THE HIGH COURT

2012 No. 5061P

BETWEEN:

JENNIFER WALSH

Plaintiff

– and –

THE HEALTH SERVICE EXECUTIVE, BAXTER AG AND

BAXTER HEALTHCARE LIMITED

Defendants

JUDGMENT of Mr Justice Max Barrett delivered on 19th June, 2017.

I. Background

1. It appears that in December, 2009, Ms Walsh was administered a dose of swine flu vaccine which retails under the trade-name 'Celvaplan'. Thereafter, Ms Walsh claims to have suffered irritation and redness of the eyes and weeping eyes, and to have been diagnosed with an inflammatory ocular condition that requires continuing care by a consultant ophthalmic surgeon. As a consequence of the foregoing, Ms Walsh has commenced the within personal injuries proceedings, in the context of which she has brought the discovery application that is now before the court. So far as Ms Walsh's case against the Baxter parties (hereafter 'Baxter') is concerned, it appears to comprise the following allegations, *viz.* that Baxter failed (i) to test adequately, or at all, the vaccine prior to its release, (ii) to warn Ms Walsh adequately or at all of the risks (and the absence of adequate testing of the vaccine) prior to administration, and (iii) to warn Ms Walsh of the risks inherent with Celvaplan.

II. An Aside on Celvaplan

2. Among the affidavits sworn as part of the within affidavit application, the court has been supplied with an affidavit sworn by Ms C. Christle, a solicitor acting for the Baxter parties, in which, *inter alia*, Ms Christle sets out a brief summary of the regulatory framework under which Celvaplan was granted a marketing authorisation by the European Commission on application by Baxter through what is known as the 'centralised procedure'. It is informative and helpful to recount at this juncture the details supplied by Ms Christle:

> *"Celvaplan H1N1 was licensed on the basis of a pandemic 'mock-up vaccine concept, based on European Guideline EMEA/CPMP/VEG/4717/2003 which allows for the submission and approval of a core pandemic dossier during non-pandemic periods. When a pandemic is subsequently declared, the procedure allows for fast-track approval of a pandemic variation. A mock-up licence can only be granted after a pandemic has been declared and the pandemic variation has been approved. Baxter's initial application for a Marketing Authorisation('MA') for Celvaplan through the centralised procedure was first supported by a core dossier for pandemic influenza vaccine H5N1. On 4 March 2009, the European Commission issued an MA under exceptional circumstances for the HFN1 mock-up vaccine of Celvaplan.*
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> *On 11 June 2009, the World health Organisation ('WHO') declared a 'Phase 6' official influenza pandemic, reflecting the global spread of a new strain of human flu virus H1N1. On 22 September 2009, following the onset of the pandemic and WHO declaration, Baxter filed a formal Pandemic Variation to update the composition of the strain to H1N1 and updated the Quality Documentation sections which were product specific to H1N1 as opposed to the previous H5N1.*
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> *On 1 October 2008, the European Committee for Medicinal Products for Human Use ('CHMP') adopted a Positive Opinion to change the pandemic strain vaccine to H1N1 and the European Commission Decision was subsequently issued on 6 October 2009. There was no requirement to provide H1N1 specific clinical data prior to variation approval. H1N1 specific clinical data was collected in children, adults and the elderly during the pandemic.*
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> *In April 2010 the CHMP reviewed further information on the centrally authorised pandemic influenza vaccines Celvaplan, Feocetria and Pandemrix and concluded that data from post-marketing surveillance of 40 million people since September 2009 was sufficient to allow al three vaccines to be used outside a declared influenza pandemic. On 12 August 2010 the European Commission issued a modification of the original MA to a full MA in light of the positive data on the clinical efficacy and safety of Celvaplan.*
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> *On 10 August 2010, the WHO announced that the influenza pandemic was over and the H1N1 2009 pandemic entered its post-pandemic phase. Pharmacovigilance/adverse events updates which had been published regularly by the European Medicines Agency since December 2009 ended on 8 August 2010. The Agency undertook to publish any changes to MAs into the future.*
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> *The most recent opinion in relation to Celvaplan issued by the CHMP on 26 February 2015 based on a review of available information stated that the quality, safety, and efficacy of Celvaplan continues to be adequately and sufficiently demonstrated and that the benefit/risk profile of this medicinal product continues to be favourable. The CHMP recommended that the renewal of the MA be granted with unlimited validity. The MA for Celvaplan was renewed by the European Commission on 6 May 2015. Baxter AG is no longer the MA holder for Celvaplan."*

3. The court does not understand any of the above-quoted averments to be disputed.

III. The Decision in *Framus*

4. There is no disagreement between the parties to the within proceedings as to the general legal principles applicable to discovery. Even so, it seems to the court that it is helpful to commence its judgment by considering in some detail the principles of discovery outlined by Murray J., for the Supreme Court, in *Framus v. CRH plc* [2004] 2 IR 20 (paras.26–36), to which reference was made in the course of the hearing and which the court has found helpful in adjudging upon the within application. Those principles might be summarised as follows:

1. Party Seeking Discovery

(1) A party seeking discovery must pinpoint the documents or category of documents required.

(2) A party seeking discovery must give reasons why the pinpointed documents or category of documents are required.

(3) Blanket discovery requests are not allowed.

(4) Documents sought on discovery must be relevant, directly or indirectly, to the matter in issue between the parties in the proceedings.

(5) A party seeking discovery must show it is reasonable for the court to suppose that the documents contain information which may enable the applicant to advance his own case or to damage the case of his adversary.

(6) A party seeking discovery cannot obtain discovery based on (a) mere speculation or (b) what has been traditionally characterised as a 'fishing expedition.' [1]

[1] The phrase 'fishing expedition', though commonly used, is not especially informative. If objection to discovery is to be made on grounds of want of relevance and/or necessity and/or proportionality and/or some other ground, e.g. that what is being sought is a speculative exercise, it would seem preferable that the objection be raised precisely and not by way of nebulous metaphor, in order that a court might engage with the precise difficulty(ies) claimed to present. However, the phrase 'fishing expedition' has passed into common usage; this being so, as good a definition as to any as to what it seems generally intended to embrace is to be found in the judgment of Kerr L.J. in In Re State of Norway's Application [1987] QB 433, 482:

> "The Solicitor-General stated: 'Although Freshfields have attempted to explain to me the distinction between a request for evidence which amounts to a 'fishing expedition' and one which does not, I confess to having had some difficulty in grasping the concept.' This is readily understandable; although 'fishing' has become a term of art for the purposes of many of our procedural rules dealing with applications for particulars of pleadings, interrogatories and discovery, illustrations of the concept are more easily recognised than defined. It arises in cases where what is sought is not evidence as such, but information which may lead to a line of inquiry which would disclose evidence. It is the search for material in the hope of being able to raise allegations of fact, as opposed to the elicitation of evidence to support allegations of fact, which have been raised bona fide with adequate particularisation."

In short, the phrase seems to anticipate a speculative exercise whereby, under the guise of discovery, a party seeks to elicit potential information of potential relevance on which a case might potentially be constructed or by reference to which it might potentially be buttressed; this form of discovery is not permitted.

(7) A party may not seek discovery of a document in order to find out whether the document may be relevant.

(8) A general trawl through the other party's documentation is not permitted.

2. Party of Whom Discovery Sought

(9) The party of whom discovery is sought must, upon receipt of the preliminary letter seeking discovery: (i) be in a position therefrom to know the document or category of documents referred to, and (ii) be able to exercise a judgment on whether the reasons given for requiring these documents to be discovered was valid.

3. The Court in Any Related Application

(10) The just-described process also assists a court in any related discovery application in knowing (1) why the moving party sought the documents in question, and (2) the grounds upon which the moving party believed that the documents sought to be discovered, might help to dispose fairly of the cause or save costs.

(11) The court must decide as a matter of probability as to whether any particular document is relevant to the issues to be tried.

(12) It is not for the court to order discovery simply because there is a possibility that documents may be relevant.

(13) The court is entitled to take into account the extent to which discovery of documents might become oppressive.

(14) The court should be astute to ensure that the procedure of discovery is not used as a tactic in the war between the parties.

4. Relevance

(15) Relevance must be determined in relation to the pleadings.

(16) Relevance is not to be determined by reason of submissions as to alleged facts unless such submissions relate back to the pleadings or already discovered documents.

5. Necessity

(17) If there are relevant documents in the possession of one party, it will normally be unfair if they are not available to

the opposing party (i.e. necessity is generally an adjunct of relevance).

(18) The overriding interest in the proper conduct of the administration of justice will be the guiding consideration, when evaluating the necessity for discovery.

(19) To establish that discovery of particular categories of documents is 'necessary for disposing fairly of the cause or matter,' the applicant does not have to prove that they are, in any sense absolutely necessary.

(20) The notion of 'litigious advantage', *i.e*. that one party should not enjoy an unfair advantage or suffer an unfair disadvantage in litigation as a result of a document not being produced gives guidance as to the context in which necessity has to be considered.

(21) Consideration of the necessity for discovery includes having regard to all relevant circumstances, including the burden, scale and cost of the discovery sought.

(22) The court should be willing to confine categories of documents sought to what is genuinely necessary for the fairness of the litigation.

(23) The primary test is whether the documents are relevant to the issues between the parties. Once that is established it will follow in most cases that their discovery is necessary for the fair disposal of those issues.

6. Proportionality (Oppression)

(24) Each case must be considered according to the issues raised; but where there are numerous documents of slight relevance and it would be oppressive to produce them all, some limitation may be imposed.

(25) In certain circumstances a too wide ranging order for discovery may be an obstacle to the fair disposal of proceedings rather than the converse.

(26) There must be some proportionality between the extent or volume of the documents to be discovered and the degree to which the documents are likely to advance the case of the applicant or damage the case of his or her opponent in addition to ensuring that no party is taken by surprise by the production of documents at a trial.

IV. A Discovery 'Check-List'

5. *Framus* is, if the court might respectfully observe, a particularly helpful decision of the Supreme Court in the area of discovery. Although, in the years since *Framus* was decided, proportionality has perhaps become a more distinctive pillar on which any order of discovery must be constructed, the principles that *Framus* identifies nonetheless continue in effect today. Is it possible, however, in the interests of consistency, efficiency and predictability to reduce the principles identified in that decision still further to a 'check-list' of questions by reference to which a court might readily adjudicate upon a discovery application in a manner that is consistent with *Framus* and responsive to the particular circumstances of an individual case? It seems to the court that the following check-list might usefully be deployed:

A. Form of Application

(1) **Has the party seeking discovery pinpointed, i.e. identified with great accuracy or precision, the documents or category of documents required?** If 'yes', go to (2). If 'no', the application for discovery as sought ought generally to be declined.

(2) **Has the party seeking discovery given good reason why the pinpointed documents or category of documents are required?** If 'yes', go to (3). If 'no', the application for discovery as sought ought generally to be declined.

B. Relevance

(3) **Are the documents sought on discovery relevant[1], directly or indirectly, to the matter in issue between the parties in the proceedings?** If 'yes', go to (4). If 'no', the application for discovery as sought ought generally to be declined.

> *[1] The adjective "relevant" is defined in the Oxford Online Dictionary as meaning "closely connected or appropriate to what is being done or considered". Relevance must be determined in relation to the pleadings. Relevance must not be determined by reason of submissions as to alleged facts unless such submissions relate back to the pleadings or already discovered documents. The court must decide as a matter of probability as to whether any particular document is relevant. It is not for the court to order discovery simply because there is a possibility that documents may be relevant.*

(4) **Has the party seeking discovery shown it is reasonable for the court to suppose that the documents contain information which may enable the applicant either to advance his own case or damage the case of his adversary?** If 'yes', go to (5). If 'no', the application for discovery as sought ought generally to be declined.

(5) **Has the applicant for discovery avoided the following in respect of each document or category of discovery required: (i) mere speculation; (ii) what has been traditionally characterised as a 'fishing expedition'; (iii) seeking discovery merely to find out whether documentation may be relevant; (iv) seeking a general trawl through the other party's documentation; (v) utilising the discovery process as a tactic in the battle between the parties?** Go to (6) in respect of each document or category to which the answer to all of (i)-(iv) is 'yes'. Discovery as sought ought generally to be declined in respect of any category to which the answer to any of (i)-(iv) is 'no'.

C. Necessity

(6) **Is discovery of the document or category of documents required necessary for disposing fairly of the cause or matter or for saving costs?**[1] If 'yes', go to (7). If 'no', the application for discovery as sought ought generally to be declined.

[1] The primary test is whether the documents are relevant to the issues between the parties. Once that is established it will follow in most cases that their discovery is necessary for the fair disposal of those issues. The overriding interest in the proper conduct of the administration of justice is the guiding consideration, when evaluating necessity. The applicant does not have to prove that the document or category of documents sought is or are, in any sense, absolutely necessary. The notion of 'litigious advantage', i.e. that one party should not enjoy an unfair advantage or suffer an unfair disadvantage in litigation as a result of a document not being produced gives guidance as to the context in which necessity has to be considered. Consideration of the necessity for discovery includes having regard to all relevant circumstances, including the burden, scale and cost of the discovery sought.

D. Proportionality (Oppression)

(7) Discovery of any document or category of documents that reaches this point ought generally to be ordered. Limitation may be imposed by the court where (i) there are numerous documents of slight relevance and it would be oppressive to produce them all; and/or (ii) there is a want of proportionality between (a) the extent or volume of documents to be discovered and (b) the degree to which the documents are likely (I) to advance the case of the applicant or (II) damage the case of his or her opponent, in addition to ensuring that no party is taken by surprise by the production of documents at a trial.

V. Categories of Documentation Sought

CATEGORY 1

6. Documentation Sought: All documentation in relation to complaints and other reports or notifications regarding adverse effects related to the vaccine, in the possession of Baxter, including but not limited to complaints, reports and notifications of the following: red eye(s), puffy eye(s), streaming eye(s), blurred vision, aversion, aversion to glare of lights and/or natural light, pain in eye on waking, gritty feeling in the eye(s), burning sensation in the eye(s), skin irritation.

7. Rationale Offered for Seeking Documentation Sought: Discovery of this category is claimed to be necessary as Ms Walsh pleads in her personal injury summons that Baxter manufactured a defective vaccine and failed to test adequately or at all the vaccine prior to its release. Ms Walsh further pleads that she had the adverse reaction as pleaded in the personal injury summons. This is not admitted by Baxter and Ms Walsh is therefore placed on full proof of same. Accordingly, the fact that others may have suffered similar adverse reactions will be, it is claimed, important in corroborating Ms Walsh's symptoms but more importantly in assisting her in establishing that these symptoms were caused by the vaccine. Furthermore, Baxter specifically denies negligence and that the product was in any way defective. Thus Baxter's prior knowledge of adverse reactions will be, it is claimed, important in overcoming that plea.

8. Documentation Offered: Periodic Safety Update Reports ('PSUR') and Simplified Periodic Safety Update Reports ('S-PSUR') for Celvaplan pandemic flu vaccine of Baxter Healthcare Corporation, limited to the period 6 October, 2009 to 10 August, 2010 and limited to the content relevant to the specific adverse reaction which the Plaintiff attributes to the administration of Celvaplan, namely an eye condition.

9. Court Response: If one returns to the 'check-list' identified above, in particular Question (1), has Ms Walsh in the context of Category 1 pinpointed, *i.e*. identified with great accuracy or precision, the documents or category of documents required? The answer to this question is 'no'. Ms Walsh has not imposed any temporal limitation on Category 1, nor has she limited Category 1 to documents relevant to her alleged injury. Rather than limit Category 1 to a finite and limited set of documents, she has framed her request for discovery as a widespread and general trawl. As a result, the discovery as sought falls to be declined.

10. As to the documentation offered, PSURS and S-PSURS are pharmacovigilance reports which provide a summary of relevant data to assess the safety of a product. PSURS and S-PSURS were submitted by the MA-holder to meet its pharmacovigilance obligations in respect of Celvaplan. The period 6th October, 2009, to 10th August, 2010, is the relevant period. Celvaplan was first authorised on 6th October, 2009, via centralised European procedures. Ms Walsh alleges that she was administered Celvaplan in two doses, on 21st December, 2009, and 25th January, 2010. The WHO declared a Phase 6 official influenza pandemic on 11th June, 2009, reflecting the global spread of a new strain of human influenza virus H1N1 and on 10th August, 2010, declared the end of that pandemic.

11. Order to be Made: The court will **order** discovery of the documentation offered.

CATEGORY 2

12. Documentation Sought: All documentation in relation to warnings, disclaimers and/or potential side-effects of the vaccine which were issued (either by Baxter or others) to the HSE, Department of Health, health authorities, healthcare professionals, administrators of the vaccine and the general public which were in Baxter's possession (a) prior to 25th January, 2010, and (b) subsequent to that date.

13. Rationale Offered for Seeking Documentation Sought: Discovery of this category is necessary, it is claimed, as Ms Walsh pleads in her personal injury summons that the defendants (in particular, Baxter) failed to warn her of the risks inherent with the vaccine. Furthermore, in view of the fact that liability is denied by the second and third-named defendants, discovery of this category of document is, it is claimed, particularly necessary, Ms Walsh asserting that it is surely of some significance that even though the entirety of her claim is either denied or not admitted that Baxter would nevertheless issue warnings (if such occurred) to others after 25th January, 2010.

14. Documentation Offered: Celvaplan product packaging for batches VNV9J020A and VNV9J016A.

15. Court Response: If one returns to the 'check-list' identified above, the answers to each of Questions (1)-(6) so far as the documentation sought in Category 2 is concerned is 'yes'.

16. Order to be Made: The court will **order** discovery of Category 2 as sought.

CATEGORY 3

17. Documentation Sought: All documentation in relation to research, testing, clinical trials (including details of all phases) and post-marketing surveillance performed by or on behalf of Baxter prior to the release of the vaccine.

18. Rationale Offered for Seeking Documentation Sought: It is pleaded in Paragraph 12(b) of the personal injury summons that there was a failure on the part of Baxter to test adequately or at all, the vaccine prior to its release. In a letter of 25th November, 2013, Ms Walsh has pleaded that there was a failure to carry out proper investigations and trials before submitting same to be licensed. It was further pleaded in a letter of 25th November, 2013, that Baxter failed to withhold the product until all necessary research and clinical trials had been completed, reported upon and considered. Post-marketing surveillance is, it is claimed, an important part of the licensing process. Any adverse effects which subsequently come to light are, it is claimed, relevant to whether pre-release testing was adequate. Liability is denied by Baxter in its Defence of 22nd June, 2015.

19. Court Response: If one returns to the 'check-list' identified above, the answers to each of Questions (1)-(5) so far as the documentation sought in Category 3 is concerned is 'yes'. However, the answer to Question (6) is 'no'. It seems to the court to be important to note in this regard that Celvaplan had all necessary regulatory approvals required under European Union law at all material times and, indeed, nothing to contrary is being alleged. In addition, the PSURs and S-PSURs which will be discovered under Category 1 provide summary data relevant to post-marketing surveillance and clinical studies. Further, there is available to Ms Walsh extensive information published by the CHMP in relation to its continuing assessment of Celvaplan, commencing with its report of 1st October, 2009, and concluding with its report of 24th June, 2010. Ms Walsh, with respect, appears to the court to have ignored the factual matrix presenting in the within proceedings, specifically that Celvaplan was granted a full MA in August, 2010 in light of the positive data on the clinical efficacy and safety of Celvaplan. Ms Walsh, with respect, also appears to the court to have ignored the regulatory system which was in place at European Union level in relation to the authorisation of human influenza flu vaccine, specifically that there was no requirement to provide H1N1-specific clinical data prior to variation approval being granted by the European Commission. In addition, in April, 2010, the CHMP reviewed further information on the centrally authorised pandemic influenza vaccines that included Celvaplan and the European Commission issued a modification of the original MA to a full MA in light of the positive data on the clinical efficacy and the safety of Celvaplan. Though the matter is perhaps somewhat starkly put by Ms Christle in her affidavit evidence, the court cannot but respectfully agree with the logic of her averment that *"If, of course, the Plaintiff wishes to assail the regulatory system, that is another matter and, indeed, another case."*

20. Order to be Made: The court declines to order discovery of this category of documentation.

CATEGORY 4

21. Documentation Sought: All documentation in relation to the licensing and/or granting of the MA and release of the vaccine submitted to the European Medicines Agency and/or the Irish Medicines Board (laterally known as the Health Products Regulatory Authority).

22. Rationale Offered for Seeking Documentation Sought: The said documentation, it is claimed, is relevant to the issues of whether adequate testing, research, safety warnings and endorsements were in place. As a licensed product, Baxter had to submit all of the foregoing to the relevant authority. What evidence, Ms Walsh asks, did it produce in that regard? Such 'evidence', she maintains, is relevant, in particular in light of the Defence delivered herein.

23. Court Response: If one returns to the 'check-list' identified above, the answers to each of Questions (1)-(5) so far as the documentation sought in Category 3 is concerned is 'yes'. However, the answer to Question (6) is 'no'. Baxter points to the fact that publicly available reports are available from the relevant competent agencies and contain the data that is relevant to Ms Walsh's claim, with all commercially confidential information deleted therefrom; it does not identify these reports or where they are available online (if available online). By contrast, the product dossier (as amended), together with all documents and filing submitted by Baxter to the European Medicines Agency or any other regulatory agency in support of its application for an MA is replete with confidential information.

24. Order to be Made: The court will decline to order discovery of this category; however it will order that Baxter specify the publicly available reports that contain the data relevant to Ms Walsh's claim and where they are available online (if online).

CATEGORY 5

25. Documentation Sought: All documentation in relation to pharmacovigilance and post-marketing surveillance subsequent to the release of the vaccine.

26. Rationale Offered for Seeking Documentation Sought: Following release of the vaccine to the market additional pharmacovigilance activities and surveillance were, it is claimed, recommended in respect of the vaccine by the then Irish Medicines Board. Healthcare professionals were, it is claimed, specifically requested to report suspected adverse reactions and post-immunisation events. It is pleaded in Paragraph 12(b) of the personal injury summons that there was a failure on the part of Baxter to test adequately or at all, the vaccine prior to its release. Post-marketing surveillance is, it is claimed, an important part of the licensing process. Any adverse effects which subsequently come to light are, it is claimed, relevant to whether pre-release testing was adequate. Furthermore, the Plaintiff pleads that she had the adverse reaction as pleaded in the Personal Injury Summons. This is not admitted by Baxter and the Plaintiff is placed on full proof of same. Accordingly, the fact that others may have suffered similar adverse reactions will be, it is claimed, important in corroborating the Plaintiff's symptoms but more importantly in assisting the Plaintiff in establishing that these symptoms were caused by the vaccine. Furthermore, Baxter specifically denies negligence and that the product was in any way defective. Thus Baxter's subsequent knowledge of adverse reactions will be, it is claimed, important in overcoming that plea.

27. *Court Response*: If one returns to the 'check-list' identified above, the answers to each of Questions (1)-(5) so far as the documentation sought in Category 5 is concerned is 'yes'. However, the answer to Question (6) is 'no'. The relevant documentation is captured by Category 1. In addition, Ms Walsh has access to the publicly available documentation referred to in Category 5; this

provides the relevant data in relation to pharmacovigilance and post-marketing surveillance subsequent to the release of the vaccine.

28. Order to be Made: The court declines to order discovery of this category of documentation.

CATEGORY 6

29. This category has been agreed.

CATEGORY 7

30. Documentation Sought: All documentation passing between the HSE and Baxter in relation to the guidance for use and/or administration of the vaccine and the vaccine batches.

31. Rationale Offered for Seeking Documentation Sought: Ms Walsh has specifically alleged that the first, second and third-named defendants were negligent in the administration of the vaccine. This is denied by the second and third-named defendants in their Defence. While it is accepted that neither Baxter nor its staff physically administered the vaccine, Ms Walsh is nonetheless concerned as to what instructions and guidance, if any, were given by Baxter to the HSE or its staff or others who were in fact administering the vaccine.

32. Court Response: This category is duplicative of Category 2.

33. Order to be Made: The court declines to order discovery of this category of documentation.

VI. Confidentiality

34. Baxter claims that the documentation within the various categories of discovery as sought contains commercially confidential information (e.g. trade secrets, know-how, proprietary data, and business, financial commercial information), the disclosure of some or all of which would cause harm to the competitive position of the party making discovery. Consequently, Baxter claims the usual implied undertaking as to confidentiality by the party seeking discovery in favour of the party making discovery does not suffice in the within proceedings. Baxter has therefore sought, somewhat unusually, that, to borrow from the wording of Ms Christle's affidavit evidence "[I]*nsofar as the Court may be disposed to order discovery in favour of the Plaintiff it should be a condition that the Plaintiff enters into a confidentiality agreement with the Defendants in terms acceptable to Baxter".*

35. As the court indicated at hearing, it is not disposed to 'out-source' the policing of confidentiality so that discovery is made of documents on such terms as Baxter may determine to be acceptable; what documents are to be discovered and on what basis is a matter for the court to determine after hearing the parties. Moreover, although it was proper for Baxter to flag the issue of confidentiality when it did, it properly admitted that it could not define with specificity what level(s) of confidentiality it was seeking until it knew what level of discovery was to be ordered. Conversely, of course, the court cannot make any order as to confidentiality until it knows what precisely Baxter is seeking – and it may be that despite Baxter's claim to the contrary, the standard implied undertaking may ultimately be found by the court to suffice. After the parties have had an opportunity to consider the within judgment and before any order ensues, the court will hear any further submissions that the parties may wish to make as regards confidentiality.