SUPERIOR COURT

CANADA
PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

No.: 500-06-000788-162

DATE: February 7, 2023

BY THE HONOURABLE MARTIN F. SHEEHAN, J.S.C.

JOAN LETARTE
Plaintiff
v.
BAYER INC.
and
BAYER HEALTHCARE LLC
Defendants

JUDGMENT ON OBJECTIONS

OVERVIEW

[1] Plaintiff has filed an Application for directions asking that the Court rule on objections to certain questions[1] and undertakings[2] raised during the written examination of the Defendants, dated May 6, 2022.

CONTEXT

[2] On April 15, 2016, Plaintiff, Ms. Joan Letarte, filed an Application for leave to commence a class action against defendants Bayer Inc., Bayer Healthcare LLC and Bayer Corporation. She alleged that women implanted with the permanent contraceptive Essure® manufactured or distributed by the Defendants had experienced health problems.

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1 Exhibit 1 to the Application for directions.
2 Exhibit 2 to the Application for directions.

[3] On March 20, 2019,[3] Justice Chantal Lamarche authorized the filing of a class action (the "**Authorization Judgment**") on behalf of the following group (the "**Class**"):

> All women residing in Quebec, including their successors, assigns, family members, and dependants, who were implanted with Essure and who were diagnosed with urinary tract infections, perforated organs, implant migration, pelvic pain, menorrhagia or autoimmune symptoms between July 1, 2011, and the date of the Judgment authorizing the class action.

[4] The Authorization Judgment identified the questions of fact and law to be treated collectively as follows:

> 4.1. Does Essure cause, exacerbate or contribute to a risk of having urinary tract infections, perforated organs, implant migration, pelvic pain, menorrhagia and autoimmune symptoms?
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> If the answer to question 1 is yes:
>
> 4.2. Did the Defendants commit a fault in failing to adequately warn the class members and/or their physicians about a risk associated with the use of Essure?
>
> 4.3. Did the Defendants commit a civil fault by marketing, packaging, promoting, advertising, distributing, labelling and selling Essure the way they did?
>
> 4.4. Are members of the class entitled to damages?
>
> 4.5. Are members of the class entitled to punitive damages?

[5] After an unsuccessful motion for leave to appeal by the Defendants,[4] Plaintiff filed her action on August 8, 2019 (the "**Originating Application**").[5]

[6] Since then, the case has proceeded slowly.

[7] A first case protocol was approved on August 26, 2020, but the early deadlines for filing of expert reports were not respected.

[8] A second case protocol was signed on December 15, 2020, which provided that the case should be ready by December 2022.

[9] On November 30, 2021, this court dismissed the proceedings against Bayer Corporation, for failure to notify this defendant within the prescribed delay.[6]

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3 *Letarte* c. *Bayer inc.*, 2019 QCCS 934 (Motion for permission to appeal dismissed, 2019 QCCA 1108).
4 *Bayer inc.* c. *Letarte*, 2019 QCCA 1108.
5 Originating Application dated August 8, 2019, Exhibit 3 to the Application for Directions.
6 *Letarte* c. *Bayer inc.*, 2021 QCCS 4947.

[10] On January 31, 2022, the remaining Defendants, Bayer Inc. and Bayer Healthcare LLC (together "**Bayer**") filed their plea.[7]

[11] Pre-trial examinations by both parties were scheduled to be completed by April 29, 2022.

[12] In April 2022, the parties agreed that Bayer's examination would proceed in writing. Bayer decided that it would not examine Ms. Letarte again and would rely on the examination it had conducted prior to authorization.

[13] The written examination was sent to Bayer on May 6, 2022. Bayer responded to most questions on July 7, 2022 and had provided most of the undertakings by September 2022.[8] Objections were raised with regard to the rest. Discussions ensued. Some questions were reformulated or withdrawn but many objections remain.

[14] A hearing to rule on these objections was scheduled for January 24, 2023. The Court extended the delay for trial readiness to that day and asked the parties to agree on a new protocol for the remaining pre-trial matters.

[15] At the end of the hearing, the Court extended the delay for inscription to July 28, 2023.

ANALYSIS

1. Applicable Law

1.1 General Principles

[16] The principles which should guide the court when it is called upon to adjudicate on objections or document requests made during the pre-trial phase can be summarized as follows:

> 16.1. Examinations for discovery and document requests are essential elements of the exploratory phase in civil matters. Their goal is to facilitate the search for truth which remains the "ultimate aim" of any civil or criminal trial. Early disclosure of evidence also ensures that trials are conducted fairly and efficiently. Finally, it allows the parties to evaluate the strength of their respective cases and encourages out of court settlements.[9]

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7 Defense of Bayer Inc. and Bayer Healthcare LLC dated January 31, 2022 (the "**Plea**"), Exhibit 4 to the Application for directions.

8 Exhibits 5 and 6 to the Application or directions.

9 *Imperial Oil* v. *Jacques*, 2014 SCC 66, paras. 24 to 26; *Glegg* v. *Smith & Nephew Inc.*, 2005 SCC 31, para. 22.

16.2. The court should encourage the fullest and earliest possible disclosure of evidence. Such disclosure is in line with the duty of transparency and cooperation required for the sound management of proceedings and a fair judicial debate, as opposed to a trial by ambush (articles 19 and 20 C.C.P.).[10]

16.3. Document requests are no longer restricted to documents that the other party intends to file during the hearing. They may bear on all the facts related to the dispute or the evidence which supports them. Furthermore, a party may present a document request before or even in the absence of a pre-trial deposition of the opposing party.[11]

16.4. A witness may refrain from answering when an objection is made on the grounds of privilege or because a "substantial and legitimate interest" would be compromised by answering.[12] This later notion must be interpreted restrictively. If the court finds that a "substantial and legitimate" interest exists, but that the implied undertaking of confidentiality or some other means of protection or control may resolve the disclosure issue, it must dismiss the objection.[13]

16.5. Generally, when an objection does not invoke a fundamental right or a substantial and legitimate interest, the witness is required to answer. This is so for example when the objection is based on lack of relevance.[14]

16.6. Nonetheless, while the right to pre-trial disclosure must be interpreted broadly, it is not unlimited. The court may put an end to an examination when it considers it "excessive or unnecessary".[15] Parties must respect the principle of proportionality and their conduct must facilitate the progress of the proceedings rather than having them delayed, complicated, or even jeopardized by the introduction of evidence that does not assist in establishing the rights being advanced (articles 18 and 19 C.C.P.). Fishing

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10 *Imperial Oil* v. *Jacques*, *supra*, note 9, para. 28; *Grid Solutions Canada* c. *Murphy*, 2019 QCCA 1141, para. 6; *Société financière Manuvie* c. *D'Alessandro*, 2014 QCCA 2332, para. 22 (Discontinuance of the motion for leave to appeal to the Supreme Court (S.C. Can., 2015-06-26) 36309); *Sotramont Gatineau Inc.* c. *Original Baked Quality Pita Dips Inc.*, 2020 QCCS 143; *Envac Systèmes Canada inc* c. *Montréal (Ville de)*, 2016 QCCS 1931, para. 27. Denis FERLAND and Benoît EMERY, *Précis de procédure civile du Québec*, 6th ed., Montréal, Éditions Yvon Blais, 2020, volume 1, para. 1-1336.

11 Article 221 C.C.P.; *CMC Électronique inc.* c. *Procureure générale du Québec*, 2020 QCCS 124, para. 31; *Construction Canmec Euler inc.* c. *Groupe TNT inc.*, 2018 QCCS 637, para. 33; *Moreno* c. *Lalanne Zéphyr*, 2017 QCCS 4149, paras 18 to 22.

12 Arts. 12 and 228 C.C.P.

13 *Sierra Club du Canada* c. *Canada (Minister of Finances)*, 2002 CSC 41, paras. 49, 50, 51 and 55; *Ministère des Travaux publics et Services gouvernementaux Canada* c. *David S. Laflamme Construction inc.*, 2017 QCCA 96, para. 6; *CMC Électronique inc.* c. *Procureure générale du Québec*, *supra*, note 11, para. 27; *Nolicam Location de camions inc.* c. *Budget Rent A Car Licensor*, 2019 QCCS 747, para. 6; *Siciliano* c. *Éditions La Presse ltée*, 2016 QCCS 3702, paras. 24 and 29 (Out of court settlement (C.A., 2016-06-23) 500-09-026076-166); *Luxme International Ltd.* c. *Lasnier*, 2016 QCCS 6389, paras.10 and 11.

14 Art. 228 C.C.P.

15 Art. 230 C.C.P.

expeditions, repeated demands and indiscriminate searches are not allowed. The court has discretion to refuse disclosure of information when complying with the request would require the analysis of a disproportionate number of documents, an excessive number of hours or impose disproportionate costs. The court may also reduce the financial and administrative burden on the party from whom documents are requested by imposing reasonable constraints.[16]

16.7. It is generally accepted that courts should not order witnesses to perform analytical work or force them to prepare a document that does not exist as is, especially when the analysis or preparation would require significant effort and the information requested is not available in the desired format.[17] However, disclosure can be ordered when the information can be prepared with relative ease and by following simple procedures.[18]

16.8. A party who wishes to obtain communication of documents has the burden of showing that they are relevant and that the request respects the principle of proportionality.[19] However, since the judge who assesses relevance at a preliminary stage does not have the benefit of having heard all the evidence, the notion of relevance must be interpreted broadly and any doubt as to the relevance of a response must favour disclosure. At the pre-trial stage, a party must only demonstrate that disclosure of the information is useful, appropriate and likely to advance the debate based on an acceptable objective that it seeks to achieve.[20]

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16 *Imperial Oil* v. *Jacques*, *supra*, note 9, paras. 31 and 85; *Grid Solutions Canada* c. *Murphy*, *supra*, note 10, paras. 6 and 7; *Duguay* c. *Compagnie General Motors du Canada*, 2019 QCCA 1058, para. 8; *Digital Shape Technologies inc.* c. *Comte*, 2018 QCCA 955, para. 7; *Lanteigne* c. *Société des Casinos du Québec*, 2022 QCCS 4752, paras. 40 and 49; *Gestion Guy St-Louis inc.* c. *Caisse Desjardins de Brome-Missisquoi*, 2022 QCCS 1273, paras. 1, 2 and 33 to 39; *Option Consommateurs* c. *Société des loteries du Québec (Loto-Québec)*, 2021 QCCS 244, paras. 22 and 23; *Union des consommateurs* c. *Bell Canada*, 2019 QCCS 3756, paras. 23 to 25; *Kloda* c. *CIBC World Markets Inc. (CIBC Wood Gundy)*, 2019 QCCS 761, paras 16 to 19; *Nolicam Location de camions inc.* c. *Budget Rent A Car Licensor*, *supra*, note 13, paras. 6 and 16; *A.* c. *Frères du Sacré-Coeur*, 2019 QCCS 258, para. 28; *Axxess International courtiers en douanes inc.* c. *Boulay,* 2018 QCCS 5363, para. 50; *Sintra inc. (région Estrie)* c. *Ville de Lac-Mégantic*, 2017 QCCS 4477, para. 30; *Charland* c. *Hydro-Québec*, 2017 QCCS 2623, paras. 13, 39 and 46 (Permission to appeal denied, 2017 QCCA 1707); *Association professionnelle des audioprothésistes du Québec* c. *Procureure générale du Québec*, 2017 QCCS 1960, para. 10 (Requête pour permission d'appeler rejetée, 2017 QCCA 1112); *Distributions d'acier de Montréal* c. *Tubes Olympia ltée*, 2016 QCCS 1635, para. 4.

17 Jean-Claude ROYER and Catherine PICHÉ, *La preuve civile*, 6th ed., Montréal, Éditions Yvon Blais, 2020, para. 653; *Commission scolaire des Affluents* c. *Commission des droits de la personne et des droits de la jeunesse*, 2006 QCCA 81, para. 36; *Mutuelle du Canada (La), Cie d'assurance sur la vie* c. *Cie d'assurance-vie, Manufacturers*, [1987] R.D.J. 192 (C.A.), para 5; *Entrepreneurs de construction Concordia inc.* c. *Régie des installations olympiques*, 2021 QCCS 3236, para. 34.

18 *Charkaoui* c. *Canada (Procureur général)*, 2013 QCCS 7132, para. 39.

19 *Lanteigne* c. *Société des Casinos du Québec*, *supra*, note 16, paras. 59 and 60; *Kloda* c. *CIBC World Markets Inc. (CIBC Wood Gundy)*, *supra*, note 16, para. 16; *Lambert (Gestion Peggy)* c. *Écolait ltée*, 2017 QCCS 5429, paras 28 to 31.

20 *Société financière Manuvie* c. *D'Alessandro*, *supra*, note 10, para. 22; *Siciliano* c. *Éditions La Presse ltée*, *supra*, note 13, para. 48.

16.9. A party who wishes to oppose disclosure on the basis of privilege or a substantial interest has the burden of proving same.

[17] In summary, the court's role is to find the delicate balance between two equally important objectives.

17.1. On the one hand, we must facilitate the timely disclosure of evidence to facilitate the search for truth, ensure that trials are conducted fairly and efficiently and allow parties to rapidly evaluate the strength of their respective cases so that settlements are encouraged.

17.2. On the other hand, we must apply the principle of proportionality to protect access to justice, promote a fair and economical application of procedural rules and ensure that cases proceed smoothly rather than being delayed or complicated by the introduction of evidence that does not contribute to the resolution of the dispute.

1.2 Applying these General Principles in the Class Action Context

[18] Weighing these objectives in the context of class action proceedings requires that the Court consider the particular features of this procedure.

[19] Relevance is not appraised differently in class action proceedings. Nonetheless, as part of the authorization process, the class has been defined, the common questions and the conclusions have been identified. This preliminary judicial filter undoubtedly assists the Court in framing the dispute and making sure that the request falls within this frame.[21] Then again, relevance must be assessed with regard to the allegations of the proceeding, the common questions and conclusions not only as they apply to the class representative but as to the class as a whole. Given the special relationship between class counsel, the class representative and the class members, the court must be mindful that much of the relevant evidence may not be in possession of the class representative. For example, information regarding claims of other class members often lies only in the hands of the defendant.[22]

[20] Assessing proportionality in the class action context also demands added scrutiny. Class actions can result in large-scale litigation whether one considers the scope of issues raised, the number of potential class members or even multiple defendants. If pre-trial disclosure in class actions was simply equivalent to what would be disclosed in an individual claim multiplied by the number of class members, the result would risk unnecessarily clogging up the courts with excessive documents.[23] For example, in a consumer law claim, the full content of a customer's file may be relevant regardless of whether the claim is an individual one or part of a class action. However, the proportionality of the request could be evaluated differently if the disclosure relates to one

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21 *Lanteigne* c. *Société des Casinos du Québec*, *supra*, note 16, paras. 78 to 81.

22 *Benamor* c. *Air Canada*, 2020 QCCA 1597, para. 42; *Sibiga* c. *Fido Solutions inc.*, 2016 QCCA 1299, paras. 62 and 76.

23 *Lanteigne* c. *Société des Casinos du Québec*, *supra*, note 16, paras. 79, 98 and 99.

client file or several hundred thousand or millions of files. In some cases, it may be more appropriate to proceed with a sample disclosure at the common question stage and postpone full disclosure to the evaluation of the individual claims stage, if need be.

2. Discussion

[21] Plaintiff alleges that most of Defendants objections are based on lack of relevance and therefore should be dismissed at this stage.

[22] Bayer pleads that it has already provided extensive answers and over 10,000 pages of documents. It considers that the remaining requests are overly broad, constitute a fishing expedition and an attempt to conduct an indiscriminate search in their files.

[23] There is merit in both submissions.

[24] The parties were not able to agree on the various subject matter categories of the objections to be decided.[24] Thus, the Court has proceeded to regroup the objections into the following categories:

2.1 Information and documents related to the acquisition of Conceptus (Questions 6 and 7 / Undertakings 4, 5 and 6)

[25] Questions 6 and 7 of the Written Examination read as follows:

> Question 6: What were the reasons and the strategic decisions behind the acquisition of Conceptus?
>
> Question 7: In 2013, list the relevant documents/data/regulations and literature on Essure that Bayer Healthcare LLC reviewed prior to the acquisition of Conceptus and supported this decision?

[26] By way of Undertakings 4, 5 and 6, the Plaintiff seeks communication of:

> Undertaking 4: A copy of the Agreement and Plan of Merger between the Defendants and Conceptus.
>
> Undertaking 5: All data received from Conceptus in regard to Essure (including clinical investigation records) prior to the acquisition as well as copies of any audits/inspections performed by the Defendants or their agents to ensure compliance with CGMP Regulations (FDA) or GMP Regulations (Health Canada)
>
> Undertaking 6: A copy of all the adverse reactions reported to Conceptus around July 2013. Any and all research/studies done by Bayer before buying Conceptus.

[27] Defendants object to all requests on the basis of lack of relevance. They also object to Question 7 and Undertakings 5 and 6 on the basis of solicitor-client privilege.

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[24] *Directives de la Cour supérieure pour la division de Montréal*, article 48.

[28] With regard to relevance, Bayer states in its plea that Conceptus, Inc. ("**Conceptus**") was responsible for the marketing, distribution, and sale of Essure in Canada from November 2001 until approximately July 2013 (the "**Conceptus Era**"). From July 2013 to August 2017, the product was distributed by Bayer.[25]

[29] This being said, even considering the notion of relevance in a broad and generous fashion, the strategic reasons behind the Conceptus acquisition or an in-depth analysis of the due diligence process would not help to advance the litigation.

[30] Plaintiff alleges that the information is required for three reasons:

30.1. To determine if Bayer is legally responsible for damages that may have been caused by Essure during the Conceptus Era;

30.2. To verify what Bayer knew with regard to potential adverse effects of Essure during the Conceptus Era;

30.3. To challenge Bayer's assertion in their plea that Essure was discontinued for commercial reasons.

[31] With regard to the first point, Bayer will be ordered to disclose whether the Conceptus acquisition proceeded on the basis of a share purchase or an asset purchase. If the acquisition was on an asset-purchase basis, Bayer will provide the extracts of the asset purchase agreements that relate to the liabilities assumed by the vendor and the purchaser with regard to the distribution of Essure during the Conceptus Era.

[32] With regard to the second point, in her Originating Application, Plaintiff alleges that Bayer knew of the health risks related to Essure and failed to adequately inform the public of these risks.[26] Bayer concedes that adverse effects may have occurred among certain Essure patients but pleads that these adverse effects were not caused by the product or that the possibility of adverse effects was adequately disclosed in a timely fashion.[27]

[33] There is no doubt that Bayer's knowledge of Essure related safety risks as well the date it acquired this knowledge is relevant to determine whether Bayer complied with its continuous duty to warn users of the product's risks and dangers.[28] Adverse events disclosed to Conceptus or to Bayer are relevant to this determination as are any studies that Bayer conducted in response to the adverse effects it became aware of.

[34] However, as will be discussed later, Bayer has already provided relevant extracts of its global adverse effects database which includes all adverse effects disclosed to Conceptus during the Conceptus Era.

[35] Thus, Bayer will be ordered to provide:

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25 Bayer's Plea, paras. 46 to 48.
26 Originating Application, paras. 35 and 37.
27 Bayer's Plea, paras. 32 and 63.
28 *Brousseau* c. *Laboratoires Abbott limitée*, 2019 QCCA 801, paras. 102 and 136 (Application for leave to appeal to the Supreme Court dismissed (S.C. Can., 2020-04-09) 38745).

35.1. a list of documents it consulted during the due diligence process that disclose health risks related to the use of Essure as defined in the Class description ("adverse side effect of urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms") (the "**Adverse Event Information**");

35.2. any studies that Bayer performed or requested on the Adverse Event Information provided by Conceptus.

[36] Bayer's argument with regard to solicitor-client privilege is either unfounded or premature. Bayer's assertion, that any information obtained from Conceptus in the course of the due diligence process is covered by solicitor-client privilege, is incorrect. Solicitor-client privilege only applies to information exchanged between Bayer and its solicitors for the purpose of obtaining legal advice.[29]

[37] However, it may be that some of the studies covered by the undertaking were performed for the purpose of obtaining legal advice. If that is the case, Bayer will be allowed to raise privilege and identify the study in question. The objection may be adjudicated in due course if required.

[38] With regard to the third point raised by Plaintiff in support of its request, the information obtained during the due diligence would not assist the court to determine why the distribution of Essure was discontinued in Canada. This point will be discussed later when evaluating objections to other questions or documents requests.

2.2 Concerns Regarding Adverse Event Information Reported (Question 9)

[39] Question 9 asks:

> Did the Defendants have any concerns regarding the adverse reactions reported by women implanted with Essure around the world, at the time of buying Conceptus?
>
> Answer 9: yes or no

[40] Bayer provided a detailed answer to this question:

> All medical devices approved for use in Canada are associated with spontaneous, voluntary reports of adverse reactions/events. For Essure, these reports are rare when considered as a proportion of the total women with Essure. Spontaneous adverse event reports are subject to significant limitations, including that they can be incomplete, inaccurate, untimely, unverified or biased. These limitations make it impossible to rely on these reports to draw conclusions about overall incidence rates or any causal relationship between a device and a reported reaction. At the time of the acquisition, Bayer had concluded, based on the totality of information available about Essure including the scientific literature and studies and adverse event reports, and Health Canada's issuance and subsequent renewals of the

[29] *Solosky* v. *The Queen*, [1980] 1 SCR 821, p. 837.

> medical device license for Essure, that Essure was safe and effective and that, in general, its clinical benefits for women seeking permanent contraception outweighed its potential risks.

[41] Plaintiff submits that Bayer should answer the question with a yes or no.

[42] Such a request is unfounded.

[43] It is true that questions asked during a written examination must be "clear and specific" (article 223 C.C.P.). So must be the answers (article 224 C.C.P.). However, it is not necessary that all questions elicit yes or no answers. It is sufficient that the questions be closed rather than open-ended and that they not be likely to give rise to vague or ambiguous answers. Similarly, answers do not have to be limited to yes or no and may be qualified if needed.[30]

[44] This question was answered. The objection is thus moot.

2.3 Regulatory History of Essure Outside Canada (Questions 11, 12 and 13)

[45] Questions 11, 12 and 13 read as follows:

> Question 11: During the class period, was the renewal of the licence of Essure denied in Canada or elsewhere in the world? If yes where, when and why?
>
> Question 12: During the class period, was the licence of Essure suspended in Canada or elsewhere in the world? If yes where, when and why?
>
> Question 13: During the class period, was Essure recalled in Canada or elsewhere in the world? If yes where, when and why?

[46] Defendants answered the portion of the questions pertaining to the regulatory history of Essure in Canada but objected to the portion of each question that sought to elicit information about facts that occurred elsewhere in the world.

[47] Even though the information solicited relates to events outside of Canada, the information is relevant to Bayer's knowledge of Essure adverse effects and health risks.

[48] Moreover, the questions are precise and can be answered simply.

[49] These objections are dismissed.

2.4 Adverse Event Information and how Bayer Responded to This Information (Questions 14 and 15 and Undertakings 10a), 10b) and 11g))

[50] Questions 14 and 15 read as follows:

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[30] *Corporation d'hébergement du Québec* c. *Decarel inc.*, 2012 QCCS 4444, para. 12; *Norcan Hydraulic Turbine* c. *Sherbrooke (Ville de)*, 2011 QCCS 4292, para. 9; J.*B. Laverdure inc.* c. *Mediterranean Shipping Company*, 2017 QCCQ 4679, para. 43.

> Question 14: During the class period, how many women who were required a full hysterectomy to remove Essure implant from their body were reported to the Defendants in Canada and the US? What steps, if any, were taken by the Defendants during the class period regarding this issue?
>
> Question 15: During the Class period, what steps, if any, were taken by the Defendants in regard to reported adverse reactions to Essure?

[51] By way of Undertakings 10 a), 10 b) and 11 g), the Defendants seek to obtain:

> Undertaking 10a): Provide any or all documents/ communications/ studies related to the reported adverse reactions to the Defendants during the Class period.
>
> Undertaking 10b): Provide any or all documents/ communications/ studies related to the reported hysterectomy undergone by women as to remove Essure from their body during the Class period.
>
> Undertaking 11g): Copy of all the adverse events received by the Defendants during the Class Period in the US and Canada.

[52] Defendants objected to Questions 14 and 15 on the basis that the questions were answered. They objected to Undertakings 10a), 10b) and 11g) on the basis that the requests constitute a fishing expedition and were overly broad, vague, disproportionate and irrelevant.

[53] Under reserve of their objections, the Defendants communicated:

53.1. A copy of a log of Essure-related complaints (including adverse reactions) reported to Conceptus for the period 2001-2013;

53.2. A copy of a report from Bayer's global adverse event database containing Essure-related adverse event data reported to Bayer (and including Conceptus-era imported data);

53.3. Copies of reports from Bayer's global product technical complaint database containing Essure-related product technical complaints reported to Bayer that were associated with an adverse event.

[54] The spreadsheet from the Bayer global adverse event database contains information such as (a) country; (b) initial receipt date; (c) report type; (d) patient age and gender (if known); (e) description of the event as reported; (f) outcome (if known).[31]

[55] The Court considers that the documents provided adequately respond to the questions and undertakings as they pertain to Adverse Event Information related to Essure. The extracts of the database give Plaintiff information about all global adverse events which includes that date it was reported to Bayer as well as a description of the adverse event in question. The request to obtain the bulk of the underlying documentation

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[31] Annex J to Bayer's Plan of Arguments.

through which the Defendants were made aware of an adverse event involving Essure is redundant and overbroad. That request is dismissed.

[56] However, this decision does not prevent Plaintiff to ask for additional documents regarding a specific adverse event listed in the database if further details are needed on such specific events.

[57] With regard to Bayer's reaction or steps taken in response to Adverse Event Information, Bayer objected to the second part of Questions 14 and 15 on the basis that the questions were vague, overly broad and ambiguous, but nevertheless answered the questions under reserve of this objection.

[58] Bayer stated that reports of hysterectomies involving Canadian patients with Essure were treated as adverse events in accordance with the applicable laws and regulations in Canada. To the extent that such reports involved patients in the US, they were treated as adverse events in accordance with the applicable laws and regulations in the US. Bayer has also disclosed the information it provided to Quebec physicians related to Essure health risks.

[59] Thus, the objections, at this stage, are now moot.

[60] Defendants nonetheless ask that the Court sustain the objection to preserve their right to raise the objection at trial.

[61] Such a reserve is not necessary, nor would it be appropriate.

[62] For one thing, the Court of Appeal has repeatedly stated that a reservation of rights in the operative part of a judgment, unless it is provided for by law, has no effect. Either the statement establishes rights that a party already has and, in this regard, it is useless. Or it declares rights that the party does not have and, in this regard, it is misleading because the reservation is insufficient to create or recognize such rights.[32]

[63] Here the reserve is unnecessary. Even though article 228 C.C.P. provides that a party should answer a question asked during a pre-trial examination despite an objection on the basis of lack of relevance, it recognizes the party's right to have that objection noted on the record. This has already been done.

[64] Furthermore, because the notion of relevance is assessed differently at trial than it is at the pre-trial phase, any assessment of relevance at this stage does not bind the trial judge.[33]

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[32] *Droit de la famille — 21366*, 2021 QCCA 453, para. 17; *Blumenthal* c. *Di Zazzo*, 2020 QCCA 1032, para. 15 (Application for order to reopen investigation abusive and dismissed, 2021 QCCS 3834); *Lacasse* c. *Laflamme*, 2018 QCCA 1916, para. 28; *Montréal (Ville de)* c. *Bergeron*, 2012 QCCA 2035, para. 15; *9059-1330 Québec Inc.* c. *Optimum Société d'assurance Inc.*, J.E. 2004-694 (C.A.), para. 8 (C.A.).

[33] *Société financière Manuvie* c. *D'Alessandro*, *supra*, note 10, para. 22.

[65] Thus, the Court sees no purpose in adjudicating objections when the information has already been disclosed.

[66] However, to avoid any argument that may be made to the effect that the objections were dismissed because the Court considered the information relevant, the Court will simply note in its conclusions that any objections raised at trial will be dealt with by the trial judge.

[67] The request as it pertains to studies conducted on Adverse Event Information will be discussed below in dealing with Undertaking 9.

2.5 Physician Training (Question 21 and Undertakings 13, 14 and 15)

[68] Question 21 and Undertakings 13, 14 and 15 read as follows:

> Question 21: After completing the Essure training, did physicians receive any kind of certification or a recognition of a qualified physician to recommend and implant Essure to the patient?
>
> Undertaking 13: Provide any and all documentation supporting the requirement of a mandatory training, if applicable.
>
> Undertaking 14: Provide any and all documentations or correspondence by the Defendants supporting the verification of doctors who completed the training before being authorized to place or recommend Essure, if applicable.
>
> Undertaking 15: Provide any and all documentations or correspondence by the Defendants supporting the verification of gynecologist as being “skilled in hysteroscopy”, if applicable.

[69] In answer to Questions 17 to 20, Bayer described the training provided to Quebec physicians.

[70] In response to Question 21, Bayer answered that “[d]epending on the timing and the type of Essure training a physician participated in, they may or may not have received a certificate or other recognition upon completion of Essure training”.

[71] This answer is incomplete. Bayer will be ordered to explain in which cases a Quebec physician would have received “a certificate or other recognition upon completion of Essure training” and in which cases in would not have received such recognmition.

[72] In response to Undertaking 13, Bayer has indicated that the requirement for Quebec physicians to complete Essure training appears in the Instructions for Use which were already provided. They added that information distributed to physicians in Canada was also provided.

[73] However, it is unclear if the training material used by Bayer to train Quebec physicians was disclosed. If not, it will have to be provided.

[74] Any information with regard to training of physicians outside of Quebec is either irrelevant or disproportionate in the context of the current proceedings.

[75] The class includes “All women residing in Quebec […] who were implanted with Essure and who were diagnosed with urinary tract infections, perforated organs, implant migration, pelvic pain, menorrhagia or autoimmune symptoms”. Plaintiff pleads that it is therefore theoretically possible for a woman to have been implanted outside Quebec and to have suffered damages while she was a Quebec resident. This remote possibility would not justify disclosure of training material used throughout the world. First of all, the Originating Application describes the Defendants as being involved in the chain of distribution of “Essure in Canada”.[34] Furthermore, the original class description sought by Plaintiff referred to Essure “as manufactured, imported, distributed, promoted, marketed, sold, or otherwise placed into the stream of commerce in Canada by the Respondents”. While this precision was not retained in the conclusions of the Authorization Judgment, the allegations of the Original Application and the original class description sought by Plaintiff show that the intent was always to limit the class to those women who were implanted with the product authorized for sale in Canada.

[76] Therefore, the training of physicians outside Quebec is probably irrelevant to the issues before the Court. In any event, even if a fact is logically relevant, a court retains the right to refuse otherwise admissible evidence when its probative value is low and the evidence risks a) causing confusion with regard to the issues in dispute; b) unduly prejudicing a party, a witness or a third party; or c) if it involves an inordinate amount of time which is not commensurate with its probative value.[35] This is the case here. Opening the door to training of physicians throughout the world would likely lead to confusion and distract from the primary focus of the debate. It would prolong the trial in Quebec without a measurable benefit to the class.[36]

[77] With regard to Undertakings 14 and 15, Bayer alleges that it does not have an obligation to verify physician training, to authorize physicians to place or recommend Essure or to verify a physician’s skills.

[78] That may the case, but this is an issue to be decided by the judge who will hear the merits of the case.

[79] In the meantime, the Court notes that Bayer alleges in its plea that “Essure devices were intended to be placed only by gynecologists who were skilled in hysteroscopy and who had completed Essure training” and that these intermediaries “play a key role” in advising patients of the risks involved in birth control methods.[37]

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34 Originating Application, para. 5.

35 J.-C. ROYER and C. PICHÉ, *supra*, note 17, para. 218; Claude MARSEILLE, *La règle de la pertinence en droit de la preuve civile québécois*, Cowansville, Éditions Yvon Blais, 2004, paras. 41 and following; *R.* c. *Mohan*, [1994] 2 R.C.S. 9; *9217-4887 Québec inc.* c. *Yves Rocher Amérique du Nord inc.*, 2016 QCCS 5123, para. 32; *Thouin* c. *Ultramar ltée*, 2014 QCCS 3946, para. 9.

36 *A* c. *Watch Tower Bible and Tract Society of Canada*, 2018 QCCS 5182, para. 23.

37 Bayer’s Plea, paras. 23 to 27.

[80] The issue of training verification is thus relevant but the undertakings, in their current format are overly broad.

[81] Instead, Bayer will be required to answer the following questions:

> Undertaking 14: Does Bayer ensure that only doctors who have followed Essure training are entitled to recommend or place Essure devices and, if so, how?
>
> Undertaking 15: Does Bayer verify that gynecologist who place Essure are "skilled in hysteroscopy" and, if so, how?

2.6 Revenue Derived from the Sale of Essure in Canada (Undertaking 7)

[82] By way of Undertaking 7, the Plaintiff requested communication of:

> Undertaking 7: Ledgers and/or statements of all revenue and net income derived by the Defendants from the sale of Essure distributed in Canada from 2013-2018

[83] Defendants object on the basis that the information is irrelevant.

[84] The Authorization Judgment identifies one of the common questions as follows:

> Are members of the class entitled to punitive damages?

[85] The Supreme Court of Canada[38] teaches that punitive damages have a preventive objective. Their purpose is "to discourage the repetition of undesirable conduct." They may be awarded in the presence of "intentional, malicious or vexatious" violations of the CPA or intentional violation of rights protected under the Quebec *Charter of Human Rights and Freedoms*.[39] Such an evaluation requires consideration of "the whole of the merchant's conduct at the time of and after the violation."[40]

[86] The *Civil Code of Quebec* states that punitive damages are assessed in the light of all the appropriate circumstances, including the "gravity of the debtor's fault" and "his patrimonial situation".[41]

[87] Thus, the revenue generated from Essure may be relevant[42] and courts have ordered disclosure of financial documents in the context of a punitive damage claim in the past.[43]

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38 *Richard* v. *Time Inc.*, 2012 SCC 8.
39 Quebec *Charter of Human Rights and Freedoms,* RSQ, c. C-12.
40 *Ibid.*, para. 180.
41 Article 1621 C.C.Q.
42 *Richard* v. *Time Inc.*, *supra*, note 38, para. 201; *Fillion* c. *Chiasson*, 2007 QCCA 570, para. 107; *Conseil québécois sur le tabac et la santé* c. *JTI-Macdonald Corp.*, 2012 QCCS 3566, para. 8 (Leave to appeal dismissed, 2012 QCCA 1848 and 2012 QCCA 1847).
43 *Lussier* c. *Expedia Group Inc.*, 2019 QCCS 4927, paras. 42 to 49; *Bolduc* c. *Arthur*, 2008 QCCS 6085; *Gauvin* c. *Arthur*, J.E. 2002-1577 (C.S.), para. 19; *Grenier* c. *Arthur*, [2001] R.J.Q. 674 (C.S.), para. 50.

[88] Bayer will be ordered to provide yearly revenue generated by the sale of Essure in Canada for each year from 2013 to 2017. Year 2018 is not included as Canadian distribution of Essure ceased in 2017.

[89] Any concern with regard to confidentiality is attenuated by the implied undertaking that surrounds pre-trial disclosures.[44] To further protect Bayer, an order is issued imposing on Plaintiffs a 30-day prior notice before filing the financial information in the court record in order to allow Bayer to make representations on measures which should be taken to protect any substantial interest in confidentiality.

2.7 Documents Related to the Decision to Discontinue the Distribution and Sale of Essure in Canada (Undertaking 8)

[90] By way of Undertaking 8, the Plaintiff seeks communication of:

> Undertaking 8: Any and all documentation by the management board supporting the decision to discontinue the distribution and selling of Essure on August 31, 2017, in Canada

[91] Defendants objected to Undertaking 8, on the basis that it is disproportionate and irrelevant.

[92] In its plea, Bayer alleges that Essure was voluntarily discontinued in Canada as of August 31, 2017, for commercial reasons.[45]

[93] The information sought is relevant to this allegation.

[94] The information is not overly broad as it is limited to information available to the managing board and limited to Canada.

[95] The objection is dismissed.

[96] However, the same reserve will apply to allow Bayer to raise objections with regard to solicitor-client privilege.

2.8 Studies Related to Essure (Undertakings 9b), c), d), e) and g))

[97] By way of Undertakings 9b), c), d), e) and g), the Plaintiff seeks communication of:

> Undertaking 9b): Copy of all completed post approval studies of Essure in the US and Canada
>
> Undertaking 9c): Copy of all the ongoing post approval studies of Essure in the US and Canada

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[44] *Lac d'amiante du Québec Ltée* v. *2858-0702 Québec inc.*, 2001 SCC 51, para. 69; *Société financière Manuvie* c. *D'Alessandro*, *supra*, note 10, para. 48 (Discontinuation of the motion for leave to appeal to the Supreme Court (Can C.S., 2015-06-26) 36309).

[45] Bayer's Plea, paras. 16 and 48.

> Undertaking 9d): Copy of all post approval observational / follow up studies in the US and Canada
>
> Undertaking 9e): Full versions of clinical trials of the Essure, including external and internal research and studies and results in the possession or control of the Defendants regarding the role, efficacy and safety of the implant
>
> Undertaking 9g): Any other efficacy studies conducted by the Defendants from 2011 to 2019 during the class period

[98] Defendants objected to these undertakings as drafted, on the basis that they were overbroad and irrelevant to the issues authorized in this class action, since they were not limited to the models of Essure marketed and sold in Canada during the class period.

[99] Under reserve of their objections, they nonetheless communicated:

99.1. Reports from completed clinical studies in their possession and control conducted on models of the Essure device that were marketed in Canada;

99.2. Protocols and any interim data or reports from ongoing clinical studies in their possession and control conducted on models of the Essure device that were actually marketed in Canada;

99.3. Clinical Evaluation Reports that contain information about Essure from all Bayer sponsored studies, the literature and post-marketing surveillance data.

[100] As previously mentioned, Bayer's knowledge with regard to potential adverse effects of Essure is relevant to these proceedings. Moreover, Bayer relies on clinical and post-market studies in support of their allegation that the Essure related risks were no more significant than those associated with laparoscopic tubal ligation.[46]

[101] As part of the global database, Bayer has already provided detailed information about all adverse events.

[102] It was not made clear whether there were studies conducted or sponsored by Bayer related to the Adverse Event Information that Bayer obtained. If Bayer conducted or requested such studies, they should be provided.

[103] The relevancy of any additional information contained in clinical trials that do not relate to models of Essure sold in Canada would be so limited that such information would not respect the principle of proportionality.

2.9 "Test data" Related to Essure (Undertakings 9h) and i))

[104] By way of undertakings 9h) and 9i), the Plaintiff seeks communication of:

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[46] Bayer's plea, paras. 60 to 62.

> Undertaking 9h): All test data received from the Manufacturer Conceptus relating to Essure from 2001 to 2013
>
> Undertaking 9i): All test data for Essure distributed in Canada during the Class Period, including the post market studies and evaluations

[105] In their recent submission, Plaintiff specified that they are seeking "clinical trial data required to be submitted to regulatory agencies".

[106] Defendants objected to these undertakings on the basis that they are overly broad, vague, disproportionate, and not relevant to the questions authorized in this class action.

[107] However, they have communicated, in response to Undertaking 11 and its sub-paragraphs, the Canadian regulatory file, including all clinical trial data that was submitted to Health Canada between 2001-2017.

[108] To the extent that, through the reformulated Undertakings 9h) and 9i), the Plaintiff seeks to obtain communication of data submitted to regulatory agencies other than Health Canada, such a request would be irrelevant or indeed overly broad.

[109] The objection is sustained.

2.10 All Internal Emails, Communications and Documents Exchanged (Undertakings 12a), 12b) and 12c))

[110] By way of Undertakings 12a), 12b) and 12c), Plaintiff requested communication of:

> Undertaking 12a): All internal emails, communications and documents exchanged regarding the reported adverse reactions of ESSURE implant during the Class period;
>
> Undertaking 12b): All internal emails, communications and documents exchanged regarding any problems with manufacturing, production, and labelling of ESSURE implant during the Class period;
>
> Undertaking 12c): All internal emails, communications and documents exchanged discussing steps to be taken or not taken relating to the discovery of the reported adverse reactions;

[111] Defendants objected on the basis that the requests were overboard, disproportionate and irrelevant.

[112] Plaintiff subsequently reformulated the requests to limit them to communications "between the relevant entities/department of the defendants".

[113] The requests may seek relevant information given the broad interpretation that the Court must apply at this stage.

[114] This being said, requests that begin with the words “All internal emails, communications and documents exchanged” should immediately raise suspicion. Such wording is imported from common law jurisdictions that impose extensive document disclosure obligations. These obligations are tempered in Quebec by the court’s duty to ensure that the case is conducted in a sound, efficient and orderly manner keeping in mind the objectives of proportionality and cost control.

[115] The requests as worded are clearly overbroad and have all the characteristics of what courts have considered to be fishing expeditions.

[116] The proposed reformulation provides no cure for the initial vice.

2.11 Marketing Materials Deployed Outside Québec (Undertakings 12e) and 16a))

[117] By way of these undertakings, the Plaintiff requested communication of:

> Undertaking 12e): copy of the marketing materials (general public, patients and physicians) including on the Defendants’ website (Canada and US) promoting Essure during the Class period
>
> Undertaking 16a): Copy of all versions of Essure brochures, guide, instructions of use that was available to the public (hard copy and on the Defendants’ website) during the Class period

[118] Defendants provided marketing material used in Quebec. They objected to the portion of Undertakings 12e) and 16a) that concerns marketing materials deployed outside of Quebec on the basis that it is overbroad and irrelevant.

[119] Under reserve of their objections, Bayer communicated copies of the relevant Essure Instructions for Use used in Canada between 2001 – August 2017 (in response to Undertaking 11i)).

[120] The objection to marketing material used outside Quebec is sustained.

[121] As discussed above, opening the door to representations made by the Defendants throughout the world would likely lead to confusion and distract from the primary focus of the debate. It would prolong the trial in Quebec without a measurable benefit to the class.[47]

[122] An exception will be made with regard to extracts of the US website that relate to Essure. Indeed, Bayer was asked to provide extracts of the Canadian website relating to Essure. In its response dated September 2, 2022,[48] Bayer indicated that it was not able to locate this information. The content of the website is important as Plaintiff mentions in her deposition that she remembers consulting the website. This fact was noted by Justice

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47 *A* c. *Watch Tower Bible and Tract Society of Canada*, *supra*, note 36, para. 23.

48 Annex F to Bayer’s plan of argument.

Lamarche in the Authorization Judgment.[49] In the absence of the Canadian website, Bayer will be ordered to produce the US website and will be allowed to indicate which information, if any, would not have appeared in the Canadian equivalent.

CONCLUSION

[123] Defendants will be ordered to provide limited additional information on the following subjects:

123.1. Liability assumed by Bayer or Conceptus in the course of the Conceptus acquisition;

123.2. Adverse Event Information consulted during the due diligence process;

123.3. Studies performed or requested by Bayer relating to Adverse Event Information (including studies on information provided by Conceptus);

123.4. Physician training certification, materials and verification;

123.5. Essure yearly Canadian revenue; and

123.6. Essure's US website.

[124] As both parties were partially successful, no costs will be awarded.

[125] Finally, in order to ensure the efficient progress of the case, a new case protocol will have to be filed.

[126] The deadlines imposed will take into consideration that Plaintiff's lawsuit was authorized in March 2019 and notified in August 2019. It relates to medical procedures performed between 2011 and 2017.

[127] The parties must work together to ensure that the case is inscribed within a reasonable delay.

FOR THESE REASONS, THE COURT:

[128] **SUSTAINS** objections to Questions 6, 9, 14 and 15 as well as to Undertakings 9h), 9i), 10a), 10b), 11g) and 12 (with regard to information that goes beyond what has already been provided);

[129] **DISMISSES** objections to Questions 11, 12 and 13 as well as Undertaking 8;

[130] With regard to Undertaking 4, the Court **ORDERS** Bayer to:

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[49] Authorization Judgment, para. 40.

> Disclose whether the Conceptus acquisition proceeded on the basis of a share purchase or an asset purchase
>
> If the acquisition proceeded on an asset-purchase basis, Bayer will provide the extracts of the asset purchase agreements that relate to the liabilities assumed by the vendor and the purchaser with regard to the distribution of Essure during the Conceptus Era;

[131] With regard to Question 7 and Undertakings 5 and 6, **ORDERS** Bayer to provide:

> A list of documents it consulted during the due diligence process that disclose Adverse Event Information
>
> Any studies that Bayer performed or requested on the Adverse Event Information provided by Conceptus.

[132] With regard to Question 21 and Undertaking 13, **ORDERS** Bayer to:

> Explain in which cases did a Quebec physician receive "a certificate or other recognition upon completion of Essure training"
>
> Disclose any training material used by Bayer to train Quebec physicians on placing Essure

[133] In lieu of Undertakings 14 and 15, **ORDERS** Bayer to answer the following questions:

> Undertaking 14: Does Bayer ensure that only doctors who have followed Essure training are entitled to recommend or place Essure devices and, if so, how?
>
> Undertaking 15: Does Bayer verify that gynecologists who place Essure are "skilled in hysteroscopy" and, if so, how?

[134] With regard to Undertaking 7, **ORDERS** Bayer to provide yearly revenue generated by the sale of Essure in Canada for each year from 2013 to 2017;

[135] With regard to Undertakings 9b), c), d), e) and g) **ORDERS** Bayer to provide

> Any studies that Bayer performed or requested on Adverse Event Information

[136] In response to Undertakings 12e) and 16a), **ORDERS** Bayer to provide extracts of the US website that relates to Essure and **ALLOWS** Bayer to highlight the information that would not have appeared in the Canadian equivalent website;

[137] **ALLOWS** Defendants to raise an objection to the disclosure of any document which may be covered by solicitor-client privilege;

[138] **DECLARES** that the present ruling does not bind the trial judge and that any objections reiterated at trial will be dealt with by the trial judge;

[139] **ORDERS** that answers and documents related to dismissed objections should be provided before March 10, 2023;

[140] **DECLARES** that any document disclosed further to the present judgment is subject to the implied confidentiality rule *Lac d'Amiante du Québec Ltée* v. *2858-0702 Quebec Inc.*;[50]

[141] **ORDERS** Plaintiff to give Defendant a 30-day prior notice before filing financial information obtained from Bayer into the Court record in order to allow Defendants to make representations on measures that should be imposed to protect the confidentiality of such information;

[142] **PRAYS ACT** of the parties undertaking to file a new case protocol by February 17, 2023, that respects the following deadlines:

142.1. Plaintiffs will advise Defendants by February 17, 2023whether they wish to proceed with an oral examination of a Defendant representative and, if so, will advise Defendants of the subjects they wish to cover so that an appropriate witness can be identified;

142.2. If there is any debate with regard to this examination, the parties will jointly advise the Court of the nature of this debate and how long they require to have the issue decided;

142.3. If an examination is to take place, it will be scheduled prior to May 31, 2023;

142.4. Defendants will file their expert report prior to April 30, 2023;

142.5. Plaintiff will have until June 30, 2023, to file a reply expert report that is limited to answering issues raised in the Defendants report;

142.6. The declaration of readiness and inscription will be filed at the latest on July 28, 2023;

[143] **THE WHOLE** without costs.

MARTIN F. SHEEHAN, J.S.C.

[50] *Lac d'Amiante du Québec Ltée* v. *2858-0702 Québec Inc.*, *supra*, note 44.

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Hearing date: January 24, 2023