

COPY

JUDGMENT

AMSTERDAM COURT

Civil law

Case number: C/13/726782 / HA ZA 23-2

Judgment dated **May 1, 2024**

in the matter of

CLARA WICHMANN FOUNDATION,
based in Amsterdam.
plaintiff,
hereinafter referred to as: BCW,
lawyer: mr. E.J. Zippro in Amsterdam,

at

the private limited liability companies

1. ABBVIE B.V.,

based in Amstelveen,

hereinafter referred to as: AbbVie NL, and

2. ABBVIE NETHERLANDS HOLDINGS B.V.,

based in Zwolle,

hereinafter referred to as: AbbVie NL

Holdings, and the legal entities under

foreign law

3. ALLERGAN LTD,

based at Barlow (United Kingdom),

hereinafter referred to as: **Allergan UK**,

4. ALLERGAN UNLIM-ITED COMPANY,

based in Dublin, Ireland,

hereinafter referred to as: **Allergan Ireland ULC**,

5. ALLERGAN COSTA RICA S.R.L.,

based in Heredia, Costa Rica,

hereinafter referred to as: **Allergan Costa Rica**,

6. ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED,

based in Dublin, Ireland,

hereinafter referred to as: **Allergan Ireland Limited**,

7. ALLERGAN, INC,

based in Irvine, United States of America,

hereinafter referred to as: **Allergan I/SA**, and

8. ABBVIE INC,

based in North Chicago (United States of America). hereinafter

referred to as: AbbVie USA,

lawyer: mr. P.L. Reeskamp in Amsterdam,

Defendants, hereinafter collectively referred to as: Allergan et al.

1. What is this case about?

1.1. This is the continuation in the mass tort case against U.S. pharmaceutical company Allergan, now AbbVie, as the manufacturer of certain textured breast implants that have been discontinued in 2019. According to the plaintiff (BCW), these implants can lead to serious illness or health conditions, namely BIA-ALCL, a rare form of lymphoma, and ASIA, an autoimmune syndrome. BCW is therefore seeking damages through what is known as a class action as an advocate for the group of individuals who have or have had the implants. That group, according to BCW, consists of approximately 60,000 individuals (referred to by the parties as: the Women).

1.2. In this case, the court issued an interlocutory judgment on February 14, 2024. In that judgment, the court ruled, among other things, that BCW can and may bring the collective action on behalf of the group of Women who underwent treatment for implantation of the implants in the Netherlands.

1.3. The court also held in the interlocutory judgment that the WCAM (the old class action law) applies to claims involving Implants imported into the European Economic Area (EEA) before November 15, 2016 and that the WAMCA (the new mass tort law) applies only to claims by Women from the following narrowly defined group:

All Women who have had treatment in the Netherlands for placement (implantation) of Implants put into circulation after November 15, 2016.

1.4. The court appointed BCW as the exclusive advocate for the Women from the narrowly defined group.

1.5. Because the outcome of the WAMCA proceedings binds the persons in the narrowly defined group, in principle, the persons in this group must be given the opportunity to declare that they do not want to participate in the proceedings (opt-out) or rather, if they live abroad, that they do want to participate in the proceedings (opt-in). About this opt-out/opt-in phase, the court makes some decisions in this judgment.

2. The proceedings

2.1. The course of the proceedings is evidenced by:

- the interlocutory judgment dated February 14, 2024, and the documents cited therein,
- BCW's deed with regard to the opt-out phase,
- the response deed with regard to the opt-in/opt-out phase and statement of application pursuant to Article 1018f (5) of the Code of Civil Procedure (Rv) by Allergan et al,
- each party's letters dated March 13, 2024, containing BCW's conditional deed request and Allergan et al.'s response thereto,
- the March 19, 2024 email from the clerk of the court to the parties that there is no room for further deed exchange at this time and that the case is referred to the docket for judgment.

3. The further review

3.1. In the interlocutory judgment of February 14, 2024 (hereinafter also referred to as the interlocutory judgment), the court gave BCW in the WAMCA proceedings the opportunity to submit a text proposal for the announcement of the opt-in/opt-out phase and its practical implementation. Allergan et al. were allowed to respond to this, and, in addition, to comment on BCW's request for an opt-out system to apply to those in the narrowly defined group living abroad.

Request to explain or at least redefine narrowly defined group

3.2. BCW requests in the first place that the court explains the narrowly defined group as such that a distinction is between the old and new Article 3:305a regimes, which should be connected to the moment of implantation of the Implants in the Women, and otherwise, to reverse the decision on the narrowly defined group and redefine the narrowly defined group as follows:

All Women who have had treatment for placement (implantation) of Implants in the Netherlands after November 15, 2016.

3.3. To this end, BCW argues that the distinction of when the Implants were put into circulation means that for the Women it is impossible, or only after immense effort on the part of the Women, BCW and Allergan, to determine whether they belong to the narrowly defined group (from the WAMCA proceedings). According to BCW, the court may ground the review on changed understanding after being made aware of the practical implications of the decision and the impossibility of entering the opt-out phase on this basis.

3.4. Allergan et al. oppose granting these requests. Among other things, they argued that the doctrine of "reversal of final binding decisions" does not apply here and that, apart from that, it is relatively simple to determine when an implant was first put into circulation.

3.5. The court rejects BCW's request. The decision on the narrowly defined group is an interlocutory decision in the form of a binding final decision. According to established case law, the court may reverse such a decision if the requirements of due process necessitate it, for example because the interim decision is based on an incorrect legal or factual basis. That situation does not arise here. The issues pointed out by BCW were already part of the parties' debate and the court has already ruled on them. BCW has not pointed to any new facts or circumstances in the matter, nor have they otherwise appeared.

Nor does a weighing of all the interests and circumstances involved lead to the conclusion that it is unacceptable to stand by the decision given. Accordingly, the court does not reverse this decision.

Possibility of opt-out and opt-in

3.6. The parties agree that for the Women from the narrowly defined group residing in the Netherlands, the opt-out possibility of Section 1018f(1) Rv should be opened.

3.7. For Women from the narrowly defined group who live abroad, the outcome of these proceedings does not apply unless they use the opt-in option of article 1018f paragraph 5 Rv. BCW has requested that this be deviated from and that an opt-out system also apply to Women from the narrowly defined group living abroad. The aforementioned article 1018 paragraph 5 Rv offers an exception possibility for this purpose. In this regard, BCW explained that it is sufficiently clear which group of foreign aggrieved persons is involved. Since all these persons have suffered damages in the Netherlands, it is also not illogical or unforeseeable for these persons to participate in Dutch proceedings. It is obvious that Women who have obtained Implants from a Dutch clinic with an insert mentioning a Dutch entity of the Allergan group will check whether their interests can be represented in the Netherlands after becoming aware of the possible defectiveness of these Implants. As early as July 2021, they came across BCW's initiative via a Google search and were able to register with BCW to be kept informed.

3.8. Allergan et al. oppose granting this request.

3.9. The court denied BCW's request for the following reasons. The basic principle of the law is that an opt-in regime applies to persons from the narrowly defined group living abroad. The legislator wanted to make one exception to this, namely in the case where it is sufficiently clear which approximate group of foreign victims is involved. The court assumes that while Allergan et al. have insight into the amount of implants they put into circulation in the EEA after November 2016 that were distributed to the Netherlands, they do not have insight into the size of the group of non-Dutch interested parties. BCW informed that of the over 6,000 participating women there are 60 women living abroad. That is not enough to apply the exception. If the court were to so decide, the opt-out would apply not only to the Women Abroad already known to BCW, but to all Women Abroad who fall within the narrowly defined group. It does not appear that all Women in the group living abroad could be aware of the present proceedings and an impending opt-out phase. A sufficient safeguard on this point is lacking. However, this is required in order for an opt-out system to apply, because under such a system it is assumed that the persons from the group at issue *can be* aware of the proceedings. This means that, in accordance with the main rule, the court will allow an opt-in system to apply to the Women in the group living abroad. In doing so, the Court determines that the question of whether a person is domiciled or (long-term) resident in the Netherlands must be answered according to the situation as it applies as of the date of this interlocutory judgment, May 1, 2024.

Mode of publication

3.10. It is then necessary to determine the manner in which publication should take place, and the wording thereof. The parties were also allowed to comment on these follow-up questions.

3.11. The parties agree that to inform the Women from the narrowly defined group that:

- a) the interlocutory judgment will be made available for inspection at the Registry;
- b) the interlocutory judgment will be published in the Central Register of Collective Claims;
- c) the interim judgment will be published in PDF on BCW's website and in Dutch and English on BCW's collective action website against Allergan;
- d) BCW will send a letter by regular mail and e-mail to all Women registered with it informing them of BCW's designation as exclusive advocate, the class action and the narrowly defined group;
- e) BCW will make the announcement to be discussed below in NRC or the Volkskrant within two weeks of the interlocutory ruling.

3.12. The court will rule accordingly. BCW additionally suggested that the Women may send any opt-out statement to the court by regular mail. The court stipulates that the Women may also send the statement to the court by e-mail. That option is also preferred because of administrative convenience.

Deadline for opt-out and opt-in

3.13. BCW proposed that the deadline for Women to use the opt-out and opt-in option be set at one and two months, respectively. Allergan c.s. suggests a period of four months in each case, to give the Women the opportunity to be advised and make an informed and considered decision. The court will set the deadline for both options at two months. The court considers this period sufficient on the one hand for the Women to be able to make a careful consideration, and on the other hand not so long as to lead to unnecessary and unreasonable delay of the proceedings. The deadline will run two weeks after this interlocutory judgment, that is, on May 15, 2024, so that BCW first has the opportunity to inform the Women of the opt-out and opt-in possibility.

Authorization or representation when opting out; exclusive authority to communicate

3.14. BCW asks the court not to allow anyone other than the Women themselves to issue opt-out statements, for example through authorization or representation. BCW explains that this request serves to prevent a third party from approaching the Women for the purpose of issuing a collective opt-out statement on behalf of a group of Women. BCW's designation as exclusive advocate and the interests of aggrieved persons in the present case preclude anyone other than BCW from approaching the Women during the opt-out/opt-in phase regarding the collective action at issue.

Allergan et al. opposed this request.

3.15. BCW additionally requests that BCW be granted exclusive authority to communicate with the Women about the opt-out and opt-in phases, and more specifically to prohibit Allergan et al. from contacting Women belonging to the narrowly defined group during this phase on the subject matter of these proceedings themselves or through an intermediary or other third party. Allergan et al. also opposed this request by BCW.

3.16. The court rejected these requests by BCW, in both cases because there is no legal basis for granting them. With regard to the first request, it is furthermore important to note that the issuance of an opt-out statement is a legal act and that the law provides that persons may, in principle, be represented when performing such acts, whether by proxy or otherwise. The legislature has made no exception to this principle for the issuance of an opt-out statement.

Communication and text for the announcement

3.17. BCW proposed a text for the letter to the Women from the narrowly defined group known to it and for the announcement of the opt-out/opt-in phase.

3.18. It follows from Section 1018f(3) Rv that the letter must give notice of: the designation of the exclusive representative, the collective claim, the narrowly defined group, the opt-out and opt-in possibility, and the court's ruling, or at least the manner in which a copy can be obtained.

3.19. The announcement contains the same information as the letter. In its proposed text for the letter and notice, BCW included a passage to the effect that BCW will withhold from any right to compensation established in the proceedings, up to 15% because of the funding it has raised for this class action, except where the Women are entitled to reimbursement of this amount by their legal expenses insurance for this class action. The court omits this passage. The notice is not intended, and therefore not the place, to (potentially) bind members of the narrowly defined group to withhold up to 15% of the compensation.

3.20. In its proposed text, BCW additionally asks the Women to send along with their opt-out statement a piece of evidence that they belong to the narrowly defined group. The law also provides no basis for such a requirement or condition, so the court will also omit this passage.

3.2. Furthermore, the court added missing elements and omitted other insufficiently neutral information. There are no working hyperlinks in this judgment, but BCW may include them in its notice and letter(sent by e-mail). In this way, the court arrives at the following text for the announcement:

Collective action against Allergan over textured breast implants

Stichting Bureau Clara Wichmann (BCW) is bringing a civil suit before the Amsterdam District Court against breast implant manufacturer Allergan and a number of other Allergan entities. Allergan currently trades under the name AbbVie and previously (before 2006) also under the names McGhan and Inamed.

BCW's action against Allergan is called a "collective action." BCW is bringing this collective action on behalf of persons (referred to by the parties as: the Women) who have had treatment in the Netherlands to place (implant) textured implants or tissue expanders made by Allergan. These breast implants include the names Biocell or Natrelle. A list of the implants covered by this collective action can be found at: www.siliconenzaak.nl/informatie-over-allergan-borstimplantaten/. The court issued an interlocutory judgment. The judgment can be found at <https://uitspraken.rechtspraak.nl>, under number ECLI:NL:RBAMS:2024:745 and www.clara-wichmann.nl (in Dutch) and at www.siliconenzaak.nl (in Dutch and English). In this ruling, the court designated BCW as the exclusive advocate for the interests of the following group:

All Women who have had treatment in the Netherlands for the placement (implantation) of textured implants of Allergan placed in circulation after November 15, 2016.

The class action for this group falls under the new class action law. BCW is seeking damages from Allergan because, according to BCW, the implants can cause a particular form of lymphoma (BIA-ALCL) and systemic symptoms (known as ASIA or Breast Implant Illness).

The following is important for Women who have had treatment in the Netherlands for placement (implantation) of textured Allergan implants that were put into circulation after Nov. 15, 2016.

Different rules apply to Women who were or were not living or residing in the Netherlands on May 1, 2024. If you lived in the Netherlands, but were abroad on vacation only on May 1, 2024, the same rules apply as to those who lived in the Netherlands at that time.

If you were a resident or long-term resident on May 1, 2024, and

- if you want BCW to represent your interests in these proceedings as well, you do not have to do anything;

- If you *do not want* your interests in these proceedings to be represented by BCW, you can let the Court of Amsterdam know. You will then not be bound by the ruling in these proceedings and the ruling will not apply to you.

If on 1 May 2024 you were not living or a long-term resident in the Netherlands and

- if you *do* want BCW to represent your interests in these proceedings, you can let the District Court of Amsterdam know. You will then be bound by the judgment in these proceedings and Allergan et al. will be bound to you by the judgment in these proceedings;

- if you *do not* want your interests in these proceedings to be represented by BCW, you do not have to do anything.

How can you let the Amsterdam court know what you want?

You can submit your choice through the following website:

<https://www.rechtspraak.nl/Registers/centraal-register-voor-collectieve-vorderingen>

On this web page, in the folder Stichting Bureau Clara Wichmann tegen Allergan c.s. is an "opt-out" button and an "opt-in" button. If you click on the relevant button, an e-mail message will be generated. In it, you fill in the requested information and then click send.

You may also opt-out or opt-in by mail. Please send a letter to the District Court of Amsterdam, attn. team handel (Postbus 84500, 1080 BN Amsterdam).

If you live in the Netherlands and do not want BCW to represent your interests, you can use the following text for the opt-out statement:

"My name is [...] and I live at the address [...]. I have had treatment in the Netherlands for placement (implantation) of textured implants of Allergan that were put into circulation after November 15, 2016.
I don't want the Clara Wichmann Foundation to represent my interests."

If you live abroad and you do want BCW to represent your interests, you can use the following text for the opt-in statement

"My name is [...] and I live at the address [...]. I have had treatment in the Netherlands for placement (implantation) of textured implants of Allergan that were put into circulation after November 15, 2016. I was not living or residing in the Netherlands on May 1, 2024, but would like Stichting Bureau Clara Wichmann to represent my interests."

The following applies to Women who have had treatment in the Netherlands for placement (implantation) of Allergan textured implants that were put into circulation before November 15, 2016.

If you have had treatment in the Netherlands for placement (implantation) of textured implants of Allergan that were put into circulation before November 15, 2016, Stichting Bureau Clara Wichmann will also conduct proceedings for you regarding Allergan's liability. You do not have to do anything in this case. You can find more information about this at www.siliconenzaak.nl.

For more information in English on the collective action of Stichting Bureau Clara Wichmann against Allergan regarding their textured breast implants, see: www.siliconenzaak.nl

Time limit for trial of a settlement (Section 1018g Rv)

3.22. The parties argue about the appropriateness of setting a deadline for trying a settlement. BCW does not need such a deadline, Allergan et al. do.

3.23. The court considers that BCW was known to be the sole acting advocate from the beginning of the proceedings. Moreover, the case will be halted for two months because of the opt-out/opt-in phase to be inserted. Allergan et al. may use this period to approach BCW for settlement negotiations. For the purpose of trying a settlement, the court considers an additional one-month period sufficient. That period also allows the parties to include the outcome of the opt-out/opt-in phase in any settlement. Accordingly, the court will determine that the period for the trial of a settlement will extend one month beyond the opt-out/opt-in phase and thus end on August 14, 2024. If desired, the parties can always jointly request an extension of time in due course.

3.24. BCW has indicated that, in the event no settlement is reached, it needs to supplement the grounds of the claim under Section 1018g Rv.

Preliminary deadline for statement of defense Allergan et al.

3.25. After expiration of the time limit for trying a settlement, BCW will first be able to submit its additional grounds, after which the case will be referred to the docket for submission of a statement of defense on the side of Allergan et al. **The court is tentatively reserving the week of December 9, 2024, for an oral hearing and requests that the parties keep this week free for the time being.**

3.26. As a result, the schedule for further proceedings will be as follows (subject to change):

- May 15, 2024: start opt-out/opt-in phase
- July 15, 2024: end opt-out/opt-in phase
- August 14, 2024: end of deadline for trial of settlement
- August 21, 2024: docket date for any additional grounds BCW

In conclusion

3.27. The court will instruct the clerk to make a note of this judgment in the Central Register of Collective Claims.

3.28. Any further decision is stayed.

4. The decision

The court

- 4.1. instructs BCW to publish the announcement (see under 3.21) on its websites and to publish it in NRC or the Volkskrant within two weeks;
- 4.2. instructs BCW to promptly send the letter mentioned under 3.18 by mail and/or e-mail to all the Women known to it from the narrowly defined group, insofar as it has their (current) (e-mail) addresses,
- 4.3. instructs the clerk to:
 - a. arrange for the entry of this judgment in the Central Register of Collective Claims,
 - b. take care to record the notice (see subsection 3.21) in that register,
- 4.4. determines that the case will return to the **August 21, 2024**, roll for supplemental grounds by BCW, after which a deadline for reply will be set,
- 4.5. reserves any further decision.

This judgment has been rendered by Mr. J.W. Bockwinkel, chairman, and H.J. Schaberg and T.T. Hylkema, Judges, and pronounced in public on May 1, 2024.



VOOR AFSCHRIFT CONFORM
De griffier van de
Rechtbank Amsterdam

