. This was disputed by the Claimants, and in particular by Mr O'Hara and Professor James.

156. Having carefully considered the evidence on this issue I find that it would have been possible to achieve successful US clinical trials. BacLite had been shown to achieve satisfactory sensitivity results in a number of UK clinical trials and evaluations. For the reasons set out later in the judgment I find that the swab age issue was surmountable. With very careful monitoring and an exact adherence to the trials protocol and with MSA-Ox as the comparator I consider that sufficiently good results for FDA approval would have been achievable. I therefore reject 3M's case that it would have been futile to continue to seek regulatory approval or that the failure to do so was of no consequence.

157. It would, however, have taken time to achieve approval. As was accepted, further beta testing was required, and in particular clinical tests in relation to the swab age issue. There was no point in recommencing the US clinical trials unless and until it was reasonably clear from the beta testing that they were going to be successful. I find that this further testing would have taken about 3 months. Clinical trials would then have had to be carried out, which would have taken about another 3 months. It is therefore unlikely that an FDA submission could have been made earlier than the start of October 2008. FDA approval – assuming that it was granted without further issues being raised - would have taken up to 6 months to come through. In all the circumstances I find that the product would not have been FDA approved and ready to be launched until February 2009, at the earliest. This accords with the date estimated by 3M's expert, Mr Powell, at paragraph 32 of his report.

158. In summary I find that as from the end of March 2008 3M was in breach of its obligation diligently to seek regulatory approval for BacLite in the US and that had it complied with its obligation such approval would have been obtained by the beginning of February 2009. This is subject to 3M's claim which I address below, that it was entitled to stop the BacLite business in any event because the vendors' consent was unreasonably withheld.

*Regulatory approval in Canada*

159. The original launch plan for Canada was to launch in June 2008, shortly after a US launch. Mr. Ingebrand pushed for a Canadian launch to take place as quickly as possible, but it was still thought that the process, allowing for a 6 month delay for any regulatory approval to be received, could not be completed sooner than April 2008.

160. Dr. Huckle accepted that a plan to launch in Canada in June 2008 shortly after launching in the US was not unreasonable.

161. It was the Claimants' case, however, that 3M's obligation was diligently to seek regulatory approval as from the date of the SPA and that whilst it may have been a reasonable decision not to do so immediately, or to link it with the US approval and launch, 3M's contractual obligation was to seek such approval from the outset.

162. I accept that this was 3M's obligation and that whilst it would have taken some time to prepare for seeking such approval, the difficulties that were subsequently encountered in the US did not mean that regulatory approval in Canada could not be sought and obtained. I find that, allowing for a preparatory period and a delay of up to 6 months in obtaining the approval, approval could and should have been obtained by January 2008.

163. However, it was common ground among the witnesses that it would not make sense to launch in Canada until the issues that arose in the US trials, especially the issue of false negatives, had been fully resolved. This was accepted by Mr O'Hara and by Dr Huckle.

164. As Dr Huckle accepted in evidence, a responsible company would not have launched BacLite in new territories, such as Canada and Australia, until the issues had been resolved and it would only have damaged the product in the marketplace to roll it out into new territories without having first fixed those issues.

165. As I have found, these issues would not have been resolved until October 2008 and this was the earliest time that BacLite could have been successfully launched in Canada. Any attempt to do so earlier would have been fruitless and self defeating.

*Conclusion on regulatory approval*

166. In summary, I find that 3M was in breach of its obligation diligently to seek regulatory approval and that had that obligation been complied with approval would have been obtained in the US by the beginning of February 2009 and in Canada by the beginning of January 2008. However, I further find that the failure to obtain regulatory approval in Canada was of no consequence until October 2008 which is the earliest time BacLite could have been launched in Canada.

**Was 3M in breach of its contractual obligation actively to market BacLite?**

167. The SPA required 3M actively to market BacLite in the EU, the US, Canada and Australia. The Claimants contended that 3M never marketed BacLite in any of the US, Canada and Australia and that it did not actively market BacLite in the EU save during the period September 2007 until March 2008.

168. In considering what 3M was required to do in order to fulfil its obligation actively to market BacLite under clause 4.14(a) the Claimants contended that the following matters were of particular relevance:

i) The context and the fact that the consideration to be paid under the SPA was divided into the initial consideration of £10.4m and the Earn-Out Payment under clause 4.1. The initial consideration was intended broadly to compensate the shareholders for their existing investment in Acolyte. In order to earn a return on their investment, the shareholders were dependent upon the Earnout Payment. The level of their return would therefore depend upon the skill and effort that 3M devoted to the Acolyte business from the moment of acquisition through to the end of December 2009. The various complementary provisions of clause 4.14 of the SPA were designed to protect the shareholders' interest in the Earn-Out Payment and ensure that 3M did a proper job in marketing BacLite.

ii) The other provisions of clause 4.14 and in particular the fact that 4.14(c) requires 3M to devote various resources to the BacLite business, including marketing, to a similar overall degree as such resources are made available to the other businesses in 3M's Medical Division. Clause 4.14(d) required sales representatives for BacLite to be compensated in the same general manner as 3M's other sales representatives. Clauses 4.14(e) and (f) required 3M to develop a training module, and marketing and other training and customer support materials, which would be of a similar quality to those for its other medical products. Overall, it can be seen from the contract that the parties intended that 3M should devote the same kind of skill and effort to marketing BacLite as it did to its other medical products.

iii) Although under clause 4.15 it was acknowledged that 3M was under "no obligation or duty to conduct its business in a manner that increases the amounts payable under this clause", this was "except as expressly set forth in Clause 4.14" thereby recognising that the provisions of clause 4.14 may indeed have that effect.

iv) At the time when the SPA was concluded, all parties were forecasting that BacLite would achieve sales in 2009 of at least £17.554m. While those sales were not guaranteed, the parties clearly anticipated that 3M would devote the kind of energy and resources worldwide that would be necessary to generate sales of that order.

169. 3M submitted that "actively" was used in contrast to "passively" and that as long as some active steps were being taken to go out and sell BacLite then the obligation was satisfied. The substance of the obligation was to be found in the requirements of 14(c) to (f) as to the resources and procedures to be adopted, but there was no longer an allegation of breach of any of those requirements.

170. The Claimants contended that this construction would deprive the word "actively" of meaningful content and that it required, in accordance with the dictionary and ordinary meaning of the word, that marketing was carried out diligently, energetically and briskly.

171. I accept that it is clauses 14(c) to (f) that set out the main specific requirements that have to be followed in relation to marketing. However, I also accept that "actively" means more than simply the taking of some active marketing steps. In my judgment it means that the marketing efforts of 3M viewed overall can be said to be "characterised by action", a general definition given in the Oxford dictionary relied upon by the Claimants.

172. On the other hand I also accept 3M's case that this involves a reasonable margin of appreciation being accorded to 3M so long as it acted in good faith with a view to marketing BacLite successfully in pursuit of the common commercial interest of both parties.

173. 3M had an additional argument that the obligation was actively to market BacLite generally rather than specifically in each of the Major Markets, but I agree with the Claimants that the SPA clearly requires that be done in each of the four specified markets.

*The UK and EU market*

174. The Claimants contended that in breach of its obligations under clause 4.14(a) of the SPA, 3M failed to pursue, throughout the life of the SPA, the number and quality of customer evaluations in the UK and Europe that it should have done. In particular:

i) 3M failed effectively to begin the marketing exercise until around September 2007. It did not recruit and train sufficient sales reps until around that time and the BacLite business had been left rudderless between May and August 2007 as a result of the departure of Ms Dillow.

ii) By as early as 21 January 2008, 3M was looking to limit its marketing by stopping marketing communications and reassigning the sales force's time to other projects.

iii) In March 2008, no more than 6 months into a minimum 9 month sales cycle, 3M began to reassign its EU sales force to other projects. After that date, it commenced only seven new customer evaluations in Europe (including the UK).

iv) Despite having identified significant numbers of qualified prospects and potential evaluations across Europe, 3M stopped actively marketing BacLite in Europe in June 2008, well before even seeking the vendors' consent to do so.

*(1) Alleged failure to begin marketing until September 2007*

175. The Claimants pointed out that 3M had recognised from prior to the acquisition of Acolyte that it would be necessary to recruit and train a dedicated sales force to market BacLite. In the PAR II report that was prepared on 27 October 2006 in order to seek internal 3M approval to proceed with the acquisition, one the key risks was identified as "New sales skills required for success", with the plan to mitigate that risk involving "Specialized sales representatives planned for in model to compliment existing sales organization". In preparing its forecasts for the sales

of BacLite, 3M was proceeding on the basis that the sales team would be in place from the date of BacLite's launch. For example, the 'Assumptions' prepared on 22 August 2006 refer to the assumption that there would be "Fully Resourced Sales & Mktg Teams in Subsidiaries at launch".

176. The "Commercialization Plan", which formed part of the PAR III presentation dated 23 January 2007 also identified the need to "Execute sales coverage model – 15 reps deployed across Europe – Q1". The more detailed "Resource Plan" confirmed that there should be "15 sales reps across Europe (staged), 4 in the UK, 2 FR, 2 GE, 1 SP" and that they should be in place by January 2007 (which was the date 3M had originally been expecting to complete the acquisition of Acolyte).

177. The Claimants contended that it was important to have sales reps in place from the very beginning because 3M was due to continue the marketing activities that Acolyte and BioStat had undertaken to date. As at the date of the acquisition, there was already an established pipeline of potential sales opportunities for BacLite in the United Kingdom. For example, on 25 September 2006, Mr Collier provided a spreadsheet showing UK sales prospects for BacLite, which listed 149 hospitals in the UK and set out detailed notes in relation to the marketing progress with each one.

178. Contrary to the plans set out in the PAR III presentation, however, 3M failed to recruit and train its sales team in sufficient time to begin actively marketing until September 2007:

i) In relation to BacLite sales representatives in the UK, 3M hired one rep in March 2007 (Nicola Allen), appointed one in May 2007 (Gerard McBride), two in July 2007 (Angus Gordon and Brendan McKeown), one in September 2007 (Vinutha Ginimav) and one in March 2008 (Ivan Whelan).

ii) In relation to BacLite sales representatives in Europe, 3M appointed one in June 2007 (Livia Olgiati), three in July 2007 (Nuno DeOliveira, Sylvie Viste and Maria Christina Anger), three in October 2007 (Christos Moshetas, Lone Carlsson and Debbie Polet), one in January 2008 (Ainhoa De Endaya), one in March 2008 (Benoit Deveugel) and one in June 2008 (Tariq Farha).

179. In effect, therefore, the Claimants contended that 3M did not actually begin actively marketing BacLite in the UK or Europe until September 2007, some seven months after the acquisition. In this connection the Claimants relied on internal emails commenting on the slow recruitment of sales reps and the fact that this would be harming sales. For example:

i) In an email on 22 March 2007, Mr O'Hara had reported to Gary Stapleton that: "concerns were expressed about the lack of sales team (Bio-Stat terminated but no replacement in place). Recruitment potentially unlikely until Mid to end of May, with training and summer run risk will be starting sales cycle in Sept". Mr Whitworth commented: "I cannot disagree with Steve".

ii) Ms Dillow had reported to Mr Kummeth on 13 May 2007 as follows:

> 25. "1. We did exit the distributor immediately upon signing (which will be a good thing for OI). However, this left us without a sales force. They are having a hell of a time finding reps, despite having the reqs and many interviews.
>
> 26. 2. Only 2 out of the 6 reps have been hired thus far.

> 27. ...
>
> 28. This is start-up. It's a long sales cycle. Month to month will not be very accurate until we get going. End of year should be where it needs to be. Reps need to get hired, trained and SELLING, though. This is my biggest worry."

iii) Ms Dillow provided a further update to Mr Ingebrand on 22 May 2007:

> 29. "The bad news is that UK is behind on getting the sales reps hired (as is rest of Europe). Mark Whitworth and Jonathan Young (S&M Manager, Diagnostics, UK) have said that they have never seen this level of interest in a new 3M product. However, the fact remains that if we don't have reps on the street ... we can't convert accounts and start getting sales."

iv) In an email to Mr Sauer on 22 September 2007, Koen Wilms reported that one of the key points that would mean lower than expected sales in 2008 was "longer time to hire people with the right skills sets (about 4-5 months between time of REQ and time of hire!)".

v) In her presentation of 26 September 2007, Ms Gilsoul recorded that "9 Months Sales Cycle is the absolute minimum and exclude any breaks: This year we hit summer period post Trials with "low" coverage".

180. Whatever the reasons for the delay, the Claimants submitted that the fact remains that 3M did not have an effective sales force in place until September 2007 and it was not actively marketing BacLite in the UK and Europe in the seven month period from the acquisition of Acolyte in February 2007. The most immediate and telling impact of this delay was the failure to initiate customer evaluations. In the remainder of 2007, 3M set up only two evaluations in June, three in October and five in November. Similarly, 3M made little or no progress in identifying and qualifying customers in various European countries. On 26 October 2007, Dominique Gilsoul circulated an "EU Pipeline Tracking" document, which indicated that 3M had not by that stage identified any prospects in France, Germany, Ireland and Italy as well as a range of other European countries.

181. 3M contended that the Claimants' focus on the delay involved in the recruitment of sales reps ignores the extensive and wide ranging marketing which 3M was carrying out throughout this period.

182. In relation to the UK, 3M ensured that marketing and sales efforts in the UK previously conducted by Acolyte would continue unabated by hiring, immediately after the acquisition, those individuals primarily contributing to such efforts, namely Mr. Collier, Mr. Robinson and Mr. O'Hara. 3M also paid BacLite's former distributor in the UK, BioStat to continue operating as 3M's distributor until the beginning of April 2007 and, for any leads that BioStat had previously developed before the acquisition, thereby permitting 3M to continue to exploit all existing sales opportunities for BacLite as 3M set up its own dedicated UK marketing, sales and technical support force.

183. The process of recruiting additional sales staff commenced at once. It took a few months for 3M to find suitable people, make them offers, for them to give notice in their previous jobs and to train them up. However, as Mr O'Hara said, this was

"not a criticism in terms of 3M's process, it was the fact of the matter that is how long it took."

184. Although Messrs Collier, Robinson and O'Hara had to work very hard in the period immediately following the acquisition, the lack of a full sales force for a few months did not mean that any promising lead was lost or not followed up. 3M stressed that the Claimants were not able to point to a single potential customer which they say was lost for this reason.

185. 3M contended that there is ample evidence that the UK funnel of leads was fully and properly serviced from the day of the acquisition. For example:

Mr. Whitworth said:

> "A. I go back to my point earlier, that we paid good money for the goodwill of what we believed was the "funnel", if I can use that phrase again, from Bio-Stat. From day one we were ready for any customer who wanted a trial. Any customer who wanted to buy, we were ready. We had James Collier, Peter Robinson. At the end of March we had Bio-Stat. We were ready, in the context of the UK, to support that. We put huge effort --something I had never seen in my 3M career -- into the effort of building an organisation that was capable of sales and marketing in all the countries in Europe. That was a huge sales and marketing effort. We were in the sales cycle effectively from day one, because we inherited a funnel. In nine weeks we expanded that to 14 countries, and we had a sales cycle with 350 leads."

Mr. Collier denied that the process of getting out there and selling to hospitals did not start until September 2007 and said that the process of selling was "ongoing all the time". He expressly denied that there was a "lull" after the acquisition. He was remarkably impressed with the speed with which 3M got resources up and running. Mr. Collier was pressed on whether the relative dearth of new trials between February and September 2007 meant that there was a delay before sales really got underway. In response he denied there was a delay and explained that his more detailed pipeline document showed that what had happened was that very few of the leads developed as far as a trial because they had various issues with BacLite including workflow and the body site issue.

186. I accept the evidence and submissions of 3M on this issue. Although there was a delay in recruiting and training up the UK sales force, and this took considerably longer than had been anticipated, that did not mean that no active marketing was being carried out. Mr Collier, Mr Robinson and Mr O'Hara worked hard on pursuing the leads in the inherited funnel or pipeline. Although it is possible that more leads could have been found if the sales reps had been up and running earlier on, this does not mean that there was no active marketing going on. The role of sales reps is just one part of marketing and there was much active marketing without them. Customer evaluations continued. Trials were carried out at 3 UK sites. Potential trial sites were identified and follow up meetings planned.

187. In her 26 September 2007 summary of what had been achieved in the UK during the period February to September 2007 Ms Gilsoul pointed out that there were now 16 active accounts; 5 successfully completed trials; 8 new trials due to start and one major London hospital ready to buy. Viewed overall I find that 3M's UK marketing during this period was characterised by action notwithstanding the delay in recruiting and training the intended sales force. There was much active marketing that could be and was done even without that sales force.

188. In relation to the EU market outside the UK, 3M's marketing and sales efforts in other EU countries commenced from almost a "standing start." Huge time and resources were expended on the launch of BacLite in the EU at the 2007 ECCMID conference, despite having only weeks to prepare for that event after the acquisition. The level of financial, personnel and other resources devoted by 3M to marketing and sales activities for BacLite in the EU greatly exceeded the resources devoted to other products in its Medical Division.

189. At the ECCMID conference in Munich at the very start of April 2007, 3M held a substantial training session for its sales staff and launched BacLite itself to potential European customers. 53 people from 3M were present and BacLite was showcased at the Congress and at a dinner for 23 KOLs, and at a series of scientific symposia. A large number of leads were generated, around 350.

190. Mr. Collier explained that the effort in Europe was continuous, with local managers going out in the field while more junior reps were recruited. Mr Robinson explained that they did "a massive amount of marketing through exhibitions and congresses".

191. In a European Commercialisation Update document in early September 2007 a number of accounts were recorded as being qualified in mainland Europe, in Germany, France, the Netherlands, Norway, Switzerland, Slovenia and Bulgaria. Launch activities were listed with 15 customer events being planned during the remainder of 2007.

192. In her September 2007 report Ms Gilsoul recorded that there were over 15 active accounts with 5 hospitals committed to evaluation in the last quarter; she identified the top EMEA accounts and noted that Munster had had good results and that there were trial starting dates planned for a number of hospitals. She also reported that aside from the ECCMID launch, BacLite had been launched in France in June 2007 and was to be launched in the Nordic countries in September 2007.

193. Again, I accept 3M's evidence and submissions on this issue. Whilst it is correct that, despite 3M's best efforts, there was a delay in the recruitment of sales reps, a considerable and impressive amount of active marketing was nevertheless being carried out throughout this period and I find that viewed overall 3M's marketing in the EU outside the UK during this period was characterised by action.

194. I accordingly reject the Claimants' case on breach during this initial period.

*(2) The 60 Day Plan*

195. In January 2008 3M prepared a 60 day plan to attempt to accelerate that sales process and to limit the costs associated with the project. The plan was circulated by Mr Whitworth on 21 January 2008. Mr Whitworth and his team were coming under increasing pressure from senior management to show results from 3M's substantial investment in BacLite and the idea of the plan was to focus 3M's

activities so as to produce concrete results to demonstrate the viability of the product.

196. Whilst this involved a more targeted marketing of the product and a redeployment of some resources it did not mean there was no active marketing. The focus had moved away from launch and visibility and there was a concern to reduce costs, but there was plenty of continuing marketing activity and viewed overall that marketing continued to be characterised by action. I reject any allegation of breach in respect of this period.

*(3) The reassignment of the EU sales force in March 2008*

197. In March 2008 3M began to reassign some of its EU sales force to other projects. On 28 March 2008, Mr Whitworth sent an email to a wide 3M distribution list as follows:

> 30. "Results so far.
>
> 31. Since the EMEA Regional Launch in April 2007, 30 3M BacLite MRSA systems have been placed across 12 countries for evaluation and a further 8 are scheduled in the coming few weeks. This reflects high interest in the technology and the value proposition. Last week the UK team gained a new customer in Middlesbrough with annual revenues in excess of $200,000. This week the German team gained their first customer order, in Munster. We have received verbal commitment for orders from additional sites in UK and Gulf. We now have 6 customers.
>
> 32. But we are far from where we planned to be. Why?
>
> 33. Key Learnings
>
> 34. 1. The market segment for Rapid screening is in infancy phase in a few markets and only embryonic in many others.
>
> 35. 2. The Selling Cycle is proving much longer and much more resource intensive than planned.
>
> 36. 3. We got some of our Customer targeting and qualification wrong last year.
>
> 37. 4. The product is not performing to customer needs in some sites in some Countries.
>
> 38. Is this fixable? YES, absolutely. Overnight? No, not everything."

198. He therefore set out an action plan as follows:

> 39. "Action Needed
>
> 40. Overall, because of the need to more carefully qualify and evaluate, this does mean a need to really prioritise and focus our resources. This does mean we need to prioritise our selling activities across the region and we are asking you in the countries to evaluate your current resources for 2008 to align with the designations below …"

199. He then set out the following table:

| Market Stage | Direction | Countries | Resourcing Guidelines |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Market ready, product fit | Full steam with tighter protocols | UK, Gulf, Ne, Fr, Ge, De | maintain resource 2008 |
| Product does not yet fit, market embryonic | Existing evaluations only; aim for one customer/reference site/development site | Sp, It, Gr, Be, Slo, Au, Hu, Sw, Ch | Reduce 2008 SG&A now. Rechannel HC but retain skillset for 2009. |
| Market not proven yet | Market assessment, customer VOC, Pre-launch preparation | Remaining EMEA Countries | Halt SG&A 2008. Take a Project approach. Refocus resource but retain for 2009 |

200. The result of the reassignment was that the full sales efforts were to be focused on the key EU markets, and in particular UK, France and Germany. This was in fact the sales policy which both Mr O'Hara and Dr Huckle advocated. They considered that 3M had adopted too broad and ambitious a marketing programme and that they should in the first instance have concentrated on the most important and developed markets and built up from there – a "rifle" as opposed to a "shotgun" approach. In a sense they criticised 3M for doing too much marketing.

201. The Claimants contended that 3M's contractual obligation was to go "full steam" ahead in all EU countries in which there was a market and that limiting this to just a few countries was a clear breach of contract, notwithstanding the support for this approach given by their own expert. However, I consider that this is an oversimplified approach. The plan was for active marketing to be carried out in all the identified countries, but for that to take a different form according to the nature of the market in each country. In any event, the obligation was actively to market in the EU, not throughout the EU. At this stage 3M were still actively marketing in the EU, albeit on a more targeted basis. Viewed overall I find that 3M's marketing in the EU as a whole was still characterised by action. I reject the Claimants' case on breach in respect of this period.

*(4) The alleged stopping of all active marketing in June 2008*

202. The Claimants contended that despite having identified significant numbers of qualified prospects and potential evaluations across Europe, 3M stopped actively marketing BacLite in Europe in June 2008, well before seeking the vendors' consent to do so. The final customer evaluations were commenced in May 2008 (Rostock), June 2008 (Nuneaton) and September 2008 (Lab Arnaud, Tours).

203. They contended that this was potently illustrated by a debate over Mr O'Hara's travel costs. On 23 June 2008, he asked Mr Whitworth for approval to incur costs of £130 to travel to Eire to visit a prospective customer, which was granted. When Lisa James came to ask for authorisation to book Mr O'Hara's tickets, however, Mr Stapleton emailed Mr Whitworth:

> 41. "Mark obviously I have to question this trip for Steve. If you are adamant because you don't want people getting suspicious can't you just say that I have requested a travel ban on Diagnostics because they are so far off plan?"

204. Mr Whitworth replied on 28 June 2008:

> 42. "I'm stuck between a rock and hard place … this is "business as usual" … Steve is being asked to play his role and the customer activity is at exactly the right stage to do that. I do not see a reason for stopping which is not ear pricking for SOH or Ivan … and these are big talkers.
>
> 43. I don't like it anymore than you …"

205. Subsequently, Mr Whitworth emailed Mr Stapleton on 30 June 2008:

> 44. "We can stop this customer trip and Ireland now with two calls, but this is another little spot of rain in all the messages out there right now … folks are sensitive, nervous and intuitive.
>
> 45. recent messages which individually stand but build a theme:
>
> 46. 1. Deep Dive Event – not clear definitive outcome until September …
>
> 47. 3. No decision to formally kickoff Generation II or other R&D works in Lough
>
> 48. 4. Manufacturing going into hibernation …
>
> 49. 6. 2009 ECCMID Congress – no sponsorship or exhibition booth to be reserved.
>
> 50. 7. Total stop on Adv/Merch in Europe.
>
> 51. 8. James & Joerg 50% reassigned to new roles. Maria 100%.
>
> 52. 9. Several Eu – non UK – Reps now reassigned fully or partially.
>
> 53. The sooner we achieve and drive one action and communication the better … we all agree … but are we clear through mgmt and legal on the risks associated with "almost stopping" … when do we hear back from McKinley … we could be ready to go the whole way and effectively stop in 2/3 weeks?"

206. The Claimants submitted that this showed that by the end of June 2008, 3M was in the position of "almost stopping" all marketing activity and was in a position to have completely stopped within 2 or 3 weeks. Consistently with that, BacLite manufacturing had been put into hibernation, 3M had booked no space at the 2009 ECCMID conference, there was a total stop on all advertising and merchandising in the UK. Most of the BacLite sales force was re-assigned with the remaining personnel, such as Mr Collier and Mr Joerg Siekmoeller, being re-assigned for 50% of their time.

207. This "almost stopping" coincided with the decision at the Deep Dive review that 3M did not wish to continue with BacLite. Although this was still subject to the vendors' consent, everyone at the meeting had agreed that this was the correct course of action.

208. Whilst Mr Whitworth was put in the uncomfortable position of maintaining that it was "business as usual", the Claimants submitted that the reality was that 3M was now running down the BacLite business and was not actively seeking new customers. Mr Whitworth accepted in evidence that, as he said at the time, what they were doing was "almost stopping", although he pointed out that they did not stop altogether.

209. 3M contended that marketing continued after this time and in particular that Mr Collier continued to seek to work the opportunity pipeline. However, from the end of June 2008 I accept and find that 3M was no longer actively marketing BacLite in the EU (including the UK). It was effectively winding down its marketing operation. Although some marketing activities were continuing, there was no real effort to find or market BacLite to new customers, as opposed to continuing dealings with already interested potential customers. I find that viewed overall 3M's marketing was no longer characterised by action and that it was in breach of the obligation actively to market in the EU from the end of June 2008 onwards.

*(2) United States*

210. As the Claimants submitted, 3M's undertaking actively to market BacLite in the four Major Markets was not qualified by clause 4.14(a) of the SPA. It was not an obligation that only arose once regulatory approval had been obtained to sell the product in any particular market. That said there was limited marketing that could be done before such approval. Preparatory steps could be taken and visibility raised but no effective sales launch could be made until approval had been obtained.

211. 3M did in fact carry out some marketing activities in the US. However, Mr Anderson confirmed that with the decision in March 2008 not to seek FDA approval for BacLite in its then form, 3M effectively ceased marketing BacLite in the US at that point and he accepted that there was "not what I would consider wide-scale marketing efforts going on after that date".

212. Even if, however, 3M was in breach of its obligation actively to market in the US as from the end of March 2008 that would have been of no consequence until FDA approval had been obtained, which I have found to be February 2009. I accordingly find that there was no material breach of its contractual obligations prior to that time.

*(3) Canada*

213. 3M did carry out some market research in Canada and Mr Chaudhry presented the results of his research to Mr Anderson and Ms Lathem in a telephone conference on 2 November 2007. He found there to be some enthusiasm for BacLite in Canada. Mr Sauer also considered that Canada was a good potential market and that 3M was not moving quickly enough. In the event marketing efforts were understandably put on standby pending resolution of the US trials issues.

214. As I have already found, 3M could and should have obtained regulatory approval in Canada by the end of 2007. However, it could not sensibly launch BacLite in Canada until the US clinical trials issues had been resolved, which would not have been until October 2008. If 3M had fulfilled its obligation to obtain regulatory approval it would thereafter have been in a position to launch and actively market BacLite in Canada but there was no material breach of its contractual obligations prior to that time.

*(4) Australia*

215. The Claimants' pleaded case was that marketing in Australia should have commenced in mid-2008, but their expert case was that it should have commenced in November 2007. Given that no regulatory approval was required and that there was no particular delay involved in obtaining the requisite import licence I find that, had there been no US trials performance issues, marketing could and should have commenced by the end of December 2007. However, those issues had arisen before then.

216. In relation to 3M's efforts in Australian, Mr Anderson accepted that apart from occasional contact, he had little direct involvement with the Australia team over the relevant period. His evidence was that:

> 54. "We were also actively monitoring the market opportunity in Australia and Canada. Ms Sira was working with the local subsidiaries in these countries. The local subsidiaries in Australia, Canada and Hong Kong allocated Medical Division personnel to support BacLite's commercialisation and launch in their regions".
>
> 55. "Shortly after we acquired Acolyte, I held meetings with Ines Sira … Ms Sira was responsible for marketing in the Asia/Pacific region. Following this meeting, we undertook extensive discussions with the local 3M business team in Australia, including [Simon Hearne and Carmen Byrne] …
>
> 56. In December 2007 we were planning for a launch in Australia on 30 April 2008 … At this time Ms Byrne and Mr Hearne were undertaking discussions with key opinion leaders in Australia and were investigating and dealing with the applicable regulatory requirements. They were very eager to get started on selling BacLite. However, as the local team undertook their research and market planning, we began to see very serious performance issues arise with BacLite in the US clinical studies and in the UK and the rest of the EU … We thought it better to wait until the problems had been resolved rather than risk their reoccurrence in other countries. In January 2008, it was agreed that .. the proposed customer evaluations in Australia and other countries would be put on hold."

217. I accept and find that once the performance issues had arisen it was a sensible and reasonable decision to defer any launch in Australia until they had been resolved. As was accepted by the Claimants' marketing expert, attempting to launch the product before these performance issues had been resolved would be likely to have damaged the brand and undermined any marketing efforts. Even if there was technically a failure actively to market in Australia I accept and find that no effective launch could be made until these problems had been resolved, which, on my findings, would have been not before October 2008. I accordingly find that there was no material breach by 3M of its contractual obligations prior to that time.

*Conclusion on active marketing*

218. In summary, I find that 3M was in material breach of its obligation actively to market as follows:

i) In the EU as from the end of June 2008.

ii) In the US as from February 2009.

iii) In Canada as from October 2008.

iv) In Australia as from October 2008.

**(3) Did the vendors act unreasonably in withholding consent from the Defendants (together, or when unnecessary to distinguish, "3M") to terminate the Acolyte business in late 2008?**

**(4) How and when did the SPA come to an end? Did either party accept the other's repudiation and if so which?**

*The Law*

219. In relation to the issue of the withholding of consent the Claimants relied upon the principles which have been developed mainly in the context of landlord and tenant cases. The requirement for consent not to be unreasonably withheld is frequently used in leases in relation to matters such as assignment, change of use and alterations by a tenant. The same provision also appears, however, in a wide range of commercial agreements and, the Claimants submitted, it should be construed in a similar way.

220. The Claimants referred to *International Drilling Fluids Ltd v Louisville Investments (Uxbridge) Ltd* [1986] 1 Ch 513, at 519-521, in which the Court of Appeal derived the following principles from the authorities:

> 57. "(1) The purpose of a covenant against assignment without the consent of the landlord, such consent not to be unreasonably withheld, is to protect the lessor from having his premises used or occupied in an undesirable way, or by an undesirable tenant or assignee ...
>
> 58. (2) As a corollary to the first proposition, a landlord is not entitled to refuse his consent to an assignment on grounds which have nothing whatever to do with the relationship of landlord and tenant in regard to the subject matter of the lease ...
>
> 59. (3) The onus of proving that consent has been unreasonably withheld is on the tenant ...
>
> 60. (4) It is not necessary for the landlord to prove that the conclusions which led him to refuse consent were justified, if they were conclusions which might be reached by a reasonable man in the circumstances ...
>
> 61. ...
>
> 62. (6) There is a divergence of authority on the question, in considering whether the landlord's refusal of consent is reasonable,

whether it is permissible to have regard to the consequences to the tenant if consent to the proposed assignment is withheld … in my judgment a proper reconciliation of those two streams of authority can be achieved by saying that while a landlord need usually only consider his own relevant interests, there may be cases where there is such a disproportion between the benefit to the landlord and the detriment to the tenant if the landlord withholds his consent to an assignment that it is unreasonable for the landlord to refuse consent.

63. (7) Subject to the propositions set out above, it is in each case a question of fact, depending upon all the circumstances, whether the landlord's consent to an assignment is being unreasonably withheld …"

221. They also referred to *Ashworth Frazer Ltd v Gloucester City Council* [2001] UKHL 59, [2002] 1 All ER 377, in which Lord Bingham held as follows:

64. "[3] When a difference is to be resolved between landlord and tenant following the imposition of a condition (an event which need not be separately considered) or a withholding of consent, effect must be given to three overriding principles. The first, as expressed by Balcombe LJ in *International Drilling Fluids Ltd v Louisville Investments (Uxbridge) Ltd* [1986] 1 All ER 321 at 325, [1986] Ch 513 at 520 is that—

65. 'a landlord is not entitled to refuse his consent to an assignment on grounds which have nothing whatever to do with the relationship of landlord and tenant in regard to the subject matter of the lease.'

66. The same principle was earlier expressed by Sargant LJ in *Re Gibbs & Houlder Brothers & Co Ltd's Lease, Houlder Brothers & Co Ltd v Gibbs* [1925] Ch 575 at 587, [1925] All ER Rep 128 at 134:

67. '… in a case of this kind the reason must be something affecting the subject matter of the contract which forms the relationship between the landlord and the tenant, and … it must not be something wholly extraneous and completely dissociated from the subject matter of the contract.'

68. While difficult borderline questions are bound to arise, the principle to be applied is clear.

69. [4] Secondly, in any case where the requirements of the first principle are met, the question whether the landlord's conduct was reasonable or unreasonable will be one of fact to be decided by the tribunal of fact … The correct approach was very clearly laid down by Lord Denning MR in *Bickel v Duke of Westminster* [1977] QB 517 at 524.

70. [5] Thirdly, the landlord's obligation is to show that his conduct was reasonable, not that it was right or justifiable. As Danckwerts LJ held in *Pimms Ltd v Tallow Chandlers Co in the City of London* [1964] 2 QB 547 at 564:

71. '… it is not necessary for the landlords to prove that the conclusions which led them to refuse consent were justified, if

> they were conclusions which might be reached by a reasonable man in the circumstances ...'
>
> 72. Subject always to the first principle outlined above, I would respectfully endorse the observation of Viscount Dunedin in *Viscount Tredegar v Harwood* [1929] AC 72 at 78, that one 'should read reasonableness in the general sense'. There are few expressions more routinely used by British lawyers than 'reasonable', and the expression should be given a broad, commonsense meaning in this context as in others."

222. In support of the applicability of such cases to commercial agreements, the Claimants relied upon the case of *British Gas Trading Limited v Eastern Electricity*, *The Times*, 29 November 1996, which concerned a long-term gas supply contract which required the customer's consent to any assignment of the supplier's rights and obligations under the contract, such consent not to be unreasonably withheld. The question for the Court was whether it was reasonable for the customer to withhold its consent, in circumstances where the supplier was undergoing a reorganisation (following a report by the Monopolies and Mergers Commission Report) and the resulting change in control would entitle the customer to terminate the contract in any event, unless the contract was first assigned. At first instance, Colman J made extensive reference to the landlord and tenant authorities and concluded that, in the circumstances of that case, consent to the assignment was being unreasonably withheld. That decision was upheld on appeal: [1996] EWCA Civ 1239.

223. The Claimants submitted that of particular importance in this case are the following principles, to be derived from the above authorities:

i) First, the burden is upon 3M to show that the Claimants' refusal to consent to the cessation of the Acolyte business was unreasonable.

ii) Second, it is not for the Claimants to show that their refusal of consent was right or justified, simply that it was reasonable in the circumstances.

iii) Third, in determining what is reasonable, the Claimants were entitled to have regard to their own interests in earning as large an Earn Out Payment as possible.

iv) Fourth, the Claimants were not required to balance their own interests with those of 3M, or to have any regard to the costs that 3M might be incurring in connection with the ongoing business of Acolyte.

224. In this case, Mr McKinley, who was the vendors' nominated representative under the SPA, explained in evidence that the vendors remained of the view that BacLite remained a very marketable proposition and that 3M's concerns were predicated on its own internal financial position rather than a genuine belief in the viability or otherwise of the BacLite product. In particular, the vendors felt that 3M's offer to pay US$1.07m did not reflect the likely level of earn-out that would be achieved if 3M complied with its obligations under the SPA.

225. The Claimants submitted that, applying the principles set out above, this was a perfectly reasonable stance to adopt. In particular:

i) The structure of the original sale of Acolyte was such that the initial compensation was intended only to compensate the vendors for their existing

costs of their investment in Acolyte. The only prospect of the vendors making any substantial return on that investment would be through any Earnout Payment earned under clause 4.1 of the SPA.

ii) 3M's own projections of the likely Earnout Payment, as at January 2007, had been US$33m. It was therefore a highly surprising suggestion that by August 2008, the level of anticipated earn out was said to be only US$1.07m.

iii) The vendors had had no involvement in Acolyte or the business of developing and selling BacLite since the acquisition by 3M in February 2007. 3M was required to provide only very limited information to the vendors about the progress of that business.

iv) 3M's own marketing experts now estimate that sale of BacLite during 2009 might have been as high as US$1.08m, even if BacLite performed as badly as 3M claims. On its own, this demonstrates that it was not unreasonable for the Claimants not to accept 3M's own assessment of US$1.07m.

v) In fact, the offer to provide compensation of US$1.07m was only made on 15 August 2008 and was withdrawn with effect from 28 August 2008. It was not unreasonable for the vendors not to have consented to the cessation of the BacLite business in such a short period of time.

vi) The material presented by 3M at the time made it clear that 3M was heavily motivated by its own costs. This was not a matter to which the vendors were required to have any regard.

226. The Claimants further relied on the fact that even in the period August to October 2008, the sum of US$1.07m offered by 3M was not and was not perceived to be the maximum sum which the vendors were likely to receive under 4.14. In particular:

i) Mr Ingebrand, the author of the 15 August 2008 letter, relied on forecasts for EMEA sales in 2009 of US$1.992m but this was the "base case", the best case being US$5.525m.

ii) The figure of US$1.07m was obtained by Mr Whitworth stressing to Ms Gilsoul that he wanted a "Conservative!" figure for 2009 sales from existing customers. Nothing was included for prospective customers. Mr Ingebrand accepted that it was concerning that it was a conservative figure and admitted that he did not know whether or not it included prospective as well as actual customers. He stated that "it was an estimate and it could be higher".

iii) Mr Collier was not involved in producing the US$1.07m figure and stressed in evidence that "he was absolutely in no way involved in that process whatsoever". Even in November 2008, Mr Collier's forecasts for 2009 were US$1.2m.

iv) Nothing was included in the offer to reflect sales which could be achieved in 2009 if 3M had actively marketed BacLite in the US, Canada and Australia, as it should have done.

227. The Claimants therefore submitted that, while the burden remains on 3M to show otherwise, they acted reasonably in declining to consent to the cessation of Acolyte's business.

228. 3M disputed the applicability of principles derived from landlord and tenant cases to a commercial agreement such as the SPA. However, I accept, as Colman J did in

the *British Gas Trading Limited v Eastern Electricity* case that they provide some assistance and that the approach set out in paragraph 223 is appropriate in this case.

229. 3M contended that the Claimants' refusal to consent was unreasonable. In particular, after 3M had provided a large quantity of information and explanation and reiterated and extended its earlier offer of payment in its letter of 31 October 2008, the Claimants' response by MWE's letter of 12 November 2008 was wholly unreasonable. There was no attempt by the Claimants to engage in discussion with 3M either by asking for further information or by seeking to negotiate the figure offered to them by 3M. There was not even a statement that consent was refused. Instead, the letter made clear that the Claimants would not be responding to the request at all, on the grounds that 3M had "damaged the Acolyte business in breach of its contractual obligations" and that "3M would only continue to cause further damages if enjoined".

230. 3M submitted that if the Claimants had engaged with the request of 31 October 2008, then they could not reasonably have refused it. 3M had set out a reasoned case for their view that US$1.07m was the maximum amount of net sales to be expected in 2009 and had offered to pay that sum. In the light of the information then available, no reasonable vendor could have anticipated that more would have been received from sales of BacLite which had failed to make any headway in a market that was fast moving against it.

231. 3M further contended that the SPA came to an end by 3M accepting the vendors' repudiation. It submitted that MWE's letter of 12 November 2008 made it clear that the Claimants did not propose to make any substantive response to the request for consent made by 3M and purported to terminate the contract because of 3M's alleged earlier breaches. The letter expressly stated that the Claimants did not request that 3M continued to perform. This approach was misconceived, because the Claimants had already affirmed the contract in relation to the earlier breaches alleged by them; and there was and is no sensible basis upon which it could be contended that the letter of 31 October 2008 amounted to a renunciation of the contract.

232. 3M accorded the vendors a further opportunity to respond to the request for consent, by writing again on 20 November 2008, but the opportunity was not taken up. Thus, as from 12 November 2008, the vendors (i) refused to comply with their contractual obligation to consider and give a substantive response to the request for consent contained in the letter of 31 October 2008; (ii) wrongfully purported to terminate the contract in circumstances where they must have known (through their legal advisers who wrote the letter) that there was no proper grounds to do so; (iii) expressly requested 3M to cease performing. This conduct amounted to a clear repudiation of the SPA, which 3M accepted by announcing the termination of the Acolyte business on 8 December 2008. Thus, the SPA came to an end as a result of the vendors' repudiation of it and 3M had no further obligations under it.

233. Having carefully considered the parties' submissions and the evidence in relation to the issue of whether the vendors' consent was unreasonably withheld I find as follows:

i) The request for consent fell to be considered against the background of the mutual estimates of sales for 2009 of around £22 million which had been made in November 2006 and 3M's estimate of sales of about US$28 million

which was made and communicated to the vendors in January 2007. This reflected a mutual belief in the strong commercial prospects of BacLite.

ii) The Earn Out Payment was contemplated by the parties as being the principal return to be made by the vendors from their sale of Acolyte.

iii) The vendors had little knowledge of and no involvement in the business following 3M's acquisition of Acolyte.

iv) Against the above background the suggestion that the business had effectively failed and that sales of no more than US$1.07m would be made would reasonably cause considerable surprise to the vendors and would reasonably justify their scepticism.

v) Although a considerable amount of information was provided by 3M to the vendors it was reasonable for them not to be satisfied thereby. The reasons for the failure of the business are complex and varied, as this lengthy trial has demonstrated. It was reasonable for the vendors not to accept all the explanations given at face value and to consider that further inquiry and investigation was required. It was also reasonable for them to suspect that the failure of the business had been contributed to by 3M's own breaches of the SPA.

vi) The consequence of agreeing to the termination of the business would be that no payment would be received other than the US$1.07m being offered. It was reasonable for the vendors to consider that more would be earned if the business continued, and that more would have been earned if the SPA had been performed according to its terms.

vii) In so far as the costs to be incurred by 3M is of relevance, although 3M would incur considerable costs if the business was to continue it was always going to have to bear the costs of achieving the 2009 sales and the greater those sales were the greater those costs were likely to be. Achieving sales of around the level projected would involve lesser costs than would have been involved in achieving the earlier estimated sales.

viii) The reasonableness of the vendors' refusal is borne out by the fact that there were a number of 3M estimates at the time which exceeded the figure offered and that the figure was meant to be conservative. Further, as set out below, I find that the achievable sales would have exceeded that figure.

234. For these reasons, and those given by the Claimants, I conclude and find that the vendors' consent was not unreasonably withheld.

235. In relation to the issue of repudiation I find as follows:

i) Whilst 3M's letter of 15 August 2008 was arguably repudiatory in that it stated that 3M "will" "take such actions as it deems necessary to cease, significantly scale back or dispose of the Acolyte business" if consent was not given, it was not accepted as such and was overtaken by subsequent matters, including 3M's letter of 31 October 2008.

ii) 3M's letter of 31 October 2008 was a request for consent. Whilst it reserved 3M's rights "to take whatever action 3M deems appropriate" if consent was not given it was not a repudiation or renunciation of the SPA, or at least was not clearly so.

iii) The vendors' letter of 12 November 2008 was a refusal to consent to 3M's proposals. It was not a repudiation or renunciation. In particular, it did not state that the vendors would never consent to the cessation of the business. It was a clear rejection of the proposals which had been made and the explanations which had been given, but it did not state or infer that no consent would be provided whatever terms might be offered. Nor did it purport to terminate the SPA. Although it stated that further expenditure by 3M was not being demanded it said nothing about the status of the contract itself and was clearly relying upon and asserting rights under the contract.

iv) 3M's cessation of the business on 8 December 2008 was a repudiation of the SPA and it remained in repudiation at all material times thereafter. That repudiation was accepted by the Particulars of Claim in these proceedings.

236. For completeness, I should record that the Claimants advanced a further reason why the letter of 12 November 2009 could not be a repudiation, namely that it was not written on behalf of a vendor majority as defined by clause 29(4) of the SPA. It is not necessary to rule on that issue.

**(5) How much would the net sales of BacLite in 2009 have been if 3M had performed its obligations under the SPA and the Acolyte business had continued through 2009?**

*The law*

237. The Claimants submitted that where, as here, the very actions of the defendant in breaching the contract have made the quantification of damages more difficult, the Court should resolve any uncertainties in favour of the claimant. They relied upon the old decision of *Armory v Delamirie* (1722) 1 Strange 505, in which a boy chimney sweep had found an item of jewellery in a chimney and taken it to a goldsmith to be valued. The goldsmith told the boy that the piece was worth three halfpence, which the boy refused, and the goldsmith returned it to the boy having removed the jewel. The boy sued the goldsmith in trover. Pratt CJ directed the jury that "unless the defendant produce the jewel, and show it not to be of the finest water, they should presume the strongest against him, and make the value of the best jewels the measure of their damages".

238. In *Browning v Brachers* [2005] EWCA Civ 753, [2005] PNLR 44, Jonathan Parker LJ described the principle at [205] as being that:

> 73. "in a case where the defendant has wrongfully deprived the claimant of property of value (be it an item of physical property or a chose in action), the court will, save to the extent that it is persuaded otherwise by the defendant, assess the value of the missing property on a basis which is generous to the claimant."

239. That was a case which concerned the inability of the claimants to pursue a claim in earlier proceedings as a result of the negligence of their solicitor. In those circumstances, Jonathan Parker LJ held that, when seeking to quantify the value of the claim that had been lost, the principle raises:

> 74. "an evidential (i.e. rebuttable) presumption in favour of the claimant which gives him the benefit of any relevant doubt. The

> practical effect of that is to give the claimant a fair wind in establishing the value of what he has lost."

240. In a different context, the Court was required in *Fearns v Anglo-Dutch Paint & Chemical Co Ltd* [2010] EWHC 1708 (Ch), to consider the damages to which the claimant was entitled as a result of the defendants' unlawful conduct in inducing the claimant's franchisees to buy paint directly from the defendants. George Leggatt QC (sitting as a Deputy Judge) rejected the claimant's argument that the defendants' conduct had caused the collapse of his business. He held that it was nevertheless necessary to determine what loss had been suffered, and noted at [70] that while this "necessarily involves a large element of conjecture", the need for such conjecture "is itself a consequence of the Defendants' conduct". The Deputy Judge held that the principle in *Armory v Delamirie* applied and required the Court "to resolve uncertainties by making assumptions generous to the Claimant where it is the Defendant's wrongdoing which has created those uncertainties". He noted that this accorded with the principle applicable to the assessment of damages in a case of patent infringement, that while the object remains to compensate the claimant and not punish the defendant, "damages should be liberally assessed": see Lord Wilberforce in *General Tyre & Rubber Co v Firestone Tyre & Rubber Co Ltd* [1975] 1 WLR 819 (cited by the Deputy Judge at [24]).

241. Most recently, in *Double G Communications Ltd v News Group International Limited* [2011] EWHC 961 (QB), the Court was required to estimate the likely sales of a board game based on the Sun Newspaper's 'Page 3' brand. Eady J referred to the principle of *Armory v Delamirie* and gave the claimant "as fair a wind as the evidence permits" when assessing damages (at [99]).

242. 3M submitted that the Claimants' reliance on these authorities for a supposed principle that generous assumptions should be made in their favour on the assessment of loss was misplaced. It was 3M's case that the *Double G Communications* decision was the most relevant and recent authority and that it shows that where the Court has to assess damages flowing from the breach of an obligation to market a product, reference to this line of authority is not "of much practical help, since the Court has to approach the evidence specific to this particular case and come to a conclusion, in the light of it, as to how successful the product would have been on a balance of probabilities" (at [6]). As that decision also confirmed (at [4]), in such a case, "the burden lies clearly upon [the Claimant] to establish its losses, according to the civil standard of proof" (at [4]).

243. Reference was also made to the Court of Appeal decision in *Zabihi v Janzemi & Othrs* [2009] EWCA Civ 851 in which *Armory v Delamirie* was distinguished and it was stated that the application of the principle is subject to limitations – see [31-32] and [50-51]. Moore-Bick LJ further observed that the decision was difficult to reconcile with the indemnity principle and the principle that the claimant must prove his loss. I respectfully agree.

244. This is not a case concerning the value of goods which the defendant has refused to produce or of the suppression of evidence, as in *Armory v Delamirie*. Nor is it a case involving the loss of the chance of success in legal proceedings, as in *Browning v Brachers*. It is a claim for lost profits for breach of contract. There is factual and expert evidence before the court relating to that claim. There is documentation before the court relevant to the claim. The evidential playing field is a level one. Whilst it is correct that the claim involves a degree of conjecture,

that is the case in relation to very many contractual damages claims and in all such cases it can be said that it is the defendant's breach of contract which has made that conjecture necessary. As a matter of authority there is no requirement to apply the principle of *Armory v Delamirie* to a case such as the present, and as a matter of principle I consider that there is good reason not to do so and that the application of the principle should not be extended further than is necessary.

245. Even if that be wrong, in accordance with what was stated in *Browning v Brachers,* any presumption would only arise in a case of doubt and in arriving at the findings set out below I have not found there to be sufficient doubt to give rise to any presumption that might otherwise be applicable.

*The facts*

*The parties' cases and expert evidence*

246. The Claimants relied upon the expert evidence of Dr David Huckle. In his report, he sought to estimate the likely sales of BacLite and its associated products in 2009 by determining first, the overall size of the market for MRSA screening devices in each of the four major markets before considering, with reference to the particular characteristics of BacLite, what proportion of each market it might reasonably have been expected to reach. He estimated that, assuming regulatory approval to sell BacLite in the US had been obtained by the end of 2007, 3M would have achieved total sales in 2009 of US$56.45m. 3M's experts fundamentally disagreed with Dr Huckle's estimates of both the size of the available market and BacLite's achievable market share.

247. In support of their case, and in rebuttal of the contrary expert evidence of 3M's experts, the Claimants stressed the following points in particular:

i) First, 3M conducted thorough due diligence on BacLite prior to the acquisition. It had the opportunity to review the technical data on BacLite and its performance and to see the assay being used. Its willingness now to claim that BacLite was not easy to use therefore rings hollow.

ii) Second, 3M took the opportunity prior to acquiring Acolyte to discuss BacLite with various UK hospitals who were using it at that time. They all gave favourable reviews. This undermines the claims of 3M's witnesses that BacLite was unattractive to actual users.

iii) Third, in the actual marketing of BacLite in Europe, BacLite achieved a satisfactory technical close in a significant number of evaluations and attracted a number of customers. In the UK alone, BacLite achieved a conversion rate of about 50% in its customer evaluations.

iv) Fourth, the actual sales figures of BacLite have to be considered in light of the fact that 3M failed effectively to begin marketing BacLite until September 2007 and that it had a sales cycle of around 12 months, meaning that substantial sales would not be expected until around September 2008 in any event. By that time, of course, 3M had effectively given up on BacLite in any event.

248. In summary, the Claimants submitted that when 3M gave it a chance, BacLite did perform and it did sell.

249. 3M contended that the nature of the exercise cannot be as Dr Huckle contends, namely to put forward a total figure for the "market" at large (which is disputed), and then identify a percentage of that total figure which BacLite might have been able to secure. This is particularly so in relation to those markets, such as the EU, where there was a pipeline of possible and likely leads. The more appropriate way to conduct the inquiry is to consider how many conversions might have been secured by a reasonably active approach to marketing during the relevant period.

250. 3M stressed that there was a major change in the market between 3M's acquisition of Acolyte in February 2007 and the termination at the end of 2008. The original hope for BacLite was that it could capitalise on an extensive middle ground between very fast, but very expensive molecular tests and much cheaper, but much slower culture based tests. However, the middle ground was squeezed to vanishing point as the slower tests became faster and the faster tests became cheaper. The market for rapid testing was always very small. BacLite had to hope to take market share from the slower test methods. However, that hope became forlorn once those methods reduced their timescale from 2-3 days as in the 2006-2007 Acolyte literature to 24 hours. Since most clinics required confirmed positives to act upon, and BacLite could not provide those in less than 24 hours anyway, BacLite had no significant competitive advantage to set against its higher cost.

251. 3M further pointed out that even this assumes BacLite meeting its performance claims. In fact, BacLite never did and it fundamentally lacked robustness. It was 3M's evidence that they thought they were buying a fully commercialised product, whereas what they actually obtained was a prototype.

252. For all these reasons in the real world, 3M submitted that there were just too many difficulties and imponderables. A busy and cash strapped clinical laboratory was not interested in regular tweaks to the protocol or frequent visits from technical support. They required an assay that could actually be used reliably using their own staff and premises. Very few laboratories found that BacLite fitted that bill.

253. 3M further submitted that it is no answer to this to say that 3M conducted due diligence or that the product received favourable reviews from one or two UK hospitals. There is no question but that BacLite was presented at the turn of 2006-2007 as a product that had achieved good results in UK trials and was in use in at least one hospital. 3M certainly believed that this was representative of the true merits of the product; otherwise, it would never have acquired it at all. The problem was that it transpired both that the UK trials were not representative of the results achievable in other clinical environments and that the market was moving quickly away from BacLite in 2007 and 2008. The poor results from customer evaluations in Europe and elsewhere chimed closely with the poor results from the US clinical trials. If clinics of the calibre of those involved in the trials could not operate BacLite successfully, it is not surprising that other potential customers also found it beyond them.

254. Before considering the estimated achievable sales in each of the "Major Markets" there are three general matters which need to be addressed, namely: (1) performance/suitability issues; (2) market developments and (3) sales experience.

*(1) Performance/suitability issues*

255. Dr Huckle's evidence was based on the assumption that BacLite met its performance claims. This was disputed by 3M. In relation to the main disputed performance issues I find as set out below.

(i) Technical Performance (Sensitivity/Specificity)

256. As already found, I find that BacLite was capable of achieving its claimed sensitivity and specificity. This is borne out in particular by the four sets of clinical studies that were undertaken in the UK to obtain EU regulatory approval, in which BacLite performed well. It is also borne out by the number of successful technical closes which were achieved.

257. I find, however, that its claimed performance, and in particular its claimed sensitivity, was not easily achieved. It required an absolute adherence to the test protocol that is not readily achievable in a real world setting. This was borne out by the clinical trials and the beta testing carried out in the US. Further, although there were a number of successful technical closes, this was often after the hospital had been persuaded to exclude a number of results in which BacLite had not performed as claimed.

258. As Mr. Robinson said: "Virtually every trial we set up had performance issues which, at least, required some explaining and/or justifying to the potential customer." As he and Mr. Collier explained, those trials which had a "positive technical close" almost invariably involved an element of selection, or "cleaning", of the data to be included and persuading the customer why BacLite had in fact performed better than appeared to be the case. Whether or not these false results could be explained by factors such as the exact temperature of an incubator or the length of time a swab had been stored, the result was that the test was delicate and difficult to get right in the real world of clinical laboratories with their everyday constraints of time, human operators and financial constraints.

259. I accept the evidence of 3M's witnesses on this issue and find that BacLite was not robust. As Ms Jacobsen put it: "it was too sensitive to minor changes in environment or deviations from the "ideal" operating protocol".

(ii) Ease of Use/Hands on Time

260. BacLite was a sophisticated piece of laboratory equipment and required some care in its use. It was only suitable for use by a trained laboratory technician but there were no highly skilled requirements. As Dr Kluytmans put it in evidence: "It is not extremely complicated, but it is something that needs some special attention and you have to do things right and again compared to the alternatives it is complicated....I would say that this test is not the most complicated test that I run in my lab, but it is a relatively complicated test with more hands on time than was claimed."

261. The amount of hands on time required was an issue. It was not simply the amount of overall time required, but it was also the number of manual interventions. The operator would need first need to prepare the samples, which involved pipetting and vortexing and would take around 20 minutes hands on time. The samples would then be incubated for two hours, which would involve the operator preparing

the processor and capturing the reagents on the plate. The samples would then be vortexed and put on a plate, which would take about 5 minutes hands on time. There would then be a processing period, during which the operator would be preparing reagents and the reader. This would take about 38 minutes. The operator would then add the AK control which would take about 3 minutes hands on time. The results would then be read which would take about 16-21 minutes depending on the number of samples. There would then be a second incubation period of 102 minutes. There would then be a final reading of results which would again take about 16-21 minutes depending on the number of samples. These times, which assume an experienced user, mean 50-60 minutes hands on time spread over four different parts of a 5 ½ hour period. The need for frequent manual interventions made it difficult for technicians to get on with other tasks. As Dr Gordts explained: "He or she can do something else in between different steps, but she cannot take a completely different work post for half a day. It blocks your technicians".

(iii) Time to Result: 5 Hour Test

262. Although the actual test could be run in 5 hours, if one included sample preparation time it would almost inevitably be longer. In addition, the time required for the various manual intervention stages would often be greater in practice than that for an experienced user indicated above. There was a significant body of evidence from those involved in using and trialling BacLite that in reality it was a 5 ½ to 6 hour test, and I so find.

263. This made it more difficult for BacLite to be a same day test and meant further adjustments to hospital working practices might be required for this to be achievable. On the basis of a 5 hour test and normal lab hours of 9.00 to 17.30 the evidence was that it would generally be necessary to ensure that the swabs were received in the lab by around 11.00 in order for results to be obtained and released by the end of the working day. The longer the test took the earlier this would need to be, and the less easy it would be to perform more than one test run in a day.

264. Although in its submission to the NHS, 3M indicated that it was possible to perform three BacLite runs during a single laboratory day, I accept the evidence of 3M's witnesses that this was somewhat 'theoretical'. On the basis of normal working hours the best that would be likely to be achievable would be two runs, and this was how it was generally marketed, as Mr Collier explained in evidence.

265. A very real issue for BacLite was always whether hospitals would be prepared to adapt their workflow to ensure that a BacLite test could be commenced sufficiently early in the day to ensure that the results were obtained, and could be acted upon, before the laboratory closed in the evening. As Mr Robinson explained, this was a recurring issue.

266. Some hospitals, such as BacLite's "flagship", Salisbury, were willing to adapt their working practices so as to optimise the use of BacLite. Ms Skyrme explained that Salisbury undertook substantial work to integrate BacLite into its workflow and laboratory routine, and a system was developed so that urgent samples were taken before 10.00am and the BacLite run would be started by about 11.30am. Salisbury had standard laboratory hours of 9.00am to 5.30pm, five days a week. Some hospitals in the UK had longer laboratory hours, although it was Mr Collier's

evidence that this was very much a minority (under 25%). However, many hospitals were reluctant to change their working practices, or at least reluctant to do so unless a very compelling case for change could be made out. This undoubtedly made the selling of BacLite more difficult. In some countries, such as Spain, the working hours adopted at most hospitals meant that BacLite could never be accommodated.

267. Further, for hospitals which would mainly act on positive results BacLite was in any event not a same day test, as the positive result would need to be confirmed, which would take a further 24 hours. Some hospitals, such as Salisbury, were mainly interested in and would act on negative results, but 3M's UK market research indicated that 85% of hospitals acted only on confirmed positives.

(iv) Batch Testing/Flexibility

268. BacLite was capable of being run in batches of up to 43 samples at a time. If fewer samples were run then the price of the test would increase. This could be mitigated by running two tests of 20 samples, but they would have to be done within 24 hours as the reagents could not be used thereafter. BacLite was therefore most suitable for hospitals which had a daily need for the testing of 20 to 80 samples. For hospitals with lesser testing needs it was unlikely to be cost effective. For hospitals with greater testing needs it would not be sufficient, although capacity could be increased by buying more than one machine. It also required a hospital for which the collection of 20 or 40 samples for testing fitted in with their working practices. There was therefore an inherent inflexibility about the product. The right number of samples had to be accumulated at the right rate. It needed a hospital for which batch testing, and testing in batches of 20 or 40 samples, was appropriate.

(v) Swab Age

269. A major issue that arose in connection with the US clinical trials was that of swab age. This was an issue which Acolyte had been investigating at the time of its acquisition by 3M. Acolyte's report on this – "D14" – was issued on 30 January 2007. The report's "overall conclusion" based on analytical tests was that:

> "... swabs should be tested as soon as possible after collection, since even 24 hours storage can lead to a reduction in signals from MRSA. Storage should be at 2-8°C rather than ambient.
>
> Note however that the test system used in this study - bacteria in 1% BSA solution - may not accurately mimic the environment or physiological state of organisms on a clinical swab. Data showing acceptable clinical performance for the BacLite*flex* MRSA International assay have been gathered exclusively with swabs at least 24 hours old."

270. Acolyte's Instructions for Use of BacLite dated January 2007 specified that swabs could be used up to 24 hours after collection:

> "Specimens should be transported to the laboratory at ambient temperature to be tested as soon as possible. Specimens that are not tested on the same day should be stored at 2-8°C. The

accuracy of results from specimens older than 24 hours may be compromised."

271. Dr Brennan carried out analytical studies which are reported in the Technical Report which indicated that the sensitivity of the BacLite assay declined for stored swabs even within the 24 hour period. Although Professor James made a number of criticisms of these studies in his evidence, these criticisms had not previously been raised by him and were not put to Dr Brennan and I accordingly disregard them. I also reject the late suggestion made that Dr Brennan's work was somehow designed to demonstrate flaws in BacLite. All of his work was carried out conscientiously and in good faith.

272. I accept and find that Dr Brennan's studies supported the provisional conclusions that he reached, and that on any view 3M were entitled to rely on those conclusions. These were:

> "The slight decrease sensitivity of the BacLite MRSA assay during the U.S. clinical study decreased with swabs that were stored at 2-8° C. Earlier data from Acolyte generated with culture isolates showed that RLU signals decreased with swabs stored at 2-8° C for 24 hours and suggested that swabs be tested as soon as possible. Because of these two observations, the impact of swab age on the BacLite assay was further investigated.
> Testing of spiked swabs showed that the sensitivity of the five hour assay dropped from 90% with fresh swabs to 25% with swabs stored at 2-8° C for 24 hours. The sensitivity returned to 90% with stored swabs in a six hour assay.
> ....
> Testing of S. *aureus* nasal carriers showed a slight decreased in sensitivity (100% down to 93%) with swabs stored at 2-8° C for 24 hours, which supports the observations made with spiked swabs. The BacLite assay appears to have performed fairly well with the heavily loaded clinical specimens from Denver Health."

273. The Report also noted that "... Studies with clinical specimens are needed to validate these observations made with pure clinical isolates because clinical swabs will contain nasal mucus, proteins, bacteria at various concentrations, mixed bacterial populations, and possibly blood, all of which could potentially affect the performance of MSA-Ox, CHROMagar MRSA as well as the BacLite assay" and concluded that "Additional studies with clinical specimens are needed to confirm or challenge our current observations".

274. The Technical Report did not therefore state that BacLite would be unable to achieve the requisite level of sensitivity in a clinical setting. Dr Brennan's analytical studies with spiked swabs did not mimic the environment of clinical swabs and therefore did not establish how BacLite would perform in a clinical setting, as the Report itself recognised.

275. It was Mr O'Hara's firm belief and evidence that swab age was not an issue in the clinical setting. Support for this is to be found in the UK clinical studies. BacLite achieved 94.6% sensitivity in the fourth round of UK clinical studies. In April 2008, 3M reviewed these studies to determine whether they provided support for the claim in the IFU that BacLite could be tested with swabs that were up to 24 hours old. It summarised the data obtained, according to the age of the swabs, both

including and excluding the spiked swabs. This showed that with unspiked, clinical swabs that were up to 24 hours old, BacLite achieved sensitivity of 100% (13/13 positives detected) and that even with unspiked, clinical swabs that were up to four days old, BacLite achieved sensitivity of 88.2% (30/34 positives detected). As recorded by Mr McLaughlin in his email of 30 April 2008:

> 75. "After thorough assessment, it is the consensus of the technical team that the EU clinical data does not refute the IFU claims as documented. Therefore the recommendation from the technical team is to accept the submitted data as sufficient for supporting the EU IFU claims inclusive of the performance claims for aged swabs up to 24 hrs".

276. It is also of significance that there was no record of swab age being reported as a problem in any of the customer evaluations that took place, nor of a customer suggesting that BacLite had problems in detecting MRSA in swabs up to 24 hours old.

277. Whilst there is clearly evidence to show that swab age is an issue, and certainly an issue that required investigation and resolution in the light of the US clinical trials and tests, I find that it was not as significant an issue in the clinical setting as suggested by the analytical studies, and that BacLite was capable of performing satisfactorily with swabs of up to 24 hours old.

(vi) Swab Validation/Body sites/Particle Loss

278. The fact that BacLite was validated only for use with the MWE swab was unusual and was a problem for some users. This was particularly important in non-UK markets, where the MWE swab was far less well known and sometimes not available at all. Although this was potentially surmountable, it was a deterrent for some hospitals, particularly where consequent changes in practices were required.

279. BacLite was restrictive as to the body sites from which samples could be taken, being limited to the nose and groin. For some hospitals and indeed some countries, this meant that it was not appropriate.

280. Another technical issue that became apparent with BacLite was "bead loss" or "particle loss". This problem was worse with nasal swabs than with others and worse with clinical swabs than with spiked swabs. This was an issue which remained under investigation throughout the relevant period. As Mr. O'Hara said: "We never understood what caused it and we never resolved it." However, there was no evidence that it gave rise to particular problems with actual or potential customers.

*(2) Market developments*

281. The idea behind BacLite was that it would be able to capture the "middle ground" in the market. It was considered that the market for MRSA detection techniques could be divided into three parts:

i) The traditional market for culture based tests, generally sold on low price, but with very slow results.

ii) A market for very fast tests, willing to pay a high price - dominated by the newer, molecular methods.

iii) The "middle ground" of customers who wanted results on the same day, but were not willing to pay the high price of the molecular technology.

282. However, between 3M's acquisition of Acolyte in February 2007 and the termination at the end of 2008 the "middle ground" was increasingly "squeezed" as the slower tests became faster and the faster tests became cheaper.

283. BacLite's competitive position deteriorated in several respects. In particular:

(1) The price of PCR tests fell significantly from around $40 per test to about US$25.

(2) The technical performance of chromogenic methods improved so that results could be read between 18 and 24 hours instead of between 36 and 48 hours. This specific factor led some customers to cancel trials with BacLite.

(3) The price of chromogenic tests reduced dramatically during the period from about $5-6 per test in 2007 to about US$2.50 per test in 2008, to around 50p in 2009, at least for UK NHS hospitals.

284. BacLite needed to take market share from the slower test methods. However, that became increasingly difficult once those methods reduced their timescale from 2-3 days to 24 hours. Since most clinics required confirmed positives to act upon, and BacLite could not provide those in less than 29 hours anyway (5 hours for the BacLite test itself, followed by a further 24 hours for the confirmatory testing), BacLite had no significant competitive advantage to set against its higher cost.

285. A particular risk for BacLite as a market proposition was that customers would adopt a "polarised" or "triage" approach, where the bulk of testing was undertaken with a cheaper method and a few really urgent cases were dealt with by a PCR method. If this approach was adopted, then there would be no room for BacLite. There was evidence that this is indeed what customers increasingly did.

*(3) BacLite's sales experience*

286. In any estimate of what future sales BacLite would have achieved, its record of actual sales is an important matter. Of particular relevance is its sales record in the UK market. BacLite was developed in and initially for the UK market. Versions of BacLite had been sought to be sold in the UK since early 2005. By the time of the termination of the Acolyte business in December 2008 it had been sold into the UK market for over 3 ½ years. If BacLite was to be a successful product one would expect that to be reflected in its sales experience in the UK market. In fact its record of sales throughout was poor.

287. Acolyte secured its first sale to Salisbury Hospital, which had taken part in the trials. Salisbury was very close to Acolyte's base at Porton Down and personal relationships were involved in securing them as a customer, in particular through Mr O'Hara. Salisbury was to remain BacLite's "flagship" customer.

288. To seek further sales, Acolyte appointed BioStat as exclusive UK distributor for BacLite. However, in the period from May 2005 through until the 3M acquisition in February 2007, BioStat secured only two further customers, London Independent Hospital and Lister Hospital, despite apparently spending some £200,000 on their marketing efforts.

289. The product had been developed for the UK market, which meant essentially the National Health Service, but had been sold to only one, fairly small, NHS hospital (Salisbury). The inability to sell into the NHS was a matter of concern to Acolyte, including its Chief Executive, Dr Mullen, because, as he accepted, if BacLite could not be sold to the NHS it would not be "worth a candle".

290. Acolyte recognised in September 2006 that it was "well behind" in its sales results in the UK. At the same time BioStat was warning that selling into the NHS was getting more difficult and taking longer. The fact that St Bartholomew's in particular was not buying was a major negative. Dr. Mullen's view at the time was that the last few months of 2006 would be a critical time for sales. However, no further sales were achieved by the end of the year or prior to acquisition by 3M.

291. After the acquisition, 3M took over the "pipeline" which Acolyte had built up and sought to take it forward and to achieve as many evaluations and sales as possible.

292. In 2007 3M obtained 2 further customers, Chelsea and Westminster and Poole hospitals.

293. In 2008 3M obtained 2 further customers, Leicester and Middlesbrough hospitals.

294. In over 3 ½ years BacLite therefore only obtained 7 UK customers. Further, the continuing poor sales after 3M's acquisition cannot be explained away as the consequence of a failure actively to market BacLite since I have found there was no such failure prior to the end of June 2008.

295. BacLite's poor sales experience in its main market over a prolonged period of time is clearly of significance to any estimate of future sales.

296. The three general factors identified above, namely (1) performance/suitability issues; (2) market developments and (3) sales experience are compelling reasons why BacLite as it was would never have been a commercial success and why future sales of the product would have been limited even if the SPA had been fully performed. With those considerations in mind I shall now address each of the major markets.

*The UK market*

297. A further general factor which militated against BacLite in the UK market was the Darzi effect.

298. Lord Darzi's interim report on "Our NHS Our Future" was published in October 2007. It stated the UK Government's intention to "Introduce MRSA screening for all elective admissions next year, and for all emergency admissions as soon as practicable within the next 3 years." The implication of this was that NHS hospitals were likely to have to carry out a great deal more MRSA screening. Although on the face of it, that might suggest a greater market opportunity for BacLite, in reality it meant that all hospitals would be forced to invest in the cheapest systems to carry out mass screening of low risk patients which might well make them less likely to choose the "middle ground" BacLite system. As Mr. Collier put it:

> "Darzi, like many recommendations, came up with clear guidelines and rules but without any money following it. Hospitals had to find the money. The money put aside for Darzi would not really have benefited. The only

> possible benefit is a special MRSA room might have had a bit more extra room for a BacLite system".

299. Throughout the relevant period the NHS was in dire financial straits. The requirement for more bulk screening under Darzi further emphasised price as a key factor. Pre-admission screening also made speed a less important factor. Unsurprisingly, the chromogenic method was the clear market leader in the UK.

300. It was around the end of 2007 that the move by the chromogenic companies to market themselves as 18-24 hour tests started. The move accelerated into the Spring of 2008 as the chromogenic manufacturers made their new claims official and combined this with a reduction in price.

301. The combination of Darzi and the improvement in the chromogenic methods coming together in late 2007 and early 2008 squeezed BacLite's position in the UK market. A general reaction to BacLite at this time was that the conversation would have to be "parked" and re-started at some later date after the Darzi requirements had been sorted out by gearing up with chromogenics. BacLite lost a considerable number of agreements for evaluation because the customer concerned could stay with an improved version of what they were already using.

302. On 9 April 2008, Mr O'Hara circulated a memorandum in which he said that he did not believe that BacLite could compete in the very rapid area. He noted that the chromogenic agars were moving towards 24 hours and "are getting all the sales". He explained the importance of developing a "low cost, easy to use" assay which allows negatives and positives to be confidently reported on the same day.

303. On 22 May 2008, a major UK hospital, Pinderfields, terminated a trial of BacLite. They explained:

> "My consultants feel that during our trial we found the system to be unreliable with low sensitivity and specificity and therefore they wish to draw a line under this. Therefore we have to cancel the visit to Salisbury.
>
> We are currently seeing a massive increase in samples and this is expected to increase even further in the next 18 months, therefore we do not feel that the Baclite is suitable for coping with mass screening, the hands on time for us to run at least 4 plates a day is too great and the costs would be prohibitive both for staff and revenue."

304. Mr. Young of 3M forwarded the Pinderfields email with some comments including:

> "Clearly, this is only one account, but I held an account review with my team today, and there is evidence of other accounts 'parking' their rapid/BacLite projects whilst they are ramping up their Chromogenics to meet the Darzi requirements."

305. Market conditions were therefore increasingly difficult for BacLite in the UK and prospective sales have to be considered in this context.

306. In relation to existing customers, 3M's expert, Dr Stammers, arrived at a figure of US$762,396 on the basis of an estimate made by 3M itself. That figure included nothing for Salisbury on the basis that, according to the evidence of Ms Skyrme, it

had been decided not to renew the BacLite contract prior to the communication of the decision to terminate the Acolyte business. I accept her evidence that that decision had effectively been made, but bearing in mind that renewal was not due until January/February 2009 I consider that 2 months revenue for Salisbury should be included, namely US$16,700, making a total of approximately US$780,000.

307. 3M contended that there was real reason to doubt whether the other existing customers would have stayed with BacLite, but there is no firm evidence of any decisions not to do so having been taken and I am satisfied that they are likely to have remained as customers, at least for 2009, and I so find.

308. In relation to new customers the Claimants contended that the minimum likely level of sales was that reflected in an Opportunity Pipeline Summary Document produced by 3M in April 2008. This split the identified accounts into different stages (Prospecting; Engagement; Agreement for Evaluation; Evaluation Trial; Contract Negotiation; Contract Management) and gave a confidence figure for each stage resulting in a "Risk Adjusted" value for the opportunities. Leaving aside existing accounts, it gave a risk adjusted figure of nearly US$6 million for the EMEA area.

309. As Mr Collier explained, these documents need to be approached with some caution as they adopt a formulaic approach with a pre-determined confidence figure being ascribed to each stage and he did not agree with the approach or the figures. It was his view that only those accounts in contract negotiation had a reliable prospect of conversion. The other categories were possibilities only. This was borne out by the fate of some of the "Top 10" prospects listed, a number of which, as Mr Collier explained, did not convert. I accept and agree with Mr Collier's reservations and find that these documents do not purport to provide and do not provide reliable sales forecasts. They are essentially summaries of opportunities.

310. I also accept Mr Collier's evidence that the most reliable factual basis for sales forecasts are the pipeline documents which were produced listing each hospital in each country and the stage that negotiations had reached, including where they had come to an end. The main pipeline documents before the court were dated September 2008. The Claimants contended that these were not reliable since they reflected the fact that 3M had not been actively marketing BacLite, at least since the end of June 2008. However, although the re-assignment of sales reps may have had some effect, it was Mr Collier's evidence that the main reason for the decline in opportunities was changes in the market and trials issues rather than any scaling back of the sales effort. Further, the mid-summer period in Europe is in any event a quiet period when little is achieved so that scaling back the sales force would be unlikely to have made much difference over that time. I accordingly find that the opportunities reflected in the September 2008 pipeline documents were not materially affected by 3M's breach of its obligation actively to market BacLite in Europe from the end of June 2008 onwards.

311. The UK September pipeline document records that there were 16 UK hospitals that were still potential customers. Of these two, Nuneaton and Southend, subsequently rejected BacLite for their own reasons, and one, Middlesborough, became a customer and has been included in the existing customer figures. There were therefore 13 remaining identified prospects.

312. Dr Stammers' opinion was that, assuming BacLite performed as claimed, there would have been 6 new accounts in 2009 at an average annual income of US$90,000 each for an average of 6 months each (taking into account the fact that the customers would have commenced buying throughout the course of the year), giving a total figure of US$270,000. If BacLite performed as described by the 3M witnesses Dr Stammers' view was that there would have been no new accounts.

313. Dr Huckle's opinion was that 3M should have secured UK sales in 2009 in the region of US$5.2 million, representing 52 accounts and over 10% of his estimated market.

314. I agree with 3M that in evaluating the prospects of new accounts it is important to have regard to Mr Collier's evidence (and his detailed pipeline document) showing the pipeline of prospects in the UK had already been identified and worked through and that it showed that it is unlikely that a large number of further conversions was possible. I also agree with 3M that the estimation should be based on the pipeline and the actual prospects rather than theoretical estimates of achievable market share, which was Dr Huckle's approach. The experience already acquired in relation to marketing BacLite in the UK shows such an approach to be unrealistic.

315. Having regard to the factual, documentary and expert evidence, and the findings made in relation to performance/suitability issues, market developments and sales experience and the particular features of the UK market, but assuming active marketing throughout the relevant period, I conclude and find that 3M would have obtained no more than 6 new accounts in 2009. This accords with Dr Stammers' more optimistic estimate and is slightly higher than that of 3M itself in November 2008 (which was four). Those accounts should be valued as Dr Stammers suggests, resulting in a total figure for the UK of US$780,000 plus US$270,000, being US$1,050,000.

*The EU apart from the UK*

316. In relation to existing customers I accept Dr Stammers' estimate of US$144,762, rounded up to US$145,000. This includes US$75,000 in respect of Tawam hospital in the Gulf.

317. In relation to new customers, the focus had become France and Germany, as Dr Huckle agreed that it should be. Although it is possible that the odd account might have come forward from the other countries in which BacLite had already been launched (and there was evidence of opportunities, for example, in Greece and Hungary) the majority of the new accounts would come from France and Germany. Both had identified pipelines.

318. In relation to the pipeline for Germany, it is striking that most of the opportunities had come to a halt. Indeed the only listed open opportunity was Bremerhaven.

319. In relation to the very extensive pipeline for France, there were more apparently open opportunities, although it was the evidence of Mr Robinson that out of 150 "qualified" leads, only 7 were still viable.

320. It is clear on the evidence that several countries were never going to buy BacLite whatever 3M might have done. For example, Spanish laboratory hours meant that a 5 hour test that in reality took 6 and required large batches in order to be economic could never succeed. Some countries with very low incidence of MRSA were never going to choose BacLite because their interest was solely in obtaining confirmed

results as quickly and as accurately as possible (such as the Netherlands and Sweden). Countries like the Netherlands universally used throat swabs which BacLite could not handle. Countries like Belgium had high levels of MRCoNS and other strains of non-MRSA bacteria that caused unacceptable levels of false positives in BacLite's results. Many Southern European countries were not yet ready to spend money on MRSA detection. Other countries did not have the resources readily to purchase a system like BacLite.

321. 3M's own estimate for EU sales in November 2008 was approximately US$300,000 based on securing Toulouse, Hygeia, and one account in each of France, Germany and Greece. This estimate suggests an average value of US$60,000.

322. Dr Stammers' opinion was that, assuming BacLite performed as claimed, there would have been 10 new accounts in 2009 at an average annual income of US$50,000 each for an average of 6 months each (taking into account the fact that the customers would have commenced buying throughout the course of the year), giving a total figure of US$250,000. If BacLite performed as described by the 3M witnesses Dr Stammers' view was that there would have been no new accounts.

323. Dr Huckle's opinion was that 3M should have secured EU sales (excluding the UK) in 2009 in the region of US$16.15 million, representing over 150 accounts and about 8.5% of his estimated market.

324. Again, I agree with 3M that the estimation should be based on the pipeline and the actual prospects rather than theoretical estimates of achievable market share, which was Dr Huckle's approach.

325. Having regard to the factual, documentary and expert evidence, and the findings made in relation to performance/suitability issues, market developments and sales experience and the particular features of the EU market, but assuming active marketing throughout the relevant period, I conclude and find that 3M would have obtained no more than 10 new accounts in 2009. This accords with Dr Stammers' more optimistic estimate. Those accounts should be valued at US$60,000 in accordance with 3M's own estimate, resulting in a total figure for the rest of the EU of US$300,000 plus US$145,000, being US$445,000.

*The US*

326. In relation to the US there is no pipeline or other detailed identification of prospective customers and so the estimation exercise necessarily depends on more generalised evidence.

327. Although there were no pipeline evaluation trials, BacLite was in effect trialled at 7 of the 9 sites of the clinical study and also put through the beta testing at sites including Marshfield and Washington University. In not one site did the product succeed technically. Although criticism is made of the conduct and monitoring of the trials and testing, this is nevertheless evidence that BacLite would be likely to have faced technical performance challenges in the US even if FDA approval had been obtained.

328. Aside from performance issues, 3M and their expert, Mr Powell, identified a number of other considerations that would have militated against BacLite being a commercial success in the US, namely:

(1) As Acolyte itself found in research carried out in 2005 and as later studies confirmed, US customers expected a higher level of automation than BacLite could provide and did not like the hands on time required to operate BacLite.

(2) If approval had been on the basis of a comparison with MSA-Ox, this may well have damaged BacLite's prospects in a market where MSA-Ox was not well known or accepted as a comparator.

(3) BacLite's consumables – the swab, bijoux etc, were not widely available in the US.

(4) US laboratories would probably have had to have found funding and space for a dedicated incubator for BacLite, since their standard incubator temperature was 35°C, not 37°C.

(5) PCR methods were well established in the US and would have been hard for BacLite to dislodge with its inferior usability.

329. In addition, market research carried out by 3M based on BacLite's stated value proposition, did not generate the strong enthusiasm among US customers that would be expected for a new product, as was explained by Mr Anderson in evidence.

330. The Claimants placed particular reliance upon the interest in BacLite shown by the Department of Veteran Affairs (VA) who agreed to include BacLite in trials it was conducting. However, I find that it is unlikely that BacLite would have outperformed BD GeneOhm had the proposed trials taken place. In any event the trials were delayed and even if they had taken place and BacLite had been successful it is unlikely that this would have led to any significant sales in 2009.

331. There was a significant dispute between the experts both as to the size of the US market and the likely share of it that BacLite would have achieved.

332. In relation to the size of the market Dr Huckle's estimate was US$380m. Mr Powell's estimate was that the overall market size was about US$310m but that the realistic market for BacLite was only US$41.6m on the basis of the market being for reagents only and excluding the PCR market. I find the overall US market size to be US$350m but that BacLite would only have been able to achieve limited penetration into the PCR market, a difficulty that Mr O'Hara acknowledged. I find that the available US market for BacLite was no more than US$100m.

333. In relation to market share, Dr Huckle estimated 7% based on US launch in January 2008 and 4% based on US launch in June 2008. He provided no estimate based on US launch in February 2009 but it would clearly be significantly lower.

334. Mr Powell estimated a 1% share based on one full sales cycle which was then discounted on the basis of a US launch on 1 February 2009 according to whether one assumed a 6 month or 9 month sales cycle. If it was a 12 month sales cycle then he considered there would be no sales based on a 1 February 2009 launch since sales would not commence until the end of that period.

335. In relation to probable market share based on FDA approval being obtained in February 2009, given the timing issues, the shortcomings identified above, and the performance/suitability issues which I have found BacLite to have, I find that Mr

Powell's approach is far more realistic than that of Dr Huckle. As already found, I accept that BacLite could have competed to some limited extent in the PCR market.

336. Mr Powell estimated that BacLite could at best have achieved a 1% market share in the US. Based on a market size of US$41.6m, a sales cycle of only 6 months, and FDA approval by 1 February 2009 he estimated total sales of US$173,333.

337. Having regard to the factual, documentary and expert evidence, and the findings made in relation to performance/suitability issues, market developments and sales experience and the particular features of the US market, but assuming active marketing throughout the relevant period, I accept Mr Powell's approach and figures save that the relevant market size is US$100m and the resulting sales figure is therefore US$416,665, which I shall round up to US$417,000.

*Canada*

338. In Canada, there were a number of disadvantages which BacLite faced, in addition to the general difficulties identified above. In particular:

i) The BacLite bijoux were not available and could not be ordered for Canadian delivery.

ii) MWE swabs were not used in Canada.

iii) 80% of Canadian potential customers used two or more body sites for screening and at least in Canada's most populous province, Ontario, rectal swabs were required for MRSA screening.

339. As to the size of the market, Mr Powell estimated it to be 6% of the US market. Dr Huckle estimated it to be 20% of the size of the US market. I find Mr Powell's figure to be more realistic.

340. In relation to market share, Dr Huckle estimated 8% based on US launch in January 2008 and 6.5% based on US launch in June 2008. He provided no estimate based on a launch in October 2008 but it would clearly be lower.

341. Mr Powell estimated that BacLite would achieve a 1% market share, based on one full sales cycle, but based on a launch in October 2008 there would have been more than one full sales cycle.

342. Having regard to the factual, documentary and expert evidence, and the findings made in relation to performance/suitability issues, market developments and sales experience and the particular features of the Canadian market, but assuming active marketing throughout the relevant period, I find that BacLite would have achieved no more than a 2% share of a US$6m market, being US$120,000. However, given the sales cycle, revenue is unlikely to have commenced before April 2009, which results in total revenue of US$90,000.

*Australia*

343. Issues in Australia included the fact that the MWE swab was not available in Australia and that Australia showed the lowest interest level in pricing study.

344. As to the size of the market, Dr Huckle estimated it to be US$35m. Dr Stammers considered this to be a considerable over estimate as it would represent about 2/3 of the total Australian expenditure on microbiology IVD. I find that US$10m is a more realistic figure.

345. In relation to market share, Dr Huckle estimated 6% based on US launch in January 2008 and 5% based on US launch in June 2008. He provided no estimate based on a launch in October 2008 but it would clearly be lower.

346. On the basis that BacLite performed as claimed, Dr Stammers estimated sales of 5 units at an average revenue of US$50,000 for an average of 6 months each, being US$125,000. If it did not so perform he estimated no sales.

347. Having regard to the factual, documentary and expert evidence, and the findings made in relation to performance/suitability issues, market developments and sales experience and the particular features of the Australian market, but assuming active marketing throughout the relevant period, I find that BacLite would have achieved no more than a 2% share of a US$10m market, being US$200,000. However, given the sales cycle, revenue is unlikely to have commenced before April 2009, which results in total revenue of US$150,000.

*Conclusion on damages*

348. I accordingly find that the net sales which would have been achieved if 3M had not breached the SPA and the Acolyte business had continued throughout 2009 to be as follows:

i) UK - US$1,050,000.

ii) EU other than the UK – US$445,000.

iii) US – US$417,000.

iv) Canada – US$90,000.

v) Australia – US$150,000.

349. The total net sales are therefore US$2,152,000. The damages recoverable by the Claimants are 60.4% of that figure being US$1,299,808. In arriving at that figure I have given the Claimants as fair a wind as could be justified on the evidence.

**(6) Did 3M US knowingly induce the breaches of contract by 3M UK?**

350. The Claimants contended that although the contractual obligations under the SPA were those of 3M UK, the party which controlled, directed and carried out most of the activities which constituted performance (or breach) of those obligations was 3M US.

351. The Claimants further contended that it is clear that 3M US appreciated that stopping the BacLite business (without consent of the vendors) would be a breach of the SPA.

352. It was the Claimants' case that, at the Deep Dive Review on 9 June 2008, senior executives of 3M US took the decision effectively to stop the BacLite business and cease active marketing as required under the SPA, only pretending to continue "business as usual", and that that decision was made with knowledge that it would place 3M UK in breach of contract and intending that that would be the case.

353. I accept that following the Deep Dive Review it was decided that 3M should seek to terminate the BacLite business and that in the meantime, marketing efforts would be significantly scaled back. However, there was no decision to terminate the business with immediate effect. On the contrary the business was going to be carried on, albeit with reduced resources, whilst the vendors' consent to a cessation of the business was sought.

354. Whilst I have found that 3M was in breach failing actively to market from the end of June 2008 there is no satisfactory evidence that this was known and intended by 3M US. Marketing was still being carried out and whether or not there was a breach of the vague obligation actively to market would have been a moot point.

355. There is equally no satisfactory evidence that 3M US knew that the termination of the business was a breach of contract and intended such breach to take place. For the reasons fully set out in its letters of 12 and 20 November 2008 3M US could reasonably conclude that the vendors' refusal to consent was unreasonable.

356. In short, the requisite "intentional causative participation" in the breach has not been proved – see *OBG Ltd v Allan* [2008] 1 AC 1 at [191]-[192] per Lord Nicholls. Further, the Claimants have never identified the individuals who it is alleged had the requisite knowledge and intent, nor was any serious attempt made at trial to put and prove such a case.

357. I accordingly reject the Claimants' case on this issue.

## Conclusion

358. I find and hold that the Claimants' damages claim succeeds in the amount of US$1,299,808.

IN THE MATTER OF THE *COMPANIES' CREDITORS ARRANGEMENT ACT*, R.S.C. 1985, c. C-36, AS AMENDED

AND IN THE MATTER OF A PLAN OF COMPROMISE OR ARRANGEMENT OF FIRSTONSITE G.P. INC.

Applicant

Court File No. CV-16-11358-00CL

***ONTARIO***
**SUPERIOR COURT OF JUSTICE**
**COMMERCIAL LIST**

Proceeding commenced at Toronto

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