



Neutral Citation Number: [2023] EWHC 1792 (KB)

Case No: BL-2019-LIV-000003  
Claim No.: QB-2020-003824  
Claim NO.: QB-2021-002000  
Claim No: QB-2022-001081

**IN THE HIGH COURT OF JUSTICE**  
**KING'S BENCH DIVISION**

Royal Courts of Justice  
Strand, London, WC2A 2LL

Date: 14/07/2023

**Before :**

**SENIOR MASTER FONTAINE**

**And**

**MASTER SULLIVAN**

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**Between :**

**KAREN LOUISE TONGUE and 177 others**

**Applicants/  
Claimants**

**- and -**

**(1) BAYER PUBLIC LIMITED COMPANY**

**Respondents/  
Defendants**

**(2) BAYER PHARMA (AG)**

**(3) NHS INDEMNIFIED BODIES**

**(4) CARDIFF AND VALE UNIVERSITY**

**HEALTH BOARD**

**(5) SWANSEA BAY UNIVERSITY HEALTH**

**BOARD**

**(6) BETSI CADWALADR UNIVERSITY**

**HEALTH BOARD**

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**Gareth Shires (instructed by Pogust Goodhead Solicitors) for the Claimants**  
**Toby Riley-Smith KC and Anna Hughes (instructed by CMS Cameron McKenna Nabarro  
Olswang LLP) for the First and Second Defendants**  
**Neil Block KC (instructed by Capsticks LLP) for the Third Defendant**  
**Henry Bankes-Jones (instructed by NWSSP Legal and Risk Services) for the Fourth to Sixth  
Defendants**

Hearing dates: 4 May 2023

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**Approved Judgment**

This judgment was handed down remotely at 4pm on 14 July 2023 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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## **The Court :**

1. On 4<sup>th</sup> May 2023 the court heard the claimants' application for a Group Litigation Order ("GLO"). The first and second defendants ("the Bayer defendants"), by the time of the hearing, supported the application. The claimants and the Bayer defendants have agreed, subject to the Court's approval, a draft order, list of GLO issues and Schedule of Information. At the conclusion of the hearing we announced that we were persuaded that a GLO should be recommended to the President of the King's Bench Division and indicated we would provide our reasons in a written judgment. These are our reasons.
2. The claimants are represented by Pogust Goodhead Solicitors. There are four other known claimants represented by two other firms who are content for a GLO to be made and for Pogust Goodhead to be lead solicitors. There are approximately 200 claimants. They are all women who had the Essure contraceptive device fitted. Each Claimant sues one or other of the Bayer Defendants as the producer of their Essure Device.
3. The Essure Device is a medical device designed to act as a permanent form of contraception without the need for laparoscopic surgery. It was designed to be inserted into the proximal end of each fallopian tube via the vagina and cervix in the course of a procedure performed under local anaesthetic. The device consisted of an inner and outer coil and polyethylene tetrahalide (PET) fibres. These inserts elicited an inflammatory response to the presence of a foreign body in the fallopian tubes. Over a 12-week period of time, fibrous tissue grew around the implants which anchored the devices in place and blocked the fallopian tubes. This resulted in the occlusion of the fallopian tubes and permanent sterilisation. To ensure that the procedure had been successful, a confirmation test was undertaken three months after the procedure.
4. The Claimants allege that the Essure device was defective under section 3 of the Consumer Protection Act 1987 because it gave rise to an unacceptably high rate of serious complication and it had a lack of countervailing benefits. A claim is made in the alternative in negligence.
5. The claimants all allege they suffered injury as a result of being fitted with the Essure device, including one or more symptoms of pain, abnormal bleeding, device migration with associated complications including bladder, bowel and urinary problems, dyspareunia, allergic or hypersensitivity reactions and surgery to remove the device, including complications of that surgery.
6. Many of the claimants also have claims in clinical negligence against the treating doctors who fitted or removed the devices. Those claims have been stayed with the agreement of the non-Bayer Defendants.

## Legal Framework

7. A GLO is an order to provide for the case management of claims which give rise to common or related issues of fact or law (the GLO issues) (CPR 19.21)
8. CPR 19.22 provides:

*(1) The court may make a GLO where there are or are likely to be a number of claims giving rise to the GLO issues.*

*(2) A GLO must –*

- (a) contain directions about the establishment of a register (the 'group register') on which the claims managed under the GLO will be entered;*
- (b) specify the GLO issues which will identify the claims to be managed as a group under the GLO; and*
- (c) specify the court (the 'management court') which will manage the claims on the group register.*
- (d) be made in the Kings Bench Division with the consent of the President of the King's Bench Division... "*

9. PD 19B provides *inter alia*:

*2.1 Before applying for a Group Litigation Order ("GLO") the solicitor acting for the proposed applicant should consult the Law Society's Multi Party Action Information Service in order to obtain information about other cases giving rise to the proposed GLO issues.*

...

*2.3 In considering whether to apply for a GLO, the applicant should consider whether any other order would be more appropriate. In particular he should consider whether, in the circumstances of the case, it would be more appropriate for – (1) the claims to be consolidated; or (2) the rules in Section II of Part 19 (representative parties) to be used."*

...

*3.2 The following information should be included in the application notice or in written evidence filed in support of the application:*

- (e) a summary of the nature of the litigation;*
- (f) the number and nature of claims already issued;*
- (g) the number of parties likely to be involved;*
- (h) the common issues of fact or law (the 'GLO issues') that are likely to arise in the litigation; and*
- (i) whether there are any matters that distinguish smaller groups of claims within the wider group.*

10. In order to make a GLO, the court must be satisfied that (1) the claims give rise to common or related issues of fact or law; and (2) there are a sufficient number of claimants who seriously intend to proceed in their claims giving rise to those issues. If those threshold tests are met, the court has a discretion to make such an order (per Jackson LJ at paragraph 35 in *Alyson Austin and Others v Miller Argent (South Wales) Limited* [2011] EWCA Civ 928).

### Threshold issues

11. It seems to us that, as the parties both submit, the threshold tests are met. There are around 200 claimants who have all had the Essure device fitted, who have suffered one or more of what are described as common symptoms, although with a recognition there will be a variance in those symptoms for each individual, and who have either had the device removed or have been recommended to have it removed or who have been informed that the device is causing their symptoms but it cannot be removed for

medical reasons. The claims are all based on an allegation that the device was defective under the CPA.

12. Those approximately 200 claims have undergone review by the claimants' solicitors to ensure that they meet the proposed minimum requirements of the GLO. There is no minimum number of claims to be suitable for a GLO, but that number is clearly a sufficient number of claimants who seriously intend to proceed and whose claims raise common or related issues of fact or law, namely whether the Essure device was defective or provided negligently to all the claimants.
13. Although it is not required that *all* the issues in the claims are common or related, excluded from the proposed cohort are claims where it is alleged that:
  - i) the device has migrated and where the confirmation test failed or was not carried out because the claimant complained of symptoms in the three month period following implantation;
  - ii) the device perforated a claimant's tissue at the time of insertion of the device; or
  - iii) the device fragmented on removal which occurred before the three month confirmation test.

Those categories of cases raise issues that the symptoms may be more properly due to clinical negligence and will fall outside of the proposed GLO.

14. Issues of quantum of damages are likely to be individual rather than common issues, but that is not unusual in group litigation and there may be some quantum issues that would conveniently be managed collectively.

#### Discretion

15. The Court must then consider whether to exercise its discretion to order a GLO. The discretion is to be exercised in accordance with the overriding objective and in particular the Court must consider whether such an order will help to conduct the cases justly and at proportionate cost.
16. For this group of claims the following are relevant factors in our consideration:
  - i) The value of the claims is such that individually the claimants may have real difficulty in being able to fund individual actions given the costs of such actions. Funding is in place to bring and manage the claims on a group basis.
  - ii) Although the defendants are denying the claims, there is no suggestion they are so unmeritorious that they should be struck out and as the defendants point out, if they are unmeritorious, the most proportionate and cost effective way of achieving dismissal of the claims would be to manage them using a GLO.
  - iii) Collective case management of some sort is required for these claims and dealing with them separately would create a risk of inconsistent judgments.

- iv) The costs of conducting group litigation can be high, but in this group of claims, the costs of running the group register and advertising will be minimal. One firm of solicitors will be running the litigation so the costs that would be involved in larger group actions requiring a steering group do not arise. The information required to populate the group register is easily accessible and the register can be maintained with limited input as there are unlikely to be significantly greater numbers of claimants to be added, certainly not in the thousands. Compared to running individual cases or other forms of case management, the costs of evidence will not be higher as a result of the group litigation order.
- v) The cost of expert evidence for individual claims rather than on a collective basis is likely to be higher and not cost effective.
- vi) Alternative forms of collective case management such as test cases or “GLO Lite” management would not manage the cases more efficiently. It is likely that under a GLO the cases will proceed with test or lead cases, but it is likely that a significant number of test cases, perhaps 6 or more, would be required and those are best managed through a GLO structure. The GLO structure would facilitate the efficient selection of appropriate lead cases and provide reserves should any of the lead cases be discontinued.
- vii) A GLO Lite would manage the cases in a similar way to a formal GLO but without making the order. It is unlikely that would provide any significant savings in costs for this group of claims and would be without the advantages that would be brought by a group register and cut off date for claimants to join. Equally the findings on the generic issues are not binding in a GLO lite.
- viii) The parties have agreed that if a GLO is ordered, they will file and exchange documents prior to the first CMC setting out incurred and estimated costs and would be willing to consider costs budgeting in order that the costs can be managed.

### Conclusion

- 17. The claims meet the threshold tests and, in our discretion, a GLO is the most effective route to manage them justly and at proportionate cost in accordance with the overriding objective.
- 18. The parties have agreed the terms of the GLO with some slight amendments following discussion in the hearing. We will recommend that the President of the Kings Bench Division makes a GLO in the terms agreed between the parties.