[2020] IEHC 427

THE HIGH COURT

[2017 No. 9907 P.]

BETWEEN

BENJAMIN BLACKWELL A MINOR SUING BY HIS MOTHER AND NEXT FRIEND NATALIE BLACKWELL

PLAINTIFF

AND

THE MINISTER FOR HEALTH AND CHILDREN, THE HEALTH SERVICE EXECUTIVE, THE HEALTH PRODUCTS REGULATORY AUTHORITY AND GLAXOSMITHKLINE BIOLOGICALS S.A.

DEFENDANTS

JUDGMENT of Mr. Justice MacGrath delivered on the 18th day of August, 2020

The Application

1. This is the plaintiff's application for an order pursuant to O. 31, r. 1 of the Rules of the Superior Courts granting him leave to deliver interrogatories for examination of the fourth named defendant.

2. In the underlying proceedings, the plaintiff claims damages for personal injuries allegedly arising in consequence of the administration to him of the swine flu vaccine, Pandemrix on the 22nd February, 2010 at Ratoath National School when he was aged five. It is alleged that he developed symptoms of excessive sleepiness and was subsequently diagnosed with narcolepsy and cataplexy. He alleges negligence, breach of duty, breach of his constitutional rights and breach of the provisions of the Liability for Defective Products Act, 1991 ("*the Act of 1991*"). It is pleaded, *inter alia*, that the fourth named defendant was in breach of the provisions of the Act of 1991 in failing to give adequate warnings of the increased incidences of adverse events associated with Pandemrix compared to its other flu vaccines. Pandemrix was developed by the fourth named defendant in response to the human swine flu in 2009 and was produced at its Dresden plant in Germany. Of particular relevance to this application is an allegation that another swine flu vaccine, Arepanrix, which was produced by the fourth named defendant at its plant in Canada, had far fewer adverse reactions than Pandemrix. Pandemrix was used in Ireland and other European countries. Arepanrix was used in Canada.

3. The application is brought by way of notice of motion dated 28th February, 2020. Initially, six interrogatories were raised on behalf of the plaintiff for the examination of the first, second and fourth named defendants. The parties have come to an agreement in relation to all but one which is addressed to the fourth named defendant being:-

> *"Did not the fourth defendant conduct an analysis of the disparity in adverse events associated with the Pandemrix and Arepanrix vaccines respectably, which was evident from its Enhanced Safety Review Team Reports for the period from week 46 of 2009 (4-10 November) to week 6 of 2010 (3-10 February)."*

4. The plaintiff claims that prior to his vaccination the fourth named defendant was aware of the risks associated with the use of the vaccine including those revealed by post marketing pharmacovigilance data which, it is alleged and contended showed that the Pandemrix vaccine was significantly less safe than the alternative H1N1 vaccines. It is

contended that a disparity was evident from the pharmacovigilance data produced by the fourth named defendant from November, 2009 to the date of the plaintiff's vaccination on 22nd February, 2010. It is alleged that the fourth named defendant, as the market authorisation holder of the product, failed in its obligations to notify the appropriate authority of a disparity in the incidents of adverse events between Pandemrix and Arepanrix. The authority is the European Medicines Agency ("EMA") which authorised Pandemrix for use in Ireland. It is alleged that the fourth named defendant was in breach of its obligations under EU law including Regulation 726/2004, regarding procedures for the authorisation and supervision of medicinal products for human and veterinary use arising from the alleged failure to notify the EMA of the pharmacovigilance data; and that the fourth named defendant was in breach of its duty to share ongoing pharmacovigilance data which, it is further alleged, was breached by the fourth named defendant acquiescing in what is described as a system of disinformation which was adopted by the first and second named defendants. The first and second named defendants are not parties to this application. All matters are in dispute and these allegations are denied by the fourth named defendant.

Affidavit in Response to Request for Discovery

5. This is one of a number of proceedings brought by plaintiffs in which somewhat similar complaints are made. In *Aoife Bennett v. Minister for Health and Children, HSE, GlaxoSmithKline Biologicals SA and Health Products Regulatory Authority* (Record No. 2012/12009P) (the "*Bennett proceedings*"), extensive discovery was made. The *Bennett* proceedings have since been compromised. Following the conclusion of the trial in the *Bennett* matter, a number of motions were issued in these proceedings, relating to discovery and this application for leave to deliver interrogatories. Counsel for the plaintiff, Mr. Kilfeather S.C., explained to the court that the obligations of the fourth defendant as the market authorisation holder are the subject of more significant focus than they were in the *Bennett* proceedings. He also informed the court that in the discovery application, the plaintiff sought documents relating, *inter alia*, to the roles and involvement of two teams within the fourth named defendant company and as to what protocols were in existence. It is explained that in the context of the ongoing requirement to monitor data received following the administration of the vaccine, information was fed and collated in the fourth named defendant's global database, known as the OCEANS database, which held details of adverse events reported to the fourth defendant for each of its products.

6. In the context of discussions regarding the making of discovery, the parties agreed that an affidavit be sworn on behalf of the fourth defendant in which explanations and answers be provided in respect of a number of matters, including the role of the two teams, and concerning applicable and existing rules and protocols. It was also agreed that documentation supporting the answers would be exhibited. This affidavit was prepared and sworn by Mr. Roderick Bourke, solicitor and partner in the firm McCann FitzGerald on 12th May, 2020. Although not now on record for the fourth defendant in these proceedings, Mr. Bourke's firm have advised the fourth defendant in respect of litigation surrounding Pandemrix since 2012 and assisted in the preparation of discovery in the *Bennett* proceedings.

7. Mr. Bourke explains that in these proceedings the plaintiff sought discovery of two categories of documents. Arising from discussions it was agreed that the proposed categories would include all documents which record and/or refer to the rules, protocols or guidance established by Team 1 and Team 2 in respect of internal or external communication of information contained in the OCEANS database enhanced safety reports during the period between 1st September, 2009 and 23rd February, 2010 and operated by the fourth defendant for each of H1N1 pandemic vaccines produced by the fourth named defendant in the declared flu pandemic of 2009 and 2010. The second category are documents which record and/or refer to the disclosure during the period of the enhanced safety review team reports in respect of the H1N1 pandemic vaccines by the fourth defendant to the first and second defendants and the EMA.

8. Mr. Bourke explains that the revised "*Blackwell categories*" were different to the categories of documents discovered in the Bennett proceedings. Given that his firm had assisted the fourth defendant in making discovery in those proceedings he was instructed by the fourth named defendant to check for documents possibly relevant to these two categories. As a result of those inquiries approximately 60,000 documents were identified which required to be reviewed for the two revised "*Blackwell categories*". In light of the time and the cost involved in reviewing that number of documents, the parties reached an agreement through counsel on 13th March, 2020 as follows:-

> *"First, instead of discovering documents within the ambit of category two in the plaintiff's discovery motion or any of the revised versions thereof, an Affidavit will be sworn on behalf of the Fourth Defendant by a solicitor in the office of McCann FitzGerald which will:*
>
> *(i) address the following question 'Did not the Fourth Defendant fail to transmit the data contained in its Enhanced Safety Review Team Reports for the period from week 46 of 2009 (4-10 November) to week 6 of 2010 (3-10 February) inclusive to the CMPH/the EMA prior to 22nd February 2010?'; and*
>
> *(ii) exhibit supporting documentation in respect of the answer provided in that regard.*
>
> *Secondly instead of discovering documents within the ambit of category 1 in the Plaintiff's discovery motion or any of the revised versions thereof, said Affidavit will*
>
> *(i) explain what is meant by team one and team two and how they operated during the period between October 2009 and March 2010 and*
>
> *(ii) exhibit supporting documentation in respect of the answer provided in that regard."*

9. Mr. Bourke's affidavit was prepared on the above basis. It is extensive. He explains that Team 1 and Team 2 were groups within the fourth named defendant who were active during the H1N1 influenza pandemic and who, respectively, evaluated safety data

received by the fourth named defendant and co-ordinated certain non-regulatory communications relating to safety information.

10. In correspondence it is accepted that Mr. Bourke's affidavit deals with all but the disputed interrogatory. By letter of 22nd May, 2020, Mr. Boylan wrote to Mr. Bourke stating that he intended to call him as a witness as to fact and to give evidence in relation to his affidavit and matters contained therein. The fourth defendant maintained in its letter of 29th May, 2020 that the disputed interrogatory is unreasonable and unnecessary for disposing fairly of the matter or for saving costs. It also outlined its objection that the premise of the question of the alleged disparity in adverse events associated with Pandemrix and Arepanrix was disputed, with reference being made to a number of published articles, to some of which I shall refer below. It was stated that the interrogatory was such that, unless the answer involved a complete deconstruction of the question, it would require acceptance of the disputed premise.

11. Mr. Boylan in his reply of 2nd June, 2020 accepted that the affidavit of Mr. Bourke provided a response to all but the interrogatory the subject matter of this application. The letter proceeds as follows:-

> *"You contend that it is not possible to answer this interrogatory as you don't accept that there is any disparity between the adverse events associated with Pandemrix and Arepanrix in the first instance. This is frankly very difficult for us to understand in light of the copious documents which you have discovered which demonstrate this disparity. Indeed, several of our liability witnesses have advised us that they would have expected this safety signal to have been investigated and analysed by the Fourth Named Defendant. Moreover, the Fourth Defendant's former solicitor Mr Bourke has sworn that Arepanrix produced a rate of 7.3 adverse events per million doses distributed between 21st October 2009 and 9th February 2010 whereas Pandemrix produced a rate of 134 adverse events per million doses distributed for the period between 12th October 2009 and 31st January 2010. Pandemrix produced a rate of 128.4 adverse events per million doses distributed. This averment demonstrates that Pandemrix was producing a rate of approximately 18 times the number of adverse events as Arepanrix during this period.*
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> *The grounds of opposition to answering interrogatory 4, identified in your letter of 29th May 2020 make no sense in the light of the averments of Mr. Bourke and unless an answer to this interrogatory is forthcoming, it will be necessary to proceed with the Plaintiff's motion for leave to deliver this sole interrogatory."*

Grounding Affidavit

12. The application is grounded on an affidavit sworn on the 21st February, 2020 by Mr. Michael Boylan, solicitor representing the plaintiff. It was sworn some time prior to the preparation by Mr. Bourke of his affidavit and it is clear that matters have progressed somewhat since. Mr. Boylan avers that documents containing pharmacovigilance data discovered by the fourth defendant in the *Bennett* proceedings demonstrated that between November, 2009 and the date of the plaintiff's vaccination on 22nd February

2010, Pandemrix was producing many more adverse events than Arepanrix. In support, he refers by way of example to an email of the 26th November, 2009 from Ms. McHugh of the fourth named defendant, forwarding the fourth named defendant's "*Enhanced Safety Review Team Report*" for the week of 18th to the 24th November, 2009 to a number of colleagues and a number of recipients in the Irish Medicines Board. These showed that the administration of Pandemrix had at that stage given rise to 687 serious adverse events while Arepanrix had given rise to only 76 such events.

13. Mr. Boylan avers that the interrogatories sought to be delivered to the fourth named defendant concern, *inter alia*:-

> *"whether the fourth Defendant analysed the disparity in adverse events between the two vaccines, which was evident from the pharmacovigilance data. The answers which may be provided by the fourth named defendant to the proposed interrogatories in respect of… issue (b) is relevant to determining whether, as is claimed by the Plaintiff (at paragraph 23(vi)), the fourth Defendant knew by the date of the Plaintiff's vaccination that the Pandemrix vaccine was significantly and materially less safe than alternative vaccines."*

It is also averred that the answer to the interrogatories will result in a considerable shortening of the length of trial by obviating the requirement that the plaintiff establish in evidence the facts in respect of both the analysis by the fourth named defendant of the pharmacovigilance data and the communication of that data to the EMA.

Affidavit of Dr Seifert in response to the disputed interrogatory

14. Dr Seifert is the senior director and head of Pharmacovigilance Alliances at GSK, the fourth defendant, in Philadelphia. From 2006 to 2010, he was a senior director and head of the North America Safety Evaluation and Risk Management team of the fourth defendant. In an affidavit sworn on the 21st July, 2020 in response to the request for interrogatories, (rather than in response to this application), he objects to the interrogatory on the following basis:

a. the interrogatory lacks clarity in a number of fundamental respects.

b. It is framed by reference to premises which are disputed.

c. It is impermissible as it comprises multiple requests in respect of issues which are matters for evidence.

d. It is unreasonable and unnecessary either for disposing fairly of the proceedings or for saving costs.

e. Without prejudice to the objection to the interrogatory, he avers that the fourth defendant conducted all appropriate analysis of the data in relation to the vaccines. He disagrees with the characterisation and suggestion in the interrogatory that the spontaneous adverse event report data referred to in the SRT emails (Enhanced Safety Review Team Reports) show the alleged 'disparity'. He also disagrees with

any suggestion that the fourth defendant ought specifically to have conducted comparative analysis of that data. He avers that such characterisation and suggestion are scientifically invalid for reasons which will be addressed in evidence at the trial of the action. Dr Seifert refers to what was publicly stated by the EMA and the Medicines and Healthcare Products Regulation Authority in response to a paper published on 20th September, 2018 in the British Medical Journal ("*BMJ*") by an associate editor, Mr. Peter Doshi, entitled "*Pandemrix vaccine: why was the public not told of early warning signs*" ("*the Doshi paper*"). Dr Seifert profoundly disagrees with the characterisation of the clinical trials data as a disparity and suggests that such a characterisation cannot validly be made on the basis of the available data. He avers:-

> *"In circumstances where in the clinical studies for Pandemrix and Arepanrix had different start times and were not conducted simultaneously, comparative analysis should not be carried out in respect of week-by-week data. Moreover, comparative analysis of clinical trials data must be approached with caution for reasons including that such comparisons must take account of different settings, countries and populations in which the clinical trials were carried out. While evidence will be adduced in this regard at the trial of the proceedings, I wish to highlight at this stage that the goal standard of comparing any medicinal products is via a head-to-head clinical study and, before the end of the date range included in the 'interrogatory', GSK had already submitted results from such a study to the EMA which the EMA concluded showed comparable safety profiles between Pandemrix and Arepanrix."*

Dr Seifert exhibits the EMA assessment report for Arepanrix which was published on the 26th April, 2010.

Order 31 of the Rules of the Superior Courts

15. Order 31, rules 1 and 2 RSC provide:-

"1. In any cause or matter where relief by way of damages or otherwise is sought on the ground of fraud or breach of trust, the plaintiff may at any time after delivering his statement of claim, and a defendant may at or after the time of delivering his defence, without any order for that purpose, and in every other cause or matter any party may by leave of the Court, upon such terms as to security for costs or otherwise as the Court may direct, deliver interrogatories in writing for the examination of the opposite parties, or any one or more of such parties, and such interrogatories when delivered shall have a note at the foot thereof, stating which of such interrogatories each of such persons is required to answer: provided that no party shall deliver more than one set of interrogatories to the same party without an order for that purpose; provided also that interrogatories which do not relate to any matters in question in the cause or matter shall be deemed irrelevant, notwithstanding that they might be admissible on the oral cross-examination of a witness.

2. *A copy of the interrogatories proposed to be delivered shall be delivered with the notice of application for leave to deliver them, unless the Court shall otherwise order, and the particular interrogatories sought to be delivered shall be submitted to and considered by the Court. In deciding upon such application, the Court shall take into account any offer which may be made by the party sought to be interrogated, to deliver particulars, or to make admissions, or to produce documents, relating to any matter in question. Leave shall be given as to such only of the interrogatories as shall be considered necessary either for disposing fairly of the cause or matter or for saving costs."*

Discussion and Decision

16. Order 31 make it clear that leave to deliver interrogatories shall be granted only where it is considered that they are necessary either for the fair disposal of the cause or for the saving of costs.

17. The principles applicable on an application such as this have been considered in a number of decisions, including that of the Court of Appeal in *McCabe v. Irish Life* [2015] 1 I.R. 346. Kelly J., with whom the other members of the court agreed, held that the requirement to establish an exigency requiring the delivery of interrogatories was no different from the requirement set down in the Rules of the Superior Courts that interrogatories only be allowed where they were necessary to ensure the fair disposal of the cause or for the reduction of costs and that the questions posed by interrogatories should be clear to allow equally clear answers to be sworn in reply. He considered that the archaic style of framing interrogatories in the negative had long since been abandoned in favour of the form of question used in the cases listed in the Commercial Court. He observed as follows at p. 350:-

"13. Since the decision of the Supreme Court in J. & L.S. Goodbody Ltd. v. The Clyde Shipping Company Ltd. (Unreported, Supreme Court, 9th May, 1967), litigation has increased enormously in quantity, complexity and cost. It is high time for the exhortation of the Supreme Court of 1967 to be acted upon.

14. In that decision the Supreme Court made it clear at p. 3 that:-

> *'... one of the purposes of interrogatories is to sustain the plaintiff's case as well as destroy the defendant's case ... and that interrogatories need not be confined to facts directly in issue but may extend to any facts, the existence or non-existence of which is relevant to the existence or non-existence of the facts directly in issue. Furthermore, the interrogatories sought need not be shown to be conclusive on the questions in issue but it is sufficient if the interrogatories sought should have some bearing on the question and that the interrogatory might form a step in establishing the liability. It is not necessary for the person seeking leave to deliver the interrogatory to show that it is in respect of something he does not already know.'*

15. Those observations also deserve to be brought to the attention of practitioners since many appear to have a very restricted view of the circumstances in which interrogatories may be used. That may in part explain why they are used so infrequently. It is clear from the observations of Walsh J. that robust questions may be posed on a much wider basis than is generally appreciated. "

18. In *Irish Bank Resolution Corporation Limited (In Special Liquidation) v. Catriona Fitzpatrick* [2017] IEHC 715, Baker J. noted that the threshold requirement for the granting of leave is that the interrogatories should be relevant to the cause or matter and that they be considered necessary. She observed that the approach of Kelly J. in *McCabe* was consistent with the approach of the courts in a number of areas of practice where litigation efficiency is sought to be positively supported and stated at para. 29:-

> *"His judgment is based on more than a mere desire for efficiency, but he did regard the delivery of interrogatories as desirable in the interest of justice and rejected the 'very restricted view of the circumstances in which interrogatories might be used.'"*

19. Nevertheless, Baker J. also observed at para. 35:-

> *"That litigation efficiency may be the guiding principle in certain cases seems to be undoubtedly the case, but the desire for such efficiencies is not the only factor to be taken into account by the court and fairness to the person upon whom interrogatories are sought to be delivered is also a factor and one expressly identified in the Rules, which requires the interrogatories sought to be delivered not cause an injustice or unfairness to the other party."*

Referring to the decision of Shanley J. in *Woodfab Limited v. Coillte Teoranta* [2000] 1 I.R. 20, Baker J. observed as follows:-

> *"Shanley J. quoted from the judgment of Costello J. in Mercantile Credit Company of Ireland Limited & Anor v. John Heelan & Ors and expressly adopted the criteria as further explained by Lynch J. in Bula Limited v. Tara Mines Limited, namely that questions which related to 'opinions, conduct or the meaning or effect of documents' were to be excluded."*

20. Having discussed the authorities which highlighted distinctions between facts and evidence, Baker J. was also satisfied that the questions must be "*crystal clear*" and enable equally clear answers. This much was apparent from the decision of the Court of Appeal in *McCabe*. She continued at para. 52:-

> *"I consider that the questions sought to be asked in regard to the intentions of Mrs. Fitzpatrick or her opinions, must be regarded as impermissible having regard to the tests as outlined by Costello J. Mercantile Credit Company of Ireland Limited & Anor v. John Heelan & Ors which were expressly adopted by Fennelly J. in Woodfab Ltd v Coillte Teo. I consider that it is more likely than not, that if questions in this form are put to Mrs. Fitzpatrick in the course of oral hearing, a judge would hear and*

consider her answers in the context of the totality of relevant evidence, and that the meaning and effect of the answers will be explored in examination-in-chief and cross-examination. The blunt instrument of interrogatories is not suitable for this type of answer, and for that reason, I do not consider that the interrogatories seek information or facts, but rather answers to matters more akin to opinions or meanings, the effect or the factual context of which may not admit a clear answer."

21. In *Cole v. Blood Transfusion Service Board and ors* (Unreported, High Court, Laffoy J., 11th June, 1996), interrogatories were rejected by Laffoy J. on the grounds, *inter alia,* that they were matters which would be more fairly explored in oral evidence where nuances and inferences would be best addressed. Laffoy J. noted at p. 2:-

> *"In considering the fair disposal of an action commenced by plenary summons, the Court must bear in mind that such actions are in principle to be heard on oral evidence and that the use of evidence on affidavit given in reply to interrogatories is an exception which must be justified by some special exigency in the case which, in the interest of doing justice, requires the exception to be allowed."*

22. Baker J. noted in *Fitzpatrick* that the authorities are not altogether in alignment in respect of whether a special exception must exist. Laffoy J. also reiterated that although the rules permitted interrogatories to be served for the purpose of saving costs, the interests of doing justice between the parties was the paramount consideration in an application under that rule and that an order will be refused *"if a fair hearing of the issues between the parties might be prejudiced by it, even if the costs of the proceedings would be reduced by making the order".*

23. Thus, it seems to me that in so far as the issues in this case are concerned the position may be summarised as follows. The use of interrogatories is to be encouraged. While there is some debate, on which the court finds it unnecessary to express a concluded view, as to whether it is still correct to say that the use of evidence on affidavit given in reply to interrogatories is an exception which must be justified by some special exigency, nevertheless, the question raised must be necessary in the sense described in O. 31, either for disposing fairly of the cause or matter or for saving costs. The interrogatory must be clear and be capable of a clear answer. Interrogatories should not be used to elicit opinions and, fundamentally, must not be such as to prejudice a fair hearing of the issues between the parties.

24. The plaintiff pleads, *inter alia*, that the fourth defendant had an obligation to take reasonable care that prospective consumers of the vaccine would be properly informed of the risks and uncertainties about the vaccine, its lack of prior testing, the fact that its safety would be tested post marketing rather than pre-marketing. It is also pleaded that the fourth defendant was aware that prior to the plaintiff's vaccination on the 22nd February, 2010, that the emerging post marketing pharmacovigilance data available by that date showed that the vaccine was significantly and materially less safe than alternative vaccines and that the defendants knew or ought to have known that the vaccine was significantly more reactogenic than Arepanrix. It is pleaded that there was a

failure on the part of the fourth defendant to warn the plaintiff of the emerging internal pharmacovigilance data gathered from its database system on a weekly basis beginning mid-November, 2009 which showed "*the alarming disparity in the incidences of serious adverse events between Pandemrix and Arepanrix*" and that there was a failure to pass on the information in its weekly enhanced safety reports. It is further alleged that the fourth named defendant failed to ensure the provision of adequate warnings as to the risks in the context of the lack of prior testing of the vaccine, the novelty and lack of adequate and/or prior testing of the adjuvant (whether in isolation or in combination with the antigen) and/or the emerging evidence of the serious disparity and increased incidents of adverse events associated with Pandemrix compared to its other pandemic flu vaccines.

25. In its defence, the fourth named defendant specifically denies that it failed to provide required information or that it failed to warn the plaintiff and, in particular, it is denied that the Pandemrix vaccine was several times as reactogenic as another (Celvapan) vaccine or that it was consistently and significantly more reactogenic than the Arepanrix vaccine. The alleged excess number of adverse events associated with Pandemrix is also disputed.

26. Counsel for the plaintiff Mr. Kilfeather S.C. submits, by reference, *inter alia*, to Mr. Bourke's affidavit, that the numbers of adverse reactions during this period and that Pandemrix exceeded those of Arepanrix by approximately 19 times. The purpose of the interrogatory is to establish whether this information was analysed, whether the disparity between the two rates of adverse incidents was compared in the context of that analysis. He submits that the interrogatory is relevant and the reply to the information sought is likely to lead to a saving in costs and that if no analysis of the disparity or differential in reported adverse incidents was conducted then time will not be expended on cross examination of various experts, thus leading to a saving in costs. A reply will obviate the requirement for further discovery as it is not apparent to the plaintiff, at this point in time, from studying the voluminous discovery which has been made whether such analysis was conducted. Counsel referred the court to published articles, including the Doshi paper and a reply by Mr. Arlett of the EMA, which was further replied to by Mr. Doshi and the editor of the British Medical Journal.

27. Counsel for the fourth named defendant, Mr. Douglas Clarke S.C., submits:-

    (1) The proposed interrogatory is framed by reference to terms which are wholly lacking in the requisite precision and clarity.

    (2) It is not a single question but rather impermissibly comprises multiple questions.

    (3) The interrogatory is rooted in premises and issues of fact which are disputed.

    (4) The various questions and sub-questions which are embedded in it relate to core issues in the case and are plainly matters for evidence including expert evidence at the trial of the proceedings and, therefore, are not proper matters for interrogatory.

(5) The requested interrogatory ignores the extensive discovery made by the fourth named defendant in the *Bennett* proceedings, which on the consent of the parties is available to the plaintiff in these proceedings.

(6) The application ignores what he describes as a very detailed affidavit of Mr. Bourke sworn in accordance with the agreement reached between the parties in the resolution of the discovery motion.

(7) On any view, the interrogatory is unnecessary for the disposal fairly of the proceedings or for the saving of costs.

28. Mr. Clarke S.C. submits that if the court is satisfied in respect of any one of these contentions, it should dismiss the application and that cumulatively the above must lead to the conclusion that this is a very clear case in which the application should be dismissed. He further points out that these various headings which he has advanced in defence of this application have been identified entirely independently of the affidavit of Dr Seifert sworn in answer to the interrogatory and which was sworn without prejudice to the objection to the interrogatory. It is submitted that when the application is considered in the light of the contents of Dr Seifert's affidavit, it is beyond doubt that the application is misconceived and ought to be dismissed. It is further submitted that the question is not crystal clear and counsel points to a number of aspects of the question in the interrogatory in this regard including the words "*analysis*" and "*disparity*". He queries what is meant by the term '*analysis'* in the context of the vaccine safety and pharmacovigilance issues that underlie the question and submits that this term is very broad and imprecise, highlighting that accuracy in terminology is important in the context of pharmacovigilance and vaccine safety, and that such accuracy is missing from the interrogatory. He also submits that the data upon which the plaintiff places reliance to show an apparent disparity of adverse events is rooted in a fundamental misunderstanding of the concepts of disparity and analysis in the fields of vaccine safety and pharmacovigilance and submits in this regard that the data on which the plaintiff places reliance shows an apparent disparity in adverse events reported in the fourth defendant's database in respect of the vaccines but that is "*an absolutely fundamental distinction, the interrogatory mischaracterises an apparent disparity in adverse events reported to the OCEANS database as a disparity in adverse events associated with Pandemrix and Arepanrix".*

29. It appears to me that there is much force to Mr. Clarke's submissions. In my view the interrogatory which has been raised concerns not just one issue but a number of issues which are contentious. I am satisfied that the interrogatory raises a number of questions and that counsel for the fourth defendant is correct in his characterisation of those questions as being whether there was a disparity, and whether there was an analysis and whether any such disparity was evident from the Enhanced Safety Review Team Reports. It appears to the court that the interrogatory proceeds on the basis that an essential element, a disparity, is uncontroverted and incontrovertible but it is clear that this is very much a contested issue between the parties. Again, as is clear from Dr Seifert's affidavit

the validity of comparative analysis being carried out in respect of week-by-week data is also disputed.

30. That controversy exists is also evident from a consideration of a number of papers to which the court has been referred. What follows is not intended to be a full synopsis of these papers, rather to provide some flavour of the differing views taken. In his paper, Mr. Doshi observed that in documents obtained through the pretrial discovery process in what appears to be the *Bennett* proceedings, the plaintiff:-

> *"...found a string of GSK postmarketing safety reports that show a striking difference in the number and frequency of adverse events reported for three GSK pandemic vaccines approved and used across the world: Pandemrix, Arepanrix, a similar H1N1 vaccine that also contained AS03 adjuvant, and an H1N1 vaccine without adjuvant (no brand name is given).*
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> *The BMJ learnt of the reports from my colleague Tom Jefferson, a medically trained epidemiologist who was hired as an expert witness by the solicitors representing Aoife Bennett, an Irish woman who developed narcolepsy after vaccination with Pandemrix in 2009. Jefferson took on the case in 2015, and last year the lawyers received a copy of the GSK safety reports that had been emailed within the company and to at least one regulator (Ireland). Adverse event tables embedded in nine reports spanning the four months between December 2009 and March 2010 offer a glimpse into the vaccines' safety profiles.*
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> *"When I saw those tables, I just fell off the chair. A consumer can figure out what's going on here," Jefferson told me.*
>
> *… Jefferson immediately calculated the adverse event rates for each vaccine, which showed large differences between Pandemrix and Arepanrix. Any real differences between the vaccines would be especially alarming because Pandemrix and Arepanrix are, broadly speaking, the same vaccine manufactured in different facilities and used in different countries. Divergent rates of adverse events might implicate a manufacturing problem.*
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> *"The odds ratios, the point estimates, are all high. And some of them are significantly high—5.39 [95% confidence interval 3.70 to 7.85] for deaths [for Pandemrix v the other vaccines]," Jefferson said.*
>
> *"The thing that struck me was not just that the odds ratios were high, but the fact that nobody had tabulated and analysed them," he said, pointing out that the GSK reports provided numerator and denominator data sufficient to calculate the odds ratios but did not actually contain those calculations.*
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> *The BMJ conducted its own analysis of the adverse events, most of which seem to have been reported spontaneously to GSK ... For a range of concerning adverse events, reports were coming in for Pandemrix at a consistently higher rate than for*

the other two GSK pandemic vaccines–four times the rate of facial palsy, eight times the rate of serious adverse events, nine times the rate of convulsions. Overall, Pandemrix had, proportionally, five times more adverse events reported than Arepanrix and the unadjuvanted vaccine.

And the raw numbers of adverse events were not small. Although it is often said that perhaps only up to 10% of adverse events are reported to national reporting systems, by late November, GSK had received 1138 serious adverse event reports for Pandemrix—a rate of 76 per million doses administered. By mid-December, there had been 3280 serious adverse event reports (68/million doses). The last report seen by the BMJ, dated 31 March 2010, shows 5069 serious adverse events for Pandemrix (72/million doses), seven times the rate for Arepanrix and the unadjuvanted vaccine combined. The data are insufficient to draw conclusions about cause and effect, but for Gillian O'Connor, the solicitor representing Bennett, they raise serious questions about transparency. The disparity, she wrote in an affidavit filed in court, was "of such striking difference that any person contemplating taking the Pandemrix vaccine would be likely, if in receipt of this information, not to choose to have the Pandemrix vaccination."

Mr. Doshi also wrote of alarm bells that never rang and that neither GSK nor the health authorities seem to have made the information public—nor was it clear that the 'disparity' was investigated.

31. Mr. Arlett, the Head of Pharmacovigilance and Epidemiology at the EMA was one of a number of people who replied. He expressed the opinion that to conclude that one product is safer than the other based on numbers of suspected adverse reaction reports alone, without consideration of all other relevant data, including clinical trials and epidemiological studies was invalid and that any issue raised be based on valid analysis of objective evidence. He also expressed the view that Mr. Doshi's comparisons were not scientifically valid. Observations were also submitted by persons associated with the fourth defendant. These were further replied to by Mr. Doshi and others in the BMJ. Mr. Doshi wrote:-

"In my article, I calculate and compare rates of adverse events between the GSK vaccines. EMA calls this a "scientifically invalid comparison"; GSK says it is a "scientifically inappropriate methodology." I accept that these data are insufficient to draw cause and effect conclusions—and said so in my article—but I reject the suggestion that calculating rates is somehow bad science. It should be noted that the GSK internal reports themselves contain a calculation of an adverse event a reporting rate for its pandemic vaccines. I am also criticized for comparing the adverse event reporting rates of GSK's pandemic vaccines, but a 2009 news article suggests that GSK previously did just this, assuring the public of the safety of Arepanrix because the rate of an adverse event did not exceed what is typically reported for other vaccines. Furthermore, MHRA also makes comparisons between

the reporting rates of vaccines in its letter, comparing Pandemrix and Arepanrix to "other new vaccines."

32. It is clear that a dispute exists as to whether there is a disparity. The meaning of the expression 'disparity' in this context is also not agreed. I must accept that the interrogatory is predicated not only on the disputed disparity but that such disparity "*was evident*" from the Enhanced Safety Review Team Reports for the period from week 46 of 2009 to week 6 of 2010. The manner in which the interrogatory is phrased, in my view, seeks the acceptance of a conclusion, whether directly or indirectly, of a disputed premise, namely the suggested disparity. It also raises a number of issues and I am not satisfied that it has the clarity required or that it is such as to be capable of a clear answer. I am also satisfied that given the manner in which the interrogatory is phrased, that there is a possibility that the fourth defendant could be prejudiced by being fixed with a response on affidavit to a matter which is central to an issue in the proceedings. In this regard, the court must, and does, have regard to the contents of Dr Seifert's affidavit and the objections raised by him therein which have been referred to at para. 14 above.

33. It also seems to me that no injustice will be occasioned to the plaintiff by the refusal to grant leave to deliver the interrogatory. From an examination of the information, papers and evidence opened to the court on this application, including the statements of certain expert witnesses to which the court's attention has been drawn and whose statements and reports have been exchanged, in my view the issues thus raised will be, or are capable of being, addressed through oral evidence, directly or through cross-examination at the hearing of the action. I am also satisfied that, to adopt the reasoning of Laffoy J. in *Cole* that the matters raised are such as would be more fairly explored in oral evidence where nuances and inferences would be best addressed.

34. In *McGregor v. Health Service Executive* [2017] IEHC 504 Barr J. noted that certain of the interrogatories in that case effectively sought a concession by the defendant that it was negligent and they should not be allowed. While I accept that the question posed in the interrogatory in this case is not comparable, nor does it go as far as those with which Barr J. was dealing, nevertheless, it appears to me for the reasons expressed above that granting leave to deliver the interrogatory is not necessary for the fair disposal of the cause or for the saving of costs. In this regard, I harbour considerable doubt that there will be a saving of costs and I am not satisfied that such has been demonstrated. Even if a saving of costs would or might occur, to compel a reply to the question that does not have the clarity required by law, is based upon a disputed conclusion or premise, has a number of component parts and is capable of being addressed through oral evidence, would be likely to create an unfairness to the fourth defendant.

35. In accordance with O. 31, r. 2 RSC, in deciding on this application the court is obliged to take into account any offer made in response to deliver particulars, to make admissions or produce documents relating to the matter in question. Discovery which was made in the *Bennett* proceedings is by agreement treated as discovery in these proceedings. These include documents concerning safety data submitted by the fourth defendant to the

EMA, including periodic safety update reports and internal documents. Similarly, it seems to me that it is appropriate to take into consideration the affidavit sworn by Mr. Bourke, which includes considerable detail regarding the transmission of the vaccine safety data to the EMA and how the fourth defendant conducted safety analysis of both vaccines, including information on its pharmacovigilance structures. Counsel also points out that Mr. Bourke has exhibited 293 documents relevant to the interrogatories and suggests that there is no evidence that the fourth defendant is attempting to be evasive in answering the interrogatory. An interrogatory which is no longer the subject of this application queried whether the fourth defendant failed to transmit the data contained in its Enhanced Safety Review Team Reports prior to 22nd February, 2010. It was agreed that Mr. Bourke's affidavit would deal with this and exhibit supporting documentation in respect of the answer provided. That was done and no issue has been raised on this. He provided an explanation for Teams 1 and 2 and the court has been informed and notes that Dr Verstraeten, the head of Team 1 and Mr. Campens, the head of Team 2 are listed in the fourth defendant's schedule of witnesses. The correspondence, including that referred to at paras. 10 to 12 above, in my view, illustrates that a *bona fide* dispute arose between the parties on this issue and that there is nothing in the correspondence which ought to alter the court's determination.

36. In all the circumstances, I must refuse the relief claimed. In exchanges between counsel and the court the term comparison was explored as an alternative, but it seems to me that the interrogatory goes further than this. Given the nature and extent of the dispute between the parties and the court's conclusion and reasons outlined herein, I am not satisfied that this is an appropriate case in which the court might or ought to intervene to reformulate the question.